The Politics of Cloning

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At a time when occasional voices are being raised to assert the acceptability of human cloning and even to put it more rapidly into practice, it is important that we reiterate our determination to defend human dignity against the abuse of scientific techniques.

Ontologically, of course, there is no difference between so-called 'therapeutic' and reproductive cloning. Both involve the manufacture of human embryos. If anything, in its consequences, 'therapeutic' cloning is even more ethically and scientifically unacceptable than reproductive cloning. The cloned embryo will be used as a donor without its consent; it will be manipulated, plundered and then destroyed.

The UK Parliament's decision to authorise the cloning of human embryos for therapeutic purposes without allowing proper scrutiny and debate has, I believe, exacerbated that strain and mistrust.

Developments in science are racing ahead of ethics. Parliament is struggling to catch up. The House of Commons Science and Technology Committee has recently announced an inquiry into the operation of 1990 Human Fertilisation and Embryology Act. I hope that this inquiry will help give Parliament an opportunity, at long last, to properly analyse human reproductive technologies and in particular, the threat that human cloning poses to the future of the human race.

When we debated the Human Fertilisation (Research Purposes) Regulations in January 2001 and in particular the proposal to establish a retrospective Select Committee to look into the issues of stem cell research and human cloning I likened this to a situation where a judge were to give "out the verdict and sentence before hearing the defence, the prosecution and the witnesses." (Hansard; 22.01.01 Col. 23)

Sadly, the suspicion that I and others held about this whole investigative process has been confirmed. Many individuals, such as Baroness Warnock, profoundly disagree with me on the ethics of embryonic stem cell research and cloning. What we do agree on is the need to restore public confidence in science and ensure that the fears of the general public surrounding genetics and the new reproductive technologies are heeded.

We are the only country in the world to allow human cloning without making it the object of primary legislation. Contrast this with the inordinate amount of time Parliament has spent debating fox hunting which will be the object of primary legislation.

When the Government does not allow Parliament to properly debate these matters, decision making authority becomes vested in unelected and unaccountable quangos such as the Human Fertilisation and Embryology Authority (HFEA), a body which has shown itself singularly unable to effectively regulate the IVF industry and is patently unable to regulate human cloning.

The report of the House of Lords Select Committee on Stem Cell Research, which was established after Parliament approved regulations authorising embryonic stem research and human cloning, was disappointingly predictable, bereft of any new insights, ethically compromised, and is already being eclipsed by exciting new scientific developments in adult stem cell research.

The Committee failed to fulfil its remit. Prior to its establishment I questioned the wisdom of appointing a retrospective Select Committee to look into cloning and stem cell research after Parliament had approved hastily prepared and ill-conceived Regulations authorising such research.
The Committee's remit was to "examine the ethical, legal, scientific, medical and commercial issues surrounding the Regulations" approved by Parliament in January 2001 authorising embryonic stem cell research and so-called "therapeutic" cloning.

It failed to do this.

No peer who had spoke in favour of my amendment to establish a Select Committee to investigate the crucial issues at stake prior to approval of the

draft regulations was appointed to the Committee. This follows a depressingly similar pattern.

In the late 1990s when the HFEA and the Human Genetics Advisory Commission asked a Committee of four people to act as an advisory body it appointed them knowing that all four were from scientific backgrounds, that all four had previously expressed support for cloning, and that two had links with the pharmaceutical industry. The Chief Medical Officer's 14 strong Expert Working Group on Therapeutic Cloning did not contain any dissenting voices. It has always troubled me that anyone who upholds the sanctity of human life from fertilisation is automatically excluded from the debate, and especially from key committees.

All 26 witnesses who were called to appear before the Committee to give evidence from a scientific or medical perspective were from the pro-'therapeutic' cloning, pro-embryonic stem cell lobby.

The Committee received no oral evidence from a legal perspective, despite the very serious significance of legal issues raised by the Judicial Review of the ProLife Alliance and despite the fact that major legislative concerns were aired during the January debate by various speakers including the former Attorney General, Lord Rawlinson of Ewell QC and Lord Brennan QC.

Christian religions outside the Church of England and the Roman Catholic Church were not invited to submit oral evidence. Input from the Muslim community was minimal and there were no witnesses from the Sikh or Hindu communities.

