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Jointly present the symposium:

Human Biotechnology and Public Trust

Taking stock in 2006 - trends, perceptions and regulation

Chief Sponsor:
Victorian Government, Department of Human Services



PROGRAM & ABSTRACTS

THURSDAY NOVEMBER 23, 2006

8:30 – 9:15 REGISTRATION

Chair: Prof Michael Gilding

9:15 – 9:30 WELCOME

Prof Ian Young, Vice-Chancellor, Swinburne University of Technology
Prof Russell Crawford, Dean, Faculty of Life and Social Sciences

9:30 - 10:30 KEYNOTE ADDRESSES:

9:30 – 10:00 Mr Robert Moses *Value Drivers in Australian Biotech
- A Reality Check*

10:00 - 10:30 Prof Ron Trent *The Role of the Human Genetics Advisory
Committee (HGAC)*

10:30 – 10:50 Morning Tea

Chair: Prof Margaret Otlowski

10:50 – 12:30 COMMERCIALIZATION*

Session Sponsor: Community, Place & Change Theme Area (UTas)

- 10:50 – 11:15 Prof Michael Gilding *Biotechnology clusters and networks: Australia compared*
- 11:15 – 11:40 Dr Dianne Nicol *Gene Patenting: Balancing Innovation and Access*
- 11:40 – 12:05 Prof Michael Vitale *Capricious Investor Behaviour and Company Valuations*
- 12:05 – 12:30 Dr Tom Faunce *The Impact of the Australia and United States Free Trade Agreement (AUSFTA) on Regulation of Nanomedicine in Australia*

12:30 – 1:30 Lunch

Chair: Mr Michael Gorton AM

1:30 – 3:10 PUBLIC PERCEPTIONS AND PUBLIC TRUST

Session Sponsor: Biotechnology Australia

- 1:30 – 1:55 Prof Tim Caulfield *Commercialization, Public Trust and the Popular Media*
- 1:55 – 2:20 Dr Kristine Barlow-Stewart *Australian community views on the impact and the aftermath of knowing your genetic information.*
- 2:20 – 2:45 Mr Craig Cormick *What does the public really think and who do they really trust?*
- 2:45 – 3:10 Dr Karen Farquharson *Social trust and Australians' comfort with new technologies: Trends in data from the Swinburne New Technology & Society Monitor*

3:10 – 3:30 Afternoon Tea

* Each speaker has 20 minutes to present and 5 minutes question time

Chair: Dr Karen Farquharson

3:30 – 5:10 CONSUMING BIOTECHNOLOGY

Session Sponsor: Menzies Research Institute (UTas)

3:30 – 3:55	Prof Robin Bunton	<i>Consuming and Participating in biotechnology: public health developments and dilemmas</i>
3:55 – 4:20	Dr Julie Henderson	<i>Consuming science: Professional and popular media reporting of the role of molecular genetics in causing mental illness</i>
4:20 – 4:45	A/Prof Sandy Taylor	<i>Consumer experiences with genetic testing</i>
4:45 – 5:10	Dr Lyn Turney	<i>Marketing and Consumption of Paternity Testing</i>

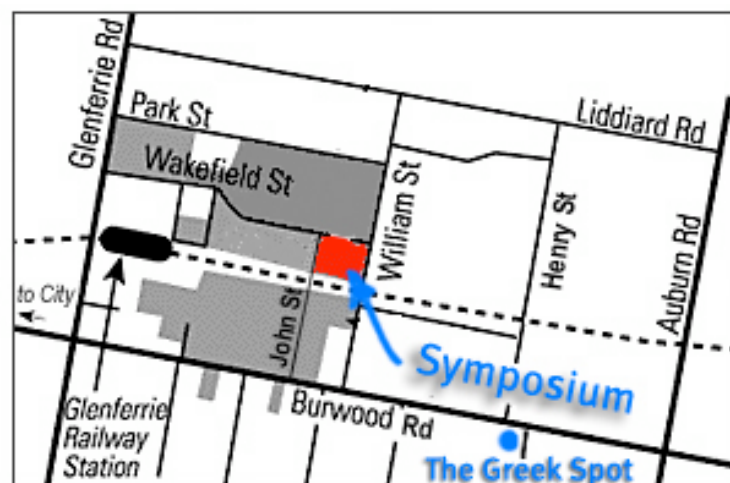
5:10 Drinks

The AGSE building, Swinburne

7:00 Dinner

The Greek Spot

559 Burwood Road, Hawthorn



FRIDAY NOVEMBER 24, 2006

Chair: Dr Mark Stranger

9:00 – 10:40 HUMAN GENETIC DATABANKS

Session Sponsor: National Health & Medical Research Council

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|---------------|------------------------|--|
| 9:00 – 9:25 | Prof Alastair Campbell | <i>Ethics and Regulatory Frameworks for Biobanks</i> |
| 9:25 – 9:50 | Prof Alan Petersen | <i>Engendering trust in biobanks: the examples of UK Biobank and the WA Genome Health Project</i> |
| 9:50 – 10:15 | Dr Oonah Corrigan | <i>Property Matters: Public and Private Ventures in Human Genetic Databases</i> |
| 10:15 – 10:40 | Ms Jennifer Fleming | <i>Issues with Tissues: What say They - Perspectives of Professionals, Donors and the Public Towards Tissue Banks and Human Genetic Research Databases</i> |

