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Embryo and stem cell research: Views from the USA

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Abstract Embryo research in the USA has been politicised by the abortion debate since 1973, when *Roe v Wade* legalised abortion. The federal government never funded therapeutic research because Congress feared it would encourage abortions. *In vitro* fertilisation (IVF), stem cell research and creation of research embryos have developed in an unregulated private sector. Bush's 9th August decision allowing funds for research on stem cells derived before that date attempted to please religious conservatives. This paper examines US history, ethical debates, religious views and future roles of the private sector.

Keywords: stem cells, embryo research, abortion debate, ethics, USA

Introduction

The recent announcement (26th November, 2001) by Michael West of Advanced Cell Technologies in Worcester, MA, that his company had cloned three human embryos produced a furore of political response. The embryos were created from adult cells in the hope of producing stem cells that would be immunologically compatible with the donor and could be used to repair damaged organs such as brain, spinal column, liver or pancreas. They died at the 4–6 cell stage, long before the 120-cell stage that would support stem cells. This use of nuclear transfer (the technique used to create 'Dolly') led Congressional conservatives to call with renewed urgency for a ban on all cloning, including both 'reproductive cloning' (to produce a baby that is identical to the cell donor) and 'therapeutic cloning' (to obtain stem cells for treatment of failing organs). The House of Representatives passed such a law early last summer, and President Bush called upon the Senate to follow suit. Many senators, however, including some prominent Republicans such as Arlen Specter of Pennsylvania, favour stem cell research and have promised to 'let the scientists have their say', probably in March, so immediate action is unlikely. Unless some new announcement from the private sector threatens conservative moral sensitivities, elapsing time is probably on the scientists' side.

In the USA, the debate over 'therapeutic cloning' may be more concerned about the fate of the embryo, which must be destroyed to derive the stem cells, than the use of cloning techniques. Until the past year, the use of adult, as opposed to embryonic, stem cells was considered morally acceptable and was extolled by the media as if it were an extension of bone marrow transplants. (In theory, if diseases could be treated by transplanting cell lines grown from adult cells, the use of embryos would be

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unnecessary. However, cells grown from a different donor would be rejected by the patient. The ideal treatment is to derive stem cells from a source that is genetically identical to the patient.) Most non-scientists were not aware that deriving the more versatile pluripotent stem cells (see Table 1) from adult cells required use of cloning technology in order to bring the cells back to their embryonic state. In the UK, the major issue was whether therapeutic cloning would serve to advance techniques for reproductive cloning, but there was considerable discussion about whether it could be right to create an embryo specifically to destroy it. Many argued that this was a new step for embryo research and were against it, despite being in favour of existing legislation that permitted creation of embryos.

Human embryo research in the USA has been politicised from its beginnings. Starting in 1973, shortly after the Supreme Court's *Roe v Wade* decision, which legalised abortions, the US government banned use of federal funds for research on foetuses in the context of abortion. Bans followed on federal funding of research with embryos and foetal tissue. These policies permitted largely unregulated research in the private sector.[1] The bans have driven most infertility research and treatment, including *in vitro* fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and gamete intrafallopian transfer (GIFT) into the private sector. (Research on embryos could be federally funded, at least in theory, if and only if the research was likely to benefit that particular embryo or foetus, but no such research was carried out.) In contrast, the UK has permitted and funded embryo research up to 14 days, and has allowed creation of embryos specifically for research since 1990. Recommendations of an expert group from the Department of Health in 2000 extended the purposes for which an embryo could be made.[2] However, all projects, whether public or private, are regulated by the Human Embryology and Fertility Authority. The following paragraphs describe US history of embryo research politics and its cultural background.

Three cultural factors underlie the differences between the USA and the UK.

First, the USA is a church-going nation. When asked whether they attended a religious service last week, about 40 per cent of the population said yes,[3] compared with perhaps 5 per cent in the UK. Genetics professionals also go to services; in one survey, 36 per cent said they attended at least once a month (D. C. Wertz and J. C. Fletcher, unpublished). In making decisions about human embryos, US politicians must answer to a sizeable segment of voters who belong to organised religious groups. Although these groups hold varying views, and some support stem cell research, most opponents of research are closely connected with conservative groups that are particularly vocal in politics.

