AusBiotech Ltd

Submission to

The Legislation Review of Australia's

Prohibition of Cloning Act 2002
and
Research Involving Human Embryos Act 2002

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AusBiotech Australia's Biotechnology Organisation

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1. AusBiotech

AusBiotech, Australia's Biotechnology Industry Organisation, represents nearly 2,500 members, covering the human health, agricultural, medical device, environmental and industrial sectors in biotechnology.

AusBiotech is dedicated to the development, growth and prosperity of the Australian biotechnology industry, by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

AusBiotech has branches in each Australian State and provides the foundation to bring together all the relevant players to facilitate the commercialisation of Australian bioscience in the national and international marketplaces.

Our membership base includes biotechnology companies, ranging from start-ups to mature multinationals, research institutes and universities, specialist service professionals, corporate, institutional, and individual and student members from Australia and globally.

This submission is based on discussions with corporate, individual and institutional members of AusBiotech together with reviews of international and Australian material pertinent to the subject areas.

While this submission is a detailed presentation of AusBiotech's positions on both pieces of legislation, we would appreciate the opportunity to expand on our points directly with the Legislative Review Committee and therefore also seek to address the Committee during its face-to-face consultations throughout Australia.

The Board and the Chief Executive Officer of AusBiotech endorse this submission:

Chair:	Dr Simon Carroll, Western Australian Biomedical Research Institute
Directors:	Ms Caroline Beasley, Enterix Australia Dr Peter Devine, Uniseed Pty Ltd Dr Leigh Farrell, GBS Venture Partners Mr Michael Gilbert, Australian Centre for Plant Functional Genomics Dr Mikael Hirsch, CSIRO Dr David Irving, Diabetes Vaccine Development Centre

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2. Executive Summary

2.1 Primary Points

- AusBiotech strongly supports the ban on the cloning of human embryos for reproductive purposes, and can see no reason for changing this position in the foreseeable future.

- To sustain a healthy, competitive and world leading research environment in Australia generally and in the area of embryonic research in particular, there are three basic requirements:
  - Progressive legislation
  - Tight regulation
  - Clear and well articulated ethical framework.

- The prohibition on creation of progenitor cells through somatic cell nuclear transfer for the purpose of deriving stem cells is no longer appropriate and will negatively impact the quality of research and researchers in Australia.

- The UK legislation, regulation and ethical framework better reflects the appropriate level of legislative and ethical oversight given the current stage and pace of embryonic research. It also achieves a balance between the public requirement for the banning of human reproductive cloning and the desire of many for science to identify new ways of preventing or treating complex, chronic multifactorial diseases such as diabetes and Multiple Sclerosis (MS).

- While not the preferred option, at the very least, the Legislative Review Committee should recommend the amendment of the *Prohibition of Human Cloning Act 2002* and the *Customs (Prohibited Exports) Regulations 1956,* to allow the importation of stem cell lines derived from nuclear transfer procedures from appropriately regulated 'approved' international Stem Cell Banks.

- Given the rate of change in this area of research, both the *Prohibition of Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* require review at least every three years to ensure their on-going relevance.

- An independently constituted Stem Cell Bank would support Australia's leadership position in stem cell research and would improve the timeliness, standards and efficiency of Australian research.

2.2 Secondary Points

- The term 'Nuclear Transfer Progenitor', to describe progenitor tissue that is created through the process of somatic cell nuclear transfer, is more scientifically accurate and is less likely to confuse or create unnecessary concern than 'human embryo clone'.

- The Legislation Review Committee should ensure that an accurate analysis of the status of regulation of embryonic research in major competitor countries be used as a basis for comparing the appropriateness of the current and future Australian legislation.

- The final report should take into account **all** major potential uses for Nuclear Transfer technology when considering the impact that the current legislative prohibition is having on Australian research, and materials provided to the public should reflect this range of potential uses.

3. Legislation Review Issues Paper

The Issues Paper prepared by the Legislation Review Committee and released in support of the Legislation Review is an excellent background document providing both scientific and contextual information as well as outlining a framework to identify matters for further consideration.

On review, AusBiotech believes that in order for there to be a comprehensive and informed discussion about both pieces of legislation there are two areas that require more detailed consideration:

- the regulation of stem cell research in the United States of America; and
- the potential uses for Nuclear Transfer Technology, including the creation of nuclear transfer progenitors.