10:40 – 11:00 Morning Tea

Chair: Dr Lyn Turney

11:00 – 12:40 STEM CELLS

Session Sponsor: National Health & Medical Research Council

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|---------------|------------------------|---|
| 11:00 – 11:25 | Prof Don Chalmers | <i>Australian stem cell regulation in the international context</i> |
| 11:25 – 11:50 | Dr Christine Critchley | <i>Stem Cell Research: What do the Australian public really think and why?</i> |
| 11:50 – 12:15 | Prof Loane Skene | <i>Cloning, Stem Cell Research, and the Lockhart Committee's Recommendations</i> |
| 12:15 – 12:40 | Dr Elizabeth Finkel | <i>In the footsteps of Galileo and Jenner: the struggles of stem cell science</i> |

12:40 – 1:40 Lunch

Chair: Prof Don Chalmers

1:40 – 3:20 PUBLIC POLICY

Session Sponsor: National Health & Medical Research Council

- | | | |
|-------------|------------------------|---|
| 1:40 – 2:05 | Prof Margaret Otlowski | <i>Exploration of key themes in the policy debate on genetic research and genetic databanks</i> |
| 2:05 – 2:30 | Dr Hans Lofgren | <i>Public policy for competitiveness in biotechnology: Australia and the rising Asian economies</i> |
| 2:30 – 2:55 | A/Prof Justin Oakley | <i>Democracy and bioethics expert advisory committees</i> |
| 2:55 – 3:20 | Prof David Weisbrot | <i>Public engagement and public policy: critical underpinnings for genetic research</i> |

3:20 – 3:35 CLOSE

Prof Don Chalmers and Prof Michael Gilding

3:35 – 4:30 Informal discussion and refreshments

ABSTRACTS

KEYNOTE ADDRESSES

Value Drivers in Australian Biotech - A Reality Check

Author: Robert Moses

The biotechnology sector of Australian Industry is comprised of about 130 companies listed on the ASX and another 50 to 100 plus unlisted companies (depending on how broadly you wish to define biotechnology). The “classic” criteria for determining the value of these companies include a number of factors that are commonly used with most types of high tech companies, but also several factors that are unique to biotechnology. Is application of these valuation techniques translating into sensible real world valuations? If not, what factors are actually driving value?

Often heard statements made by institutional and private professional investors are variations of these themes; “I know there are some biotechnology companies in Australia that will be very successful and may one day become the next Genentech or Biogen Idec worth billions of dollars – I just don’t know how to identify the good ones”, or this; “Investing in the Australian biotechnology sector is a lottery, a good way to lose your money unless you are very lucky” or this; “Most of the biotechs in my portfolio looked good initially and were flavour of the month at some stage, but their share prices tanked so I have taken them all off my radar”.

These views beg a very fundamental question: Is the biotech sector of the capital markets in Australia sufficiently strong, mature and sophisticated enough to reliably sustain value and support the capital requirements of our developing biotechnology companies? And the answer is ??? Vote “1” for “YES”, Vote 2 for “NO” or Vote 3 for “YES & NO”. The paper will explore this question.

The Role of the Human Genetics Advisory Committee (HGAC)

Author: Ron Trent

The HGAC is a new Principal Committee of the NHMRC and was established in January 2006. Its terms of reference include the provision of on-going high-level advice on: (i) technical and strategic aspects of current and emerging issues in human genetics and related technologies particularly in relation to human health and healthcare; (ii) The ELSI related implications arising from developments in human genetics and related technologies, (iii) Other matters as the Minister from time to time determines (see <http://www.nhmrc.gov.au/about/committees/hgac/index.htm>).

The HGAC’s activities during 2006 have focused on various aspects of clinical practice in genetics including DNA testing; educational issues related to genetics at the undergraduate medical student level as well as in general practice, and the use of genetic information in the insurance industry.

Biotechnology clusters and networks: Australia compared

Authors: Michael Gilding and Vikki Bunton

There is a substantial literature on the articulation between clusters, networks and innovation, with particular reference to biotechnology. It is heavily focussed upon high tech urban centres in the US and Western Europe. There is now an emerging literature on clusters, networks and innovation among firms distant from the world hubs. This literature emphasises networks over and above clusters, emphasising the ways in which firms far from the world hubs practise a 'precocious internationalism', creating alternative forms of proximity with the high tech centres.