Second, the USA has an active anti-abortion movement. Stem cell research is linked with the abortion debate. For activists, using a 'spare' embryo left over after IVF, which will otherwise be discarded, is the moral equivalent of killing a baby.

Third, from the seventeenth century, free enterprise has been at the top of the list of American values,[4] together with freedom of religion, making it difficult to forbid private companies from pursuing their own

Table 1 Types and sources of stem cells

- **Totipotent cells** exist only in the embryo's first few cell divisions, and at present cannot be derived. They can regenerate an entire organism.
- **Pluripotent cells** are found in the blastocyst, which has about 120 cells clustered inside a ball-like structure. They can regenerate most tissues from multiple germ layers, and would also be useful in research on infertility, embryonic development and drug toxicity. Cells from adults can be made to revert to their pluripotent stage by nuclear transfer to an egg.
- **Multipotent cells** are found in foetal and adult tissues. They can regenerate different types of tissues from the same germ layer (eg bone marrow stem cells can regenerate different types of blood cells). Multipotent cells have some pluripotent potential (eg blood cells in mice can become brain cells), but are not as useful as cells derived from blastocysts.

strategies, unless there is a clear and present danger to the public.

The historical outline is given in Table 2.

Basic and therapeutic research under the moratorium

Basic research on human foetal tissue obtained after elective abortions continued throughout the moratorium, using federal funds.[7] Since this type of research was not likely to attract public attention or lead directly to treatment that might lend a 'good' aspect to abortion, government regulators simply looked the other way as their own agencies used the tissue. For example, cultured cell lines from human embryonic kidneys have been used for research on insulin-like growth factor at the

Table 2 Historical outline

1930s	Possible earliest use of foetal tissue.
1954	John Enders wins Nobel Prize for use of foetal kidney cells to grow polio virus.
1973	Supreme Court decision in *Roe v Wade* rules that decisions about abortion are private, between a woman and her doctor. States may not forbid abortion in first two trimesters. This decision sparks a large, politically active anti-abortion movement that opposes research on embryos.
1973	Moratorium on federally funded research on embryos.
1974	National Commission on Protection of Human Subjects recommends guidelines for foetal research that permitted activities with no more than 'minimal risk' to the foetus.
1975	Department of Health and Human Services (DHHS) adopts regulations stipulating that no federal funding for IVF was possible without approval of an Ethical Advisory Board (EAB), a national body that had a very brief existence.
October 1987	National Institutes of Health receives request for funds for research on Parkinson's disease, using transplants of foetal tissue into patients' brains. DHHS declares temporary moratorium.
March 1988	NIH establishes Human Fetal Tissue Transplantation Research Panel.
Autumn 1988	Panel votes 18–3 that federal funding for research with foetal tissue obtained after elective abortion was 'acceptable public policy.'
November 1989	DHHS Secretary Sullivan extends moratorium indefinitely, thus endorsing the Panel's minority view that research would increase abortions.
1990	Congress attempts to override moratorium but President George Bush vetoes.
October 1992	Disease advocacy organisations file suit against DHHS Secretary Sullivan to lift ban.
January 1993	President Clinton, in one of his first acts in office, directs DHHS Secretary Donna Shalala to lift ban.
Feb.–March 1993	Ban lifted. NIH publishes guidelines, preparatory to accepting proposals for funding.
November 1994	NIH Human Embryo Research Panel supports research, and a narrow majority recommends that embryos be created solely for research.[5] Clinton overrides Panel after receiving thousands of outraged comments from public.
1995	Congress bans federal funding. Ban continues to present.
2000	In an attempt at compromise, NIH legal department rules that NIH may fund research on stem cells that have already been derived from blastocysts by private industry, but may not fund the derivation itself. In other words, federally funded researchers may work with the cells, but may not destroy early embryos in order to obtain the cells. Private industry must do the derivation. NIH invites proposals.
March 2001	Only two proposals received, because of perceived political instability. (One of these was later withdrawn.) Peer review is halted pending a decision by President George W. Bush.
July 2001	The Jones Institute, Norfolk, VA, announces that it has created embryos solely for research, using gamete donors not undergoing IVF.
9 August 2001	President George W. Bush permits NIH funds for research with an estimated 60 stem cell lines already existing as of that date. Cells must come from embryos left over after IVF. Bush addressed the nation, setting a historical precedent that made bioethics a national priority.
August 2001	The *New York Times* says 'Bush waffles'. Most opponents, except the National Conference of Catholic Bishops, are satisfied. Scientists question adequacy of existing cell lines. Patient organisations decide to wait for results of preliminary research before pressing for wider limits.
November 2001	NIH releases list of 74 acceptable stem cell lines, including some in Australia, Sweden and India, and once again invites proposals. Many existing lines have been grown in mouse media and are unsafe for human clinical trials.
2001	26 of the 50 states have laws on embryo research. These vary widely,[6] and nine states prohibit any embryo research.

