BIOSCIENCE, COMMUNITY EXPECTATIONS AND THE LAW

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The biosciences offer many benefits for human health care, but these benefits are often overshadowed by community concerns regarding the rate of development and the implications of new discoveries. The community often looks to the legislature to provide a regulatory response to these concerns. This paper describes the areas of research included within the field of the biosciences and discusses the benefits that may be expected from them. It outlines some of the concerns that have been expressed and a range of methods aimed at mitigating these concerns through informing and consulting the community about scientific research and legal responses. It is argued that the community should not press too readily for a legislative response, especially in an area of rapidly developing techniques where legislation will be hard to formulate and enforce. Instead, it is argued that scientists and commercial organisations should be as open as possible about their work and its implications and that guidelines should be published only after widespread consultation to take account of community concerns.

I THE BIOSCIENCES AND THEIR POTENTIAL APPLICATIONS

Although the biosciences are in their infancy they have tremendous potential for the development of human health care. In the 50 years since Watson and Crick identified the double helix structure of deoxyribose nucleic acid ('DNA') scientists have mapped the whole human genome and started linking genes to diseases (over 1000 genes associated with disease have already been identified). This combines the science of *human genetics* and *pathophysiology*.

It is clear, however, that genetics will not provide all the answers. A caterpillar and a butterfly have the same genetic structure (genotype). What makes their physical appearance and constitution (phenotype) different is that certain genes are 'switched on' (expressed) at each stage of development. These switches,

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initiated by protein changes within the cells, are now being explored by scientists to see how the genes are expressed at particular times and how their normal function may be disrupted by genetic disorders. This is the science of *proteomics*, or *expression proteomics*.

Other studies are investigating the link between people's genotype and phenotype to study bodily factors that arise from causes other than genetics, such as lifestyle and environment: the science of *epigenetics*. Genetic databanks[1] that include life-style information about a large number of people whose genetic samples have been analysed are invaluable in this work. One aim of these population studies is to develop drugs that are custom made for particular patients – the new science of *pharmacogenomics*. Patients obviously have different risk-benefit factors with respect to each drug due to their own genetic constitution, age, metabolism, other physical factors, and drugs that the patient is taking concurrently. When these matters are understood patients can be given the right drugs for them, improving their recovery and reducing the risk of adverse effects.[2] Within a generation the notion of prescribing the same drug for all patients suffering from heart disease will seem as outdated as the crystal set in modern telecommunications. Products aimed at healing wounds in skin and tissue are also being developed. In future bone replacement may be possible. Scientists may even be able to grow new organs from a patient's own tissue so that the transplanted organ will not be rejected.

Finally, the future holds a transition from genomics to biological resources with the application of the new technology of *bioinformatics* (the science of pattern recognition, ranging from sequence analysis, taxonomic status, and ecological associations). Clearly, the biosciences offer an exciting future and we should welcome what they have to offer, both from the perspective of health care[3] and the biotechnology industry.[4]

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[1] An example is UK Biobank, a £45 million study involving 500 000 people between the ages of 45 and 69. Its aim is to study a number of common, costly conditions, such as cardio-vascular disease, cancer and diabetes: see The UK Biobank <http://www.ukbiobank.ac.uk/> at 20 November 2003. Iceland and Estonia also have genetic data banks: see deCODE genetics <http://www.decode.com> at 20 November 2003; and the Estonian Genome Project Foundation <http://www.geenivaramu.ee/> at 20 November 2003. These databanks, and also one proposed for the island of Tonga, are discussed by Loane Skene, '"Sale" of DNA of people of Tonga', (March–April 2001) *Genetics Law Monitor* 3. The Deutsche Forschungsgemeinschaft ('DFG'), a German independent science funding agency, has recommended that a national gene bank be established in Germany: Stephen Pincock, 'DFG calls for gene bank' *The Scientist*, September 10, 2003. Other genetic data banks exist or are planned in Quebec and Newfoundland. Pharmaceutical companies, hospitals and other organisations are also establishing genetic data bases: see Howard University in Washington, USA: Andrew Pollack, 'DNA of Blacks to be Gathered to Fight Illness' *The New York Times* (New York), 27 May 2003, 1.

[2] Potential adverse effects can be very serious. For example, 4 per cent of patients who take the drug Abacavir have an allergic reaction to it that may be fatal: British speaker at 'Exploiting Genetic Knowledge: The Double Helix 50 years on', (paper presented at the British Council Seminar, International Centre for Life, Newcastle, UK, 10–14 March 2003) reported by Loane Skene, 'Conference report from the UK' (2003) 11(1) *Journal of Law and Medicine* 122.