By way of contrast, plenty of time was found to receive oral evidence from individuals who, as well as being scientists with expertise in this area, also sit on bodies which are strongly firmly in the pro-cloning, pro-embryonic stem cell research lobby. In many cases, these individuals also have vested financial interests in ensuring that embryonic stem cell research and so-called 'therapeutic' cloning is given the green light.

I would like to make two particular criticisms of the manner in which the cloning debate has been conducted in the UK by Government, by the House of Lords Select Committee on stem cell research and by the scientific and

medical establishments. Firstly, the debate has been characterised by bad ethics and a flawed philosophical analysis. Secondly, lazy science has flourished and dissenting or alternative scientific voices have been suppressed with possibly devastating consequences for human health.

Looking first of all at the ethics. I maintain that human embryos are nascent human beings and that all destructive research on human embryos, regardless of the potential benefits, is unethical. I remain profoundly concerned about the effect on society of our treating nascent human life as a natural resource to be mined, exploited and commodified and about so-called bioethicists who are happy to bestow their moral blessings on the latest innovation - to be sure, not for love, but for money. Since the passage of the Human Fertilisation and Embryology Act 1990, over 925,000 embryos have been created through in vitro fertilisation (IVF) treatment. Just 4% of these embryos have ever seen the light of day.

In the light of these shocking figures, what remains of the 'special status' of the human embryo.

Professor Leon Kass, Chair of the US President's Council on Bioethics, said in an address he gave in London last year that I was privileged to attend:

"We are desensitized and denatured by a coarsening of sensibility that comes to regard these practices as natural, ordinary and fully unproblematic. People who can hold nascent human life in their hands unblinkingly and without awe have deadened something in their souls."

I recognise that the Human Fertilisation and Embryology Act 1990 allows embryos to be created for research purposes and that we already accord an inferior value to the human embryo in its first 14 days of life. Baroness Warnock has acknowledged the "absurdities" this has produced. In a debate in the House of Lords last December she expressed "regret" that her 1984 report that led up to the 1990 legislation used the words "respect for the embryo". She went on, "You cannot respectfully pour something down the sink".

However, the absurdly arbitrary 14 day cut off point becomes ever more obsolete in the light of new research demonstrating the sheer wonder of the human embryo.

The significance of conception as the starting point of our human existence is illustrated by an article in 'Nature' magazine dated 4th July 2002. Headed, 'Your destiny, from day one' the article states, "Your world was shaped in the first 24 hours after conception. Where your head and feet would sprout, and which side would form your back and which your belly, were being defined in the minutes and hours after sperm and egg united."

Embryologists such as Alan Handyside from the University of Leeds are warning us that meddling with early human embryos might carry series adverse consequence - "It's possible you could be removing a cell with a predictable fate and causing damage".

Incredibly, the report makes no reference to an unprecedented written submission by an ad hoc group of eminent Christian theologians from the Anglican, Catholic, Orthodox and Reformed traditions on the ethical status of the human embryo. There is far more unanimity within the Christian tradition on sanctity of early human life than the Committee and its Chairman the Bishop of Oxford led us to believe.

A utilitarian outlook dominated the report and continues to dominate Government thinking on this issue. The Select Committee's failure to effectively analyse the ethical issues surrounding embryo experimentation reinforces the perception that its conclusions were fixed from the outset and that tricky ethical questions would not be allowed to frustrate matters.

My second point is that the cloning debate in the UK has been characterised by lazy science and a deliberate attempt by the Government to obfuscate and mislead on the science of cloning and stem cell research.

Yet look at what the leading scientific journals are saying:

"Like stuck records, ministers and policy makers continue to enthuse about therapeutic cloning even though the majority of bench scientists no longer

think it's possible or practicable to treat patients with cells derived from cloned embryos. They have already moved on to investigating the alternatives." 'New Scientist' Editorial - December 2001.

"the idea of 'therapeutic cloning' seems to be on the wane.....most now believe that it will be too expensive and cumbersome for regular clinical use." 'Nature' Magazine - December 2001.

Even Professor Alan Trounson, once a leading proponent of embryonic stem cell research and so-called 'therapeutic' cloning says that stem cell research (both adult and embryonic) has advanced so rapidly in the past few months that 'therapeutic' cloning is now unnecessary.

