

Opinion

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## **The Clonal Age**

By Dr Gregory K Pike

### **Little Clones and Big Biotech**

This month marks the tenth anniversary of the birth of Dolly the sheep. While she now stands stuffed in Edinburgh's Royal Museum, she ushered in the clonal age and with that a new paradigm that has blown the cobwebs off some old school ideas about cellular physiology. It was all very exciting, and at the same time tremendously challenging, as much for ethical and legal reasons as for science. At about the same time, human embryonic stem (ES) cells were isolated and cultured, and quickly scientists put two and two together and theorised that human embryos might be cloned, their stem cells removed and treatments possibly developed.

This proposal became known as therapeutic cloning, in contrast to reproductive cloning, which refers to the implantation and subsequent birth of a clone. The use of particular terminology has been an important element of the public debate about ES cells and cloning, some arguing that it has at times amounted to semantic game-playing aimed at obfuscating the facts so as to influence public opinion. The most recent terminological twist being promoted by some ES cell advocates is to no longer use the word cloning, which the public doesn't warm to, and instead use the technical sounding *somatic cell nuclear transfer*, which the public can't really respond to since it has no idea what it means.

In 2001, when stem cells and cloning became a hotly debated topic in Australia, the fanfare was amazing to watch. Here were scientists, not renowned for their media flair or political savvy, everywhere promoting the cause. There were promises of all sorts, many overblown. Recently, one of the key figures in the field, the UK's Lord Winston, was reported in the following way,

The potential benefits of embryonic stem cell research have probably been oversold to the public, fertility expert Lord Winston says. He fears a backlash if science fails to deliver on some of the "hype" around the cells - as he believes may happen. He says the notion that a host of cures for serious, degenerative disorders are just around the corner is fanciful.<sup>1</sup>

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<sup>1</sup> Amos J, Winston warns of stem cell 'hype', *BBC News*, 5 Sept 2005, an online version can be located at <http://news.bbc.co.uk/1/hi/sci/tech/4213566.stm>

Prominent figures in the entertainment industry argued on behalf of scientists, as did some disability advocates who saw in stem cell research and therapeutic cloning the promise of cures. This was a delicate area of interaction. Those promoting the science of ES cells ran a risk. While some believed that to gain permission for their research justified talking up the prospect of cures, in doing so there was, and still is, a significant risk that those disabled by various diseases would have their hopes raised only to be disappointed when nothing happened. Understandably, emotions can run high. Which makes it incongruous when passionate requests are made to keep emotion out of the debate at the same time as there are emotive appeals for the need for cures.<sup>2</sup>

The ethical lynchpin that lay at the heart of the debate was the critical proposition to grant legislative permission for human life at its earliest stages of development to be destroyed for research. Whether this meant embryonic human life leftover from IVF or deliberately created by fertilisation or cloning or by any other means, the key question was whether it should be deliberately destroyed. The various views could not have been more divergent. At one end of the scale were those who saw the embryo as merely a clump of cells with no value other than its utility for some other end. At the other were those who saw embryos as human lives with a value equal to any other human life. And in between were many others who attributed some value to embryos, but depending upon the circumstances, perhaps not sufficient to warrant their protection. There was even a strange line of argument that destroying embryos for research was consistent with affording them great respect. If someone offers you respect like that, run for your life!

One of the problematic aspects of the promotion of human embryos for research was that it represented sensible ethical science sidelining one of its own primary principles. A longstanding principle in medico-scientific research is the requirement for proof in animal experimentation before considering experimenting with humans. The fact that research on human embryos was being promoted when there was a mountain of work to do using animal ES cells to determine whether hoped-for results could be obtained<sup>3</sup>, says as much about

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<sup>2</sup> 'Keep emotion out of stem cell debate' *The Age* 12 July 2006, online article can be located at <http://www.theage.com.au/news/National/Keep-emotion-out-of-stem-cell-debate/2006/07/12/1152637730014.html> In this article, Nobel Laureate Professor Barry Marshall, when talking about the religious views of some, makes an appeal to emotion by saying, "No matter who they are, if they had a child with leukaemia or if they had severe diabetes, all that sort of stuff would go by the wayside."