This paper uses network analysis to map interorganisational collaborations among Australian biotechnology firms. In particular, it addresses their collaborations with public research organisations, venture capital firms, large pharmaceutical corporations, and other biotechnology and biomedical firms. It describes patterns of collaboration at the local, national and international levels, and compares them with those in the US (the world leader) and Sweden (a country with roughly the same number of biotech firms). The paper observes the relative inclusiveness of local biotechnology clusters in Australia; the centrality of public research organizations in local clusters; the importance of venture capital in regional and national networks; the commercial orientation of international collaborations; and the diffuseness of international collaborations, to the point that on their own they barely amount to a network at all. More generally, it emphasises enduring localism alongside precocious internationalism in Australian biotechnology.

Gene Patenting: Balancing Innovation and Access

Author: Dianne Nicol

The relationship between ownership and use of patented inventions in medical biotechnology is complex, particularly with regard to upstream gene patents and other research tool patents. Current technology transfer strategies may not achieve the most desirable outcomes, either in promoting innovation or in facilitating consumer access to new healthcare products and services. There are some proposals for reforming the law to provide better outcomes, particularly the creation of a clear experimental use exemption. The primary focus of this paper, however, is on industry-driven mechanisms that are likely to be more finely tuned to meet the needs of particular industry participants or groups of participants. Options range from streamlining negotiations with the assistance of licensing guidelines through to establishment of formal patent pools. Open access models and open source licensing also warrant consideration. It will be argued that such strategies offer benefits to the industry as a whole and also have the capacity to promote public confidence within the framework of the commercialised biotechnology research environment.

Capricious Investor Behaviour and Company Valuations

Authors: Michael Vitale and Marita Walmsley

Biotechnology is generally regarded as a “news-driven” sector. Disclosures related to clinical trial results, regulatory decisions, and research partnerships can have a significant effect on share prices. However, it is difficult to predict the direction or magnitude of these changes, or to explain them theoretically. This paper reports on an analysis of disclosures by ASX-listed biotechnology firms in 2005. It proposes that the impact of disclosures on share prices can be understood as the result of capricious investor behaviour. It also discusses the implications of this finding for disclosure policy at the level of the firm and the market.

The Impact of the Australia and United States Free Trade Agreement (AUSFTA) on Regulation of Nanomedicine in Australia

Author: Tom Faunce

Nanomedicine is a growing sub-branch of biotechnology research in Australia. Its regulation raises particular problems in the areas of safety (through the TGA) and cost-effectiveness assessment (through the PBAC). Both of these are likely to be impacted by AUSFTA Annex 2C obligations to fast track and reward "innovative" pharmaceuticals. This paper explores some of the major regulatory issues involved and outlines a collaborative program of multidisciplinary research aimed at developing relevant practical policy options.

PUBLIC PERCEPTIONS AND PUBLIC TRUST

Commercialization, Public Trust and the Popular Media

Author: Tim Caulfield

The increasingly commercial nature of biomedical research is, rightly or not, a reality of the contemporary research environment. The percentage of biomedical research supported by industry continues to grow and many public funding agencies now encourage industry partnerships. While links with industry have clear benefits, including increasing available research funds and facilitating knowledge translation, they are also associated with numerous social issues. In this presentation, I will explore the role commercial forces (and the „economic imperative“) play in the nature of public representations of biotechnology. This will include a discussion of both the coverage of positive events, such as the discovery of a new disease gene, and negative events, such as the Myriad Genetics controversy. What impact might these stories, which get a great deal of attention in the popular press, have on public trust? While the public remains supportive of biotechnology research, there is recent evidence that this support is fragile and that it may erode if the public perceives a connection between research and industry.

Australian community views on the impact and the afterwards of knowing your genetic information.

Authors: Kristine Barlow-Stewart, Sandra Taylor, Margaret Otlowski, Mark Stranger and Susan Treloar

The 2003 Australian Survey of Social Attitudes (AuSSA) of 5000 randomly selected members of the general public investigated views and attitudes (n=2087) regarding uses of genetic information. The same questions were included in the consumer survey of the Genetic Discrimination Project (GDP); respondents were individuals (n=1185) who undertook a predictive genetic test for an adult-onset genetic condition 1998-2003. Of total AuSSA respondents, 66% were supportive of genetic testing generally; these tended to be male and to be generally trustful. So, although a good majority has *general* support for testing, there is also a gender and trust divide in that support.

Does this support translate into support for *specific applications* of genetic testing; particularly in the areas of insurance, employment and immigration? It was found that 77% of AuSSA respondents and 95% of the GDP group disagreed with future mandatory genetic testing by insurance companies; this view correlates with low trust in financial institutions, broadly defined. Further 75% of AuSSA respondents disagreed with its use in the workplace, even regarding safety issues for both current and future employees. Women and respondents with low trust in others are more likely to express opposition.

In contrast, AuSSA respondents were more comfortable with using genetic tests for immigration purposes, presumably because there are fewer personal implications and because some respondents seek lower immigration. The importance of trust appears to be critical in explaining attitudes, and may be key to regulation.

What does the public really think and who do they really trust?

