

Table 8.2 continued

Countries	Newspaper	Sample characteristics			Salience	
		1973-1996	1997-2002	Total sample	Salience	Based on period
Partial sample						
Japan	ASAH	350	700	1050	18067	85-02
Canada	Globe and the Mail	82	217	299	1868	92-99
Portugal	Publico	303	675	978	1202	92-02
Norway	Aftenposten, VG	418	1064	1482		93-02
Poland	Polityka, Gloswiakopolski, Rzeczpospolita, Trybuna Ludu & Trybuna	208	158	366	n/a	73-99

Note: Countries are presented ordered by estimated overall salience. The upper part of the table comprises countries for which data are available from 1973-2002. The lower part of the table comprises countries for which partial databases are available. In countries where more than one newspaper is analysed, the intensity figures are based on (the equivalent of) one single newspaper.

# The Politics of Bioethics<sup>1</sup>

## The Case of Human Embryonic Stems Cells

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The ideas in this chapter were first published in 'Five Framings - One Entity? The Political Ethics of Human Embryonic Stem Cells', *Science Studies*, 2005, vol 18, no 1

The 1998 summer issue of *Technology Review* disclosed and pre-announced the ongoing research on human embryonic stem cells under the front-page heading 'Biotech Taboo . . . The troubled hunt for the ultimate cell . . . that could be used to grow any type of human replacement tissue' (Regalado, 1998, front page and p34). Yet a year and a half later, the front page of the 1999 Christmas issue of *Science* promoted stem cells as the 'Breakthrough of the Year . . . capturing the Promise of Youth' (Vogel, 1999, front page and pp2238-2239). In November 1999, a committee under the American Association for the Advancement of Science (AAAS) found that stem cell research 'raises ethical and political concerns, but these are not unique to stem cell research' (AAAS, 1999, piv). Yet two years later a subsequent committee under the National Research Council (NRC) stated that 'the stem cell debate has led scientists and nonscientists alike to contemplate profound issues, such as who we are and what makes us human beings' (NRC, 2001, pxi). Human embryonic stem cells have, together with cloning, attained the dubious status of the most promising as well as the most controversial among the many emerging biotechnologies.

### The derivation of a scientific discovery

Geron Corporation, Menlo Park, California, which had licensed the cells worldwide, had also coordinated and orchestrated the first public announcement of the derivation of human embryonic stem cells as a 'scientific discovery' and 'progress

in basic research' very thoroughly. Two press releases from the company provided the key background information for the printed press's front-page news 'Scientist Found Cells at Root of Human Life' on 6 November 1998 (*The New York Times*, 1998). The press releases referred back to two prestigious scientific publications: an article in *Science* by Professor James A. Thomson and colleagues from the University of Wisconsin, who had isolated human embryonic stem (hES) cells from the inner cell mass of human embryos at the blastocyst stage (Thomson et al, 1998), and another article in *Proceedings of the National Academy of Sciences* by Professor John D. Gearhart and colleagues from Johns Hopkins University, Baltimore, who had isolated human embryonic germ (hEG) cells from foetal tissues obtained from terminated pregnancies (Shamblott et al, 1998).

An essential translation and reframing had, however, taken place on the passage from the scientific periodicals via the press releases to the front-page news. Stem cells, especially from bone marrow, had been known and used for cancer treatment since the 1950s. And embryonic stem cells had been derived from mice in 1981 (Evans and Kaufman, 1981) and primates in 1995 (Gearhart et al, 1995). The 'novelty' presented in the scientific publications was thus neither the existence of stem cells as such, nor of embryonic stem cells, nor even of human embryonic stem cells, but merely the successful derivation of human embryonic stem cells. And the derivation was presented as (technical and practical) know-how more than (scientific and systematic) knowledge.

Neither of the two articles has the aura of a new theoretical insight, nor do they proclaim any controversial breakthrough. The definition of the cell lines and the operational criteria for their derivation are conveyed unchanged from the previous experiments with mice and primates. A summary and documentation of research protocols with references to preceding studies is thus the dominating content of the two articles. Description and documentation of practical procedure in the laboratories has precedence over conceptual clarification and explanations. Large passages of the two articles resemble a mix of cookbook and manual, conceptual trivialities and complicated technicalities: those were the ingredients and this is how we proceeded at the lab bench. By way of a not untypical example:

*Cells were grown in DMEM (GIBCO/BRL) supplemented with 15% fetal bovine serum (HyClone), 0.1 mM nonessential amino acids (GIBCO/BRL), 0.1mM 2-mercaptoethanol (Sigma), 2 mM glutamine. . . Cultures were grown in 5% or 8% CO<sub>2</sub>, 95% humidity and were routinely passaged every 7 days after disaggregation with 0.05% trypsin/0.53 mM EDTA (GIBCO/BRL) or 0.25% trypsin at 37° C for 5–10 min. . . Cells prepared for cytogenetic analysis were incubated in growth media with 0.1 µg/ml of Colcemid for 3–4 hr, trypsinized, resuspended in 0.075 M KCl, and incubated for 20 min at 37° C, then fixed in 3:1 methanol/acetic acid. (Shamblott et al, 1998, p13727)*

In brief, the articles do not claim to have found any new and unexpected substance, but rather to have demonstrated that the existence of an expected substance can be kept and maintained in a certain form: isolated, cultivated and

expressed. The two research teams had successfully adapted, replicated or copied in human cells what had previously been attained in cells from mice and primates. The research teams thus constituted human embryonic stem cells as a new object for science analogous to the way Gregory Mendel constituted genetics (and Crick and Watson later DNA) as objects for science (Foucault, 1971), but theoretical implications and practical applications were not part of the agenda.

