Original Article

Innovation and commercialisation in the stem cell industries in Australia: State strategies and other opportunities to build a competitive position in the global stem cell economy

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ABSTRACT **Recent research in the social studies of stem cell science has demonstrated that there is (a) a significant global economy emerging around stem cell science, and (b) that individual states are competing fiercely in an effort to obtain leadership in this global stem cell economy. Over the last several years, the governments of the United Kingdom, China, India, Canada, Singapore and Australia (among others), have been attempting to leverage the process of innovation in stem cell science by implementing a variety of strategies including, but not limited to: dedicated funding programmes, the introduction of specific licensing systems, the implementation of new regulations for human cell-based material, emulating US-based venture capital, and encouraging entrepreneurship and spin-off developments. What remains to be seen though, is how effective such attempts actually will be in encouraging the commercial development of nationally oriented stem cell industries. Given that the relationship between innovation and commercialisation is unique to national and regional contexts, as well as unique to specific industries, this article discusses the specific strategies adopted in developing the stem cell industries in Australia and highlights some of the pros and cons with a government interventionist approach to developing global economic advantage from national and regional innovation.**

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INTRODUCTION

Since human embryonic stem cells were first isolated in 1998, a global industry has developed around stem cell science. Recent research in the social studies of stem cell science has shown that one of the hallmarks of this developing global stem cell economy is intense competition between nation-states keen to capitalise on any advantage in the field.[1] Further, this competition has largely emerged in response to the processes of globalisation and the recognition that nation-states are now operating in an increasingly dynamic global knowledge economy.[2,3] Or, put another way, the transition from industry-based production to knowledge-based production in the late twentieth century has pushed governments to generate local capitalisation in knowledge intensive industries – such as biotechnology – in order to remain economically competitive in the new global economy.[4–6] In effect then, the international competition in stem cell science can be seen as simply one more aspect of the broader economic competition generated by the emergence of the global knowledge economy.

Creating economic competitiveness via intervention into innovation is now a mainstay of much government policy around the world. A key challenge for governments is developing effective policy interventions into the innovation process that will create economic leverage. By managing the innovation system such that opportunities for knowledge generation and commercialisation are maximised, states are – in theory at least – in a position to actively develop economic competiveness. Such an approach to managing innovation is termed 'the competition state'. This article is concerned with how the theory of 'the competition state' plays out in relation to stem cell science in Australia.

Arguably, the competition state is particularly central to success in biotechnology. Hans Lofgren and Mats Benner[7] propose that neither the thesis that the minimal state would best support economic growth in the global knowledge economy, nor the thesis that the state would become obsolete in the face of globalisation have been entirely accurate. Rather, they suggest, governments need to manage the relationship between innovation and the free-market in such a way that brings out the best of both elements. In particular, Lofgren and Benner argue, the high dependency of biotechnology on public funding results in a larger role for effective policy making by governments than might be necessary in other industries. In Australia, almost all biotechnology research is dependent on government funding, thus making 'the competition state' the best possible method for understanding innovation in the biotechnology sector.

Rodney Loeppky[8] describes the competition state in the following way: '… an expanded role for the state in the process of capitalist accumulation, in an attempt to position the "national" economy for optimal scientific and technological competitiveness' (p. 45). Although Loeppky is referring explicitly here to the human genome project in the United States, the message for biotechnology innovation is quite clear. Namely, that state strategies are important for achieving successful outcomes in the biotechnology sector because of their role in supporting the development of basic science (including regulation, funding, scientific training), and also supporting the infrastructure through which science can become commercialised (intellectual property legislation, tax incentives for investors). In other words, the competition-state is not simply focused on funding. Maximising competiveness in innovation includes effective policy interventions into all the other components of the innovation system too.