[3] Much interesting collaborative work is underway. See, eg, Bio 21 Molecular Science and Biotechnology Institute <http://www.bio21.org/Institute.html> at 20 October 2003.

[4] Genetic discoveries have huge commercial potential. The US bone-marrow transplant market is estimated

II COMMUNITY CONCERNS ABOUT GENETIC RESEARCH

Despite the benefits of bioscience, many people are concerned about genetic research, especially its long term implications.[5] Genetic information has a special significance. Not only is it personal medical information that people want to keep private, but it also reveals details about a person's blood relatives and their community.[6] Genetic information has a social, spiritual and emotional significance that other personal information does not have. As techniques develop it will become a readily accessible form of personal information. It is already possible to store a large amount of genetic data on a microchip.[7] People want to know who will have access to their genetic information: will pharmaceutical companies want to use their personal information or excised tissue in research, or patent their DNA in cell lines or other biological products? Could it be used by the police or by employers and insurance companies?[8] Could it be accessed or tested without their consent, for example in paternity tests? Will human tissue become a commodity thereby undermining the significance of the human body and its parts?

Use of genetic information also poses new challenges to the western liberal discourse of individual rights. It is a general legal principle of medical ethics and law that people must not be subjected to any medical procedure without their informed consent. In Australia, this is clearly stated in the common law in cases

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to be valued at US$15 billion per annum by 2015 – enough to make commercial developers excited! A recent report on stem cell therapy was commissioned by investment bankers, signaling that big business is prepared to invest in this area: Skene, above n 2.

[5] For current concerns in the UK, see Skene, above n 2. For an overview of concerns in Australia see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, Report No 96 (2003) ('ALRC Final Report'); and Centre for Law and Genetics, University of Tasmania, <http://lawgenecentre.org> at 20 November 2003. Also, in the popular arena, such concerns are raised in films like *Boys from Brazil*, in which biotechnology is used to clone multiple young Hitlers and *Gattica*, which portrays a society ruled by genetic elitism and branding; see also books like John LeCarre, *The Constant Gardener* (2001); Sir John Sulston and Georgina Ferry, *The Common Thread* (2002).

[6] The ALRC Final Report refers to Aboriginal concerns about genetic technology especially as it relates to the sensitive issues of Aboriginal identity and self-determination: ALRC Final Report, above n 5, [36].

[7] Two American companies, Affymetrix Inc. and Agilent Technologies, have reportedly 'succeeded in placing vital bits of man's 30 000 genes on a chip [small pieces of glass infused with genetic material] the size of a dime': Paul Elias, 'Human Genes Made to Fit on Dime-Size Chip' *Washington Post* (USA), 3 October 2003. The article continues, 'Now, Affymetrix, the industry leader, said researchers can buy the entire genome for between $300 and $500 each – roughly half the old price'.

[8] This is an issue, especially in the United States, as most health cover is offered by employers and many people do not have private health insurance. In Australia, the availability of genetic information is of less concern in relation to health insurance due to community rating of premiums (they are not based on medical factors). However, there are concerns about life and disability insurance, see Margaret Otlowski, 'Avoiding Genetic Discrimination in Insurance: An Exploration of the Legality and Ethics of Precautionary Measures in Anticipation of Unfavourable Test Outcomes', (2001) 20 (1) *Monash Bioethics Review* 24; Margaret Otlowski, 'Is There Scope for Lawful Genetic Discrimination in Health Insurance in Australia?' (2001) 8 (4) *Journal of Law and Medicine* 427.

such as *Rogers v Whitaker*.[9] Also, doctors must not reveal patients' personal medical information to other people without the patient's consent. This is stipulated in both federal and state privacy legislation.[10] However, there may be cases where a doctor cannot diagnose an individual patient's condition without obtaining information about a relative who has the familial mutation; it may also be necessary to test tissue from that relative (the 'index case') to make a diagnosis.[11] Further, if a familial mutation is found, that will obviously have important implications for other blood relatives.

III RESPONSES TO COMMUNITY CONCERNS

One may observe at the outset that people have a natural resistance to change and innovation. In time, however, developments are accepted and we wonder at the initial alarm about them. This is especially so with medical treatment. Procedures that were once contentious, like organ and tissue transplants and in vitro fertilisation, are now commonplace. Also, many of the reservations that were expressed in the past about new developments were not borne out by experience.