The triangle of collaboration between the private company Geron, the partly public universities and their partly outsourced research teams was a response to the political reality, that the US since 1996 had had a de facto ban on public funding of research 'in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in uteri'. Congress had taken the decision ad hoc as the Dickey-Wicker amendment to the Department of Health and Human Services annual budget – and against the recommendations of the National Institute of Health and the Clinton administration. Yet as only the use of public funding was forbidden, a paradoxical consequence became, in the words of one of the Clinton administration's key advisors, Dr Ronald M. Green,

*[that] although much of the previous animal research on ES cells that had led to Thomson's achievements was federally financed, the commercial benefit would now be in private hands. (Green, 2001, p9)*

Geron had been founded by Dr Michael D. West back in 1990. Following the publication of the derivation of embryonic stem cells from primates in 1995, Geron had funded the research of Thomson and Gearhart as well as Professor Roger Peterson, University of California, San Francisco (considered by many to be the most promising candidate to succeed (Regalado, 1998, p38)). Investments in funding for licences turned out to be an immediate financial success. Two applications for patents were filed well in advance of the scientific publication and were subsequently approved. On the very day of announcement, stocks rose from \$6 to \$23, and one month later, convertible debentures worth \$15 million were sold to venture capitalists.

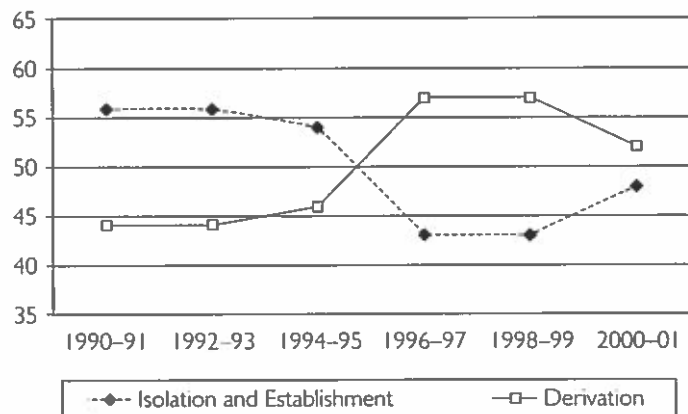
The two scientific publications closed with reservations characteristic of the genre. In the words of Thomson and colleagues, 'Substantial advances in basic developmental biology are required to direct ES cells efficiently to lineages of human clinical importance' (Thomson et al, 1998, p1147). Yet the patent applications present themselves as being as certain and convinced as the scientific articles are modest. They are both 'continuation-in-part' of earlier applications, but much longer and more detailed, and the 'Scientists' are completed in the standard formula as 'Inventors'. Gearhart's application (US Patent 6,245,566 filed 31 March 1998 and approved 21 June 2001) has the largest number of formal 'Claims' – 36 – all concerning methods of producing and/or maintaining 'human pluripotent embryonic germ cells'. The 11 claims in Thomson's application (US Patent 6,200,806 filed 26 June 1998 and approved 13 March 2001) are presented in another 'logic'. The first eight are different variants of 'a purified preparation of pluripotent human embryonic stem cells', the next two are methods of isolating

such cell lines, and the last claim is finally the very cell line developed by the method.

In short, both claim protection for process as well as product, method as well as result. The pursuit of a maximum of legal protection appears to be the rationale behind the comprehensive claims – and a possible explanation of the contrast to the modest reservations in the scientific publications.

The criteria for patentability may have influenced even the choice of the key concept ‘derivation’. ‘Isolation’ and ‘establishment’ (partly used as synonyms) were the key terms in the articles reporting the use of identical procedures and techniques on mice in 1982 and primates in 1995. But ‘derivation’ was also the key concept in the 1997 article announcing the cloning of the sheep Dolly, where it referred to the very different reality of a ‘viable offspring’, that is, the birth of an entire living animal (Wilmut et al, 1997). And these examples appear to be only illustrations of a general trend. During the 1990s, the use of the terms ‘isolation’ and ‘establishment’ versus ‘derivation’ in the prestigious scientific periodicals changed accordingly. ‘Isolation’ and ‘establishment’ were most frequently used in the beginning, but latterly ‘derivation’ has taken over. And this significant change took place just after the middle of the decade, around the time when Dolly and the human embryonic stem cells both were derived (see Figure 9.1).<sup>3</sup>

The new trend need not be permanent, but the relative increase of the term ‘derivation’ at the expense of ‘isolation’ and ‘establishment’ is both significant and meaningful. The concept ‘derivation’ is increasingly used to describe two quite different phenomena: the isolation, cultivation and expression of embryonic stem cells as well as the cloning of viable offspring, that is, two of the most promising and controversial of the many new biotechnologies. We do not know the degree to which the tendency reflects substantial changes in research priorities, mere changes in editorial criteria or even merely a change of habitual wording.