3.1 Regulation of Stem Cell Research in the USA

There is an impression in the public arena that is not clearly addressed in the Legislation Issues Paper, that the type of regulation of embryonic and stem cell research conducted in the US is as stringent if not more so than that currently applied in Australia.

This impression has developed since US President's announcement in August 2001 that federal funds could only be used to study embryonic stem cells derived from lines that were useable at that date (approximately 24 lines). This position was taken to prevent any further destruction of embryos for the purposes of this research. Obviously, this decision also meant that federal funding could not be used to support the creation of nuclear transfer progenitors.

A 'seemingly' more progressive position was taken by the Australian Government and is reflected in the Australian legislation which has allowed the use of surplus embryos created prior to April 2002 for the purposes of extracting embryonic stem cell lines, but has banned reproductive cloning and the creation of nuclear transfer progenitors through somatic cell nuclear transfer (also known as therapeutic cloning).

What has not been made clear is that the federal US decision does not prevent any other sources of funding – ie state or private – being used to support this research. In other words, the creation of embryonic stem cell lines from surplus embryos is perfectly legal, as is the creation of nuclear transfer progenitors and subsequent extraction of the disease or patient specific stem cells.

It is also interesting to note that despite the strong position against reproductive cloning that the US took in the United Nations as part of the March 2005 Agreement, again, at a federal level it has not enacted any legislation banning reproductive cloning.

So, while there is a perception that the US has restrictive regulatory regime covering embryonic research, the opposite is in fact true. Researchers in the US in reality have the same opportunities as their colleagues working under progressive legislative frameworks in, for instance, the UK, Singapore, and South Korea.

(Theoretically, the fact that the US has not banned reproductive cloning means that its regulatory framework is probably the most liberal of all.)

Given that California has passed supportive legislation which permits creation of nuclear transfer progenitors and has recently undertaken to invest US$300 million a year for the next 10 years in embryonic stem cell research in that one state alone, lack of access to federal funds will not prove to be a major barrier to continued research in the US.

AusBiotech recommends that the Legislation Review Committee ensure that an accurate analysis of the status of regulation of embryonic research in major competitor countries be used as a basis for comparing the appropriateness of the current and future Australian legislation.

Australia's comparatively restrictive legislative regime therefore puts its scientists at a distinct disadvantage compared with its major international competitors in the UK, the US, Singapore and South Korea. This disadvantage not only relates to areas of research and discovery but potentially to attraction of international private investment. The consequences of this will be dealt with in greater detail in the body of this submission.

The Australian community (and in the longer term, the international community) is also disadvantaged by not having timely access to experimental therapies through clinical trials process and more broadly through the loss of intellectual and creative capital as researchers (and research investment) move off shore.

3.2 Potential uses for Nuclear Transfer Technology, including the creation of Nuclear Transfer Progenitors

As outlined in the Issues Paper, the creation of nuclear transfer progenitors (NT progenitors), referred to in the legislation as human embryo clones, through somatic cell nuclear transfer is prohibited under the *Prohibition of Human Cloning Act 2002*.

The Paper also outlines the potential uses for NT progenitors and more specifically the stem cell lines that are derived from them. The emphasis in the Issues Paper, and in much of the public discussion about nuclear transfer is on the use of the stem cells derived from NT progenitors to grow cells or organs that are a match for the person from whom the material for the somatic cell was obtained. Doing so would, for instance, prevent problems associated with rejection.

One of the major downsides of the use of nuclear transfer stem cell lines for this type of patient specific therapy is that it is now and will probably continue to be inefficient and expensive because of the requirement for the use of many donor eggs. Although work in South Korea indicates that with time and experience the number of eggs required to successfully derive an stem cell line decreases.

A more efficient potential use for stem cells derived from nuclear transfer progenitors is to prepare research models for certain diseases such as diabetes or Parkinson's Disease.

Such models will allow scientists to study the way in which these diseases progress and potentially when to intervene to prevent or treat the disease and what types of interventions could be used (eg genetic or pharmaceutical). The benefits of this work are numerous and varied and include:

- Work that is currently undertaken in animal models will now be able to be ethically undertaken using human tissue.

- The ability to ensure timely and accurate treatment intervention either to prevent, treat or manage complex and costly diseases such as diabetes or MS will eventually have huge social and economic impacts.

- The ability to identify new drug and treatment targets will encourage interest and investment from the private sector – particularly major pharmaceutical companies.

That the focus of nuclear transfer technology, including the creation of NT progenitors has been on the more controversial and less efficient side of the science and has not explored or highlighted other uses has meant that the opportunity for informed public debate on this issue has been restricted.