National Cancer Institute and the National Institute of Diabetes and Digestive and Kidney Diseases, on signal transduction at the National Institute of Dental Research, on follicle-stimulating hormone at the National Institute of Child Health and Human Development, on gene therapy at the National Institute of Neurological Disorders and Stroke, and on gene expression in Wilms' tumour at the Veterans' Administration. Foetal and embryonic tissue has been used by the Environmental Protection Agency to study effects of teratogens on foetal palates, by the University of California at San Francisco to study wound healing, by the University of Miami to study neural transmitters and by the University of Iowa to study effects of maternal diabetes on lung development, to name just a few institutions. The American Type Culture Collection lists 32 cell lines available commercially from human embryos and 28 from human foetuses.

Only therapeutically oriented research on embryos has been banned from federal funding. This includes all infertility research, IVF, genetic therapy on embryos and research on the time at which HIV enters the embryo or foetus. Why?

The answer is that Congress feared that 'therapeutic' research would encourage women to have abortions. The possibility of donation for a beneficial purpose might offer redeeming value to what many Americans consider an act of murder.

Ethical issues and religious views

In the USA, the ethical issues of greatest concern are (1) whether the foetus has intrinsic value, even outside the mother's body and (2) whether embryo or stem cell research can be separated from the abortion debate. There are other issues that are neglected by comparison: the effects of research on the donors, the recipients, commercial companies, the uninsured and society. Political and ethical discussion, however, focuses on the embryo. For many people, embryos have intrinsic value from the moment of conception, whatever their stage of development, wherever they are and whatever their likely future. It does not matter that the embryo may be one of several hundred thousand left over after IVF and awaiting almost inevitable discard. (There are no national figures on the number of frozen embryos, but most of the approximately 400 infertility clinics store embryos, and most of those reporting numbers have at least a thousand.) Believers in intrinsic value regard embryos as human persons deserving of respect, and point hopefully to the half-dozen or so embryos that have been adopted and brought to birth. No amount of benefit to already born persons is worth destroying a valued unborn person, even if that person will never develop beyond the first few cells. Human dignity must not be denied.

A contrasting view says that value is not intrinsic to embryos, but is assigned by interested parties (such as the parents), on the basis of factors such as location (inside or outside the womb); if outside, whether the embryo is likely to be implanted. One might call these situational values as compared with intrinsic values. The value of an embryo in the mother's body stems from its potential to develop into a full person. An embryo outside the mother's body has no potential except early death, unless drastic steps such as implantation are undertaken.

Religious traditions hold varying views of the embryo's value. Catholic doctrine holds that embryos have intrinsic value. The National Conference of Catholic Bishops is much in the news as the most vocal opponent of stem cell research, even after Bush's decision. However, this conservative body does not represent all American Catholics or all Catholic moral theologians. Polls suggest that the majority of Catholic laypeople approve stem cell research. There is some latitude in moral theology. Although the Pope publicly expressed his disapproval to President Bush before 9 August, he did not speak *ex cathedra*, which could have made the statement 'infallible' according to Catholic doctrine. A growing number of Catholic moral theologians do not regard very early human embryos as individual human entities and would allow

research before the development of the 'primitive streak' at 14 days, which marks the point at which some cells are destined to become the embryo and others to become the placenta.[8] This dividing line is widely recognised as having enough symbolic significance to permit research beforehand and prohibit it afterwards. This view is analogous to a centuries-old tradition of 'ensoulment'; according to Thomas Aquinas (following Aristotle and St. Augustine) rational souls entered males at 40 days and females at 90 days, thereby establishing personal existence and completing the process of conception. Embryos in the earliest stages had only a 'vegetative' life force. However, nineteenth-century scientific discoveries about the timing of conception pushed ensoulment into the background. In July 2000 the Pope listed cloning and stem cell research as among 'the evils of Western culture.'