"My view is that there are at least three or four other alternatives that are more attractive already."

In the New England Journal of Medicine a letter to the editor was published calling previous Journal articles addressing the ethics of "therapeutic" cloning and embryonic stem cell research "inadequate". The letter was signed by a number of experts including C. Everett Koop, M.D., former Surgeon General, and other leading doctors and bio ethicists.

The House of Lords Select Committee report implies that no clinical or pre-clinical trials have been carried out with adult stem cells, despite the clear evidence provided from peer-reviewed journals of success in trials using adult stem cells in diabetes, severed spinal cord, demyelinated spinal cord, heart attack, stroke, traumatic brain injury, liver failure, Parkinson's Disease, Alzheimer's Disease, various forms of blindness, full-thickness burns, severe bone disease, and so on.

It has been announced that it will soon be possible to use the body's own stem cells to repair the damage caused by heart attacks.

The Government and the House of Lords Select Committee report have ignored the known serious risks of tumour and cancer formation using embryonic stem cells and, despite all the available evidence and clear warnings from a number of witnesses, stated that embryonic stem cells are safe.

However, Professor Ian Wilmut (best known for the creation of 'Dolly' the sheep admits that cells used in "therapeutic" cloning may lead to disease, and particularly to tumour formation, as a result of epigenetic abnormalities in cloned tissue. He calls for more studies to test the safety of "therapeutic" cloning:

It also appears that there may be inherent biological barriers to the success of 'therapeutic' cloning of primates. One of the most prominent embryonic stem cell scientists who has been attempting CNR with human oocytes, Roger Pedersen, published an article in the September 2002 issue of Nature Biotechnology (volume 20, pages 882-883. "Feeding Hungry Stem Cells"), in which he states with reference to 'therapeutic' cloning in humans that, "discouraging results so far suggest that there may be intrinsic biological impediments to the use of this strategy with primates."

Profound abnormalities in cell division leading to wrong chromosome numbers have been found to occur in 100% of cases in cloned primate (monkey) embryos, resulting in cells with the wrong numbers of chromosomes. It appears that this abnormal cell division may be the cause of the total failure of all attempts to clone monkeys from adult cells

There appears to be the same problem with human cloned embryos as there is with monkey cloned embryos. Professor Schatten, who has carried out this work, says that preliminary research suggests that human eggs have the same biological characteristics that cause abnormal cell division in cloned (non-human) primate embryos. "Primate eggs are biologically different," he states. (Vogel, 2003). He also believes that, "with current approaches, primate nuclear transfer to produce embryonic stem cells may prove difficult - and reproductive cloning unachievable."

Professor Jaenisch of the Massachusetts Institute of Technology, who studies cloning in mice states, "The failure to clone any primate so far has been startling." (Vogel, 2003).

The use of cells with wrong chromosome numbers for "therapeutic" cloning could also cause tumours, as this defect is characteristic of cancer cells.

Scientists are attempting to find ways around the problem of abnormal cell division with cloned primate (human and monkey) embryos. However, this has

not yet been achieved, and it is uncertain whether it can be overcome. However, there are even more fundamental problems with cloning.

There are widespread abnormalities of gene expression in cells of cloned embryos. This could result in various unpredictable abnormalities in cells used for "therapeutic" cloning, resulting in a medical risk to the recipient of the cloned tissue.

Despite all these problems, the House of Lords Select Committee recommended that, "even if CNR is not itself used directly for many stem cell-based therapies," it should still be permitted as a research tool to enable cell-based therapies to be developed. The Government concurs with this recommendation. The Select Committee report takes the view that CNR research provides "the only realistic means" of studying the process of dedifferentiation. The report believes this to be essential for adult stem cell therapies to be developed (chapter 3, paragraphs 17 and 18).

However, first, cell nuclear replacement is a very faulty model to use for studying dedifferentiation. The vast majority of early embryos produced by cell nuclear replacement are abnormal. Therefore, the vast majority of cells used to study the biochemical processes of dedifferentiation would provide erroneous data.

Second, owing to advances in adult stem cell research over the last two or three years, it is clear that dedifferentiation of adult stem cells prior to their redifferentiation is completely unnecessary for a number of reasons.

