



**Submission to the Senate Community Affairs
Committee**

***Inquiry into the Legislative Responses to
Recommendations of the Lockhart Review***

Executive Summary

Women's Forum Australia is an independent women's think tank that undertakes research, education and public policy development about social, economic, health and cultural issues affecting women.

Research cloning (sometimes inaccurately and misleadingly called 'therapeutic cloning') raises issues of particular significance to women. Cloning depends on a continuous supply of ova which can only be achieved with high doses of ovulation stimulating agents. There is increasing evidence that the super-ovulation process is associated with serious health risks, including death. The long-term health impacts might include reproductive cancers.

Research cloning always amounts to the commodification of women's bodies because even if egg donors are motivated by altruism, the biotechnology companies are profit making ventures.

Since research cloning is impossible without access to thousands of women's ova, advocates of this research bear the onus of demonstrating that sufficient ova can be sourced without harm to women. They have failed to discharge this onus.

Various proposals for alternative egg sources have been put forward. This is an implicit recognition of the difficulties of obtaining sufficient ova and the health impacts on women.

Proposals such as the use of animal ova, cadaver ova, surplus IVF ova and altruistic donation have been discredited. It is irresponsible and premature to allow research cloning without identifying a viable source of ova that is safe for women.

The Bills specifically prohibit commercial payment for ova. Yet international experience shows that this is the only way to obtain near sufficient supplies. Only a few years after the legalisation of research cloning in the UK, the licensing authority has begun to authorise commercial incentives for supplying ova for research. If Parliament allows research cloning, it will open the way to an eventual commercial trade in ova, inducing women – particularly the disadvantaged – to assume the serious health risks of ova extraction for money.

Treating women's ova as commodities would lead to the further objectification of women. Women would be regarded as marketable sources of raw material for lucrative research.

Community standards require that women be protected from exploitation and harm in the application of science. This is consistent with international standards.

This submission recommends that:

1. *The Somatic Cell Nuclear Transfer (SCNT) and Related Research Amendment Bill*

2006 not be supported;

2. The *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill* 2006 not be supported;

3. The prohibition of all forms of human cloning in the *Prohibition of Human Cloning Act 2002* continue;

4. The prohibition of commercial trade in gametes continue.

Health Risks to Women

The Egg Extraction Process

Women's bodies are central to research cloning. Cloning depends on a continuous – and large - supply of ova from women. Extracting sufficient ova can only be achieved with high doses of ovulation stimulating agents.

Women describe the extraction process as invasive and uncomfortable, requiring several clinic visits and multiple injections of hormones. Often a dozen or more eggs are produced at a time, instead of the usual one or two per cycle.

A recent edition of the journal *Nature* (Pearson 2006) describes a typical egg extraction procedure:

- A gonadotropin-releasing hormone agonist is taken daily for 1 -2 weeks. This stops the pituitary from stimulating ovulation.
- The woman then injects gonadotropins such as follicle stimulating hormone to trigger the development of several egg-containing follicles
- A third hormone triggers final maturation of the eggs
- Eggs are collected with a needle inserted through the wall of the vagina into the ovary.

Short Term Health Risks

There is increasing evidence that the super-ovulation process is associated with serious health risks. Between 0.3 and 5% or up to 10% of women who undergo the process experience a serious condition known as ovarian hyper stimulation syndrome (OHSS) (Magnus 2005 and studies cited therein). When OHSS occurs thirty or more eggs start to develop simultaneously, fluid leaks out of the blood vessels and collects in the abdomen (Pearson 2006).

Less serious symptoms of OHSS include (Kalfoglou 2000; Beeson and Lippman 2006):

- Pain associated with intramuscular injections
- Hot flushes

- Bloating
- Moodiness
- Headaches
- Nausea
- Vomiting
- Diarrhoea
- Abdominal distention
- Increased appetite
- Weight gain
- Tiredness
- Accumulation of serous fluids in the spaces between tissues and organs in the pleural and abdominal cavity
- Respiratory difficulties

Kalfoglou's study of 33 former egg donors found that nine women 'reported a week or more of discomfort so significant that it kept them in bed, prevented them from working, or interfered with their ability to care for their children.'