Relative occurrence of 'Isolat#' and 'Establish#' versus 'Deriv#' in titles of *Nature*, *Science* and *Proc. Natl. Acad. Sci.*

**Figure 9.1** 'Isolation' and 'Derivation'

The typical response from a handful of researchers in the field, when asked about the change, was that they had not previously been aware of any such change, that it nevertheless seemed plausible that it had happened, but that it did not require any special explanation. 'It is quite simply the concept we use.' We don't know why, but we do know that the concept 'derivation' has a prehistory from patenting in organic chemistry, where the 'derivation' of a substance was considered sufficient to satisfy one of the three crucial criteria for an invention. Although a substance of nature, a derivation was considered an invention, since it would not have existed in that form without the intervention of science. And a derived substance can, in principle, be granted patent for the process as well as the product, the 'making' as well as the 'use'.

### Restoration to immortality: The promise of a regenerative medicine

The second framing as a medical hope is often presented as just the other side of the framing as scientific progress or basic knowledge, as the step from 'pure' to 'applied' science.

All stem cells, including adult stem cells, produce the enzyme telomerase, which was isolated for the first time in 1989 and maintains the non-coding bits of DNA attached to the end of each chromosome. Telomerase 'resets' – with a biochemical explanation for philosophers – 'the cell's chromosomal clock and prevents the timed death suffered by most differentiated cells' (Green, 2001, p35). Stem cells hence have the capacity for 'prolonged self-renewal' and are able to produce 'at least one type of highly differentiated or specialized descendant'. And embryonic stem cells have three additional capacities. They are *pluripotent*, that is, able to differentiate to all types of tissues in the body; they are *malleable*, that is, can be manipulated without losing the structure of the cell; and they are *immortal*, that is, able to continue differentiation apparently for ever (Weismann, 2000; Fuchs and Segre, 2000). The three unique capacities recurred in *Science's* presentation of the human embryonic stem cells as the breakthrough of the year. 'If it lives up to its early promise, it may one day restore vigor to aged and diseased muscles, hearts, and brains – perhaps even allowing humans to combine the wisdom of old age with the potential of youth.' Human embryonic stem cells 'may one day be used to treat human diseases in all sorts of ways, from repairing damaged nerves to growing new hearts and livers in the laboratory; enthusiasts envision a whole catalog of replacement parts' (Vogel, 1999, p2238).

The potential of embryonic stem cells is thus an important part of the 'regenerative medicine' that has enlarged the scope of medical therapy 'from simply halting the progression of acute or chronic disease to include restoration of lost organ functions'. And 'regenerative medicine would', writes Dr Thomas Okarma (Michael West's successor as Chief Executive Officer (CEO) of Geron), 'be a totally new value paradigm for clinical therapeutics', bypassing surgery's interventions in the body and pharmaceuticals' side effects. Okarma can thus revolve the moral argument against the bioethicists. 'Not to develop the technology would

do great harm to over 100 million patients in the US alone' (Okarma, 2001, pp3–13).<sup>4</sup> The real threat to morality is the sceptic bioethicist, who is willing to deprive one-third of the population of their cure, not the optimistic scientists.

*Technology Review* has depicted 'the human body shop' as a scenario behind the use of embryonic stem cells in regenerative medicine:

*A decade from now and an elderly man gets the grim news that his heart is rapidly decaying and that the left ventricle – the chamber that squeezes blood out to the body – needs to be replaced. His physician takes a biopsy of the heart cells that are still healthy and ships the tissue to a lab that is really an organ factory. There, workers use that patient's own cells and special polymers to fashion and grow a replacement part – certified by the original manufacturer. In three months, the new ventricle is frozen, packaged and sent to the hospital, where the patient undergoes a standard surgical procedure: the insertion of a living implant created from his own tissue. (Garr, 2001, p73)*

The aura is high-tech, but the medical use of embryonic stem cells is depicted as *low intervention*. The stem cells are 'organic', the body's own internal healing mechanisms, and 'personal', one's own, and 'clean', uncontaminated cells. The real 'magic', however, is the promise to *break the arrow of time*. 'The immortal Cell' presents a shortcut to 'The eternal Life'. Destiny and fate are no longer untouchable. Science and medicine promise to accomplish, here and now, what previously barely religion believed possible, and then only in the next world. 'There and then' might become 'here and now'. Life is about to become reversible or restorable, the permanent beginning or the continuous renewal (Alexander, 2003; Hall, 2003).

Medical hopes are high, but thus far 'proofs of principles' are the only reality. Experiments *in vitro* and with model animals have demonstrated that the principle *can work*, that is, new tissues can differentiate and old ones can be restored. The step from scientific principle to medical practice is, however, at the very least a question of degree and type of differentiation, density and intensity, compatibility, targeting, and possible side effects. The old blood-forming stem cells in bone marrow (HSC) are currently 'the only type of stem cell commonly used for therapy' (National Institutes of Health, homepage, 17 March 2003).

*Overselling*, promising too much too fast, is the severe shadow hanging over the medical hope. Even the pioneer scientists soon warned of a likely backlash. 'I'm not looking forward to the backlash three years from now when people say, "What happened to stem cells?"', said Thomson as early as 2002. 'We need to educate the public that science takes a long time' (Holden and Vogel, 2002, p2119). Yet Michael West was still keen to insist on the non-scientific, i.e. not invincible, nature of all obstacles. 'We have the basic discoveries within our reach to put regenerative medicine into the hands of physicians. We are missing only two components – an organized effort and time' (West, 2003, p220).