AusBiotech recommends that the Legislation Review Committee final report take into account all major potential uses for NT technology when considering the impact that the current legislative prohibition is having on Australian research. Doing so will ensure that the community will be fully informed of what they will potentially miss out on if the prohibition remains in place.

Further, we would recommend that materials provided to the public reflect this range of potential uses.

In the body of this submission, AusBiotech will also address in greater detail the consequences of continuing the ban on both the creation of NT progenitors and the importation of stem cell lines from prohibited embryos.

4. Issues – definitions and terminology

- **Are the definitions of 'human embryo' and 'human embryo clone' clear and unambiguous? Do they appropriately reflect community standards? Do they cover all of the activities that should be regulated under the legislation?**

AusBiotech does not propose any changes to the definition of 'human embryo'. It is the organisation's position, however, that the term 'human embryo clone' is both scientifically dubious, provocative and creates and reinforces a misconception.

The use of the term clone implies that the embryo, which has been created by placing the genetic material from one individual into a donor egg that has had its nucleus removed, would be genetically identical to the individual. The presence of mitochondrial DNA from the egg donor in the embryo negates this possibility.

Further, in the minds of the public there can be confusion about the term clone such that as in the case of reproductive cloning, there is an expectation that these embryos are being created with a view to producing a viable human being.

That is patently not the case. The creation of NT progenitors is undertaken for the purpose of extracting embryonic-equivalent stem cell lines for a range of research and development purposes. That this requires the destruction of the oocyte at around day 5 in order to extract the stem cells further ensures that a cloned human being would not be possible.

In order to be clear and specific about this process it would, therefore, be more appropriate to refer to these embryos as nuclear transfer progenitors.

It is AusBiotech's view that the term nuclear transfer progenitor, to describe the cell mass that is created through the process of somatic cell nuclear transfer, is more scientifically accurate and is less likely to confuse or create unnecessary concern.

- **Are other definitions and terminology used in the Acts helpful for understanding and interpreting the legislation? Do they appropriately reflect community standards?**

AusBiotech does not have any comments to make on this question.

- **Does the legislation need to define stem cells? Is the focus on the use of excess ART (Assisted Reproductive Technology) embryos sufficient?**

It is AusBiotech's view that the primary focus of both pieces of legislation regulates the use of embryos. The derivation and use of embryonic stem cells is but one possible secondary use and is already regulated appropriately under NHMRC Guidelines (National Statement on Ethical Conduct in Research Involving Humans) – as is research on all other human cells.

On this basis the legislative focus on the embryo rather than secondary issues is appropriate and makes the need to define stem cells redundant.

Currently, the focus on excess ART embryos is appropriate given the prohibitions on the creation of embryos other than for the purpose of ART and the use of surplus ART embryos for deriving embryonic stem cell lines. Should the legislation be amended in the future to include embryos created through Somatic Cell Nuclear Therapy, this would obviously require a broader focus.

- **Have there been any problems in interpreting or applying any of the definitions or terminology in the Acts in research or ART practice?**

This has not been raised as an issue with AusBiotech.

- **Do you foresee any problems arising (for example, because of new scientific advances, changing scientific understanding of biological processes, or changes in ART practice)?**

As the Issues Paper itself states "Since 2002, medical and scientific research has continued at a rapid rate". There is nothing to indicate that situation will not continue.

The UK Government recently released its response to the Report from the House of Commons Science and Technology Committee and in it addresses issues including mitochondrial research, parthenogenesis and the creation of artificial gametes. They too have commenced a review of their Human Fertilisation and Embryology Act and will no doubt look further at these emerging issues in this context.

These types of changes and the speed of change highlights the need to ensure that legislation is progressive, flexible and able to respond to this dynamic field.

AusBiotech is strongly of the view that at the very least, both the *Prohibition of Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* require review at least every three years to ensure their on-going relevance.

5. Issues – Prohibited Embryos and Practices

AusBiotech does not think it is necessary for the purposes of this submission to engage in the debate about the value of adult versus embryonic stem cell research. That the Australian legislation already permits both supports the necessity of continuing to explore the potential of both lines of inquiry.

It is appropriate to briefly refer to recently publicised research that has shown that adult stem cells fused to laboratory grown stem cells have produced a hybrid cell that reverts back to its embryonic state. The potential for this technology is the ability to produce ES cells for research and therapy without the creation or destruction of embryos.

