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EDITORIAL – *Ian Freckelton QC*

Medicinal cannabis law reform: Lessons from Canadian litigation – *Ian Freckelton QC*

This editorial reviews medicinal cannabis litigation in Canada's superior courts between 1998 and 2015. It reflects upon the outcomes of the decisions and the reasoning within them. It identifies the issues that have driven Canada's jurisprudence in relation to access to medicinal cannabis, particularly insofar as it has engaged patients' rights to liberty and security of the person. It argues that the sequence of medicinal schemes adopted and refined in Canada provides constructive guidance for countries such as Australia which are contemplating introduction of medicinal cannabis as a therapeutic option in compassionate circumstances for patients. In particular, it contends that Canada's experience suggests that strategies calculated to introduce such schemes in a gradualist way, enabling informed involvement by medical practitioners and pharmacists, and that provide for safe and inexpensive accessibility to forms of medicinal cannabis that are clearly distinguished from recreational use and unlikely to be diverted criminally maximise the chances of such schemes being accepted by key stakeholders. 719

LEGAL ISSUES – *Bernadette McSherry*

Support for the exercise of legal capacity: The role of the law – *Bernadette McSherry and Andrew Butler*

In 2014, the Australian Law Reform Commission released a report dealing with recognition before the law and legal capacity of people with disability. The report recommended that "supported decision-making" should be introduced into relevant Commonwealth laws and legal frameworks. This column explores what is meant by "support" to exercise legal capacity and what role the law may play in attempting to move beyond the traditional substituted decision-making model for those with mental and intellectual impairments. 739

MEDICAL ISSUES – *David Ranson*

The loss of Malaysia airlines flight MH17: A forensic and humanitarian task – *David Ranson*

While forensic medical tasks are usually associated with supporting the criminal justice system, there are a range of forensic medical skills that can be brought to bear on addressing humanitarian activities. Disaster victim identification is a procedure that has achieved international standardisation through the work of a multinational Interpol Standing Committee. While part of a police organisation, it includes forensic pathologists, anthropologists, odontologists and molecular biologists who provide most of the specialist scientific input regarding identification that is integrated with police processes such as document examination and fingerprinting. The loss of Malaysian Airlines Flight MH17 represented a major activation of these procedures in an environment that had both humanitarian and forensic criminal investigation components. The information that is derived from the processes involved in disaster victim identification has a value that goes

far beyond the determination of identity. It has an important humanitarian role in supporting the family and friends of the victims in their bereavement journey. 745

BIOETHICAL ISSUES – *Grant Gillett*

Think of the children: Sex selection and child welfare – *Rachael Wong and Grant Gillett*

This column considers the phenomenon of social sex selection and whether its legal prohibition can be justified in Australasia. It looks at whether the liberal autonomy framework is an adequate ethical basis for assessing sex selection and whether sex selection may raise ethical concerns about the nature of parenting and the welfare of future children in the Australasian context. It argues that with sex selection comes the implicit instrumentalisation and commodification of children, which both stem from and encourage attitudes contrary to those underpinning the virtues required of parents. It concludes that in lieu of robust arguments in favour of sex selection and in light of the probable (or at least plausible) negative impact on the nature of parenting and the welfare of future children, the legal prohibition on social sex selection should be maintained in Australasia. 751

NURSING ISSUES – *Kim Forrester*

Recognising and responding to the deteriorating patient – *Kim Forrester*

The timely and appropriate identification of, and response to, a patient's deteriorating condition by health professionals is essential for optimal patient outcomes and the avoidance of preventable harm. National regulatory authorities, the Australian Commission on Safety and Quality in Health Care, State, Territory and federal health departments, health care facilities and institutions have all recognised the importance of implementing frameworks, standards and processes to facilitate the prompt recognition of the deteriorating patient and appropriate mechanisms for responding to and escalating such matters. Factors that may affect identification and response include the level of knowledge and skill of the health professionals, the culture of the organisation and the parameters of the assessment and audit tools. The 2014 findings of the Coroner in the inquest into the death of Graeme Barry Gulliver highlights the significance to nursing practice of recognising and responding to the deteriorating patient in an appropriate and timely manner. 763

MEDICAL LAW REPORTER – *Thomas Faunce*

Australian Competition and Consumer Commission v Pfizer: Evergreening and market power as a blockbuster drug goes off patent – *Thomas Faunce*

In *Australian Competition and Consumer Commission v Pfizer Australia Pty Ltd* [2015] FCA 113, the ACCC alleged that Pfizer's "Project LEAP" involved a scheme to lock pharmacists into substituting its generic version of the high sales volume anti-cholesterol drug, patent-expired atorvastatin (Lipitor), which took advantage of a substantial degree of market power for a purpose proscribed by s 46(1)(c) of the *Competition and Consumer Act 2010* (Cth). The ACCC also claimed that Pfizer's actions constituted a course of exclusive dealing pursuant to s 47(1)(d) and (e) for the proscribed purpose of lessening competition. Flick J in the Federal Court of Australia, in a judgment heavy with quotations but sparse in reasoning, dismissed the ACCC's Amended Originating Application alleging abuse of market power and ordered the ACCC to pay Pfizer's costs. The ACCC has now appealed the decision. This column explores this case in the context of Pfizer's broader strategies to preserve its income globally from this high sales volume drug in the period following its patent expiration. 771

ARTICLES

The Australian quarantine and biosecurity legislation: Constitutionality and critique – Anthony Gray

Australia's quarantine and biosecurity laws have been in focus recently with the serious outbreak of the ebola virus and the not-so-serious incident involving an actor's dogs apparently gaining unauthorised access to Australia. These incidents have coincided with the move to replace Australia's existing quarantine legislation with a modern regulatory framework for managing biosecurity risks. This article critiques the existing and new Australian legislation, comparing them with approaches in other jurisdictions and discussing some relevant public policy issues. In particular, the article comments on the constitutionality of the provisions relating to the detention of individuals for public health reasons, such as to control or limit the spread of disease, finding the new legislation to be an improvement on the existing one. 788