## Playing God? Old ethical concerns in new voices

The framing as a new medical paradigm emphasized the good promises of health and the hope for cure of illness, but it did not succeed in setting the tone of the public discourse and thus dominating the political agenda. From the very beginning, the legitimacy of the scientific breakthrough was instead questioned by old ethical concerns. If science was about to replace religion as the explanation of life, then Christian (or Creationist) religion was soon to return with accusations aimed at the new technologies of 'playing God'. The most prominent international spokesmen were those of the Vatican, but the recently inaugurated US president, the Republican George W. Bush, followed along the line. One month prior to 11 September 2001, on 9 August, he addressed the nation, in a primetime broadcast from Crawford, Texas, 'to discuss . . . a complex and difficult issue, an issue that is one of the most profound of our time' (Bush, 2001).<sup>5</sup> And his speech touched upon the two arguments most frequently voiced by opponents and sceptics.

The first and foremost argument gains its immanent strength by ascribing *a special moral status to the embryo*. The Christian background is manifest in the President's description of the embryo as 'a sacred gift from our Creator'. Most believers in the argument regard the status of the embryo as emerging gradually (that is, increasing from (some time after) fertilization to the full born baby), but a more radical version considers the status as absolute and beginning from fertilization. The President's wording of the argument alludes to the absolute version. Paraphrasing the President, 'The beginning of Life [should also be] The end of Science'. But the President is politician enough not to engage directly in the controversial dispute between the two versions, splitting the religious communities.

The second moral argument alluded to by the President is a formal and generalized *maxim* on the proper relation between means and end. The maxim is usually referred back to Immanuel Kant's practical imperative, but the President's version is different.<sup>6</sup> In his wording, 'Even the most noble ends do not justify any means'. The version is open-ended and anticipates its own application. The question is whether a prolonged and/or healthier life (i.e. the 'most noble' end) can justify the destruction or 'killing' of embryos to harvest the required stem cells (i.e. 'any means').<sup>7</sup>

A strict interpretation and radical application of the two arguments prescribes a 'no' or a 'ban' to all research in and on human embryonic stem cells. The status is violated and the maxim infringed. Attributed an absolute status, the embryo resists its own use in science. The technologically unavoidable is morally untouchable, the required source itself morally problematic. And, although not exclusively, stem cells in research are definitely *also* used as means to an end. Ethics stands versus science and science versus ethics. No compromise seems possible. But the President did not take the radical consequence indicated by his rhetoric and supposed by his arguments. Instead, he concluded that:

*we should allow federal funds to be used for research on these existing stem cell lines (more than 60 lines as a result of private research), where the life and death decision has already been made. (Bush, 2001)*

The unexpected conclusion was intended as a political balance with concessions to the most influential interest groups and their lobbyists. The scientists were offered (some) stem cell lines to work with, and the opponents (including the anti-abortionists) were assured that no new demand for embryos would be created. But the concessions soon turned into dissatisfaction on both sides. Scientists complained that the available stem cell lines were too few (and not pure enough), and the religious communities declined the conclusion as the use of moral double standards.

As unsettled and thus postponed, human embryonic stem cells remained an issue also during the next presidential campaign. The Democratic candidate, John Kerry, promised to

*overturn the ban on federal funding of research on new stem cell lines, . . . he will allow doctors and scientists to explore their full potential with the appropriate ethical oversight. Patients and their families should no longer be denied the hope that this new research brings. (Kerry and Edwards, 2002)*

Kerry's framing was the first of the two, that is, science as a necessary precondition for useful medicine. The five arguments given in the press release stating his position thus all circumvented the controversial ethical issues. The first argument was political, an appeal to consensus: 'Stem cell research has broad bipartisan support'. The last argument concerned competitiveness: the US is 'losing leadership in stem cell research'. But the three remaining arguments were all technical critiques of Bush's decision as not only insufficient, but also unimplemented. Fewer cell lines than originally promised are available, they are contaminated with mouse cells, and other cells are not available. Apart from a few empty insertions, ethical issues are unmentioned – apparently considered an argument of the opposition so profound that the best tactic might be to avoid it.

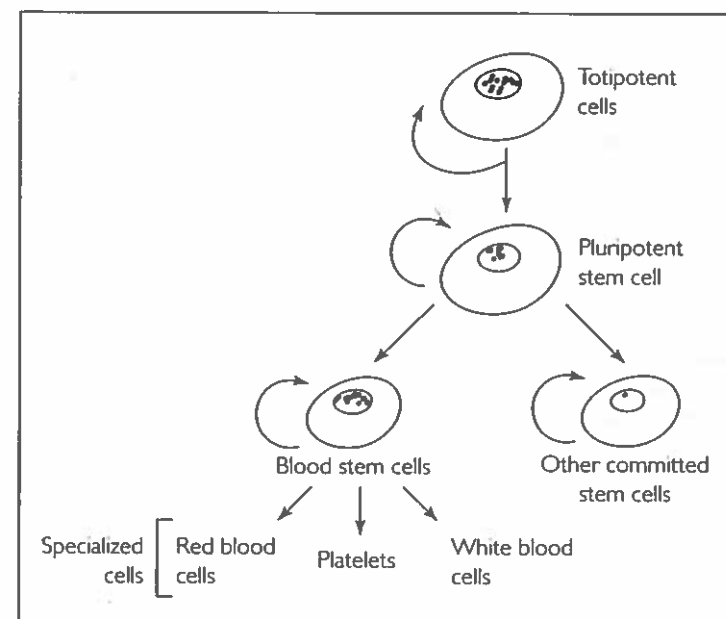
### Adult stem cells as Nature's own solution?