Protestant views vary. Historically, Protestantism supported science, believing that nature was faulty and that God intended us to discover its inner workings and repair it. In the seventeenth century, Boston's Puritan ministers preached the virtues of inoculation for smallpox from the pulpit and even administered it themselves, while the medical establishment held back.[9] This crusading spirit, originally religious, continues to affect American medical practice and scientific research. Some denominations have expressed support for embryonic stem cell research, including the General Assembly of the Presbyterian Church[10] and the United Church of Christ.[11] Others have taken the intrinsic value position, including the conservative Missouri Synod Lutheran Church,[12] the United Methodist Church[13] and the Southern Baptist Convention,[14] all three of which oppose embryonic stem cell research and hope that adult stem cells will suffice. In view of their overall support for medicine and technology, some denominations that now oppose may change their minds if embryonic stem cell research succeeds.

Jewish views hold that a foetus outside the mother's body does not have the same value as a foetus within her body. Traditionally, a foetus was 'water' for the first 40 days.[15] 'Genetic materials outside the uterus have no legal status in Jewish law, for they are not even part of a human being until implanted in a woman's womb.'[16] Most commentators speak of a 'mandate to heal' and a 'mandate to be partners with God in creation,'[15] and some would allow creation of embryos in a Petri dish solely for research.[16]

Islamic views generally place ensoulment at the 120th day, after three 40-day periods of development, and hold that a very early embryo has no moral status. According to one interpreter, 'research on stem cells made possible by biotechnical intervention is regarded as an act of faith in the ultimate will of God as the Giver of all life, as long as such an intervention is undertaken with the purpose of improving human health.'[17]

The word 'potential' appears in many of these arguments. University of Manchester philosopher John Harris warns of the 'trap of potential', meaning that we often regard the embryo in terms of what it might become, under certain circumstances, rather than what it actually is now. Looking at the actual properties of the embryo, in terms too irreverent for most American sensibilities, Harris compares it to many animals that become the Sunday roast.[18] Yet when it comes to the hundreds of thousands of embryos frozen after IVF, perhaps it is time to look at actuality rather than potential.

Bush and compromise

Compromise between those who hold that deriving stem cells is killing babies and those who hold that benefits to already born persons outweigh the brief existence of early embryos is somewhat analogous to the 'peace process' in the Middle East. Both sides have a passionate sense of right and will adhere to fundamental beliefs. Before Bush, there were several attempts at compromise, the most notable of which was a ruling by the DHHS Legal Department that the government could fund research on stem cells that had already been derived elsewhere, but could not fund the derivation itself. This ruling was an attempt to respect

the beliefs of those who thought that derivation was killing human beings, while simultaneously respecting the fervent desires of many patient groups that research proceed. Conservatives regarded this compromise as hypocritical, allowing the private sector to do the dirty work while the government funded research on an increasing supply of murdered bodies. On 9th August, eager to please just about everybody, especially his conservative supporters, Bush tried another form of compromise, in a well-worded speech that suggested personal agony as well as political astuteness and also reminded listeners, in a reference to use of foetal tissue transplants for Parkinson's disease, that promising scientific endeavours do not always succeed. He ruled that the government could fund research on stem cells that had been derived before, but not after, 9th August, provided that they came from embryos left over after fertility treatments (thereby excluding the embryos created specifically for research by the Jones Institute). The rationale was that the government should not encourage more killing, but since the damage had already been done in the case of cells derived before 9th August, and the potential to treat disease was real, use of these cells should be funded. Bush's well-worded speech did not please everyone, though most conservatives (with the notable exception of the National Conference of Catholic Bishops) have been quiet. Many scientific groups, including the American Society of Human Genetics, have offered cautious praise, largely because the statement sets a precedent for federal funding, which they hope may be expanded if preliminary research succeeds. Bush's statement is illogical and without a basis in principled reasoning. There is no reason, beyond the political, why it should be ethical to use stem cells from blastocysts killed before the arbitrary cut-off date of 9th August but not afterwards. In the end, advances (or failures) in science may decide the debate. If stem cell research demonstrates safety and efficacy, public opinion could change rapidly. Political opinion often follows public opinion.