<sup>3</sup> See Anna Salleh, Scientists divided on stem cells, *ABC Science Online*, 5 April 2002, "Sir Gustav Nossal supports the need for animal research. He told *The Canberra Times* recently that there was "a huge amount of learning to be done" in mouse experiments before embryonic stem cells could be applied to humans." <http://www.abc.net.au/science/news/stories/s520417.htm>

how some view human embryos as it does about the changing face of science itself.

One of those aspects of the changing face of science is the risk of conflict of interest. In the current climate, some scientists stand personally to gain enormous economic benefit from their work, as well as being offered the intoxicating mix of huge funding, conference circuits, media appearances and widespread acclaim. Whilst it can be argued that there is nothing intrinsically wrong with this type of gain, there are two concerns. One is that the conflicts of interest may remain unknown to the public, making it difficult to assess whether what is being said is being influenced by personal gain, and the other is that the huge stakes have the potential to significantly distort judgements, even when there is disclosure. One international casualty of this heady brew was Korean cloner Hwang whose fraud and subsequent fall from grace was meteoric. One can only hope that the complex mix of breaching ethical guidelines, fraud, and possibly outright criminal behaviour has sent a salutary message about how careful science needs to be to remain open and accountable, as well as how cautious it should be when offering accolades and huge funding.

It is important to remember how fierce and conflicted the debate was that raged in Australia in 2001, after which research on human embryos leftover from IVF was permitted. It was a watershed with plenty of unease. For years several states had protective legislation in place to prohibit destruction of human embryos, and many international bodies were, and still are, firmly against it. Interestingly, the *National Health and Medical Research Council*, in its 1996 *Ethical Guidelines for Assisted Reproductive Technology* - a document that informed those states that did not have any guiding legislation - did permit research on human embryos, but only in exceptional circumstances.<sup>4</sup>

It is also important to remember that at the same time, parliamentarians overwhelmingly rejected any form of human cloning, embryonic or full birth. The decision was unanimous. Federal member Warren Entsch said, "I am totally opposed to human cloning in any shape or form. I think it is totally abhorrent and I would never support it."<sup>5</sup> Attorney General Daryl Williams summed it up well when he said all members involved in the debate "unanimously agreed that a ban on human cloning and other unacceptable practices is crucial".<sup>6</sup> Whilst this sentiment was contrary to that expressed by key scientists who were keen on cloning embryos for research, given the resolve shown by parliamentarians, the advocacy for the research quickly faded

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<sup>4</sup> A copy of the 1996 guidelines can be found at [http://www.nhmrc.gov.au/publications/\\_files/e28.pdf](http://www.nhmrc.gov.au/publications/_files/e28.pdf)

<sup>5</sup> 2002 CPD (HofR) 5252; 20 August 2002

<sup>6</sup> 2002 CPD (HofR) 10113; 11 December 2002

away. There was however, a clause in the legislation that would see the setting up of an independent review of the legislation some three years later.

That review was headed by former Federal Court Judge John Lockhart, the other members being a lawyer and four medico-scientific experts. During 2005, the committee took evidence in the form of written submissions as well as oral presentations, producing a report that was a major work containing 54 recommendations<sup>7</sup>.

Since the handing down of the review and partly because of its recommendations, pressure has been mounting from some quarters to revisit the *Prohibition of Human Cloning Act 2002*, with a view to permit the cloning of human embryos.

But why? Is it because so many advances have happened in the meantime that would warrant such a change? That is clearly not the case. Researchers using human ES cells from naturally fertilised embryos have not produced anything close to a treatment, and neither have they shown that stem cells can even be obtained from cloned human embryos, let alone be used for a treatment. One would have thought that the permission (perhaps a concession) made in 2002 to destroy human embryos for possible cures would have made advocates very cautious about pushing for so much more when so little had been forthcoming. Surely they would have thought the public would be skeptical when the promised cures seemed no closer. Even more acutely, advocates should have been concerned that the public were probably not aware that 70% of the embryos in licenses granted for research following passage of the 2002 legislation were earmarked for use in research that had nothing to do with stem cells.<sup>8</sup> This fact alone should have made the public wonder whether they had been misled and in fact what was being sought was a generalized access to human embryos. They might legitimately ask whether some of our researchers want human embryos to become the new laboratory resource?

Instead of scientific advance, is the call for greater freedom with embryos because community standards have shifted so much in four years to warrant consideration of such a dramatic change? Besides the difficulty in determining what constitutes a 'community standard', changes within such a short time frame are highly unlikely.