It is most unfortunate that the Select Committee report ignored the wealth of peer-reviewed evidence that it was provided with, which detailed the various ways in which the idea of dedifferentiation of adult stem cells is now redundant. As a result of this, the report takes the very definite, but completely erroneous, view that it is essential for adult stem cells to first be dedifferentiated in culture and then redifferentiated into new cell types. It is claimed that basic research using CNR and embryonic stem cell research are essential if adult stem cell therapies are to be fully developed.

However, there are various ways in which adult stem cells can be used which completely bypass the need for dedifferentiation before redifferentiation.

For example, there are many trials demonstrating the very effective treatment of serious diseases in animals, and even in human patients, where adult stem cells have been safely injected into the bloodstream, and found to travel to the injured area and have been very effective in repairing the damage. No prior dedifferentiation, or even redifferentiation in culture were required, as the body appears to have all the relevant signals to direct appropriately both migration of the stem cells to the damaged area, and their differentiation once they arrive. This has already been found to be highly effective for heart attack, a severe bone disease liver failure, stroke, traumatic brain injury and demyelinated spinal cord.

Mobilisation of adult stem cells from internal stores has also been highly effective in treating heart attack, and it is to be expected that this will be an effective strategy for other diseases.

The Committee received this information, but unfortunately derived its conclusions through utilising completely outdated information. There is no need for research on CNR to provide information on dedifferentiation for adult stem cells.

The efficacy and safety of various procedures which do not require dedifferentiation or differentiation of adult stem cells in culture has been demonstrated by the remarkable level of healing that they effect with a variety of serious diseases - heart attack, severed spinal cord, demyelinated spinal cord, stroke, traumatic brain injury, diabetes, Parkinson's Disease, severe bone disease and liver failure.

Notwithstanding the massive scientific problems with human cloning, it is also unworkable at the practical level, a point that those who have been promoting 'therapeutic' cloning at the political level have chosen to ignore. Vast numbers of eggs would be required for 'therapeutic' cloning.

Scientists involved in animal cloning have estimated the numbers of eggs that would be required for therapeutic cloning for one patient as, "optimistically,

about 100 human oocytes" (Mombaerts, P., 2003) and, "at least 280 oocytes." (Colman and Kind, 2000).

Thomas Okarma, chief executive officer of the lead cloning company Geron Corporation says, "The odds favouring success are vanishingly small, and the costs are daunting...It would take thousands of (human) eggs on an assembly line to produce a custom therapy for a single person." (Los Angeles Times, 10th May, 2002).

Suppose you need at least 100 eggs for one patient: If one considers that one patient group alone that has been claimed could be helped by 'therapeutic' cloning - type 1 diabetes - has 350,000 sufferers in Britain, and another has 385,000 (Alzheimer's), an absolute minimum of 73,500,000 eggs (and probably far greater numbers) would be needed just to treat these two patient groups. Since an average of about 10 eggs is produced in one forced ovulation induction cycle, this means that at least 7,350,000 forced ovulation induction cycles of women between the age of about 20 and 35 would be required to treat these two patient groups.

These eggs would either have to come from egg donors, or from women undergoing IVF who give some of their eggs for cloning. What about the serious health risks to these women?

Fortunately, these (and numerous other serious) diseases have already been significantly helped by adult stem cells. Type 1 diabetes, for example, has been reversed in animal models of the disease, using adult stem cells obtained from the pancreas, spleen or liver (Ramiya et al., 2000; Kodama et al., 2003; Yang et al., 2002). Alzheimer's disease in animals has been significantly helped with stem cells from umbilical cord blood, with a considerable extension of life span (Ende et al., 2001).

In view of the serious health risks associated with embryonic stem cell research and cloning I am profoundly concerned that the Government continues to express confidence in the work of the HFEA, an organisation in disarray, and entrusts regulation of embryonic stem cell research and 'therapeutic' cloning to this body. Even the HFEA's most ardent supporters recognise that it is in trouble.

In July last year this year the House of Commons Science and Technology Committee, in its report, "Developments in Human Genetics and Embryology, was highly critical of the HFEA:

"The Lords Stem Cell Research Committee reported that the HFEA's is 'highly regarded, both at home and abroad..... [and] has the full confidence of the scientific and medical research community'. We are unclear on what evidence it based this assertion."

