PARLIAMENT OF VICTORIA
SCRUTINY OF ACTS AND REGULATIONS COMMITTEE

Inquiry into Infertility Treatment Amendment Bill

Melbourne — 4 April 2007

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Dr N. Tonti-Filippini, ethicist, consultant.
The CHAIR — I declare open these private hearings of the Scrutiny of Acts and Regulations Committee considering the amendments proposed to be made to the Infertility Treatment Act 1995 by the current bill before the Parliament. The amendments in this bill mirror those found in the counterpart commonwealth amendment act and are based on the recommendations of the Lockhart review.

This committee is holding these private hearings pursuant to the provisions of section 17 of the Parliamentary Committees Act 2003 and section 30 of the Charter of Human Rights and Responsibilities Act 2006. Bearing in mind the committee’s terms of reference, our objective or focus in these hearings is to report to the Parliament where the proposals may infringe one of its terms of reference.

In respect to this bill the committee is seeking evidence as to whether provisions in the proposed laws may constitute an undue trespass to rights or freedoms, or whether they were incompatible with the charter’s rights. The relevant charter rights that are most likely to be invoked by the provision in this bill is section 10 of the charter in relation to the right to protection from medical and scientific experimentation without full and free consent.

The first witness is Dr Nicholas Tonti-Filippini, whom I thank for attending the session. I just have to inform you that anything you say or publish before the committee is protected by parliamentary privilege; however, once you leave the hearing anything you say or publish outside the room is not so protected, so you have got an opportunity here to say what you like.

Dr TONTI-FILIPPINI — To dump on somebody!

The CHAIR — In due course you will be provided with a draft copy of the transcript, which is an opportunity to correct anything that Hansard reporters may not have correctly reported. However, this is not an opportunity to write anything additional or different to what was actually said by you at the hearing. I would like to invite you now to make a statement to the committee on the relevant issues that you see may be invoked in the proposed legislation. Following your opening address committee members will want to ask a few questions.

Dr TONTI-FILIPPINI — Thank you. Under section 5 of your charter I think the Declaration of Helsinki is a document that is relevant to your considerations, because it forms a part of and informs international law, and section 5 refers to recognition of any other law.

I also think that the common law is relevant here in relation to common law that would exist and would not be overridden by the statute. So if there were common-law rights — and I think there are common-law rights that are not protected by the statute — I think those would still hold.

Clause 8 of the declaration refers to dependent subjects. It also refers to those who give consent under duress, and it also refers to those who will not benefit personally from the research. It seems to me that women whose eggs are used in cloning experimentation that is made possible by this bill — and in fact would be explicitly licensed under this bill — fits into each of those categories. In those categories, though, I think it raises questions for your charter 10(c), in relation to whether the consent is full and free if they are dependent subjects.

In the material I have sent to you there were several categories in which I think women are dependent subjects. The first is the recruitment of women on ART programs. They are in a doctor-patient relationship, so there is a dependency that is recognised under the Declaration of Helsinki. It is also recognised in our National Health and Medical Research Council’s National Statement on Ethical Conduct in Research Involving Humans that that is a dependent relationship. There would be the possibility that they would be giving consent to research for the convenience of the clinician and the clinician’s researcher colleagues as part of that package of getting treatment.

The second category is those who are undergoing tubal ligation or hysterectomy, who are similarly in a doctor-patient relationship — and so a dependent relationship, dependent subjects — and that also raises similar concerns about those procedures.

The third category is those who are not in a doctor-patient relationship but are simply volunteers to give their eggs for research. The issue has arisen in relation to the University of Seoul experimentation where they used young women researchers in the institution to obtain their eggs. Bearing in mind that you would expect that very few women would step up for general anaesthesia and surgery and ovarian hypersimulation in order to give their eggs, it is a huge ask. The concern would be that women students and junior women researchers would be in a difficult situation and again — if they were to give their eggs — would be seen as again dependent research subjects.

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The fourth category is those who are undergoing termination of pregnancy. The bill explicitly allows for the use of precursor cells from human foetuses, which means most likely you would be getting those from women who are undergoing a process of surgical termination of pregnancy, who are already in difficult circumstances, and again are in a doctor-patient relationship, so dependent subject provisions apply.