Author: Craig Cormick

Biotechnology Australia has been conducting qualitative and quantitative research into public attitudes towards biotechnology applications since 1999. Tracked findings of attitudes towards human applications and biotechnology, and changing levels of trust will be examined in this presentation, looking at awareness, perceptions of usefulness and risk and moral acceptability. The data shows that different applications of biotechnology have moved in different directions over the past six years. Attitudes towards cloning and understanding of terminology used in the public stem cell debate are also examined. Differences of attitudes between genders and non-English speaking are highlighted and in regards of trust, the presentation looks at significant changes in trust across the community and how these relate to biotechnology applications, both in terms of sources of information and general trust.

Social trust and Australians' comfort with new technologies: Trends in data from the Swinburne New Technology & Society Monitor

Authors: Karen Farquharson and Christine Critchley

The Swinburne New Technology and Society Monitor is an annual cross-sectional survey of the Australian population that tracks attitudes towards new technologies and levels of trust in Australian social institutions. This paper reports findings from the Monitor, focussing on changes in Australian attitudes towards new technologies over the years 2003-2005. Among other findings, we note that most Australians believe that science and technology are continually improving our quality of life. We also find that the digital divide in Australia is increasing in that those people who use the internet are very comfortable with it, but those who do not use it are significantly less comfortable with it in 2005 than they were in previous years.

CONSUMING BIOTECHNOLOGY

Consuming and Participating in biotechnology: public health developments and dilemmas

Author: Robin Bunton

This paper reviews enduring public health concerns with human biotechnology, highlighting dilemmas for 21st century medicine which, on the one hand, places citizen responsibility, participation and consumerism centre stage whilst, simultaneously, drawing upon esoteric knowledge and encountering new risks and dangers associated with the new technologies of public health. Related moral and ethical concerns are placed within broader concerns for the 'medicalisation' of life, over simplification of personal and group identity and attacks on personal freedoms. It argues that key concepts of public health are continually transformed by technological developments which have implications for consumption, health and identity.

Consuming science: Professional and popular media reporting of the role of molecular genetics in causing mental illness

Author: Julie Henderson

This paper explores reporting of the relationship between genes and mental illness in professional and popular media through content and thematic analysis of four print sources: the research journal of the Royal Australian and New Zealand College of Psychiatry, *The Australian and New Zealand Journal of Psychiatry*, and three Australian newspapers, *The Age*, *The Australian* and *The Sydney Morning Herald* for the period 1995-2005. Analysis of these sources reveals that all promote new discoveries and herald the role of genetics in preventing and curing mental illness. Popular media sources differ from the professional journal however, in providing a forum for critique of molecular genetics. Critique occurs through investigation of the role of environmental factors in causing mental illness and exploration of the social impact of genetic technologies, issues that are largely absent from discussion of molecular genetics in the psychiatric journal. Content analysis of the information sources cited reveals that the newspapers draw upon a

range of expert opinions from within and outside of the psychiatric profession in reporting the role of genetics in mental illness, suggesting that the media are not passive consumers of scientific knowledge. These themes will be explored in relation to norms for the collection and presentation of information in professional and popular media sources, the dominance of biological psychiatry and the social context of science reporting in the popular media.

Consumer experiences with genetic testing

Author: Sandra Taylor

According to The National Health and Medical Research Council of Australia, developments in genetic technology and genetic testing will profoundly influence how we identify, treat and prevent disease as well as how we deliver health care services. Genetic tests are currently available for more than 600 gene variants and numbers of available tests are increasing; this includes tests for diagnosis, screening, carrier identification, risk determination and the prediction of future disease. Worldwide to date, a minority only of consumers with known genetic risks or susceptibilities for various genetic conditions have undertaken predictive genetic testing. This paper aims to firstly, locate consumer experiences of predictive testing within a broader sociological context regarding risk and governance; secondly, reviews clinical genetics literature regarding consumer experiences with predictive tests for a range of inherited conditions; and thirdly, presents selected research findings from the Australian Genetic Discrimination Project (GDP) regarding consumer experiences with predictive genetic testing. Findings from the GDP elucidate some of the perceived benefits, concerns, and experiences of Australian consumers regarding predictive genetic testing and its consequences for them within both formal institutional contexts and informal settings like interpersonal and family relationships and as recipients of healthcare services. The implications of research findings and literature reviews are discussed.

Marketing and Consumption of Paternity Tests

Author: Lyn Turney

Initially DNA paternity tests were government policy driven tests to identify biological fathers for child support purposes. It was not a straightforward market though, as government agencies did not buy the tests; rather, they delivered customers to the providers. These consumers were both men and women. It follows that the early markets for testing were quite narrowly focused. In the last decade however, commercially marketed tests have attracted widespread public interest and tapped into a range of different markets. The process of market development was initially serendipitous, driven by the coincidence of interests of industry entrepreneurs and men's rights activists. This paper briefly traces the development of a market for genetic paternity testing in the Australian context. Drawing from empirical work, it then profiles the various consumers of paternity tests, discussing their reasons for testing, the type of testing (whether the test was accredited or not), the extent to which the test was instigated by them or by someone else and what were the typical outcomes of testing for each consumer category.