In effect, according to Lofgren and Benner[7] and Loeppky,[8] among others,[2–4,9] the competition state is, in fact, the necessary condition for creating the right elements for successfully engaging in what has been increasingly referred to as the global knowledge-based bioeconomy, of which the global stem cell economy is only one part. The dependency of biotechnology on

public funding, the degree of personnel requirements, the length of time it takes to generate commercially viable products, the amount of money required to translate basic science into therapeutic products, and the efficacy and safety issues that go into insuring consumer protection, are all elements of the innovation process that the biotechnology industry is dependent on, and in which states can intervene. For stem cell science, both in Australia and elsewhere, the added difficulties of community conflict, heavy regulation, long time-delays in developing effective therapies, and the necessity for careful and rigorous animal and human clinical trails compounds this process and creates an even more important role for governments in facilitating stem cell innovation.

So how do specific strategies in the Australian stem cell sector compare to those adopted elsewhere? The UK government has developed one of the more sophisticated stem cell strategies,[10] but governments in the European Union (EU), Canada, Singapore, China and India have also followed suit. While Australian bioethical regulations are on a par with those in the United Kingdom, and product regulation is becoming increasingly similar to the Federal Drug Administration in the United States, what are some of the other features of Australian stem cell innovation and how effective are they at developing the competitiveness of Australian stem cell science within the global arena?

INNOVATION STRATEGIES AND STEM CELL SCIENCE IN AUSTRALIA

In 2000, the then Federal Australian government launched a new innovation action plan – the *National Biotechnology Strategy* – that resulted in 100 million dollars being directed towards biotechnology over the next 3 years.[11] This funding included provision for the establishment of the Australian Stem Cell Centre.[11] In 2004, the same Federal government launched *Backing Australia's Ability – Building Our Future Through Science and Innovation* in which a further 30 million dollars was earmarked for strengthening Australia's biotechnology capacity and also specified that support for the Australian Stem Cell Centre be continued.[11] Other data shows that the National Health and Medical Research Council provided 39.84 million dollars to stem cell research in 2005 and 40.21 millions dollars in 2006.[12] The Federal Government indicated in the last Budget that it will continue funding the Australian Stem Cell Centre until 2011,[13] but beyond that funding was still uncertain. Other funding programmes may be developed in the future.

To put this into context, Australian Federal government spending on Science and Innovation over the past 10 years has varied from as low as 2.52 per cent of Total Australian Government Expenditure in 2005–2006 and as high as 2.95 per cent in 2003–2004.[13] For 2008–2009, spending on Science and Innovation was estimated at 2.56 per cent of total government expenditure.[13] These spending figures cover all sectors of performance in science and innovation and cross a broad spectrum of agencies and sectors.[13] In comparison to other OECD countries, the Australian government's spending on Science and Innovation is fairly modest.[14] Overall, the Federal Australian government spends more on research and development (R&D) as a percentage of Gross Domestic Product than is spent in the whole EU, less than the combined expenditure in the whole OECD, less than Sweden, Finland and Japan, less than the much larger United States, less than Canada, France, Korea, Denmark and Austria and about the same as the United Kingdom.[14]

More specific data on stem cell funding is difficult to find. Apart from the Australian Stem Cell Centre, which is specifically listed in the Federal Budget Tables, the true extent of Federal government funding of stem cell science is hard to determine as it could come under the auspices of many of the other programmes and centres specifically listed. Nevertheless, as a general indicator of trends

in funding for stem cell research in Australia, the National Health and Medical Research Council (NHMRC) figures for 2005 and 2006 are instructive. The breakdown of the data for this period shows that over three quarters of the funding issued was for animal stem cell research only, and only 5.27 and 4.08 million dollars went to human stem cell research in 2005 and 2006, respectively.[12] Of this money, most was used for adult stem cell research, 5.05 million in 2005 and 2.68 million in 2006.[12] Federal funding for human embryonic stem cell research in Australia is thus comparatively small in relation to other areas of stem cell research.

At the state level the issue of funding for stem cell science gets more complicated. The state governments of New South Wales (NSW), Victoria, Queensland, South Australia and Western Australia have all distributed funding to stem cell science in the past 5–10 years. More interestingly, in each case, the funding allocated to stem cell science is part of a broader push for developing viable economic competitiveness through innovation. That is, while the rhetoric of spending on medical research, especially controversial medical research like human embryonic stem cell science, is justified by a focus on the potential for cures, the evidence is that economic competitiveness through innovation is actually a far more significant motivator for spending on scientific research.