Egg donation can have special implications for women with psychological vulnerabilities. Research indicates that egg donors in IVF treatments often have a history of sexual trauma and abortion and may be attempting to 'make up' for the loss through their donation (Cooper 1998, Kalfoglou 2000).

More serious symptoms can require hospitalisation and include unintended pregnancy, renal failure, intrauterine polyps, ovarian cysts, thromboembolism, adult respiratory distress and haemorrhage from ovarian rupture, and future infertility (Magnus 2005; Beeson and Lippman 2006). OHSS can necessitate one or both of the ovaries being removed (Steinbock 2004) At least one global study suggests that OHSS could raise the chance of deep vein thrombosis, itself thought to increase the risk of malignant disease (Ahuja 1999 and studies cited therein).

The American Society of Reproductive Medicine (ASRM) has said that the occurrence of these more severe symptoms is 'by no means rare' (2003).

Occasionally OHSS leads to death. Six women are known to have died from OHSS in the UK. The most recent suffered a complication during egg retrieval causing internal bleeding and renal complications. Last year Temilola Akinbolagbe, 33, died of a heart attack brought on by OHSS. (Beeson and Lippman 2006; Times Online 2006)

Long Term Health Risks

The long term health effects of super-ovulating drugs on women are not well understood. Dr. Suzanne Parisian, a former chief medical officer of the US Food and Drug Administration and researcher in genetics and developmental biology, emphasizes that

'many of the drugs used during these procedures have not been adequately studied for long-term safety...This is not widely understood and has led to significant misunderstanding about the risks involved for women who donate eggs,' whether for reproductive purposes or for research cloning. (Parisian 2005)

Beeson and Lippman's review of the long-term health studies revealed conflicting conclusions. 'Nevertheless, many clinical reports associate infertility treatment with ovarian cancer, and two major studies suggest a link between ovarian cancer and ovarian stimulation' (Beeson and Lippman 2006). For example, one study of never pregnant women found they experienced a sharp increase in risk (Whittemore et al 1992). Rossing et al estimated that the use of one particular ovarian stimulating drug was associated with a 2.3-fold increased risk of ovarian tumours in their study of 3837 women (1994).

Brinton et al point out that the women who first took clomiphene citrate drugs in their late 20s and early 30s are only now reaching the age when hormonally related cancers are common (2005). In the 1980's gonadotropin hormones were introduced for IVF and thus researchers have only had about ten years to study the effects of these newer drugs, with no opportunity for longitudinal studies (Pearson 2006).

Brinton et al conclude that 'it may be some time before epidemiological studies can amass the follow-up times required to fully assess long-term effects ' (2005). However, 'it's unclear who will drive the effort, particularly when private fertility clinics may have little interest in finding out the potential risks of the drugs they use (Pearson 2006).

Risks to Offspring

Human data on the effects of ovarian stimulating drugs on the offspring of treated women are lacking. However, ovarian stimulation in mice has resulted in serious abnormalities in their offspring including growth retardation, a delay in bone development and a significant increase in rib deformity (Steigenga et al 2006). Beeson and Lippman argue that:

'Questions about the degree to which these findings have implications for the use of ovarian stimulation treatments in women should be answered before thousands of women are exposed to ovarian stimulation purely for research purposes' (2006).

They point out that other hormones given to women have had serious health impacts on their offspring. For example, the hormone diethylstilbestrol was prescribed for decades to five to ten million women worldwide until research documented a high incidence of vaginal cancer and infertility in the daughters of these women and health problems for male offspring (Beeson and Lippman 2006).

Commodification of Women's Bodies

Research cloning always amounts to the commodification of women's bodies because even if egg donors are motivated by altruism, the biotechnology companies are profit making ventures.

'there is a tension between the altruism individuals are supposed to exhibit by donating their tissue for research and the current patent system, which encourages companies to stake lucrative property claims in that research.'
(Knowles 1999)

Treating women's ova as commodities would lead to the further exploitation and objectification of women. Women will be regarded as marketable sources of raw material for research, rather than as unique human beings.