It is important to note two things. Firstly, this research builds on the work that has already been done on embryos and on nuclear transfer technology, highlighting the importance of this work. Secondly, scientists have subsequently pointed out that this work, while interesting from a research perspective has no current therapeutic value due to the fact the technology produces cells that have 92 chromosomes instead of 46. In its current form, it is not a substitute for producing stem cells from either excess embryos or progenitors that are created through nuclear transfer.

Again, this example illustrates the need for various lines of research to continue in parallel to ensure that no potentially beneficial outcomes are lost and to act as a basis for identifying areas of future research.

The focus, therefore for Australian research and its future, needs to be what constitutes a prohibited embryo.

- **How has the ban on all human cloning affected research in Australia?**

The first and most important point that AusBiotech would like on the record is that it strongly supports the ban on the cloning of human embryos for reproductive purposes, and can see no reason for changing this position in the foreseeable future.

AusBiotech does, however, believe that the prohibition on creation of nuclear transfer progenitors through somatic cell nuclear transfer for the purpose of deriving embryonic-equivalent stem cells is no longer appropriate and will negatively impact the quality of research and researchers in Australia.

Between 1999 when the Australian House of Representatives Legal and Constitutional Affairs Committee was asked to start examining human cloning and stem cell research and the enactment of the legislation in 2002, the potential for stem cells derived from nuclear transfer progenitors was only beginning to be realised in animal models.

Given this situation, it was neither surprising, nor inappropriate, to take a cautious approach to this new, untested technology. It is also interesting to note that in contrast to the definitive stance that the House of Representatives Committee took in relation to reproductive cloning, the majority report supported a three year moratorium on the creation of NT progenitors by means of somatic cell nuclear transfer.

In 2004, some two years after the Australian legislation was enacted, a group from South Korea's Seoul National University announced that they had successfully created somatic cell nuclear transfer progenitors and had extracted stem cells from them.

It is AusBiotech's understanding that there are groups in Australia today who are now also ready to undertake this type of work. Under the current legislation they will not be able to progress that work in Australia and will either have to stop the work or pursue it overseas.

Since the enactment of the Australian legislation in 2002, the UK, the US, Singapore, Belgium, Sweden, and China amongst others have allowed research aimed at creating nuclear transfer progenitors and the deriving stem cells from these NT progenitors.

Our major competitors in this area, Singapore and the UK, have not only put in place progressive legislation that permits this research, they have done so in a highly regulated environment and with a very strong and publicly supported ethical framework.

The combination of progressive legislation with tight regulation and a strong, well- articulated ethical foundation is a very attractive model for scientists to work within and for investors.

It provides both certainty and clarity of boundaries.

In Australia at the moment there is a view that the current environment provides appropriately tight regulation, an ethical framework that possibly requires more clarity and legislation that is now viewed as unnecessarily restrictive.

The potential impact of this is twofold:

- Australia will continue to lose its position as a world leader in this field of research together with its leading scientists (a recent review of international stem cell research in the National Geographic, mentioned Australia only once and that was to comment on the loss of scientists to Singapore).

- The comparatively restrictive legislative environment combined with the potential for loss of leading researchers does not provide the certainty required to make Australian research an attractive investment opportunity for either private Australian or international investors. The obvious consequence of this is either a greater call on the public purse or a decline in the quantity or quality of the research being undertaken in this field in this country.

AusBiotech understands that given the amount and quality of biotechnology research currently being undertaken around the world, there is a general shortage of private funding, particularly Venture Capital. One of the problems that has arisen as a result of this is that in order to raise capital, some biotechnology Start Ups in Australia are listing publicly at too early a stage in the product development cycle. This contributes to the challenges with which these businesses have to contend increasing their risk profiles and obviously decreasing their relative attractiveness to private sector investors.

In terms of the fight for the global investment dollar it is not difficult to see that countries such as Singapore and the UK, that combine strong public financial support for early research together with appropriate legislative, regulatory and ethical frameworks, provide much more attractive investment environments than Australia.

A fundamental question needs to be asked and answered as part of this Legislative Review – what is going to happen to those Australian researchers who are now ready to embark on the work that has already borne results in South Korea and is being followed up in countries the UK, the US and Singapore right now?

Another critical factor that must be considered as part of any response to this question is the future impact of the ban on importation of stem cells derived from nuclear transfer progenitors. This is particularly important in the event that there is no change to the prohibition on the creation of nuclear transfer progenitors.

This submission will deal with that issue in more depth as part of the section on International Exchange of Embryos and Stem Cells.