The attempt of the first two framings to avoid or overtrump the ethical considerations was only partly successful. The focal public debate became a partial revival of old ethical concerns, a new version of the human embryonic research debate. Novel and unique to human stem cells, however, was the way science itself indicated new 'technical' solutions to the recurring ethical concerns. In two subsequent steps, science partly regained the framing and the agenda; first, based on the idea of adult stem cells as Nature's own solution, then by therapeutic cloning as humankind's techno-fix to the ethical challenges.

The very same article in *Science* that promoted stem cells as the breakthrough of the year also pointed to another 'astonishing development that occurred in 1999 [and that] may ease the ethical dilemma':

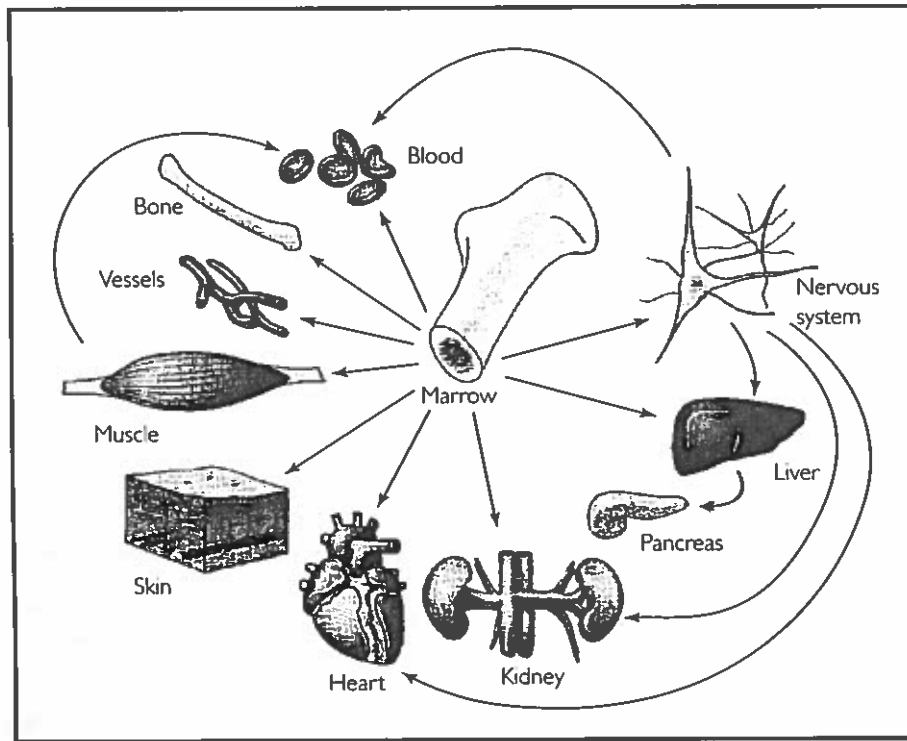
*In defiance of decades of accepted wisdom, researchers in 1999 found that stem cells from adults retain the youthful ability to become several different kinds of tissues: brain cells can become blood cells, and cells from bone marrow can become liver. (Vogel, 1999, p2238)*

If it could be demonstrated that adult stem cells had the same (or equivalent) potentials as embryonic cells, they would be 'nature's own solution' to the recurring ethical concerns, that is, a chance to obtain the advantages of stem cells without the use of embryonic cells. Even Thomson kept the theoretical possibility open. 'If it becomes possible to derive an ES cell line from a source other than an embryo, ethical controversies surrounding hES cells would greatly diminish' (Thomson, J. A., 2001). Eagerly monitored and partly funded by politicians who were sceptical towards research on embryonic stem cells, research teams speeded up their work with adult stem cells. In 2001, reports of examples appearing to prove the principle were published continually (Clarke et al, 2000; Coghlan and Young, 2001; Colter et al, 2001; Scolding, 2001), and on 21 June 2002 *Science* printed a chart to illustrate the plasticity that might be 'too good to be true . . .



Source: *Science* 2002

Figure 9.2 *The possible plasticity of adult stem cells*



Source: National Institutes of Health, 2000

**Figure 9.3** *The ontological hierarchy of stem cells*

that stem cells from a variety of tissues can produce progeny in different organs' (Holden and Vogel, 2002, p2126).

