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EDITORIAL – *Ian Freckelton*

Human rights and health law

Important statutory and common law developments are changing the landscape of health law in Australia. Human rights considerations are formally included amongst the factors to be applied in the interpretation of statutory provisions and evaluating the lawfulness of actions on the part of government instrumentalities. The *Human Rights Act 2004* (ACT) and the *Charter of Human Rights and Responsibilities Act 2006* (Vic) create limited bills of rights at State/Territory level in two Australian jurisdictions. Although neither is entrenched, they have the potential to make it more difficult for government to promulgate laws that are inconsistent with human rights, as defined. They will have important repercussions for the evolution of health law in these jurisdictions. The decision of *Royal Women's Hospital v Medical Practitioners Board (Vic)* [2006] VSCA 85 by the Victorian Court of Appeal has also provided a legitimation for parties to incorporate human rights perspectives in submissions about the interpretation of statutory provisions where health rights are in conflict. 7

LEGAL ISSUES – *Bernadette McSherry*

Access to confidential medical records by courts and tribunals: The inapplicability of the doctrine of public interest immunity

A number of Australian courts' decisions have afforded protection to public records. Statutory protection has also been given to counselling records in some jurisdictions in the context of the provision of services to victims of sexual assault. In the aftermath of the extension of public interest immunity in the particular circumstances of *Clifford v Victorian Institute of Forensic Mental Health* [1999] VSC 359, the argument was raised that a further extension should be made to protect personal health records against attempts at regulatory investigation of allegations of unprofessional conduct. In *Royal Women's Hospital v Medical Practitioners Board (Vic)* [2006] VSCA 85 the Victorian Court of Appeal unanimously declined to make such an extension. This appears to be indicative of a shift by Australian courts toward compelling disclosure of medical records in the interests of fairness save in very exceptional circumstances. 15

MEDICAL ISSUES – *David Ranson*

Ethical, professional and legal regulation of medical practice

Moral or ethical codes of practice represent one of the oldest forms of medical regulation. Legislation such as the *Medical Practice Act 1992* (NSW) enables regulatory bodies to create codes of practice for medical practitioners. Such codes can become an important aspect of disciplinary proceedings by providing the yardstick against which practitioners' conduct is evaluated. An important aspect of the New South Wales Board's Code of Professional Conduct 2005 is the obligation for doctors to report adverse events which reflect on the performance or conduct of colleagues. This is part of an increasing impetus to report adverse events in the interest of public safety. In the long term this is a constructive development as it is likely to lead to improvements in identification of risks

and hazards and thereby to result in better service provision and community health. 20

MEDICAL LAW REPORTER – *Ian Freckelton*

Vicarious liability and criminal prosecutions for regulatory offences

The parameters of vicarious liability of corporations for the conduct of their employees, especially in the context of provisions that criminalise breaches of regulatory provisions, are complex. The decision of Bell J in *ABC Developmental Learning Centres Pty Ltd v Wallace* [2006] VSC 171 raises starkly the potential unfairness of an approach which converts criminal liability of corporations too readily into absolute liability, irrespective of the absence of any form of proven culpability. The author queries whether fault should not be brought back in some form to constitute a determinant of criminal liability for corporations. 24

ARTICLES

The Lockhart Review: Where now for Australia? – *Donna Cooper*

In 2005 a Legislation Review Committee, known as the Lockhart Review, undertook a review of the Commonwealth legislation regulating human embryo research. The report that emanated from the review was released in December 2005. If the report recommendations are implemented by the Federal Government, Australian scientists will be permitted to create human embryo entities currently known as "human embryo clones" by the process known as somatic cell nuclear transfer to develop stem cell lines for research purposes. Many argue that stem cells have the potential to be developed into valuable medical therapies that could assist with, or cure, serious diseases such as Type 1 diabetes and Parkinson's disease. This article analyses the evidence presented to the Lockhart Review and the report recommendations. It assesses where the Lockhart recommendations would place Australia in terms of worldwide embryo research. It is argued that the Federal Government should fully embrace the recommendations so that Australia can progress stem cell research to its fullest potential. 27

Law, pregnancy and sport: What are the repercussions when a pregnant lady plays? – *Julia Werren*

This article reflects on the issue of pregnancy and sport that was brought to the fore in *Gardner v National Netball League* (2001) 182 ALR 408; [2001] FMCA 50 and *Gardner v All Australia Netball Association Ltd* (2003) 174 FLR 452. It suggests that these cases did not provide a definitive discussion of the tortious liability implications that initially led Netball Australia to introduce a ban on pregnant players. In an attempt to fill some of these gaps, other case law that deals with liability of sporting organisations and prenatal injury is discussed. The article primarily focuses on whether the unborn child when born alive will have an action against her or his mother as a result of injury occasioned while the mother was playing sport when pregnant. This examination is undertaken in light of recent Australian tort reform as well as changes in policy direction. The article summarises the legal position of the parties involved in sport – sporting organisations, medical practitioners, other participants and the pregnant mother – and argues that, with reference to the guidelines and case law, in only a very small number of cases would liability be found against the sporting organisation or pregnant mother as a result of injuries incurred prenatally. 45

Rewriting the competency rules for children: Full recognition of the young person as rights-bearer – *Jamie Potter*