The government of NSW announced in 2007 that it would provide 500 000 dollars specifically for human embryonic stem cell research.[15] This is quite small in comparison to other state governments, although the NSW Government invests 'approximately 1 billion dollars per annum' in R&D development in the life sciences.[16] It is however, difficult to determine the final breakdown of how much of this is for stem cell research, biotechnology or bioscience explicitly. Half a million dollars for human embryonic stem cell research was announced in 2007 as part of a joint NSW/VIC Government Stem Cell Research Grant Program that will provide funding of up to 1 million dollars over 2 years to eligible publicly funded researchers in each state that conduct stem cell research. The NSW Ministry for Health and Medical Research, in collaboration with the University of NSW, also supports the NSW Stem Cell Network, a professional network that brings together researchers, policy-makers, patient advocates and social scientists interested in the development of the stem cell sciences.

Victoria is home to one half of the Australian Stem Cell Centre, and also hosts several internationally recognised stem cell research teams. These include research groups at the Walter and Eliza Hall Institute and the newly established research park, Bio21, at the University of Melbourne. Overall, the state government of Victoria has invested more than 1.6 billion dollars into science, technology and innovation since 1999.[17] This is part of an aggressive strategy to make Victoria one of the top five biotechnology locations by 2010. Furthermore, in what can only be seen as a strategic move to support the agenda for biotechnology development, the Victorian State government was also one of the major funders of the inaugural meeting of the UK National Stem Cell Network held in Edinburgh in April 2008, with the Governor of Victoria being a keynote speaker. In addition, the Victorian Government has recently initiated collaboration with the Scottish Stem Cell Network in the United Kingdom and the California Institute for Regenerative Medicine in the United States.

In Queensland, Brisbane hosts several university-based stem cell programmes, and the University of Queensland is one of the partners in the Australian Stem Cell Centre. Griffith University also hosts the newly established National Adult Stem Cell Centre. The prominence of an active stem cell research community in Queensland is also reflective of the Queensland Government's aggressive pursuit of innovation in biotechnology as a central part of its economic strategy. The *Smart State Strategy* was first launched in 2005 and updated in 2008.[18] The strategy reflects the Queensland Government's

commitment to developing a globally competitive knowledge-based bioeconomy.

So too is the Government of South Australia keen to promote Adelaide as a centre of biotechnology excellence in order to generate economic development of the region as a whole. Adelaide is '… the location of Australia's first … biotechnology incubator'.[19] BioInnovationSA is a biotechnology development organisation and has made several inroads into facilitating the biotech incubator project, including establishing a new venture capital fund worth 35 million dollars in 2006. Adelaide was the location of several stem cell start-up companies in Australia – now based outside of Australia – and there is a Centre for Stem Cell Research at the University of Adelaide.

Stem cell scientists in Western Australia have been busy setting up the Australasian Society for Stem Cell Research. A fully incorporated association, the Australasian Society for Stem Cell Research has linkages with several other international networks and held its first annual meeting in December 2008. While the network originated from a research team at the University of Western Australia, the Western Australian government is as committed to 'positioning science and innovation as one of the key drivers of the States' economy'[20] as any of the other state governments mentioned so far.

Government involvement in stem cell science then includes funding for basic science from both Federal and State governments, specific policy initiatives designed to foster collaborative development and networking opportunities, and specific goals for making biotechnology a part of future economic security, at both the Federal and State level. All of these strategies are explicitly in keeping with the principles of 'the competition state', and the idea that innovation can be influenced in some substantial way by effective government.