Nevertheless, research in biotechnology – which involves the accumulation of large amounts of personal information and the testing and introduction of new health products – necessarily raises legitimate concerns about ethical and practical aspects of the technology. The community is entitled to have these concerns carefully considered and answered. From the perspective of scientists and commercial developers, innovation can be managed more effectively if the community is involved from the beginning in the ongoing developments. Scientists and pharmaceutical companies in the United Kingdom ('UK') are well aware of this from their long experience with animal research activists protesting against tests of new drugs on animals. They know that commercialisation of genetic information should include not only the science preceding discovery of a new drug and the steps required to take that drug into the market place, but should also involve investment in widespread community consultation on social and ethical issues to prepare the way for public acceptance of the drug.

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[9] (1992) 175 CLR 479.

[10] For example, *Privacy Act 1988* (Cth); *Health Records Act 2001* (Vic); *Health Records Information and Privacy Act 2002* (NSW).

[11] See Loane Skene, 'Patients' Rights or Family Responsibilities? Two Approaches to Genetic Testing' (1998) 6(1) *Medical Law Review* 1; Loane Skene and Julian Savulescu, 'Who has the Right to Access Medical Information from a Deceased Person? Ethical and Legal Perspectives' (2000) 8 *Journal of Law and Medicine* 81.

IV CONSULTATION AND POLICY DEVELOPMENT

Australia has a long tradition of community consultation in the development of new laws, particularly by parliamentary committees,[12] law reform commission reports[13] and ad hoc committees formed to advise the government on particular issues.[14] There are also popular means of canvassing opinions – such as newspaper reports, commentary, and letters to the editor; television programs like *Catalyst* and *Compass*; radio programs like *Ockham's Razor* and talk-back radio; public lectures and informal community discussion forums like 'spirituality in the pub' talks. However, there are a number of other ways to involve the community in ongoing debates about research and development in the biosciences.

New methods of community consultation in the UK were described by presenters at a recent British Council seminar in Newcastle, UK.[15] They stressed the need for a bottom-up approach that responds to people's lived experience and addresses what the public want to know rather than information provided by scientists and government authorities. Recent initiatives discussed at the seminar or established elsewhere include the following:

- The UK Human Genetics Commission[16] uses a panel of people with genetic conditions, or their representatives, in its consultation process. All drafts are sent to this panel for comment.
- Cafés Scientifique are conducted throughout the UK, with funding from the Wellcome Trust. These are informal meetings in a social environment where scientists and other experts present their work to a general audience and listen to the concerns that they have about the research and its potential applications.
- Citizens' juries have been used to canvas the attitudes of small farmers in India to three potential agricultural developments – genetically modified crops, growing organic crops for export and agricultural practices for self-sufficiency.[17]
- The UK Alzheimer's Society has invited 150 'consumers' (patients' families or representatives) to participate in considering, ranking and monitoring research, instead of the usual approval and monitoring of research protocols by ethics committees.[18] This group participates in each

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[12] See, eg, House of Representatives Standing Committee on Legal and Constitutional Affairs, Parliament of Australia, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001) ('Andrews Committee Report').

[13] See, eg, ALRC Final Report, above n 5; Australian Law Reform Commission, *Gene Patenting and Human Health*, Issues Paper No 27 (2003); Victorian Law Reform Commission, *Genetic Manipulation*, Report No 26 (1989); and Victorian Law Reform Commission, *Defining Privacy*, Issues Paper (2002).

[14] For example, the reports of the Victorian Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization, Parliament of Victoria, chaired by Professor Louis Waller, 1982–4.

[15] Skene, above n 2.

[16] See the Human Genetics Commission <http://www.hgc.gov.uk> at 20 November 2003.

[17] See, eg, International Institute for Environment and Development <http://www.iied.org/sarl/e_forum/authors.html> at 20 November 2003; Prajateerpu: Food Futures for Andhra Pradesh, India <http://www.ddsindia.com/prajateerpu.htm> at 20 November 2003.

[18] See the Alzheimer's Society < http://www.qrd.ion.ucl.ac.uk> at 20 November 2003.

research project by visiting researchers and presenting an independent report at the end of the project.

- The European Commission undertakes surveys of consumers' opinions in member states and publishes them on its website, the Eurobarometer.[19]
- Biotechnology Australia undertakes similar surveys, for example, on public support for stem cell research.[20]

Many people are sceptical about community consultation and the weight to be attached to community views, especially due to the possibility of respondents being ill-informed about the issues. Moral majoritarianism cannot be accepted, they say; that is not 'doing ethics'. While the vast majority of the population might support capital punishment, their opinions do not dictate that this should be the law. To make good decisions, the underlying bases of those decisions must be thoroughly analysed through the conduction of risk assessments and cost-benefit analyses. However, a wealth of wisdom inheres in the experience of a wide range of people, and these experiences should not be discounted in policy-making.