Yet researchers and scientists did disagree no less, and no less seriously, than the bioethicists. The National Institutes of Health's authoritative and widely used *Primer* was thus a reproduction of the old 'accepted wisdom'. Stem cells were here ranked in a one-way 'ontological' hierarchy which prescribed the moral dilemma for anybody giving a special moral status to the embryo. The closer to the biological origin, the greater the medical potentials – and the more suspect the morality!<sup>8</sup>

Theoretical arguments in favour of the hierarchical necessity were mostly voiced by developmental biologists and embryologists. Stephen Jay Gould's argument in favour of a 'progressive specification and differentiation' is typical:

*The very structure of material reality imposes a principle of trade-offs in both nature and human affairs. . . We have, in short, traded regenerative capacity for the undeniable evolutionary advantages of maximal complexity . . . Unfortunately, von Bauer's law, and nature's broader structural rules*

*of trade-off between complexity and flexibility, give us no alternative to embryonic stem cells for now. (Gould, 2001)*

In brief, respected scientists conceptualized the potentiality of adult stem cells as either a closed 'theoretical impossibility' or an open 'empirical possibility', and the order of stem cells was correspondingly visualized as either 'an irreversible hierarchy' or 'an emanating star'. Different levels of abstraction and scientific traditions are at stake, yet neither of the two positions and hypotheses can be the whole truth. The still unsettled disagreement resembles the state of internal 'anomie' that often precedes a new paradigm, more than the everyday routines of an accepted 'normal science' (Kuhn, 1962). *Science's* editorial stand that stem cells '[force] scientists to reconsider fundamental ideas about how cells grow up' (Vogel, 1999) might have implications even deeper than those hinted at. A new paradigm might be as badly needed in science as in medicine – and the former might be a precondition for the latter.

### Therapeutic cloning as humankind's techno-fix?

In addition to adult stem cells as Nature's own solution, cloning and parthenogenesis were soon framed and presented as humankind's own techno-fix solution to the relentless ethical concerns.

On 25 November 2001, Advanced Cell Technology (ACT), Worcester, Massachusetts (now headed by Michael West, the former CEO of Geron) made it publicly known that they had created the first human embryo using cloning techniques. Two techniques had been used, both combining a human egg with the person's own cells to create an embryo that could provide stem cells. A technique à la Dolly replaced the genetic material of human eggs with that of adult cells. Eleven attempts used adult skin cells, eight cumulus cells. None of the eggs with skin cells survived to divide, whereas three eggs with cumulus cells divided once or twice before they died. The second and most successful technique was parthenogenesis, that is, a chemical stimulation of eggs to divide without fertilization. Twenty-two attempts were made, and six eggs lived and divided for up to five days, but all died before stem cells ready to be harvested were formed.

The moment and modus of going public was no less orchestrated than Geron's initial announcement of the derivation. Key players were actually identical (they had moved from Geron to ACT). The trinity of information was a blueprint, that is, scientific periodicals, press releases and the mass media. Yet a prepublication in the January 2002 issue of the popular *Scientific American* (*Scientific American*, 2002) and a 'Rapid Communication' in the new web-journal *E-biomed: The Journal of Regenerative Medicines* (Cibelli et al, 2001) were substitutes for the prestigious *Science* and *Proceedings of the National Academy of Sciences*. The mass media generally reported the whole event as scientifically premature. Professor Weismann, a Nestor in stem cell research, even denounced the whole story as a 'non-event'. The necessary venture capitalists did not respond in any supportive way. And the ethics of cloning, not the intended revival of the framing as scientific

progress, came to dominate the public debate. The very same techniques could also be the first steps towards reproductive cloning – an issue highlighted around Christmas the same year with a series of equally premature pronouncements of the first human clone already *in utero*. The suggested techno-fix was thus considered just another moral problem, hubris, playing – or taking the place of – God. Humankind's techno-fix creation was no less offensive than research on God's own creations.

The experienced staff at ACT had, of course, foreseen and was prepared to counter the ethical critique. Ronald Green<sup>9</sup> (the former founding director of the Office of Genome Ethics under the Clinton administration) had become chairman of ACT's own Ethical Advisory Board, and the conclusions of the board were printed together with the reportage in *Scientific American*:

*[U]nlike an embryo, a cloned organism is not the result of fertilization of an egg by a sperm. It is a new type of biological entity never before seen in nature . . . we preferred the term 'activated egg', and we concluded that its characteristics did not preclude its use in work that might save the lives of children and adults. (Scientific American, 2002)*

The Ethical Advisory Board had expelled the ethical problem as a problem of (mis)understanding more than of substance – and as such to be solved on the level of concepts, neither in the labs nor on the political scene. Following the terms 'derivation' and 'regenerative medicine', the dispute over what constitutes an 'embryo', and the meaning of the term 'therapeutic cloning', the Ethical Board's conceptual manoeuvre is the fourth example of the 'power of definition' in this narrative (Wolpe and McGee, 2001). And ACT's Ethical Board was thus just one among many examples of the new role played by US bioethicists, who were increasingly hired and employed as a profession. The supply of educated bioethicists by far surpassed that of stem cell lines,<sup>10</sup> and in the absence of a comprehensive national law, they often serve as 'lawmakers' on the level of the firm. The old maxims of bioethics and the new profession of bioethicists seem to draw and to be drawn in different directions.

## The political ethics of human embryonic stem cells

The five framings differ so profoundly that the question nearly poses itself as to how they can all refer back to the very same 'clonogenic cells capable of both self-renewal and multilineage differentiation'. Are the diversities of framings just a reflection of the unique and still partly unknown potentials inherent in the cells constituted only recently as objects for science? Are the multitudes of framings rather an expression of the many external interests involved in political decisions? Or might the disparity between the framings be a mere echo of the plurality and relativism of the postmodern optics?