Also, a Federal Review of the national innovation system conducted in 2008[21] has identified many ongoing concerns with innovation policy as it currently stands in Australia. Some of these include concerns about the quality of maths and science education and training opportunities for the next generation, the effectiveness of current competitive funding models for University-based research, the impact of various taxation schemes on private investment in R&D in Australia, a relative decline in government spending on R&D in Australia since the 1980s, a transformation in the innovation process itself, and a need to include firms and corporations more deliberately in a broader understanding of innovation as it relates to commercialisation.[21] The need for a Review of the innovation system in Australia was also suggested to be long overdue because the current system was established nearly 20 years ago, and that the global economic environment has changed substantially since then;[21] the more recent global economic downturn notwithstanding.

The next section of the article will look at some of the linkages between innovation and commercialisation in the stem cell sciences in Australia.

THE COMPLEXITIES OF COMMERCIALISATION IN THE STEM CELL SCIENCES

The previous section looked at how harnessing the competitive abilities of Australian stem cell scientists is part of this drive by state and federal governments to push innovation as part of a platform for economic success. Yet, there are some problems with utilising innovation as a key to economic achievement, not least of all because of the commercialisation process.

One issue is that innovation is a contested concept and that pathways to commercialisation are not as clear-cut as they might appear to be. Which is to say; hoping that the market will do the rest once a feasible idea has been developed (the traditional model of commercialisation) is often a more complex process than it appears. The Cutler Review describes this as an over-reliance on a now out-dated perception of commercialisation as a linear process of

knowledge transmission from 'research to development to application'.[21]

A second issue is that successful innovation is not necessarily uniform across all industries, or, indeed, all regions.[22] This raises the problem of how to tailor innovation policies to the specific requirements of each industry and region. While there is some indication that the innovation process is by and large generalisable as a one-size-fits-all model, commercialisation in biotechnology, in particular biotherapeutics, for example, faces a more complex and arduous process than, say, information communication technologies. This is in part because of the complexities of ensuring safety and efficacy of an unproven technology, and also the cultural values attached to particular innovations. So although certainly some components of innovation and commercialisation might be uniform, the specifics of translating new developments into commercial products within individual industries need attention too.

A third difficulty is that evaluating the effectiveness of an innovation policy is by nature a complex process – innovation is flexible, adaptable and future-based. If the general philosophy behind the concept of innovation is the production of new and novel products and ideas, then in effect, a certain amount of unknowability exists in the innovation process itself. That is, there are no guarantees that any new idea, product or process will have the desired market success.

Taken together, these problems raise questions like: is it possible to manage innovation for economic success? How would success in innovation be measured in any case? What are the key features of a successful innovation policy? And, for the topic addressed here, how would such an innovation policy affect the stem cell industries in Australia in particular?

Stem cell science is time-consuming, expensive and technically demanding. In the previous section, we saw that a significant component of enhancing the stem cell industries in Australia occurs via funding from government sources. Yet, the majority of this funding is for basic research. Other funding sources, especially past the basic science stage, are also vital for the commercialisation process. In general terms, non-government funding usually enables the transition of basic research into commercial products. Yet, investment in scientific research by non-government sources is usually done on the basis of expecting to make a profit. This means that if a stem cell innovation is to have any chance at becoming a commercial reality, it has to have a foreseeable profit margin. One of the arguments about stem cell research is that the investment cycle (the time-frame in which investors can expect to make a profit) is much longer than in other industries. In Australia however, in addition to the profit motive there are also tax advantages to be gained from investing in R&D, which provide a further incentive for companies to invest in science and technology.[21] Whether or not this outweighs profit considerations is a decision that each investor makes individually.

In 2004 the Australian Government announced changes to existing funding arrangements for industrial R&D that effectively launched a new funding programme designed to bridge the gap between potentially profitable ideas that were unable to raise sufficient capital because of the early stage of product development and private capital. This programme, known as Commercial Ready, was a direct attempt by the Federal government at the time to patch some of the holes in the traditional commercialisation process by providing 50 per cent of the funding required for development to reach the next phase. Unfortunately, Commercial Ready was scrapped in 2008 with the Federal government citing a need to cut spending and evidence that many of the projects funded by Commercial Ready could have succeeded without government support.