V PROBLEMS OF ANTICIPATORY LAWS

Finally, the community should show caution before proceeding too rapidly in its push to legislate in response to community concerns, especially in a rapidly developing area like the biosciences. The problems that arise from anticipatory laws are illustrated by attempts to ban human cloning, motivated by fears of the *Boys from Brazil* scenario.[21]

The potential for bioscience to be misunderstood is evidenced in the following example concerning the definition of cloning. The most common definition of cloning in Australian statutes and guidelines focuses on the creation of a *genetically identical* descendant.[22] However, a cloned child would not be genetically identical to the progenitor. The DNA in a cloned embryo comes not only from the nucleus of the progenitor but also from the egg into which the nucleus is implanted (the mitochondrial DNA). The embryo is therefore not genetically identical. Indeed, the child born from the embryo would not be as

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[19] See Public Opinion Analysis sector of the European Commission <http://europa.eu.int/comm/public_opinion/> at 20 November 2003.

[20] See Biotechnology Australia, <http://www.biotechnology.gov.au/library/content_library/BA_Media_stemcells_Jul03.pdf> at 20 November 2003.

[21] See above n 5.

[22] *Gene Technology Act 2000* (Cth) s 192B(2), for example, states that it is a crime for a person to 'knowingly or recklessly undertake an activity which will result in the cloning of a whole human being'. Cloning of a whole human being means 'the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original'; see also *Infertility Treatment Act 1995* (Vic) s 3; *Reproductive Technology Code of Ethical Research Practice Regulations 1995* (SA) sch, cll 2, 6; National Health and Medical Research Council Ethical Guidelines on Assisted Reproductive Technology (1996) [11.3]. These attempts to ban cloning are discussed by Loane Skene and Brendan Gogarty, 'Stem Cell Research and Cloning: Legal Loopholes' (2002) 23(8) *Australasian Science* 7. The federal and state legislation is not the end of the matter: See, eg, Council of Australian Governments Communique, <http://www.health.gov.au/nhmrc/embryo/pdf/coag.pdf> at 20 November 2003.

close genetically to the progenitor as it would to a naturally occurring monozygotic twin (a twin born from an egg that has split to form two embryos).[23] Furthermore, during early embryonic development the cells of an embryo divide at a rapid and exponential rate. This may cause mutations in the genetic code of that life-form so that the resulting clone has small genetic differences from the parent.[24]

VI PROBLEMS OF ENFORCEMENT

Even if the problems of definition can be overcome, and we can formulate legislation in a way that will cover developments that we cannot yet predict, the issue remains whether there is really the will – or the practical means – to carry through the machinery of legislation. We may want to restrict human reproductive cloning,[25] for example, but is the desire to prohibit this single act enough to warrant the creation of an enforcement regime with the requisite administrators, police and infrastructure and all the attendant costs of that process? Maybe if a large group of renegade doctors wanted to engage in cloning such a commitment could be justified. But there is, in fact, near unanimous condemnation of this practice among the medical community.[26] Only on the very fringes do we find anyone who wants to undertake this activity and has even the slightest idea how to.

VII CONCLUSION

Despite the concerns that some people have expressed about research and development in the biosciences, the potential advantages for human health care are considerable. The most effective means of allowing the technology to proceed is not to regulate it by legislation that is difficult to draft and to enforce. It is better to maintain a continuous dialogue between scientists, pharmaceutical companies and the public so that ethical issues as well as other contentious concerns can be considered as the research proceeds. If regulation is considered necessary, it should be undertaken as much as possible through guidelines rather than legislation such as those published by the National Health and Medical Research Council ('NHMRC'). The NHMRC has a long history in Australia in

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[23] Monozygotic twins are born in about one in a hundred births and grow into independent individuals; the existence of genetic similarity is acceptable when it occurs in nature.

[24] Arlene Klotzko, 'The Debate About Dolly' (1997) 11 *Bioethics* 427.

[25] The Andrews Committee found 'meagre if any support in Australia for cloning for reproductive purposes': Andrews Committee Report, above n 12, [6.64]. The Committee said that there was 'overwhelmingly strong opposition to cloning … expressed by nearly all who provided submissions or gave evidence to the inquiry': [6.17].

[26] The Australian Research Council and Australian Health Ethics Committee, representing the research community, condemn the practice of cloning. So do the Australian Society for Reproductive Biology and the Fertility Society of Australia which represent the IVF industry (they have also passed resolutions agreeing never to attempt to clone a human person): Andrews Committee Report, above n 12, [6.24].

regulating medical research and the development of new technology. Its guidelines are flexible; changes can be made slowly focusing directly on issues that arise as new discoveries are made. If there are legal disputes they can be resolved by the courts. This enables a balance to be achieved between scientific advances and assuaging community concerns.