Professions and experts have often claimed a kind of normative priority or even precedents on behalf of 'their' framing: for science as the necessary precondition

for all the others; for medicine as the ultimate goal; for ethics due to its legitimacy to set limits for all the others; to adult stem cells as the ultimate solution; and to the techno-fix as the smartest solution. As a matter of description, however, none of the framings has had any such priority. They have all been part of the search for a truthful understanding and a fair evaluation, but none of them have prescribed unequivocal understandings and evaluations. A framing has not defined an agenda or determined an evaluation. Neither have the framings followed upon each other in a necessary succession. Nor have they existed in the pure form wherein they are here crystallized or idealized. On the contrary, politics and political decisions have over-determined, tinted and intermixed all the framings from the very beginning. To recapitulate: the scientific breakthrough was co-determined by the political requirements for funding and patents. The medical hope was embedded in general changes of lifestyle. Ethical recommendations have been altered according to political appointments. And adult stem cells and cloning/parthenogenesis were instantly presented to politics as possible solutions to the ethical concerns.

Sheila Jasanoff has mapped and emphasized substantial national differences in the American, British and German regulation of biotechnology (Jasanoff, 1995), but unrelated shifts of governments in the three nations during the early years of human embryonic stem cells have produced noteworthy shifts within the national regulations. The UK still represents national continuity, whereas the US has turned towards a more restrictive and Germany towards a more permissive regulation.

The British continuity is firmly rooted in the nation's customary scientific self-understanding and heavily institutionalized through the previous Warnock Committee, the subsequent Human Fertilisation and Embryology Act of 1990 and its corresponding executive body, the Human Fertilisation and Embryology Authority (Mulkay, 1997). Given this framework, Tony Blair's New Labour government could turn to the Chief Medical Officer for a delimited and authoritative examination. And neither government nor the parliamentary majority had problems with following the predictable recommendation that

*research using embryos . . . to increase understanding about human disease and disorders and their cell-based treatment should be permitted subject to the controls of the Human Fertilisation and Embryology Act.<sup>11</sup>*

The only legal step needed was to agree to the Human Reproductive Cloning Act of 2001, which prohibited 'the placing in a woman of a human embryo which has been created otherwise than by fertilization', that is, by reproductive cloning.

Following the President's address, broadcast on 9 August 2001, the US had to implement a new advisory structure. An Executive Order of 28 November established the President's Council on Bioethics, headed by the well-known conservative bioethicist Professor Leon Kass (Kass, 2001). Seventeen additional members were appointed on 16 January 2002, addressed by the President the following day (Bush, 2002), and the Council's report 'Human Cloning and Human Dignity: An Ethical Inquiry' was ready in July the same year. The Council



was in full agreement not to accept 'cloning-to-produce-children', that is, reproductive cloning, but split regarding 'cloning-for-biomedical-research', that is, therapeutic cloning. A majority of ten recommended 'a four-year moratorium', whereas a minority of seven recommended 'regulation on the use of cloned embryos for biomedical research' (President's Council on Bioethics, 2002). Accordance between the President's policy and (the majority of) his ethical advisors was thus re-established.

Following the shift from Helmut Kohl's CDU government to Gerhard Schröder's SPD government, Germany underwent a similar, but reverse, shift towards a more permissive policy. The Chancellor appointed the new Nationaler Ethikrat on 25 April 2001 and addressed the Rat at its first meeting on 8 June (Schröder, 2001), and the Rat's report *Stellungnahme zum Import menschlicher embryonaler Stammzellen* was ready in the following summer. Fifteen members voted for 'der vorläufige, befristete und an strenge Bedingungen gebundene Import humaner embryonaler Stammzellen', whereas ten members voted in favour of 'eine vorläufige Ablehnung des Stammzellimports' (Nationaler Ethikrat, 2002). Accordance between the Chancellor's policy and (the majority of) his ethical advisors was thus re-established.

The arguments have been absolute and the rhetoric has been strong, but bioethics has never been unambiguous, nor a superseding or decisive argument in political decisions. On the contrary, politicians have recurrently appointed ethicists (and thus also doctrines and advice) in accordance with their policies. Bioethics has always also been political. The (Christian) argument based on status and the (Kantian) maxim of means-ends have been powerful rhetorical tools, but pragmatic or even utilitarian ethics have impacted political decisions more forcibly. The attention of political bioethics has gradually but increasingly turned from the status of the biological substances and general maxims towards more comprehensive questions concerning society's justice and the individual's identity. Focus has moved to possible consequences for society at large, that is, a more hierarchical and competitive post-human world, and to the emergence of a new, liberal and unintended eugenics. Not the sources of stem cells, but their ultimate destiny 'what monsters we will soon be capable of creating' should be the real cause of worry, writes Francis Fukuyama, a US neo-liberal and a member of Bush's Council. 'The posthuman world could be one that is far more hierarchical and competitive than the one that currently exists, and full of social conflicts as a result' (Fukuyama, 2002, pp91, p218). And Jürgen Habermas, a German philosopher in the tradition of the Frankfurter School, queries the identity of individuals whose genetic make-up has been pre-selected or pre-manipulated as a matter of 'Gattungsethik' (Habermas, 2002a, p9). 'Wir müssen uns heute fragen, ob sich spätere Generationen gegebenenfalls damit abfinden werden, sich nicht mehr als ungeteilten Autoren ihrer Lebensführung zu begreifen – und auch nicht mehr als solche zu Rechenschaft gezogen zu werden' (Habermas, 2002b).