In one qualitative study (Kalfoglou 2000), some women who had experienced egg donation described feeling like a commodity. Some used metaphors such as farm animals, produce and meat to describe the experience.

"Chris' thought that 'I just got the feeling...you were second class...I wondered did they treat everybody that way, or is it 'cause I'm a donor?...I'm just the produce stand...like the cow at the market...'

Melanie likened the experience to prostitution:

'I definitely wasn't in charge there. It was a little like what I would think prostitution would be like...you've rented your body out...You would be prepped and there would be none of the small talk that usually goes on to put the patient at ease. And it's kind of like "Spread your legs, there we go"...It was like you were some kind of prized heifer or something.'

Informed Consent

The phrase 'informed consent' is commonly used in Australia to indicate a doctor's duty to disclose and warn patients of material risks to their health and well being. If women are informed about the risks of egg extraction for research, isn't it their choice as to whether they assume those risks and provide their eggs?

In short, no. Firstly, it is not meaningful to speak of 'informed consent' when there is a lack of independent assessments about the long term health risks of egg harvesting. As noted above, however, there is research which links egg harvesting to hormonal cancers. Full scientific investigation of these long term risks is required before women can genuinely give informed consent to egg extraction for research.

Secondly, consent must be viewed against the background of powerful social and economic influences that can encourage researchers to downplay the risks of egg harvesting. As Beeson and Lippman have noted, some physicians who extract eggs are also involved in cloning research. 'Seeking consent from women in these circumstances is problematic when clinicians have an interest in obtaining their eggs' (Beeson and Lippman 2006).

Risk-Benefit Calculus

The risks of egg harvesting for research are the same as the risks for harvesting for ART and like any medical procedure, the risks must be weighed against the benefits. However, Beeson and Lippman point to an important difference: a woman who undergoes ovarian hyper stimulation for ART has a 10-40% chance of producing a baby for herself. But the risk-benefit calculus is very different for a woman who assumes the same risks for research cloning: she is part of a research project that has uncertain benefits and may never benefit directly from the risks she has assumed (2006).

What model of consent fits these women? Magnus and Cho argue that if we consider them clinical patients then the doctor/patient relationship would seem to suggest 'counsel against undergoing such a procedure for no benefit' to themselves (2005).

Alternatively, should these women be viewed as research subjects? 'After all, research often requires individuals to expose themselves to risk for the benefit of others...' (Magnus and Cho 2005). However, unlike in other research, the risks to egg donors do not lie in the research itself, but in the extraction of the materials necessary for the research. (Magnus and Cho 2005). Donors of sperm for research are not exposed to similar risks.

Advocates of research cloning envisage altruistic donation of ova. Thus a better model to describe egg donation by women is altruistic organ donation by living donors to strangers (for example a kidney or liver lobe) (Magnus and Cho 2005). Neither women egg donors nor living organ donors are patients and any benefits of the donation will be to strangers, not to themselves. Magnus and Cho point out that in these circumstances 'taking the best interests of the donor in to account, it is hard to justify organ donation.' The same can be said about women egg donors.

The National Health and Medical Research Council also recognises the special ethical issues raised by organ donations in these circumstances: 'There must be a very low risk of immediate or long-term harm to the donor's physical or mental health... there must be a very high chance that there will be a good outcome for the recipient' (2006).

If this model is applied to women egg donors, it is difficult to justify the donation of ova for research. The risks to women's short term and long term health are significant. It cannot be said that there is 'a very high chance' of a good outcome for any potential recipient of a therapy derived from the use of women's ova. Embryonic stem cell research using surplus

ART embryos (permitted under the existing legislation) is still in its infancy. The benefits of this new research are, at best, speculative. The benefits of taking the next step and actually cloning embryos are even more speculative. Thus the serious risks of research cloning to women cannot be justified.

Where Will All the Eggs Come From?

Cloning has been described as 'a wildly inefficient process, often requiring hundreds of eggs to [merely attempt to] produce a single viable clone' (Dennis 2006). In South Korea, the now discredited Dr Hwang used 2061 eggs taken from 169 women and failed to produce a single cloned embryo (Steinbrook, 2006).