The final category is those women who have family members who have a genetic condition or a condition that may be supposed to be genetic. They are under some pressure then to donate their eggs, not because their eggs have the disease but because their eggs may be used in research and the researchers are struggling to get eggs to do research that would involve somatic cell nuclear transfer to those eggs using cells from somebody with the disease in order to research that disease. You could imagine those women would be in a fairly compromised position in a family if they refused to donate their eggs — so again, a kind of dependency.

It is important to bear in mind, in that respect the experience, in the UK where this has been happening for some time, where they have not been able to get significant numbers of eggs for women on ART programs, where they have looked to encourage that to occur by paying expenses, but also by offering what they call ‘egg-sharing schemes’, where women get reduced costs for their participation in an IVF program in exchange for donating some of their eggs while they are on the program.

That, I must say, is prohibited under this legislation, but there is some difficulty with the wording of that provision in section 38O of part 4A of the Victorian Infertility Treatment Act that I have referred to in the material I have given you, where the section that refers to ‘reasonable expenses’ is not actually included in the clause which prohibits the payment of valuable consideration.

The major issue that I want to raise with you is a second issue, and that is that this kind of research that is involving women in this way to get their eggs is not low-risk research, and if it is not low-risk research, then that raises a broad range of human rights concerns in relation to the impact on those women of donating eggs. I have raised the issues of dependent subjects and whether the consent is full and free; this goes beyond that but also raises common-law issues in relation to negligence and maybe even trespass to the person. I am not a lawyer, but those are two issues that would seem to get raised under the common law. The basic point that you would make from the point of view of the Declaration of Helsinki is that the wellbeing of the human subject should take precedence over the interests of science and society, and there are also some other provisions in relation to stopping research that may cause harm to the participants.

In this area it is generally regarded by anaesthetists and by surgeons that you do not do non-therapeutic procedures involving anaesthesia and surgery. The few exceptions we have are live organ donation, where there is a direct benefit usually to a relative, where there is an exception made to that. But where you are going to put somebody through this kind of procedure, you would not normally allow it. It is the sort of thing that when anaesthetists as registrars are doing their training, they often put up the proposal, ‘Well, shouldn’t we, if we’re going to be giving anaesthetics, experience anaesthesia?’, and they put up proposals that they will anaesthetise each other and intubate each other. Almost always — and in fact, in my experience, always — they are prohibited from doing that. It is thought that to do a non-therapeutic procedure with the kind of risks that attend on anaesthesia and intubation — you should not do that just for training purposes.

Bear in mind that your legislation allows women’s eggs to be taken for training purposes. There is a direct parallel. That would not be done by anaesthetists on each other, but it is proposed to be done under your legislation to women. That, I think, raises both concerns in relation to the Declaration of Helsinki and the risks to research subjects and concerns in relation to the common law in relation to the potential for negligence actions, and I have detailed those in the material I have given you.

There are two other categories that I will mention very briefly, because I know you want to ask me questions. There is the dead women category which is where, after death, women’s bodies would be used. It raises a concern in relation to the effect of the Australian organ donor register, which has a category where you can tick a box — you have probably seen the Medicare form that comes out — saying that you will donate all your organs and tissues. That is a consent now. It is not an intent register; it is now a consent register. So that is considered under Victorian law, under the Human Tissue Act, to be a consent to organ donation. No further consent is required by anybody.

The question there is, ‘Well, what about then taking the ovaries from a woman or the testes from a man, the gametes from them and the precursor cells, perhaps, and using them in cloning experiments?’. It seems to me that
there are then human rights issues involved in using those reproductive tissues in procedures which may not have been thought about and about which information may not have been given.

Your legislation requires proper consent. Proper consent is to be defined by the National Health and Medical Research Council guidelines, so it is just ethical guidelines. I do not think that is terribly reassuring for people in the community, and there is a potential here to undermine the goodwill that goes into the organ donation area.