Ethics and Regulatory Frameworks for Biobanks

Author: Alastair V. Campbell

The current rapid emergence of large biobanks – major collections of biological, genetic, environmental and health data – has raised some fascinating issues at the nexus of medical law and medical ethics. Since the controversies surrounding the Icelandic Health Sector Database (HSD), set up at the end of the last decade, there has been a growing awareness that such projects raise a novel set of ethical and legal issues, most obviously in relation to the nature of the consent gained, but also across a whole range of other social and moral concerns. In this paper I want to focus on what I regard as the two central ethical features of collections of this kind: their dependence on both altruism and trust from those who donate their samples and health data, and the corresponding duties which rest on the creators and custodians of biobanks to honour these commitments from the donors, by being “stewards” of the resource.. I shall use my experience with UK Biobank to illustrate these issues.

Engendering trust in biobanks: the examples of UK Biobank and the WA Genome Health Project

Author: Alan Petersen

Recent developments in population-based genetic databases have posed considerable challenges for scientists and policymakers. Widespread concerns about a decline in public trust in the regulatory systems governing biomedical innovations, combined with fears about the implications of genetic technologies, has meant that proponents of biobanks have had to make considerable efforts to persuade publics of their benefits and competent, ethical management. This paper will examine efforts to establish consent and legitimacy for UK Biobank and the WA Genome Health Project. Both projects have employed a similar established repertoire of ethical and regulatory mechanisms that have arguably served to narrow debate on the substantive issues at stake. The paper examines the politics of public engagement in relation to these and other recent biobank developments.

Property Matters: Public and Private Ventures in Human Genetic Databases

Author: Oonah Corrigan

The issues of commercial rights and ownership of DNA and biological samples has become salient in recent years. In relation to national biobank projects such as those in Iceland and Estonia, concerns about the commercial profiting by large pharmaceutical and biotech companies have led to significant public controversies. This chapter will examine current debate and policy surrounding commercial access to UK Biobank as well as what little is known about current practices pertaining to pharmaceutical industry repositories of DNA. While many of the problems relating to issues of future commercial access in UK Biobank remain largely unresolved, there is at least a willingness on the part of UK biobank to engage with issues of ethics and governance in an open and transparent manner. The pharmaceutical industry on the other hand has played down suggestions that

their growing activity regarding the collection and retention of DNA for genetic testing purposes presents any kind of novel concern. The latter too has received far less critical attention from ethicists and policy makers.

Perspectives on Tissue Banks and Human Genetic Research Databases: Implications for Research and Regulatory Reform

Author: Jennifer Fleming

The rapid emergence of human genetic research databases (HGRDs) offer unprecedented support to advance genetic research along with the promise new knowledge in the way our genes interact with the environment to advance new diagnostic and treatment regimes via pharmacogenomics. HGRDs provide large scale collections of genetic biological specimens, human DNA samples, cell lines and other tissue, linked with related medical information and other material to provide valuable genetic data. The sustainability and contribution of HGRDs and related genetic research, nonetheless calls for a revitalised debate on numerous ethical, legal and regulatory challenges.

Empirical research examining perspectives of professionals involved in tissue banks, the public and actual donors is critical to ensuring a balanced debate. Recognising the paucity of empirical studies in this area to date, this paper will provide an overview of findings from the speaker's research work undertaken in Australia, drawing on comparative findings from international studies. This paper aims to offer an important contribution to a renewed debate and the potential for reform of global ethical and legal frameworks to support the translation of new knowledge to clinical applications and further scientific advances.

STEM CELLS

Australian stem cell regulation in the international context

Author: Don Chalmers

Stem cell technology has been described as “one of the biggest breakthroughs in human medicine”. Most research is being conducted on embryonic stem cells and may offer new pathways for developing medical therapies. Research on embryos is highly controversial and poses great legal and ethical challenges.

The talk considers the background Report *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* in 2001 (the Andrews report) and the subsequent *Research involving Human Embryos Act* (RIHE) and the *Prohibition on Human Cloning Act* 2002. These Acts introduced a uniform national approach to regulation that closely harmonises with international regulations and standards. The RIHE Act creates a *Licensing Committee* within the *National Health Medical Research Council* that administers a national licensing scheme for embryo research in the private and public sector. The Act allows the use of “excess IVF embryos” to carry out approved research and imposes criminal offences for unlicensed research. The regulatory scheme will be assessed on the basis of its performance and whether gives a “restrictive or permissive” tilt. The recommendations of the Lockhart Report will be considered and the private members' bills introduced as a response.

Stem cell research: What do the Australian public really think and why?