The sheer number of eggs required for research cloning is a major obstacle and 'a shortage of them could hold back the entire field' (Dennis 2006). The 'main limiting factor in the research is the availability of human eggs to practise on' (Check 2006). Where will all the eggs come from? Advocates have proposed a number of sources. Each proposal is misguided and readily discredited by the available research.

Altruistic Donation

Some scientists believe that sufficient supplies of ova will come from altruistic donations. Alan Trounson says that 'most eggs are likely to come from women who have family members with a disease and want to donate their eggs to advance research on that disease' (Dennis 2006). But is there a danger that 'altruistic' donation and its attendant health risks might become a duty for women whose ova could save a loved one?

Already there are indications of such an ethic. Julian Savulescu argues that we have an ethical and economic imperative to pursue cloning and stem cell research because of the potential benefits. He says that since women have so many ova, very few of which will actually produce offspring, scientists should use the 'spare' ova for research (Savulescu 2005). Will it become the 'ethical imperative' of women to donate ova?

There is evidence of social and cultural expectations of feminine self-sacrifice which impact on women. In her ground breaking work on psychological development Carol Gilligan observed that :

'...while society might affirm publicly the woman's right to choose for herself, the exercise of such choice brings her privately into conflict with the conventions of femininity, particularly the moral equation of goodness with self-sacrifice...it is... in their care and concern for others that women have both judged themselves and been judged' (1982).

Another theorist has characterised the stereotype of the 'good woman' thus:

'She is loyal and loving, compliant and altruistic ... good women can be distinguished by their abandonment of their own interests and their overriding concern for the interests of family members' (Naffine 1990).

Seeking 'altruistic' donation from the female relatives of the sick and suffering smacks of exploitation. It would play to powerful stereotypes of female altruism and create an expectation that women sacrifice their own interests and assume the health risks of ova extraction for the sake of others.

Left Over Frozen IVF eggs

Another suggested source of ova is the frozen ova that are surplus to IVF/ART requirements. Mal Washer MP is reported to have said that one Sydney IVF clinic alone took more than 5000 unfertilised eggs from women each year that would be thrown away if not used for research (Ruse 2006).

While 5000 surplus ova from just one clinic (with the implication that thousands more are available from other clinics) might sound like a bounty, this will not be nearly sufficient for cloning research. Often hundreds of eggs are required to produce just one clone (Dennis 2006). As noted above, Dr Hwang used more than 2000 eggs and failed to produce a single clone. Thus even if tens of thousands of surplus IVF ova are available (assuming women consent to their use in research) this will not solve the egg problem.

However, there are more significant problems with this proposal. Left over IVF eggs are usually aged and have failed to fertilize following fertility treatment. When used for cloning, these eggs typically fail to reprogramme, 'probably for the same reasons they failed to fertilize,' says embryonic stem cell scientist Alison Murdoch of the University of Newcastle Upon Tyne, UK (Dennis 2006).

This is confirmed by a just published study that performed cloning using fresh ovulation-induced ova and compared these to surplus, failed to fertilize human ova. The study found that surplus ova are 'a poor source of [ova] for human [cloning]' (Hall et al 2006). Most of the surplus ova could not support cleavage and further development and there were chromosomal aberrations and aberrant spindle structures. The authors concluded that

'[p]rogression of human [cloning] is therefore dependent on alternate sources of [ova]...The ethical implications in harvesting fresh [ova] from fertile women will therefore be a critical factor for the development of human [cloning] and the generation of patient-specific stem cell lines.'

Similar conclusions were reached in a separate 2005 study (Lavoit et al 2005). The need for recently collected eggs is also acknowledged by the UK licensing authority that is currently reviewing egg donation for research (HFEA 2006).

In sum, research cloning requires freshly harvested ova. Surplus IVF ova are not a viable source.

Fresh Eggs From IVF Patients

Because women undergoing egg extraction for IVF assume the same health risks detailed above (including ovarian hyper stimulation syndrome) it has been proposed that these women donate some fresh ova for research purposes. However, experience demonstrates that only a minority of IVF patients are willing to do this.