The consultancy firm Ausbiotech has estimated that around one-third of the

applicants to the Commercial Ready funding programme were biotechnology and medical devices companies.[23] This figure is, on the one hand, a telling indicator of the high dependency of biotechnology innovation on government funding. Yet, on the other hand, the large number of applicants to the Commercial Ready programme could also be read as evidence of a very particular kind of commercial model operating in this biotechnology and medical devices sectors; one that mainly reflects the complexities of the commercialisation process for biotherapeutics. Needless to say, the scrapping of Commercial Ready has been widely interpreted as having a detrimental impact on the economic competitiveness of Australian biotechnology, and consequently, the Australian community overall in terms of economic and health benefits. Ausbiotech has also noted that the Cutler Review[21] highlighted the need to develop similar kinds of programmes in the future.

The exact extent of non-government sources of funding for scientific research in Australia are difficult to determine. There is some evidence of private investment in established stem cell companies in Australia. For example, adult stem cell company Mesoblast raised 21 million AUD at initial public offering on the Australian Stock Exchange in 2004,[24] and has successfully raised much more than this in subsequent years. Outside of these explicit instances there is almost no further information about non-public sources of investment in stem cell research in Australia. The only other accessible data shows that the Australian Stem Cell Centre has commercial partnerships with ASX listed companies Millipore, ESI and LifeCell Corporation in the form of licensing agreements and patenting deals.[25]

Australia simply does not have the investment capital for biotechnology that places like the United States have, and consequently, the Australian biotechnology sector is limited to raising capital from off-shore investors, public funds and creative business models (for example licensing arrangements, patenting deals and platform technologies) that do not apply in other industries. While patenting issues in biotechnology have become increasingly problematic in some places around the world (for example, the United States and the EU), so far in Australia similar debates around what is allowable as a patent have yet to prove particularly significant. The Cutler Review[21] suggested that firms and corporations should be more involved in developing innovative applications of knowledge and facilitating the knowledge transfer process. Although specific details on exactly how to do this are thin, it is clear that ownership of intellectual property and patents is key to facilitating these kind of relationships between inventors/scientists and investors and companies.

Furthermore, Australia does not have the philanthropic funding resources that exist in the United States and the United Kingdom that have substantially assisted stem cell science, among other research programmes, in those countries. There is some evidence of partnerships between specific patient-organisations and research groups in Australia, yet exact figures are difficult to find. Overall, it is almost impossible to determine the real extent of philanthropy in Australia (including here specific patient-organisations as not-for-profit charities), as there is no accurate reporting or surveying of giving in Australia.[26] One study conducted in 2005, however, shows that philanthropy in Australia is reasonably substantial. This study shows that 7.7 billion dollars was donated overall by individuals in Australia, representing 87 per cent of the adult population, and that 3.2 billion dollars in the previous financial year was donated by businesses in Australia, accounting for 67 per cent of all businesses.[26] Charitable foundations and trusts, of which there are approximately 2000 in Australia, are also thought to have 10 billion dollars worth of assets and disperse between half a billion and a billion dollars a year altogether.[26] Obviously, philanthropy in Australia is not as

much as in the United Story (estimated at around 500 billion USD in assets, with donations of over nearly 28 billion US dollars) but is surprisingly still more than in the much larger United Kingdom (nearly 11 000 private trusts and annual giving averaging around 2 billion pounds). How much of this might be donated to medical charities, research facilities and the like involved with stem cell science is open to conjecture.

What the figures on public and private sources of funding demonstrate is that stem cell research is a national activity in Australia, undertaken by universities, hospitals and biotechnology companies as part of a broader agenda of building economic competitiveness through innovative development of biomedical knowledge. As the health research goals of stem cell science generate continuing interest and support for stem cell science from the national community, the internationally competitive position of Australian researchers and the economic opportunities that world-class research represents will remain of significant interest for both Federal and State governments keen to capitalise on innovative advantage. Yet, given the limitations on both public and private sources of funding, what other options exist for creating economic competitiveness through a state-managed innovation system in the stem cell sciences in Australia?