Author: Christine Critchley

Previous research and media reports have assumed that opposition to stem cell research is primarily dependent upon religious beliefs. However, this paper demonstrates that attitudes toward stem cell research are also associated with trust in those who are conducting, regulating and funding the research. The results from three national Australian telephone surveys (n = 1044; n = 1013; n = 1013) suggested that respondents were significantly more comfortable with stem cell research using left over IVF embryos and adult cells if they trust scientists, Universities, and the Federal Government. Respondents were also significantly less comfortable with stem cell research conducted in private companies compared to Universities, particularly if they also reported higher levels of trust in Universities, and distrust in the Federal Government and major companies. A fourth survey (n = 1203) found that the increased support for public relative to private stem cell research was explained by greater trust in publicly funded scientists. University scientists were trusted more than private scientists because they were perceived to be motivated more by benevolence, and more likely to produce benefits that will be accessible to the public. Overall the findings imply that support for stem cell research is reliant on perceptions of who is conducting the work and why. The results also suggest that Australia's relatively high level of support for stem cell research is partly due to a belief that it is funded and controlled by public interests. The potential effects of eroding this belief on public trust are discussed.

Cloning, Stem Cell Research, and the Lockhart Committee's Recommendations

Author: Loane Skene

In December 2005, the Legislation Review Committee (Lockhart Committee) reported to the federal Government on the federal, state and territory legislation on Human Cloning and Embryonic Stem Cell Research. It recommended that the current statutory prohibition on reproductive cloning should remain in place, together with many of the other current statutory offences. However, it said that the law should be amended to allow embryos to be created for research by the process of somatic cell nuclear transfer (SCNT, the 'Dolly technique'), provided that those embryos are not implanted in a woman and are destroyed within 14 days. The Committee also made other recommendations concerning the use of fertilised eggs and embryos in research.

This paper outlines the recommendations in the Committee's report and the basis for them, together with the responses of federal and state governments and the wider community.

In the footsteps of Galileo and Jenner: the struggles of stem cell science

Author: Elizabeth Finkel

The issue of embryonic stem cell research and its most contentious offering, therapeutic cloning, has challenged country after country to decide where it stands. Over the next few

months Australia's government will make its decision. While laws need to set the limits of what the community considers allowable, they should not be so proscriptive as to block the potential benefits of visionary research. Looking back on the history of scientific advance there are numerous examples where the establishment erred on the side of blocking science which ultimately proved to have great merit. Galileo and Jenner struggled against Church interference as did Edwards and Steptoe, the pioneers of IVF. In recent times Robin Warren and Barry Marshall struggled against the medical establishment to advance their conviction that ulcers were not the inevitable result of bad genes and bad eating habits but the consequence of a curable bacterial infection. For their pains, Marshall and Warren went on to win the 2005 Nobel Prize for Medicine.

In framing legislation, the government should not allow personal ideologies or science fiction to overwhelm science. In the stem cell debate both scientific advances and social responses are highly dynamic. What was true three years ago is not true today. What is required is a flexible legal framework that can adapt to change rather than an ossified series of legal impediments.

PUBLIC POLICY

Exploration of key themes in the policy debate on genetic research and genetic databanks

Author: Margaret Otlowski

Drawing on international instruments and literature, this paper seeks to identify and outline key themes in the current policy debate on genetic research and genetic data banking, including themes of 'solidarity', 'common heritage,' 'human dignity,' 'equity', 'non-discrimination,' 'benefit sharing and 'international co-operation.' The paper evaluates what value these themes bring to the debate, and the influence they have on substantive areas of law and practice. In particular, it explores their capacity for practical implementation in promoting genetic research for the improvement of health care and the responsible use of genetic information. The paper concludes by identifying areas where more may need to be done to ensure that the aspirational goals underpinning these themes are given real meaning, both at a domestic level and internationally.

Public policy for competitiveness in biotechnology: Australia and the rising Asian economies

Author: Hans Lofgren

Sales of biologicals (biotechnology-based drugs) in 2005 grew about three times faster than the small molecule market, reaching about US\$52 billion and accounting for 27 percent of new medicines under development. Governments around the world recognise the centrality of the life sciences for industrial renewal but there is no consensus on the appropriate design of policy and regulatory arrangements. This paper identifies constraints and opportunities for Australian public policy emerging from the global dynamics of the biopharma sector, with a particular focus on the rise of Asian economies, notably India, China and Singapore. India is one nation that appears to have successfully implemented policies leading to a rapid expansion of the biopharma sector, and China and Singapore are not far behind. Low costs coupled with high quality personnel make

Indian firms particularly competitive suppliers of manufacturing and R&D services and other outsourced activities in the biopharma sector. Australia's biotechnology is comparatively strong, ranking number sixth the world in terms of number of biotech firms, and it is critical the conditions be ascertained which will enable Australia to retain an internationally competitive position, averting the marginalisation which Australia has experienced in information and communications technology.