- **How have the other prohibitions affected research in Australia?**

As outlined above, this submission will deal with the potential impact of the prohibition on importing stem cells derived from nuclear transfer progenitors as part of the section on International Exchange of Embryos and Stem Cells.

- **Are the prohibited embryos and practices described in the Act still relevant in light of advances in biotechnology since 2002? Do they appropriately reflect community standards?**

As outlined earlier in this section, the cautious approach to embryo research taken by the Government in the current legislation was an appropriate response to the available knowledge and public views at that time.

It is AusBiotech's view that the UK legislation, regulation and ethical framework better reflects the appropriate level of legislative and ethical oversight given the current stage and pace of embryonic research. It also achieves a balance between the public requirement for the banning of human reproductive cloning and the desire of many for science to identify new ways of preventing or treating complex, chronic multifactorial diseases such as diabetes and MS.

- **Has the prohibition of payment beyond reasonable expenses (valuable consideration) for gametes and embryos affected access to these items?**

AusBiotech has not been advised that this has caused issues for research groups however, we note the recent media coverage related to a shortage of surplus ART embryos being donated for use by infertile couples – which would have more to do with personal choice than an actual shortage of embryos.

Looking to the future, while AusBiotech supports continuing the policy of prohibiting payment for gametes and embryos, we believe it is worth exploring other means of accessing donor eggs – particularly if the prohibition on creation of NT progenitors is lifted.

To this end AusBiotech would support a proposal to assess whether the current organ donation model to donate ovarian tissue would be an appropriate vehicle for consenting women of the appropriate age to also list their eggs for donation. This could be extended to include women who are having full hysterectomies or those who are having their ovaries removed for other reasons.

6. Issues – use of excess ART Embryos

The questions raised in this section are more appropriately addressed by ART providers and consumers.

7. Issues – licensing and statutory arrangements

It is AusBiotech's understanding that there has been 100% compliance with the licensing system. While there was initial feedback that the system was cumbersome and slow to respond, this has been attributed to the start up period and there is confidence that things will improve with experience and time.

8. Issues – international exchanges of embryos and stem cell lines

- **How have the import and export prohibitions (including amendments to the Customs Regulations) affected the operation of ART centres, the access to reproductive materials by users of ART or the donation of reproductive materials by donors?**

These issues are most appropriately addressed by providers and users of ART services.

- **How has the legislation (including the Customs Regulations) affected stem cell research activities?**

The continued prohibition on importing stem cells derived from prohibited embryos (eg nuclear transfer progenitors) together with the prohibition on creation of nuclear transfer progenitors, ensures that Australian scientists who choose to remain here are prevented from participating in a fundamental line of research that potentially carries huge social and economic benefits for all Australians.

AusBiotech maintains that to realise these benefits, the future of Australian research in this fundamental area of biotechnology should be facilitated through the lifting of the prohibition on the creation of nuclear transfer progenitors.

While not the preferred option, at the very least the Legislative Review Committee should recommend the amendment of the *Prohibition of Human Cloning Act 2002* and the *Customs (Prohibited Exports) Regulations 1956,* to allow the importation of stem cell lines derived from nuclear transfer from appropriately regulated 'approved' international Stem Cell Banks.

This will firstly ensure that fundamental research work can continue in Australia and secondly, stipulating where these lines come from will ensure that the means of derivation will meet Australia's technical and ethical requirements.

9. Issues – national stem cell bank

While this is an area most appropriately addressed by researchers and research institutions, AusBiotech has a number of general points to make:

As a general principle AusBiotech supports stem cell banks because:

- they ensure that cell lines are produced and maintained to an internationally recognised standard;
- the history of the cell lines and their derivation is transparent;
- they ensure the most efficient use of embryos (and in the case of NT technology, eggs) by minimising the opportunity for repetitive work by researchers; and
- they reduce the overall cost of research.

An Australian Stem Cell Bank would have a number of benefits:

- access to a variety of lines will be faster, easier and cheaper than going overseas;
- provide the potential to set and maintain standards (not only of lines but of institutions/ researchers that apply to have access to lines);
- less potential for problems to occur with lines during transportation;
- ensuring that the standard of Australian lines meets internationally recognised standards;
- support Australia's reputation as a world leader in this research; and
- enable more cost-efficient research.

Given the requirements for ensuring transparency and maintaining standards of line derivation and distribution, an Australian Stem Cell Bank would need to be administered independently of any research institution, private organisation or, given its role in funding public research, the Government.