Policy decisions on stem cells have been pragmatic and balanced enough to leave room for two apparently opposing critics: one aimed at the use of dual or double standards and voiced mainly by religious communities, and another aimed

at the too restrictive regulations and voiced mainly by scientific communities and business.

The American 'moratorium' accepted the use of embryonic stem cell lines dating back to before the speech of the President 'where the life and death decision has already been made'. And the restrictive German law accepted the use of imported stem cell lines. Already existing and imported cell lines appear to be pragmatic loopholes if not inconsistency or double morality. Without loopholes, the second critic would, however, have been even more vociferous. It is thus conspicuous how the disappointed hopes have increasingly been explained and excused by the political regulations. The initial scientific framing is twisted to an argument blaming politicians giving too many concessions to the ethical concerns as the prime cause of the unfulfilled expectations. The disappointment is a question of delay, not of unsolvable problems; a matter of time, not of principles. Had science only had the freedom to follow its course, promises and expectations would also have been fulfilled. A hypothetical bogey has turned into a partial excuse.

## Notes

- 1 Research for this article, including site visits at Geron Corporation and Advanced Cell Technology and a number of interviews, started during a sabbatical at the University of California, Berkeley, 2001–2002. The article also reflects dilemmas and experiences from the Norwegian Biotechnology Advisory Board [www.bion.no](http://www.bion.no), where the author served from 2000 to 2004. The author wants to thank Siv F. Berg, Ole Johan Borge, Troy Duster, Vidar Enebak, Karen Lebacqz, Ole Didrik Lærum, Rune Nydal, Dorethy Olsen, Gisli Palsson, Antonio Regalada, Gunnar Skirbekk and Henrik Treimo.
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- 3 The figures are generated by a data-search in 'Titles' in *Nature*, *Proc. Natl. Acad. Sci.* and *Science* from 1990 to 2001. 'Isolat#', 'Establish#' and 'Deriv#' were used as truncations. The absolute number of hits was 1137, with 266 in 1990–91, 214 in 1992–92, 209 in 1994–95, 161 in 1996–97, 162 in 1998–99 and 125 in 2000–2001.
- 4 The estimated figures originate from an overview by Daniel Perry (Perry, 2000) covering the 'potential US patient population for stem cell-based therapies'. The more than 100 million potential patients is the sum of 58 million with cardiovascular diseases, 30 million with autoimmune diseases, 16 million with diabetes, 10 million with osteoporosis and 8.2 million with cancer.
- 5 Secretary of Health and Human Services Tommy G. Thompson's testimony before Congress is a more technical and detailed follow-up (cf. Thompson, 2001).
- 6 Immanuel Kant's own wording of the 'practical imperative' is: 'Handle so, dass du die Menschheit, sowohl in deiner Person als in der Person eines jeden anderen, jederzeit zugleich als Zweck, niemals bloß als Mittel brauchst' (Kant, 1965, p52). Two observations are of special relevance in the context of bioethics. The maxim is directed



- towards the use of Persons *solely as a means*. Although often assumed, the maxim does not prescribe that Persons should not be used as means at all or in any way. And the maxim does only apply to Persons; its application presupposes 'Personhood' (which has fostered the bioethical discussion of a possible 'Zygotic Personhood').
- 7 The different nature of the argument based on status and the maxim of means-ends so frequent in the public debate on human embryonic stem cells, and the four 'canonic principles' of professional biomedical ethics: autonomy, non-maleficence, beneficence and justice (cf. Beauchamp and Childress, 2001), is as striking as it is often overlooked.
  - 8 The National Institutes of Health has since changed the *Primer*, apparently in order to better reflect the possible potentials of adult stem cells. An update of 17 March 2002 has thus omitted the figure reprinted here and instead added: 'Until recently, there was little evidence that stem cells from adults could change course and provide the flexibility that researchers need in order to address all the medical diseases and disorders they would like to. New findings in animals, however, suggest that even after a stem cell has begun to specialize, it may be more flexible than previously thought'.
  - 9 Shortly before he joined ACT's Ethical Advisory Board, Ronald Green published the retrospective and self-reflexive *The Human Embryo Research Debate*, which can be read as the cleaning up of concepts necessary for the new, open position. A key insight is thus that 'biological occurrences are processes rather than events' and 'because biological realities involve processes, the determination of significant points within these processes inevitably involves choice and decision on our part' (Green, 2001, p26).
  - 10 The emerging new profession is organized around the American Society of Bioethics and Humanities and *The American Journal of Bioethics*, www.bioethics.net. Donaldson (2001) and Elliott (2001) are critical reviews of this development.
  - 11 Baroness Warnock, now a member of the House of Lords, returned during the debate to the 1990 report. She restated the legitimacy of the decision taken by Parliament 'that the early embryo did not have the right to the protection that presumably belongs to persons', but she regretted that 'in the original report that led up to the 1990 legislation we used words such as "respect for the embryo". That seems to me to lead to certain absurdities. You cannot respectfully pour something down the sink – which is the fate of the embryo after it has been used for research or if it is not to be used for research or anything else' (Warnock, 2002).

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