Meanwhile, it will be politically impossible to separate the stem cell debate from the abortion debate. The usual argument for separating the two debates goes like this: 'A shooting leads to brain death. Is it wrong to use the organs for transplantation because murder is wrong? Will the possibility of organ transplantation increase the murder rate?' Opponents of abortion counter that we can condemn homicide, but abortion is a legally supported murder-machine of gigantic proportions, largely approved by society. Use of embryonic tissue will make women feel less guilty than they should and will further increase society's approval of abortion.

Focus on the fate of the embryo has turned US public attention away from a panoply of ethical issues. These include discussion on (1) effects on the donors (parents), who may retain an emotional connection, however slight, to the embryo; (2) effects on recipients, especially for brain and neural stem cells, as in treatment for Alzheimer disease (will this alter personhood?); (3) effects on society as people live longer; (4) questions of access and economics; (5) patenting, as research becomes commercialised; and (6) unintended effects of stem cell technology on other technologies, such as an increase in our ability to perform human reproductive cloning. Access is the overarching ethical issue. The benefits of stem cell research are unlikely to reach most people in developing nations, even though companies may do a considerable amount of research in these nations. If proposed legislation passes the Senate in 2002, patients in the USA are also unlikely to benefit, because the law would forbid therapies resulting from nuclear transfer as well as the cloning technology itself. In any case, the uninsured (about 16–20 per cent of the US population) would be left out.

Arguments are pervaded by symbolism, including scientists' and the public's fantasies of rescues and magic bullets, the public's fear of contamination or armies of clones, and advertisers' admiration of the power of living cells. West, speaking at a

Harvard Medical School Ethics Division symposium on 3rd December, likened stem cells to the raw clay from which individuals are made (as in God's creation of Adam), before the first spade enters the ground. West also compared evangelical Christians to 'dragonslayers' fighting a 'battle at the border' – namely the earliest stages of life – against 'atheistic humanist attempts to destroy mankind'. In this impassioned climate, calls for reasoned debate may fall on deaf ears.

Creating embryos for research

With hundreds of thousands of 'surplus' embryos cryopreserved in US IVF clinics, it appears that there might be no need to create additional embryos solely for purposes of deriving stem cells for basic research. However, it takes far more embryos to produce stem cells than to produce babies. First of all, few parents donate their left-over embryos. For example, the Institute of Reproductive Medicine and Science at St Barnabas Hospital in Livingston, New Jersey, found that of 11,402 embryos stored for 1,595 patients, only 133 were donated for research (by 22 patients or couples).[20] Scientists at the Jones Institute, a private infertility clinic in Norfolk, Virginia, thought that only 100 of 10,000 frozen embryos might become blastocysts capable of yielding stem cells, partly because frozen embryos from older donors with infertility problems (most couples having IVF) do not develop well. Therefore the Jones Institute commissioned egg and sperm donations from young, healthy donors expressly for research, causing additional political furore in the several weeks before Bush's 9th August speech. Only 3 of 110 fresh embryos yielded stem cells.[19] If this trend continues, massive numbers of specially created embryos would be needed. Development of pluripotent stem cells from adult stem cells though nuclear transfer would also require large numbers of eggs. Opposition to egg donation, in which the woman typically receives US$2,000–4,000 for her time and discomfort, has led some feminists to testify before Congress against therapeutic cloning. These feminists, including some members of the internationally known Boston Women's Health Book Collective, fear that poor women will make 'contracts of desperation' to sell their eggs. Meanwhile, the UK DOH has approved creation of embryos for research, if sufficient numbers cannot be obtained after IVF, and points out that small numbers have been created already for infertility research.[2]

As research moves closer to clinical reality, a key reason for creating new embryos will be to match the DNA of the stem cells with the DNA of the patient, so that the patient's immune system will not destroy them. This can be done only by taking an adult cell from the patient and reprogramming it to generate a line of pluripotent stem cells. At this point in time, reprogramming requires a return to the embryonic stage, through somatic cell nuclear transfer (SCNT). The nucleus of a donated egg is removed, and the patient's adult cell is inserted into the enucleated egg. The egg's cytoplasm then reprogrammes the adult cell to the embryonic state. If the resulting embryo lives long enough, it can become a blastocyst capable of yielding stem cells that will be compatible with the patient's immune system.