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<sup>7</sup> See <http://www.lockhartreview.com.au/files/Legislation%20Review%20Reports%20Full%20Doc-19Dec05.pdf>

<sup>8</sup> Of the nine licenses granted, four involve the extraction of ES cells. The other five relate to embryo culture, preimplantation genetic diagnosis, clinical training, and chromosomal disorders. For full details see <http://www.nhmrc.gov.au/embryos/monitor/database/index.htm>

Since the Lockhart committee was established to “review the Acts in the light of any changes in scientific or community understanding of standards since 2002”, neither of which seem to have changed much at all, how could it recommend not only embryo cloning, but even more extreme things like the creation of human/animal hybrid embryos?

Something doesn't add up.

What's more, the committee has also recommended research on fresh embryos less than 24 hours from conception or deemed unsuitable for implantation or created by unusual means, for example using the genetic material of more than two persons.

Furthermore, the Lockhart committee has advocated that a licensing committee be given the freedom to make “binding rulings” that are not in the “literal wording of the Act”, but within its “tenor”. Since, according to the Collins Dictionary, tenor means “general drift of thought”, heaven knows what new technologies an unelected licensing committee might think fits the “tenor” of the Act.

The Lockhart committee received over 1000 written submissions, the great majority of which were opposed to the recommendations they eventually made. What does this tell us about community standards? Or rather, what does it tell us about the committee?

What was it that drove the committee to produce recommendations that were, in ethical terms such a quantum leap? Perhaps part of the answer lies in what appears to be the committee's unanimous commitment to the unfettered freedom of science, and biotechnology in particular. Beyond that, it may be that the committee had a particular idea about what constitutes a legitimate view on the ethics of embryo research.

One of our top scientists, Sir Gustav Nossal recently commented on differing beliefs regarding embryos when he said, “People who harbour very strong beliefs should not, in a secular society like ours, thrust those beliefs down other people's throats.”<sup>9</sup> The comment was made after Sir Gus had also said, “We should all exercise our democratic right - I certainly intend to do so - to do as much lobbying as one can ...”<sup>10</sup>. Whilst maybe not intended, this sounds like an attempt to shut down those with a non-secular view. Moreover, using the

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<sup>9</sup> Simon Grose, The Government's strange handling of a recommendation on stem cells, *The Canberra Times*, 28 June 2006.

<sup>10</sup> *Ibid.*

pejorative “thrust ... down other people’s throats”, which was in reference to religious beliefs, sounds like it is based on the assumption that Sir Gus’ beliefs about the moral status of human embryos are not beliefs as such but something else. Such a view displays an ignorance about the role of reason in religious belief as well as about how ‘religious’ non-religious beliefs can be.

When considering beliefs about closely related matters like reproductive cloning for example, it is noteworthy that there is a prevailing belief about reproductive cloning that is largely shared by all, including most scientists. To quote Sir Gus again, “Reproductive cloning is abhorrent and must be banned outright.”<sup>11</sup> It is easy to agree with this, and most scientists would, but when asked why reproductive cloning is abhorrent, the answers one gets are generally lame and based almost entirely upon the known poor success rate of cloning. This raises the question, “Will reproductive cloning become ethical when the technique is refined?”

The point is that reason seems to play a weak role in the expressed belief that reproductive cloning is abhorrent, but it doesn’t seem to matter how well reasoned the arguments are for protecting human embryos, if they can be construed as ‘religious’, they can be sidelined. We wait with bated breath for the day when reproductive cloning is safe enough to try. Perhaps the arguments against it will be ‘just religious’.

In summary, the Lockhart committee has made expansive recommendations that really push the envelope on manipulations with early human life.

Some have claimed that the decision of the impartial arbiter has been given. Anna Lavelle, CEO of AusBiotech, saluted the recommendations, stating, “ ... the independent umpire has laid out his decision. It is time to accept it and move on.” Given the free hand that the Lockhart committee has given to industry, this response is hardly surprising.

Even if the industry does plough on, what will remain is a burdened community conscience that it is using human life at its most vulnerable stage for enterprises that may not produce a result, and for which there are good alternatives.

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<sup>11</sup> Gustav Nossal, Cures, not clones, will flow from medical technologies, *The Australian*, July 13, 2006.