The final area I would mention is proof of concept. Clause 11 of the Declaration of Helsinki requires proof of concept. Usually that requires animal experimentation. There is no such requirement in this legislation, and I think it is a reasonable presumption that if you are going into medical research, you have a right for that research to be conducted according to international standards, such as the Declaration of Helsinki. It seems to me that failure to require proof of concept is a failure to respect human rights with respect to having research conducted in a proper way. Thank you.

The CHAIR — Thank you for that. We will open up for questions. The question about there being comparable non-low-risk research occurring in research institutions at the moment — I am just wondering whether this problem does not arise in other research as well.

Dr TONTI-FILIPPINI — It is the sort of thing that when a human research ethics committee is confronted with a proposal for this, they knock it back. Researchers know that you cannot put research subjects at great risk, and so basically research is generally limited to research that is of low risk. The exceptions to that are where somebody is undergoing a therapy and the research is undertaken as part of the therapy. Those are the circumstances — because there is a benefit to the patient — where you can take more than low risk. Clinical trials and so on at stage 3 and stage 4 of a clinical trial could involve more than low risk, but you would be weighing that up against potential benefit to the patient and the treatment of the condition.

Research ethics committees still look at it very closely and try to ensure that there is balance — that the likely benefit to the patient outweighs the risk, even though it may be more than low risk. But to do something which is entirely non-therapeutic, not of benefit to a patient and involving more than low risk, in my experience of nearly 30 years of association with ethics committees and so on, I have not seen a non-therapeutic research project of that kind.

Mrs PEULICH — Nicholas, you said that the legislation there is the federal legislation — although it may have been actually Carlo. Could you comment on that? Is that accurate?

Dr TONTI-FILIPPINI — It is very hard to make that judgement, because there are many different pieces of legislation. The commonwealth legislation deals only with the research areas involving human embryos. Your legislation here in Victoria deals with all of ART, so you are mixing research with clinical practice. That raises some issues of its own in terms of doing it that way. If I had been consulted about the 2002 amendments to the Infertility Treatment Act, I would have said, ‘Please don’t do that. Please don’t mess up the protections in clinical practice. Try to keep the idea of established medical procedures separate from research’. In the national statement of the NHMRC on the ethical conduct of research involving human subjects there is a clear statement that these two things should be separate. You should separate research decisions and decisions to participate in research from decisions to be involved in clinical practice.

The CHAIR — I have a few other questions. On the question of proof of concept, won’t the individual ethic boards insist that there be a proof of concept prior to their giving the go-ahead for any research using eggs?

Dr TONTI-FILIPPINI — They may. The problem here is that you have a licensing system, so that for a human research ethics committee there is something very persuasive about a licensing system where this has gone through some kind of process and the Parliament has explicitly indicated that these are the sorts of things that can happen. It seems to me that if Parliament is issuing the capacity to provide licensed activity, you can see where that takes you as an ethics committee. If somebody says, ‘Well, this is licensed. This is approved by the Parliament. What are you doing saying we cannot do something that is licensed?’, there would be something very persuasive about the Parliament issuing licences for this particular kind of research.

The CHAIR — I am interested in the issue about altruism and people’s right to give full and free consent. For example, I am on the bone marrow register and I might be called up. It is a rather intrusive technique, but I feel
good about being altruistic. I am just wondering, is that not an opportunity for women as well to provide that level of altruism?

**Dr TONTI-FILIPPINI** — Two things: being on a bone marrow register, while it is difficult, is not particularly of great risk. It is possible they might want to do a general anaesthetic to do it, but normally they would not; so there might be the anaesthetic risks. Secondly, it is of direct benefit to somebody. When you are called up there is somebody there receiving it, and you can see a direct benefit for somebody. The benefits of this kind of research are very long term, not direct, not specific like that, and so it is a kind of different category. I think people when they are faced with seeing somebody directly benefiting, saving somebody’s life — you are talking about saving somebody whose is going to die of acute leukaemia in days, so when you are called up to do that you know that your bone marrow transplant is saving that life. That is totally different from the prospect of long-term research and the possibility the research could be done by some other means and so on.

**Mrs PEULICH** — Just on the issue of mixing the two purposes, the therapeutic and the research, and suggesting that perhaps if there had been proper and full consultation it may have been possible to achieve such an objective, is it possible to take it away and redraft it and separate those two purposes and perhaps make it easier for some members of Parliament to agree to the first and not the second?