In the UK the Human Fertilisation and Embryology Authority has granted permission for researchers to ask women to donate some of their IVF eggs for research, if the women had produced 12 or more during extraction. However, this strategy failed to yield sufficient eggs for their research needs. The researchers commented:

'only a minority were willing to donate fresh oocytes reflecting the psychological importance of the oocytes...this practice demonstrated that the numbers recruited by this strategy are small and will continue to be a major rate-limiting factor in the progress of the research' (M. Choudhary et al 2006).

The researchers have called upon commercial payment for ova in order for cloning research 'to achieve its full potential' (M. Choudhary et al 2006). In the UK, commercial incentives are now being used, detailed below (Wallace 2006).

The proposal is also contrary to recent developments in fertility technology that are moving towards minimal stimulation IVF where only one ovum at a time is extracted. In this patient-friendly procedure only low doses of hormones are administered for only a few days causing few side effects. Retrieval of the egg is comparatively quick and easy and can be performed without analgesia. A peer reviewed scientific study confirms that this technique virtually eliminates the risk of ovarian hyper stimulation syndrome and is suitable for all types of patients (M.J. Pelinck, N.E.A. Vogel, A. Hoek et al 2006).

Thus the proposal to harvest extra eggs from IVF patients puts the ambitions of researchers ahead of women patients since recent research suggests that ovarian hyper stimulation is no longer medically indicated or necessary.

'The primary concern should be what is in the woman's best interests. That is to have the most minimally invasive treatment with the minimum use of drugs and the minimum harvesting of eggs' (Quintavalle 2006)

Hyper-stimulating IVF patients to produce extra eggs for research might benefit the researchers but it is against the best interests of the women patients when less intrusive techniques are now available.

Animals

Both of the proposed Bills envisage the use of animal ova to alleviate the demands on women. However, already there are doubts among scientists of the efficacy of this proposal. Even after the nucleus of the animal egg is removed in the cloning process, the animal's mitochondria genomes remain in the egg and these interact with the genomes in the nucleus of the human cell. There are doubts that mixing mitochondria and nuclei from different species will work (Dennis 2006). Researcher Doug Wallace of the University of California, Irvine had commented that '[f]rom our experience, combining the mitochondrial DNA from even a species as closely related as chimpanzees result in incompatibilities' (Dennis 2006).

Moreover, even if animal eggs are used in the early research stages, women's ova will be required in huge numbers if cells are ever to be transplanted to patients. Cells derived from animal eggs cannot be transplanted in to a human because of the mixing of inter-species DNA and the risk of infection with animal viruses. Even if cloning develops in to a highly efficient technique where only one ovum is required for each therapy, it is extremely unlikely that sufficient numbers of ova could ever be obtained to make this a reality.

Hundreds of thousands of ova would be required to treat just some of the conditions identified by scientists: in Australia one million adults suffer from diabetes (Department of Health and Aging 2006); 200,000 suffer from Alzheimer's (Department of Health and Aging 2006); and 10,000 from spinal cord injuries (Spinal Cord Injuries Australia 2006).

Advocates who promote the potential of embryonic cell transplants to treat these conditions must explain how these treatments can ever be achieved when plainly there will never be enough human ova.

Cadavers

Acting Chair of the Lockhart committee, Loane Skene, is reported to have suggested that ova could be removed from dead women after their death, in a similar way to organ donation (Jones 2006). This is a misguided proposal.

It is unlikely that sufficient numbers of mature ova would be available. Only women who die in their fertile years could be possible donors. Given the reluctance of Australians to donate their organs after death, it is improbable that women would take the even more radical decision and donate their ova, knowing the ova would be used to form an embryo after they have died.

Frozen Ovarian Tissue and Production from Stem Cell Lines

The Lockhart review suggested that other sources of eggs such as from frozen ovarian tissue or the production of eggs from stem cells might become available as research progresses. Currently, however, these are not viable sources of ova. It is premature to promote cloning on the basis of such speculative sources of ova. What we know now is

that the best ova are fresh ova from live women and scientists will look to women to assume the health risks of ova extraction.