The ethical issues include the following:

- Playing God – we do this already in much of medicine and technology, including infertility treatments. Creating embryos for research to benefit others is not ethically different.
- Destroying created embryos. Does the fact that we created its brief existence make any difference in terms of its ultimate disposition? Is destroying it any different, ethically, than discarding an embryo left over from IVF? It would difficult to make a case for difference.
- Effects on the women who 'donate' eggs (in the USA, for a price). This is perhaps the most important ethical issue. Egg donation carries risks, especially ovarian hyperstimulation from medications used to induce ovulation, which in rare cases can be fatal. It may be argued that since a research donor's ovulation cycle need not

be timed to coincide with a recipient's cycle (as it would in IVF), drugs need not be used and risks would be less. However, there are still small risks of infection. There is also a social risk that egg sales will become a way of financing college tuition and new wardrobes, leading young women to think of their reproductive organs as sources of commercial income.

Embryos should be created for research only if there is no other way to obtain enough embryos, or to obtain the right type of embryo (matched to a patient), if the conception takes place outside the body, in a laboratory, if detailed consent is obtained from sperm and egg donors, and the embryo is kept alive only to generally accepted limits (usually 14 days), and will not be implanted. In the informed consent process, researchers need to be aware of donors' possible continuing emotional relationship with their gametes and embryos. Donors need to know the specifics of potential research, some of which they may find troubling, and about possible cell immortalisation. They should also receive, if they wish, a brief communication about the general outcomes of research projects to which they contributed.

Can the private sector meet the challenge?

Infertility research in the USA has long been confined to the private sector. Some IVF clinics have done their own research for over 20 years. It is unlikely that private clinics can replicate this scenario for stem cells, in view of the immense costs and financial risks. Some biotechnology companies may suffer huge losses in the years before stem cells become profitable. University contributions will be limited, because the reach of federal regulations is broader than many people realise. Regulations (including those on embryo and stem cell research) cover all institutions receiving federal funds, regardless of department. A university receiving a federal grant or contract in physics or physical education cannot do stem cell research on cell lines not approved by the US government, even if the stem cell research is funded by a private, non-governmental foundation. Almost all universities receive federal funds of some sort. (Some spin off their own independent private foundations to try to solve this problem.) Much stem cell research will necessarily take place in private for-profit organisations. But can they afford it? Most companies doing stem cell research have received little attention from investors, when compared with other sectors of the healthcare industry or the economy.[20] The stock market has been mixed. Geron Corporation, which holds a stem cell licence from the University of Wisconsin, lost US$45m on US$6m revenues in 2000, has seen its stock fall. Novartis acquired Systemix (which researched blood stem cell treatments), but closed it as unprofitable. On the other hand, Stem Cells, Inc. in Palo Alto, California, which uses neural stem cells from fetuses, saw its stock price quadruple in 2000–2001.[20] Therapies using cells derived from blastocysts created from and for individuals so as to be immunologically compatible may present special cost problems for companies as well as consumers. Bristol-Myers-Squibb recently said that 'individualized treatment doesn't play to our core interests.'[20]

In the short run, the Bush decision will probably not reduce the US lead in research. Some scientists, including Roger Pederson of the University of California at San Francisco, plan to move their laboratories to the UK, but there will probably not be an immense exodus. West says that he is an American who loves this country and would never leave, even if Congress passes a law against therapeutic cloning for stem cell research. He hopes that future science may be able to solve some ethical problems, perhaps by creating artificial oocytes that could not support an implantable embryo, thereby separating therapeutic cloning from reproductive cloning. Many scientists expect that restrictions will be relaxed once there are therapeutically useful results. However,

if these results are a long time in coming, and private industry is unwilling or unable to carry forward a risky venture, the focus could shift to the UK, Australia and other countries.

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