**Dr TONTI-FILIPPINI** — It would not be hard to remove the research components from the Infertility Treatment Act, and it would not be hard to draft something that absolutely mirrored the Commonwealth legislation. You would just use the commonwealth legislation as your guide, and you would then remove from this act all those things. Bear in mind that in 1995 this act did not allow any of these things, so you just go back to the 1995 act in effect and remove all those things that were added after the 1995 act that dealt with research. There are some other changes, but remove all those that dealt with the research and you would be back to the clean piece of legislation that the 1995 act was.

**The CHAIR** — I have spoken to a number of researchers in the field, and they are really concerned about what happened in the UK and are very hostile to any commodification of eggs. The other issue for them is that they do believe it is possible to adequately support altruistic women in making this choice. So I suppose I am taking it back to what you see as the great practical consequence of not commodifying. How do you advise women accordingly to protect themselves and ensure they have got a full and informed decision?

**Dr TONTI-FILIPPINI** — There are two steps to that. The first is the researchers in England also expressed abhorrence of commodification and then asked for it when they could not get the eggs from women on ART programs. So that is the question I would ask here: how long would it be before they came back saying, ‘We are just not getting these eggs’? The fact of the matter is if you think about the process of ART, eggs are very hard to get. Each egg, if it is fertilised, represents a 4 per cent chance of the woman having a child via that embryo. She is not going to give up those embryos very easily. If you look at the number of women who actually get pregnant or have children on ART programs, you are looking at maybe a third to a half who manage to have a child, and the others do not. So looking ahead you are not likely to say, ‘Yes, you can take some eggs from me’, because you are going to want every possible chance you have to get pregnant.

You cannot store eggs satisfactorily, especially for research purposes, so you are going to fertilise them all. It is only when they are fertilised that they can be successfully stored. Once they are fertilised they are not of use to research. The experience in the UK bears out the fact that you are not going to get the numbers of women that you need to donate eggs to make this research workable.

**Mrs PEULICH** — Just a follow-up question, if I may: is this where you are coming from in relation to the possibility of negligence actions being taken?

**Dr TONTI-FILIPPINI** — Negligence would apply in several areas. There would be negligence in terms of whether or not women were fully informed. So there is that issue, but there are also, I think, grounds for negligence because of the responsibility a doctor has to ensure that the procedures that he does or she does are procedures that are for the benefit of that patient. We are in uncharted territory when doctors start doing non-therapeutic procedures for the benefit of their research colleagues, and even though the women may have full information and have consented, there is a possibility of an action based in negligence in terms of not properly carrying out the responsibilities of medical practice. There is an overriding responsibility of medical practice to ensure that what you do in medical practice is for the benefit of your patient. These patients are not benefiting from
this in any way, so there is a violation of a fundamental human rights obligation that is expressed in the Declaration of Helsinki in that respect and which is reflected in the sorts of principles that are embodied in the national statement here. It seems to me that the doctors would leave themselves open.

If you add to that the fact that most of these women would be in dependent relationships of one kind or another in relation to the researchers or the research institutions, then I think a court may look very dimly on a doctor who took a woman in a dependent relationship and did something that was potentially harmful to her, not low risk, not at all for her benefit but for the benefit of research, even though she consented. In other words, consent is not a complete defence. Just to take a kind of analogy, if I injure somebody deliberately in an activity, it is not a defence in our criminal justice system to say that they asked me to do it — that is, for me to deliberately harm somebody in that sort of way. There may be some exceptions for some kinds of sports where injury seems to be part of it, but even that is contestable, and we try to make those sports so that people do not get injured.

The CHAIR — Just for the benefit of the committee I was wondering if you could give us an outline of the origin and status of the Declaration of Helsinki.

Dr TONTI-FILIPPINI — It originated from the Nuremberg Code. It was the World Medical Association’s attempt to redraft the Nuremberg Code in a way that was better suited to medical practice. The Nuremberg Code was a very tough set of criteria. For instance, it prohibited any non-competent person from participating in medical research, so all children, all people who are mentally ill, all people who are developmentally disabled would not be allowed to be in research, which is actually to their disadvantage. It varied some things like that.