In the first instance it would be useful to investigate whether there is an appropriate established institution in Australia to undertake this role to avoid unnecessary costs and duplication.

10. Issues – research developments

It is appropriate for ART providers, researchers and users to address issues related to the ART area specifically so AusBiotech will limit its comments to stem cell and biotechnology research.

- **Have the advances in stem cell research been greater or less than expectations in 2002?**

- **Has access to excess ART embryos for research allowed significant advance in knowledge in this area?**

- **What are the next steps in the research? What are the potential benefits of the research and when might these occur? What are the potential risks?**

There have been significant advances in the understanding of stem cells and their potential over the past three years. Work in Australia and overseas is beginning to better define the differences between adult and embryonic stem cells, how they work and therefore how they will impact on the diagnosis and treatment and possibly prevention of disease.

For the period January 2003 until now the comprehensive digital archive of peer-reviewed life sciences journals, PubMed Central, lists 1446 published articles related to ES cells and 1038 related to adult stem cells. Each of these papers adds to the store of knowledge on stem cells and importantly informs future research.

In the adult stem cell domain advances include treatments now being trialed in humans in areas such as management of the autoimmune disease lupus erythematosus, stress incontinence, brittle bone disease, leukemia and other cancers and rheumatoid arthritis.

In the embryonic stem cell area there are now over 150 ES cell lines worldwide. These lines have formed the basis for a steady stream of research that is looking at:

- how to grow these cells to Good Manufacturing Process (GMP, which is an international standard that must be met if they are to be used by humans);
- how to differentiate them into different types of cells (eg liver cells, neurones or blood cells): and
- how in the future stem cells may be created either without requiring embryos or minimising the number of embryos to be used.

In South Korea, the possibility of developing specific disease models and patient specific therapies through derivation of stem cells from nuclear transfer progenitors, that was first proposed by Australian researchers in 2000 using a mouse model, is being realised in a human model.

Historically, Australia has been the leader in stem cell research. As noted above, people built on Australian research. It is AusBiotech's view that the legislation as it is currently framed has moved researchers back to the second tier, behind those working in Singapore, the UK, South Korea and the US.

As this submission has already stated, the consequences of not amending the legislation to better reflect international standards will impact the quantity and quality of our research and researchers. Importantly, it will also impact on the quality of healthcare provision for all Australians.

Work undertaken by the CSIRO has indicated that development of Intellectual Property in Australia has the potential to deliver not only economic benefits through licensing agreements, but more timely release of those products onto the Australian market and into community use. Biota's influenza product, Relenza, is an example of a past product that had a relatively fast move to the Australian market, while CSL's HPV vaccine may well repeat this in the future.

To help realise the potential of adult and embryonic stem cell research, in January 2003, the International Stem Cell Forum (ISCF) was established. Australia's National Health and Medical Research Council, together with 13 other research funders from across the world, is an active member.

The stated key principles of ISCF are:
- opposition to human reproductive cloning;
- use of adult somatic human stem cells as well as embryonic human stem cells;
- the generation of embryonic human cell lines should be minimised; and
- international harmonisation of ethical and intellectual property rights issues.

The establishment of this body reflects the importance that has been placed by on the need for global cooperation in order to accelerate the progress of this research in a way that provides for:
- standardised criteria for the derivation, characterisation and maintenance of cell lines;
- sharing of resources and data, including cell lines, scientific protocols and guidance documents; and
- consideration of ethical issues in stem cell research.

In a society where it is the end product (eg pharmaceutical or surgical intervention) that is considered to be valuable, the pace at which this research is moving may seem slow. After some years of media hype about the potential of this research (at times in collaboration with the research community), people are expecting this work to start delivering something 'solid'.

From an ethical and social perspective, though, there are some that would argue that this research is moving too quickly and society has not had time to consider some of the broader ramifications.

The realistic position is probably somewhere in between. While treatments and interventions that can be commercialised are probably some way off, public disappointment and growing scepticism has to be balanced against the responsible and prudent approach that researchers are taking to the development of this new technology.

To ensure that society is brought along with the technology, rather than turned against it, scientists and their institutions have chosen to proceed with caution.

The current legislation represents an appropriate response not only to where practical rather than theoretical research was up to in 2002, but to public understanding and expectations at that time.

It is the view of AusBiotech that there has been sufficient experience with adult and ES cell research in Australia and NT progenitor research overseas for the Australian legislation to be amended to reflect where both public understanding and international research is now moving.

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