Commercial Payment

Already, with cloning research only in its infancy, all indications are that this research is not practicable without the commercial sale of ova. In the UK extensive publicity campaigns have failed to recruit sperm and egg donors without commercial payment (Mc Laughlin 1998). As noted above, very few IVF patients will donate fresh ova.

Already, just a few years after the legalisation of research cloning in the UK, the licensing authority has approved commercial incentives for egg donation, dubbed 'egg sharing'. The North East England Stem Cell Institute now offers women IVF at a reduced cost in return for their surplus eggs for research (*Nature* 2006). This is payment in kind for ova and the money saved would be worth the equivalent of several thousand dollars.

A qualitative survey of egg sharing between fertility patients highlights the exploitation inherent to this practice. The survey showed that such donors are desperate to have a baby and are motivated by financial necessity because of the expense of the procedure. Some donors reported reluctance to give the eggs but believed that they had little choice given their financial limitations (Rapport 2003).

UK researchers are now calling for commercial payment of ova, over and beyond incentives such as egg sharing and payment of expenses:

'Most oocyte donation for treatment involves payment. In the USA this is routine practice...If [cloning] research is to achieve its full potential we must explore these other options...' (M. Choudhary et al 2006).

In the US, one of the few countries to permit commercial trade in gametes for ART, payment for ova has increased sharply in recent years because supply cannot keep up with demand (Lindheim 2001). The shortage of ova supply would intensify with research cloning, increasing the market value of ova. Research indicates that as payment escalates, money becomes the dominant motivation, not altruism (Lindheim 2001).

The commercial trade in ova would likely lead to further exploitation of women, particularly of the economically disadvantaged. This has already occurred in Europe where poor East European women have been physically damaged, in some cases rendered infertile, after selling their ova to London fertility clinics (Abrams 2006). It must be asked whether the high levels of payment that could be expected with research cloning would amount to an enticement that would undermine the voluntariness of the procedure (Lindheim 2001). This was the key reason for the Lockhart committee report recommending against commercial payment:

'the healthiest eggs would be those from young women...the potential exists for coercion of young women to donate eggs (such as through

social disadvantage, family or workplace pressures' (Lockhart Review 2005).

With no other viable sources for ova, the trend in the UK is towards commercial trade in ova. This trade already exists in the US for ART, with calls that it be extended to eggs for research.

Advocates of research cloning must explain why Australia would be any different should research cloning be allowed here. Despite the concerns of the Lockhart committee and the ban on commercial sale in the Bills, international experience demonstrates that when research cloning is permitted, commercial trade in ova is just down the track.

International Standards

The United Nations Declaration on Human Cloning was adopted by the General Assembly in March 2005. Australia voted in favour of the Declaration which states in part:

'Mindful of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to prevent the exploitation of women...Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences.'

The current prohibition of research cloning is the only effective way to protect women against exploitation in this area of scientific research and is thus consistent with these international standards.

Conclusion

There is evidence that research cloning would lead to serious health risks for women ova donors including ovarian hyper stimulation syndrome and attendant risks of renal failure, infertility, and even death. There are a host of other possible complications, including reproductive cancers in later life.

Research cloning would result in the increasing objectification of women and their bodies. Treating women's ova as commodities would lead to further exploitation, with women regarded as marketable sources of raw material for research

Advocates of research cloning have failed to demonstrate that sufficient ova can be sourced without harm to women. It is unconscionable to seek 'altruistic' ova donations from female relatives of the sick and suffering. This would encourage an expectation that women sacrifice their own interests and assume the health risks of ova extraction for the sake of others.

Despite the concerns of the Lockhart committee and the ban on commercial sale in the Bills, international experience demonstrates that when research cloning is permitted,

commercial trade in ova is just down the track. These Bills would open the way to an eventual commercial trade in ova, inducing women – particularly the disadvantaged – to assume the serious health risks of ova extraction for money.

The Bills seek to promote the health of the sick and disabled, but this would be at the expense of women's health. Community standards require that women be protected from exploitation and harm in the application of science. The current prohibition of all forms of human cloning must continue. Australians deserve a biotechnology that promotes the health of *all* citizens.

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