The Nuremberg Code, as you know, arose from the trials of the doctors during the Second World War. It is a very important document. It was an attempt to codify those principles by which the doctors were prosecuted. In other words, the principles did not exist in a formalised way before the Nuremburg, they did afterwards. They were said to be principles that, just as a matter of your own humanity, you should respect these principles. That was the Nuremberg Code. Then Helsinki was a more medical research-friendly drafting of those principles in the Nuremberg Code. It has been updated. I think the last update of the Helsinki was in 2004, which I have been quoting from in my document.

The CHAIR — Any other questions?

Mrs PEULICH — Could I just ask one more question? Nicholas, could you just comment also — I do not believe that you have — on clause 9 of our charter, ‘Right to life’:

Every person has the right to life and has the right not to be arbitrarily deprived of life.

Do you have concerns about that particular aspect of the charter?

Dr TONTI-FILIPPINI — I suppose there are two areas in which you could express concern. One is that there is the potential loss of life of women in these programs. We know in 2004 that 1.3 per cent of women who went on IVF programs in Australia got a life-threatening condition — ovarian hyperstimulation syndrome, which put their lives at risk. We know there have been deaths of women on IVF programs in Australia, several people in Western Australia in particular. We know that recently New Zealand and the UK have had deaths of women on IVF programs. So there is that part of it. Bearing in mind that it is one thing to accept deaths of women on an IVF program who are undergoing a treatment for themselves, and quite another for somebody who is a healthy person who is not undergoing any kind of treatment for themselves but is doing it as an altruistic act and then ends up dead. There is that issue.

The second issue which you could argue is because the charter of human rights is non-specific in relation to whom you consider to be a human person, it is an open question to argue that embryonic or foetal human life satisfies the description of human person, and then you could get an argument up. I have not based what I have said today on that. I thought that there were sufficient considerations in relation to women to warrant saying that this will raise significant human rights concerns.

Mrs PEULICH — If I may just follow up — nonetheless, we are mindful that the witnesses giving evidence today are also representative of a body of views that may be out there. Would there be a substantial number of people who would have concerns in relation to clause 9?
Dr TONTI-FILIPPINI — In terms of the status of the embryo, yes. In fact the National Health and Medical Research Council, no less, in its existing guidelines for assisted reproductive technology says that the creation of a human embryo for any purpose other than to achieve pregnancy is ethically unacceptable, which was mirrored in the legislation until the legislation that passed the commonwealth Parliament last December. There is an obvious confrontation within the NHMRC on that basis between what it used to think and whether it has changed its mind in relation to the commonwealth Parliament having voted on it.

You can hold to the view that embryonic human life should be protected in that way and not created for the purposes of research without necessarily saying that that human life has the same status as born human life, so there is a whole range of positions there. But the NHMRC took the position — and did so advisedly after public consultation — that this is a principle that should be upheld.

There is also a principle involved in all of that — that the human embryo should not be treated as mere tissue, which is another statement that is embodied in those guidelines. So there are two principles there that I think are probably fairly widely held in the community. You have to bear in mind that this is an issue totally separate from the issue of abortion where you have the circumstances of a women who is in difficult circumstances. This is actually creating the problem; creating an embryo for this purpose, and I think the community sees that differently. The numbers stack up differently if you are looking at it in terms of polls and things.

The CHAIR — My understanding is that the NHMRC guidelines are being reworked, and the new legislation refers to those. Do you have any idea when they will be finished?

Dr TONTI-FILIPPINI — I have to say two things here. I am a member of the committee that is revising those guidelines, but I cannot speak for or disclose any matters that are obviously in the process of the NHMRC. But I can say that the NHMRC published a schedule in which today was the day on which the consultation draft for the new guidelines was to be released. I checked this morning; it looks like they will not be released today, but they will be released soon, as I understand it. I think I can say that without revealing anything that is not a matter of public knowledge.

The CHAIR — Dr Tonti-Filippini, thank you very much for your time.

Witness withdrew.