The rules regarding the competency of children to consent to medical treatment have traditionally focused on the child's understanding of the proposed treatment. This article

argues that this focus has perpetuated an unjustifiably paternalistic attitude to the treatment of children that is inconsistent with obligations under the *Convention on the Rights of the Child* and the common law's preference for upholding personal autonomy. A new test is therefore proposed, abandoning the presumption of incompetency for adolescents and focusing on the understanding of the right to make medical decisions. The application of the proposed test is examined both from a general point of view and with regard to a particularly vulnerable group of young people: those suffering from mental illness. 64

Access to tangible research materials in biomedical research: Conditions of access and their effect on research – *Ann L Monotti*

Biomedical discoveries often provide the basic tools for research. Such discoveries may be patentable or non-patentable products or processes, as well as the materials necessary for further research. Without rapid access to these materials on reasonable terms, there is concern that the progress of science will suffer. In 1995, the National Institutes of Health in the United States published a Master Uniform Biomaterial Transfer Agreement (UBMTA) to improve access to biomedical materials. Guidelines for transfers were published in 1999. This article analyses a survey that the author conducted in the Faculty of Medicine, Nursing and Health Science, Monash University. It observes that a significant minority of respondents experience frustration and/or adverse effects upon their research as a result of restrictions imposed upon their access to materials. It concludes that the extensive experience and precedent material in the United States provides an immediate resource to help improve access to biological materials in Australian universities. 86

An empirical study of tissue banking in Australia: Navigating regulatory and ethical challenges – *Georgina Clark*, *Wendy Lipworth*, *Les Bokey*, *JM Little* and *Ian H Kerridge*

Collections of tumour samples can be an invaluable resource for medical research. There are, however, numerous ethical and legal challenges associated with tumour banking. While there has been extensive discussion of these issues in the legal and ethical literature, there are few available empirical data in relation to the activities of tumour banks in Australia, their practices around ethically charged issues, and their success in implementing complex regulatory guidelines. The aim of this study was to gain more information about the activities of tumour banks in New South Wales, Australia, with a particular focus on their management of, and attitudes towards, ethical and regulatory issues. A survey of 27 tumour collection and research facilities was conducted using a 55-item questionnaire. There is significant heterogeneity of research methodologies as well as of methods for gaining consent and ensuring donor privacy, and there is general concern among the research community about ethical and regulatory issues related to tumour banking. Heterogeneity of practice and uncertainty about ethical and regulatory requirements is problematic in its potential to hinder research and its potential to generate the space for unethical practice, whether intentional or unintentional. There is a pressing need to address these issues so that tumour banks can be used in the most ethical and efficient way possible. 102

Diagnostic testing of genetic disorders: Limiting the scope of patent claims through disclosure requirements – *John Abbot*

The breadth of claims in patents relating to genetic inventions has been controversial for some time. Possible adverse effects of broad claims include inhibiting research and higher costs, restricting patient access to genetic testing. The Australian Law Reform Commission's *Report on Genes and Ingenuity – Gene Patenting and Human Health* examined this issue, and concluded that the existing disclosure requirements contained in s 40 of the *Patents Act 1990* (Cth) provide adequate mechanisms to control the breadth of claims. However, application of these requirements may be problematical in practice due to lack of relevant case law to provide guidance to patent examiners. It has been suggested

that this deficit in direct judicial guidance can be obviated by developing appropriate analogies with other chemical systems in decided cases. This article focuses on gene-based diagnostic patents for human diseases, such as those held by Myriad Genetics for testing predisposition towards breast and ovarian cancer using the gene BRCA1. By examining the application of disclosure requirement by courts in genetic and non-genetic chemical inventions, it is possible to provide insight into how this might be applied by courts considering the validity of patent claims for diagnostic testing methods based on mutations in a gene such as BRCA1. 110

Genetic technologies and the regulation of reproductive decision-making in Australia – *Isabel Karpin* and *Belinda Bennett*

This article provides a critical analysis of the current Australian regulatory landscape at the interface between genetics and reproductive decision-making. The authors argue that a comparative analysis with other countries and international law and a contextual examination of the way law regulates concepts such as disease and health, abnormality and normality is necessary before we can develop appropriate policy and legislative responses in this area. Specific genetic testing technologies are considered including prenatal genetic testing, preimplantation genetic diagnosis and inheritable genetic modification. An increasing number of members of the Australian community are using genetic testing technologies when they decide to have a baby. The authors argue that as concepts of disease and health vary among members of the community and the potential to test for traits other than illness increases, a new tension arises between an ethic of individual choice and a role for government in regulating reproductive decision-making. 127

Rural doctors' attitudes to and knowledge of medicinal cannabis – *Graham Irvine*

The use of cannabis for medical purposes remains controversial. Since support from general practitioners would be needed for the successful operation of a legalised prescription regime, New South Wales Northern Rivers general practitioners were surveyed on their attitudes to and knowledge of medicinal cannabis. A representative random sample of general practitioners, stratified by age and gender, was derived and interviewed. Results indicated generally high levels of knowledge of cannabis's medical uses. The mean number of patients seen in 2004 with medicinal cannabis-treatable conditions was 66.8, with chronic pain patients accounting for 36.7. Overwhelming majorities of respondents reported they would prescribe medicinal cannabis if it were legal, professionally supported and backed by research and that they would approve of clinical trials and a legalised regulatory scheme under such conditions. These results suggest the need to conduct a Statewide general practitioners' survey to confirm or refute the present findings. 135

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