Recent 'mix-up' scandals at IVF clinics that the HFEA is supposed to be monitoring, and the shocking disclosures from the embryologist Dr Sammy Lee in the Sunday Telegraph last year demonstrate that the criticisms of the House of Commons Science and Technology Committee are certainly not unfounded. Dr Lee wrote that he knew of at least six cases where the wrong embryos were put into women. He maintains that it is "galling that the HFEA, which purports to protect patients, has sought to brush aside any meaningful discussion of why mistakes occur in IVF clinics, and how frequently."

Stem cell technology and human cloning are not extensions of assisted reproduction, but involve a multitude of scientific and medical fields which embrace nearly all aspects of disease. We need a new and completely independent organisation to monitor and assess developments in this field.

Our wholly inadequate ethical and scientific analysis of the cloning issue, taken with what is already one of the most liberal regimes for embryo experimentation in the world, leaves the United Kingdom isolated internationally.

Notwithstanding the deeply regrettable recent decision of the European Parliament to authorise European funding for embryonic stem cell research, the European Union has banned EU funding for experiments using cloned embryos.

In the US, the majority of the President's Council of Bioethics recommended a ban on cloning-to-produce-children combined with a four-year moratorium on

cloning-for-biomedical-research. Their conclusions are endorsed by the current US administration.

At the UN, a worldwide ban on both reproductive and so-called 'therapeutic' cloning was supported by the US, Costa-Rica and 43 other countries. By comparison, an alternative proposal banning just reproductive cloning was supported by only 14 countries. In the end this powerful minority, backed by the biotech industry, was able to thwart moves towards a comprehensive cloning ban and the UN agreed a two year moratorium on cloning.

I look on with a mixture of envy and admiration at the seriousness with which the current US administration and the previous one has sought to handle this sensitive issue. Rather than rush through ill-conceived regulations and then establish a retrospective Select Committee to rubber-stamp them, the President's Council on Bioethics in the US was convened to thoroughly investigate stem cell research and human cloning and then advise the President. Only then would a decision be made.

Membership of the Committee is balanced, reflecting a number of scientific and ethical perspectives. Unlike us in the UK, our American allies are not afraid of disagreement and the publication of a minority report if unanimity amongst the members of the Committee proves impossible.

In Germany destructive embryo research is prohibited. In Norway the Government has proposed legislation encompassing a ban on all destructive embryo experimentation including 'therapeutic' cloning.

The UK has isolated itself from international opinion on this issue. It is therefore wrong to caricature opposition to the report and Government policy as restricted to a narrow group of pro-lifers and religious fundamentalists.

I recognise the impossibility of reclaiming, at present, absolute status for the embryo. However, this does not excuse the inadequate consideration afforded to the vital issue of cloning by the House of Lords Committee on stem cell research, by the scientific establishment and, above all, by our Government.

In the absence of unanimity on the ethical status of the human embryo there is a broad consensus that destructive embryo research should not be permitted if there is a viable scientific alternative.

The Government has acknowledged this. The then Health Minister Lord Hunt said in 2001 that "the 1990 Act already provides the answer to the question of what happens if and when research into adult cells overtakes research using embryos: embryonic research would have to stop because the use of embryos would no longer be necessary for that research." (Hansard; 22.01.01 Col. 120)

Adult stem cell research is a viable scientific alternative and has clearly overtaken research using human embryos. It is delivering results, not merely demonstrating potential. Embryonic stem cell research companies are struggling to survive.

In cloning we are creating for the first time an entity which is asexual, with no gametes and no parents. The UK Government has expressed its opposition to live birth, or 'reproductive', cloning and rushed legislation through Parliament to ban this practice. But the knowledge of early embryonic development acquired through so-called 'therapeutic' cloning inexorably paves the way for full live birth cloning. It is disingenuous to express opposition to the latter and yet support the former.

We are staring into an abyss. Human cloning has the potential to destroy the human race as we know it. It is unethical, represents bad science and is something that the human race can do without. I hope that the international community, by uniting in opposition to <u>all</u> forms of cloning, will be able to draw the UK back into line with mainstream opinion.

An abridged version of a speech given by Lord Alton of Liverpool at a conference organised by the Centre for Bioethics and Public Policy, November 24th, at the Royal Agricultural Hall Conference Centre, Westminster.