THE INNOVATION SYSTEM AND AUSTRALIAN STEM CELL SCIENCE

Philip Cooke[27] argues that the success of biotechnology in the United States is based on an aggressive approach to sourcing and exploiting publicly funded basic research by private investors through the patenting system. Although the biotechnology innovation model in Australia is superficially similar to the US model outlined by Cooke, there are vast differences in the two innovation systems. When examining how this impacts on a very specific area of biotechnology, like stem cell science, these differences start to play out in ways that upset the traditional configurations of competitive advantage that might be expected in relation to these two countries.

For instance, Aaron Levine[28] has demonstrated that the United States is underperforming in the stem cell sciences, and attributes this to a variety of different reasons, including regulatory uncertainty, funding limitations and community pressure. Yet, stem cell scientists in Australia have not faced the same degree of difficulty, and research shows that controversial scientific research is generally well regarded in Australia, and that public trust in science is comparatively high.[29,30] Despite considerable debate, since human embryonic stem cells were first isolated, about the kinds of stem cell research that the Australian community is willing to tolerate, the outcomes of these debates in Australia have not hampered publicly funded research in Australia in the same way as has occurred in the United States over the same time period.[31–33] Although there is not nearly the same level of individual, corporate and patient-organisation involvement as exists in the United States, for a country with a population of only 24 million people, Australian leadership in the global stem cell arena is conspicuous.

One of the key differences between biotechnology innovation in Australia and the United States is that there is no formal government provision for technology transfer in Australia, such as the Bayh-Dole Act in the United States. Nevertheless, technology transfer is widely encouraged in Australia and more than half of the universities in Australia have some form of technology transfer office that provides services to academic and research staff wanting to develop innovative ideas into commercially viable products.[34] In the United States though, technology transfer has been enhanced via the development of quite specific federal legislation – the Bayh-Dole Act – that allows publicly funded researchers to develop intellectual property rights, and provided specific legislative measures

for the development of technology transfer protocols.[35] Before the development of the Bayh-Dole Act, publicly funded research in the United States was not allowed to be patented. In the late 1970s, this ban was determined to be restricting both the capacity of public universities to capitalise on their research, and also to be resulting in a disincentive for practical scientific and technological developments that would enhance US economic competitiveness. In a culture where individual entrepreneurialism is an established part of the cultural mythology of national identity, this limitation was regarded as a major barrier to national economic success and the Bayh-Dole Act one way of overcoming this limitation.

In contrast, while strong innovative ability is often cited as one of Australia's cultural advantages, and there has been no ban such as previously existed in the United States on the rights to patent by publicly funded researchers, little is known about the extent of entrepreneurialism in Australia's biotechnology industry and its comparative strength in relation to the well-documented entrepreneurial culture of US biotechnology. One study of biotechnology entrepreneurs in Australia shows that personality, in the form of personal drive and idea generation, is a critical factor in facilitating commercialisation.[36] Alternatively, some more general work on entrepreneurship in Australia argues that entrepreneurialism generally emerges from any of the 'power elites' formed through a combination of old money, institutional affiliation, and/or the accumulation of property.[37] That is, individuals with money in Australia tend to invest across a range of areas, so entrepreneurialism is dependent on getting access to these individuals.

However, more recently, with the recognition that international competitiveness in biotechnology is fundamental to the economic success of the country, students interested in the biotechnology industry in Australia are increasingly being trained specifically for entrepreneurial skills.[38] What remains to be seen though is how effective this specific training is, what impact it has on established cultures of capital-raising in Australia, and whether training biotechnology students in the specific skills required to make them successful entrepreneurs will have any impact on the national competitive ability of Australia's biotechnology industry, including the future of stem cell science in Australia.