Democracy and bioethics expert advisory committees

Author: Justin Oakley

The novel ethical problems raised by developments in biotechnology pose special problems for democratic approaches to public policy formulation in this area, as community attitudes to these developments may not be very well informed. In this context there is a clear role for bioethics expert advisory committees to play in assisting with policy formulation. As Dodds, Ankeny, Thomson, and others have recently argued, the role of such committees in democratic states can be usefully analysed and evaluated according to deliberative conceptions of democracy. In this paper I consider how bioethics expert advisory committees could use the notion of reasoned deliberation in the context of regulating embryonic stem cell research, to uncover and build upon common ground between members of the community who otherwise seem to disagree about the ethics of such research. I illustrate this with some examples of what such common ground may be in the case of embryonic stem cell research.

Public engagement and public policy: critical underpinnings for genetic research

Author: David Weisbrot

The Australian Law Reform Commission (ALRC) has now completed two major inquiries into ELSI-genetics, culminating in the reports *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96, 2003), and *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004). The ALRC's major challenge was to develop a sensible policy platform that meets twin goals: to foster innovations in genetic research and practice that serve humanitarian ends, while providing sufficient reassurance to the community that such innovations will be subject to proper scrutiny and regulation. The extensive community consultation undertaken by the ALRC demonstrated strong community support for medical research promising breakthroughs in the diagnosis, treatment and prevention of serious genetic disorders. At the same time, there is anxiety about the pace of change, with particular concerns about: ethics, discrimination and the loss of privacy; 'genetic determinism'; access and equity issues; commercialisation and conflicts of interest; and the capacity of public authorities to regulate this area effectively in the public interest. Experience elsewhere clearly points to the need for openness and transparency, and ample public education and debate, in order to ensure community acceptance and legitimacy. Once lost, trust and credibility are much more difficult to restore.

PROFILES in BRIEF

- Kristine Barlow-Stewart** *Genetic counsellor, Foundation Director, Centre for Genetics Education (NSW Health); Senior Lecturer, Northern Clinical School (Usyd); Member of the NHMRC Human Genetics Advisory Committee; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.*
- Robin Bunton** *Professor of Sociology, School of Social Sciences & Law (University of Teesside); currently undertaking research on the WA Genome Health Project and its approach to public engagement; he leads a number of contract research projects and is the Director of the Community Evaluation and Research Group (CERG) in the Social Futures Institute (Teesside); most recent book, Genetic Governance (2005); editor of the journal Critical Public Health.*
- Alastair Cambell** *Chen Su Lan Centennial Professor of Medical Ethics in the Medical Faculty, National University of Singapore; former President of the International Association of Bioethics; member of the Medical Ethics Committee of the British Medical Association; first UK Chair in Medical Ethics, (Bristol); immediate past Chair of the UK Biobank Ethics and Governance Council; foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.*
- Tim Caulfield** *Canada Research Chair in Health Law and Policy; Professor, Faculty of Law and Faculty of Medicine and Dentistry; Research Director, Health Law Institute (University of Alberta); member of the Canadian Biotechnology Advisory Committee; The Health Canada's Expert Advisory Committee on Xenograft Regulation; the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001); and the Institute Advisory Board, Institute of Health Services and Policy Research, Canadian Institute of Health Research; foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.*
- Don Chalmers** *Professor of Law; Dean, Faculty of Law (UTas); Head of School, School of Law; Director, Centre for Law and Genetics; Member, NHMRC Human Genetics Advisory Committee; Convenor and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.*
- Craig Cormick** *Manager of Public Awareness, Biotechnology Australia; previously worked as a science journalist and has taught public relations and writing at university; widely published on drivers of public attitudes towards biotechnology; a regular commentator in the media and at industry and*

research conferences, both in Australia and overseas, on causes of public concern towards applications of biotechnology.

Oonah Corrigan

Senior Lecturer in Sociology, School of Law and Social Sciences (University of Plymouth); affiliate member of the Centre for Family Research (University of Cambridge); member of the Centre for Medical Genetics and Policy (Cambridge University).

Christine Critchley

Lecturer in Psychology (Swinburne); researcher and member of the Australian Centre for Emerging Technologies and Society.

Karen Farquharson

Senior Lecturer in Sociology and Head of Social and Policy Studies (Swinburne); researcher and member of the Australian Centre for Emerging Technologies and Society

Tom Faunce

Senior Lecturer in both the Medical School and the College of Law (ANU); foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network; Project Director, of an ARC grant investigating the impact of AUSFTA on Medicines Policy in Australia; and currently developing the Australian component of the Global Database on Health Law and Bioethics for UNESCO.

Elizabeth Finkel

Holds a PhD in biochemistry; contributing editor to 'Cosmos' magazine and a correspondent for the US magazine 'Science'; previously written for 'Nature Medicine' and 'Lancet'; frequent contributor to ABC radio's Science show, Ockham's Razor and the Health Report; and author of the multi-award winning book 'Stem Cells: Controversy at the frontiers of Science' (ABC books).

Jennifer Fleming

IMB Research Scholar (PhD Candidate) at Institute for Molecular Biosciences (UQ); previous work in Clinical Research Management, and Research Ethics and Medical Education; Board member of ANZIHLE; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Michael Gilding

Professor of Sociology; Deputy Dean (Research) Faculty of Life and Social Sciences (Swinburne); Director, Australian Centre for Emerging Technologies and Society; and President Elect, The Australian Sociological Association.

