

Submission to the Senate Community Affairs Committee

From Canon Alan Nichols AM

Regulate don't legislate on stem cell research

I have come slowly and reluctantly to the conclusion that parliamentary legislation is not the way to deal with complex ethical questions about medical research. There is a better way - regulation through the National Health and Medical Research Council.

Taking this approach is not abrogating responsibility - it is delegating it to people who know what they are talking about, and ensuring adequate protection through regulations and accountability mechanisms.

Fortunately in Australia most medical research is publicly funded and conducted in public hospital and research institutes. This system provides clear lines of accountability.

As well, peer review of medical research is professional and rigorous. It was peer review for example which uncovered the South Korean stem cell fraud last year. This does not mean we just leave it all to the scientists. It means that through existing regulatory mechanisms we encourage them, fund them, test the results, and keep them accountable.

Let me explain how I have come to this conclusion. My involvement in stem cells and embryos goes back to the first IVF legislation in Victoria in 1982-83. I served later on the Victorian Government's Standing Review and Advisory Committee on Infertility (forerunner of the Infertility Treatment Authority) during the time of the 1995 legislative amendments. I remain a member of the Ethics Panel of the Authority, and I chair the ethics committee of a Melbourne hospital with an adult stem cell laboratory.

Throughout this period, and right into the recent stem cell research debates, I have held the view that legislation is the way to go, although I now recognise that in this case recourse to legislation was based on fear of the unknown - the precautionary principle.

The fact is that biotechnology research has become extremely complex. It requires a level of scientific understanding which is simply beyond most members of the public. Although I am more involved than most, when I have been to Australian Stem Centre conferences, I could only really understand about 10% at most of what is said.

But, more importantly, research is proceeding at a much faster pace than the public can follow, and much too fast for the cumbersome legislative process.

Just last month, the prestigious *Nature* journal published new research by Dr Robert Lanza in the US about successfully creating a new stem cell line from a single cell of an embryo which left the embryo viable for implantation. It used a similar process to 'preimplantation genetic diagnosis', a practice regarded as ethical and commonly used in Australia to detect predisposition to genetic disease. If this research is replicated successfully, scientists no longer need to use 'somatic cell nuclear transfer' (therapeutic cloning) which has been the focus of so much recent debate in Australia.

What's more, Dr Lanza's research was tested on animals first, so it reaches the criterion of 'proof of concept' which is the agreed standard for approving new research on humans.

In other words, today's debate might be irrelevant tomorrow. Legislation which takes ages to draft and to debate, and then lasts for four years or so (like the current Federal Acts on human embryo research and therapeutic cloning), cannot possibly keep up.

My response to the draft Bills as far as their contents have been revealed to date is this. **Parliament approves extending the embryo research law for another three years**, as the Lockhart Committee recommended, because this work has been going on for years and is yet to prove itself. The goal is clear: using stem cells, to find cures for diseases like diabetes, Parkinson's, Alzheimer's and muscular dystrophy.

Then, using one of the Private Member's Bills, **Parliament amends the second Act to delegate responsibility to the National Health and Medical Council** for regulating other processes like therapeutic cloning.

This Council, which includes ethicists and other stakeholders, has demonstrated for decades now that they bear in mind values commonly held by Australians - for example, 65% approve of research on spare embryos. The Council conforms to the approach most Australians have always taken on scientific progress - proceed cautiously, monitor and regulate, and keep research in the public realm for accountability.

If you want evidence for this cautionary approach, anyone can look at the Pharmaceutical Benefits Scheme and the way Government research funding is channelled through the National Health and Medical Research Council.

The second grid for approval of stem cell research would be the existing human research ethics committees of individual institutions. Every hospital, university and research institute has one. The community is represented there, as well as doctors, researchers and scientists. These ethics committees are each accountable to their institution, to the NHMRC and to the public for their decisions. Every single research study in stem cells or somatic

cell transfer would have to go through at least of these institutional ethics committees.

This two-tiered system of review, approval and monitoring already exists. It does not have to be created. It is the process already used nationally for genetic research. We know it works.

What this proposal does is bypass the tortuous debates on how the conscience of individual politicians has been formed, what their views are of the moral status of the embryo, and whether opinion polls show Australians by a majority favour this or that particular procedure or research technique.

For myself, I did not elect my local Members of State and Federal Parliament to vote according to their conscience. I voted for them because of their policies for the common good. Is it a good idea to support research towards uncovering the mysteries of genetic disease and reversing disability? Absolutely. Do I want politicians to vote on every research method which researchers might use to do this? Absolutely not!

If both major Parties in Parliament are giving a conscience vote to their Members, does this not really indicate that it is not a matter for the State to decide at all? Then don't legislate.

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