CONCLUSION: CRITICAL QUESTIONS AND GAPS IN KNOWLEDGE

Overall, Australia has a relatively strong biotechnology innovation system, although not as strong as in the United States. One of the main weaknesses for the success of stem cell science in Australia is using the model of biotechnology innovation that has been developed in the United States in the Australian context. Further research needs to be done on the commercial models being adopted in an environment where scientific research is excellent, supported and endorsed by governments at all levels, and yet public funding is the most significant source of capital. In what ways, for example, could private investment be encouraged in the stem cell sciences in Australia and how could this be put into practice? Increasing the existing tax incentives for companies and individuals donating to R&D, direct appeal to University Alumni and increased health activism from patient-organisations are some initial steps that might increase private investment in Australian stem cell science, and also help entrepreneurs cover the gap from basic science into commercially viable products.

Another issue that has not been addressed is whether or not the Federal and State government's push for economic competitiveness in biotechnology innovation in particular is justified. Have policy interventions like the *National Australia Biotechnology Strategy* had any effectiveness on the outcomes of biotechnology innovation? How could such impacts be measured? Is it possible to determine overall improvements

of biotechnology in Australia as a result of the *National Biotechnology Strategy*, or is the biotechnology industry only accountable to its own internal logic or, alternatively, that of the market? Some emerging evidence from elsewhere in the world suggests that state-managed innovation has produced fairly ambiguous results so far;[1] scoring well on some fronts (for example, increasing workforce capacity), but not necessarily seeing any measurable difference in terms of financial benefit.

Also, what cannot be determined at this stage is whether or not specific investments in the stem cell sciences are warranted. There are a range of arguments both for and against funding such controversial and highly technically challenging research. For example, the previous US Administration's decision to restrict funding for some forms of human embryonic stem cell research was based on a moral concern about the use of human embryos in research. In Australia, the establishment of the National Adult Stem Cell Centre in order to circumvent the need to focus on human embryonic stem cell research could also be seen to be reflective of the moral and political agendas that influence particular policy positions. Outside of the moral values attached to stem cell research involving human embryos, larger policy issues might include whether or not funding for research into therapies that are so far off is financially or culturally justifiable, given the limited resources of the Australian community.

One of the interesting aspects of medical research is that it is often self-justifying; namely, that the desire to find new medical treatments is always an acceptable goal. Of course, no one would deny this argument, but if long-awaited stem cell therapies fail to live up to their hype and expectation, will governments still be interested in providing funding? Will companies invest in commercialisation? In the absence of a major therapeutic achievement, the stem cell industries might fail altogether because of the lack of any clinical success. Although preliminary indications are promising; at this stage, again, only time will tell.

Still further questions that remain unaddressed in terms of the commercial development of human embryonic stem cell science include, how will access to services be managed across different national and international contexts? What will be the role of public health systems in delivering stem cell-based therapies to local communities? How will private health funds be expected to cover the costs? Will the emergence of expensive health technologies create an even bigger divide between those who can afford health care and those who cannot? The leveraging-up of the role of bioethics bodies and new regulatory bodies globally indicates that there are considerable technical challenges for health governance resulting from stem cell research.[1] Moreover, as therapies start to emerge, it is anticipated that these challenges will only increase. Will increasing health disparity have any impact on government innovation policy in relation to innovation health technologies? How will the relationship between innovation policy and global competitiveness and health delivery for local citizens be justified by governments in the future?

At the end of the day what will happen in Australia in the event of the successful development of stem cell-based therapies is yet to be seen. Before issues of equity and access can even begin to be considered, understanding the commercial and clinical challenges facing the future of stem cell research in Australia and internationally is critical. Although concerns around ethics and governance of emerging technologies are one part of shoring up the future of stem cell science, identifying the key issues in the relationship between clinical development and commercial application are vital to the success of the industry overall. At least part of this will involve specific government policy interventions aimed at enhancing the translation of basic research into clinical

products via the innovation system, including a comprehensive assessment of which strategies work and which strategies do not work for stem cell science as a complex niche industry of the larger biotechnology sector. Now that the regulatory and social issues around stem cell science have largely been resolved, the immediate focus for governments adopting a 'competition-state' model should be the translation of new therapeutic developments into commercially viable clinical products, and the development of innovation components that will enhance the options available for stem cell researchers, patient-activist groups and the national community.

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