Michael Gorton

Chair of the Victorian Biotechnology Ethics Advisory Committee; Deputy Chair of the Infertility Treatment Authority; Honorary Fellow of the Royal Australasian College of Surgeons and the Australian and New Zealand College of Anaesthetists; first permanent male Commissioner with the Victorian Equal Opportunity Commission; immediate Past President of the Health

Services Review Council; partner with Russell Kennedy, Solicitors, with qualifications in law and commerce; he was made a Member in the Order of Australia in January 2004.

Julie Henderson

Research Fellow at the School of Nursing and Midwifery (Flinders University); has a background in nursing with a PhD in sociology; Managing Editor of the 'Journal of Sociology' 2001-2004.

Hans Lofgren

Senior Lecturer in Politics and Public Policy, and Director, Master of Politics and Policy program, (Deakin University); published widely on pharmaceutical and biotechnology issues; currently researching biopharma developments in India.

Robert Moses

Chairman of the Board of numerous biotechnology companies in Australia, including; Antisense Therapeutics Ltd., TGR Biosciences Ltd, Sylvan Scientific Ltd. and previously Meditech Research Ltd., Amrad Corporation Ltd., and The Australian Stem Cell Centre Ltd.

Dianne Nicol

Senior Lecturer, Faculty of Law (UTas); Deputy Director, Centre for Law and Genetics; Member of the NHMRC Human Genetics Advisory Committee working group on industry and commercialisation; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Justin Oakley

Director, Monash University Centre for Human Bioethics; Associate Professor of Bioethics (Monash); teaches health professionals in the Master of Bioethics course; currently leading a team of researchers in an NHMRC-funded project on informed consent and report cards on the clinical performance of individual cardiac surgeons; co-recipient, along with Steve Clarke, of the 2004 Eureka Prize for Research in Ethics, for their research on the ethics of disclosing to patients performance data about individual surgeons; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Margaret Otlowski

Professor of Law; Deputy Director, CLG; Member of the NHMRC Human Genetics Advisory Committee working group on industry and commercialisation; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Alan Petersen

Professor of Sociology, School of Law and Social Sciences, (University of Plymouth); recent work includes investigation of UK Biobank and its processes of consultation and legitimisation; currently undertaking research on the WA Genome Health Project and its approach to public engagement; recently edited the special issue 'Biobanks: challenges for "ethics"', for Critical Public Health (15, 4 (2005)); coedited Biobanks: Governance in Comparative

Perspective (Routledge, 2007); Visiting Professor, ESRC Genomics Forum, Edinburgh; Visiting Fellow, Institute of Advanced Studies, UWA; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Loane Skene

Professor of Law (UMelb); Pro Vice-Chancellor and President, Academic Board (UMelb); Deputy Director Centre for Law and Genetics; Past Deputy Chair of the Lockhart Committee on Human Cloning and Embryonic Stem Cell Research; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Sandy Taylor

Associate Professor of Social Work at the School of Social Work and Welfare Studies (Central Queensland University); long-standing social work practitioner with individuals and families affected by Huntington disease; interest in psychosocial, ethical and legal issues associated with genetic technologies; Chief Investigator in Australian Genetic Discrimination Project and a project investigating gender and gender risk; and foundation member of the Biotechnology, Ethics, Law & Society (BELS) Network.

Ron Trent

Chairman of the NHMRC Human Genetics Advisory Committee; Professor of Molecular Genetics (U Syd); Director of the Department of Molecular & Clinical Genetics at the Royal Prince Alfred Hospital in Sydney and Executive Director of SUPAMAC – the University's high throughput DNA analysis service. Member of the Board of Directors of the Garvan Institute of Medical Research (1998-2009); Member of the NHMRC's Research Committee (1997-2009) as well as Chairman of the NHMRC's Gene and related Therapy Research Advisory Panel (1994-2006). Foundation Chief Examiner in Genetics for the Royal College of Pathologists of Australasia (1996-2002).

Lyn Turney

Senior Lecturer, Sociology (Swinburne), researcher and foundation member of the Australian Centre for Emerging Technologies and Society.

Michael Vitale

Joint professorial appointment at the Melbourne Business School and the Australia New Zealand School of Government (ANZSOG); at MBS, Director of the innovation research program and focuses his teaching, research, and consulting on commercialisation of innovation, particularly in biotechnology; chairman of a public biotechnology firm.

David Weisbrot

President, Australian Law Reform Commission (ALRC) since June 1999; Emeritus Professor of Law; Chaired the ALRC's inquiries into the protection of human genetic information (Essentially Yours, ALRC 96, 2003) and gene patenting and human health (Genes and Ingenuity, ALRC 99, 2004); Member, NHMRC Human Genetics Advisory

Committee; Member of the Human Genome Organization (HUGO); and in recent years has lectured and published extensively on the ethical, legal and social implications of genetic science and technology.