States of confusion: Jurisdictional variation in Australian medicines nomenclature – Denise Hope and Michelle King

In December 2000, the Galbally Review recommended Australia achieve national uniformity in drugs and poisons legislation. While the Commonwealth *Poisons Standard* classifies and schedules medicines and poisons, the Australian States and Territories are responsible for regulating the supply of medicines and poisons through individual medicines legislation. In December 2013, this legislation was examined to identify the nomenclature used to describe medicines. The research found considerable variation across jurisdictions in terms of the nomenclature used, in particular the terms used for Schedules in the State and Territory legislation were often inconsistent with each other and the terms used in the *Poisons Standard*. Of most concern is that the same term may be used to describe different medicines in different jurisdictions, leading to possible confusion for health practitioners working across jurisdictions as is now possible under national registration. It is therefore imperative that national uniformity of drugs and poisons legislation is achieved to facilitate a common practice reference. 811

The case for MDMA (ecstasy) regulation – Joshua Donnelly

Drug-related harm is the most rational means of determining a substance's legal status. The available evidence suggests that compared to other drugs, 3,4-methylenedioxy-N-methamphetamine (MDMA or "ecstasy") poses a low level of harm to most individual users and causes negligible harm to society. There is no sound justification for criminalising the use of MDMA. The depenalisation model adopted in Australia does not have any benefits that cannot be achieved by removing minor MDMA offences from criminal law entirely. The current model also operates within a prohibition framework that is costly to society and increases harm to ecstasy users. These arguments support the proposal by David Penington in 2012 that MDMA should be regulated on a legal market. The supply of MDMA from pharmacies appears to be a practicable law reform option with the potential to reduce harm associated with ecstasy use and the costs of prohibition. 823

Patenting genetic diagnostic methods: NGS, GWAS, SNPs and patents – Charles Lawson

This article reviews the problems posed by patent claims to genetic diagnostic methods associated with genome-wide association studies (GWAS) adopting methodologies using next-generation sequencing (NGS) and single nucleotide polymorphisms (SNP). These problems are essentially about experimental reproducibility and the credibility and veracity of reported developments. An analysis of the relevant law demonstrates that the current Australian and United States laws about suitable patentable subject matter differ,

and that the current reproducibility (sufficiency, enablement and inutility) standards are unlikely to address these problems. The article concludes that following the United States approach excluding these genetic diagnostic method claims from patenting is one solution. Failing this, improving analysis and quality controls that are now being adopted in the basic research will reduce the nature of the problems, although this will remain problematic for patent examiners and the broader public. 846

Genetic testing of stored tissue from a deceased person to define a relative's disease risk: Legal and ethical viewpoints – Loane Skene, Julian Savulescu and Martin B Delatycki

It is now possible to undertake gene sequencing on DNA obtained from stored tissue removed from a person now deceased or from stored tissue from a living person. The sequencing may assist close blood relatives who are at risk of having a mutation that predisposes them to cancer to find out their own genetic risk. If the test had been done previously, Australian law would permit the test results to be provided to close blood relatives of the “originator” without consent, even if other relatives object, although good practice is to inform all family members about proposed genetic tests. However, it is less clear whether a pathology laboratory can lawfully, and should ethically, provide stored tissue for genetic testing, without the originator's consent. This article argues that the law and ethics need to be clarified so pathology laboratories can confidently make stored tissue available for testing to assist blood relatives. 864

Double standards: Standards of proof for persons found unfit for trial – Betheli O'Carroll

This article examines the laws surrounding whether a court has to be satisfied that a person who is unfit for trial committed an offence. Currently in Western Australia, Queensland, the Commonwealth and New Zealand, there is one standard of proof for persons who are fit for trial and a different, or no, standard of proof for persons found unfit. In particular, in Western Australia and Queensland, courts do not have to be satisfied to any standard of proof that a person who is unfit for trial committed an offence. This practice is of concern as unfit persons in these jurisdictions may be subject to custody orders or be involuntarily detained without having been convicted of an offence. The legislation in these jurisdictions is compared with the legislation in the remaining Australian jurisdictions where courts need to be satisfied beyond reasonable doubt that a person who is unfit for trial committed the conduct or objective elements of the alleged offence. 871

Fitness to stand trial, human rights and possibilities from England and Wales – Jeanette Stewart, Mary Woodward and Ilana Hepner

The capacity of individuals with disability, including cognitive or mental health impairments, to access justice on an equal basis has been considered recently in several Australian jurisdictions. Impairments can render individuals vulnerable in the legal system, affecting their reliability as a witness or their fitness to be tried, especially when limited support is available to help these individuals meet the test and criteria for fitness to stand trial. This article considers the situation in Australia in light of human rights perspectives and compares it with the England and Wales approach where special support measures have been introduced to help individuals access justice. The article recommends that better support measures be introduced in Australia that would be consistent with a human rights framework calling for support to enable individuals with disability to access justice. In particular, the introduction of intermediaries, as used in England and Wales, would go some way towards helping vulnerable individuals to access justice. 886

Tasmania's Reproductive Health (Access to Terminations) Act 2013: An analysis of conscientious objection to abortion and the "obligation to refer" – Ronli Sifris

This article focuses on Tasmania's *Reproductive Health (Access to Terminations) Act 2013*, which decriminalises abortion in that State. The article first provides an overview of the Tasmanian legislation, comparing it with Victoria's *Abortion Law Reform Act 2008*. It then provides a more in-depth analysis of a doctor's right to "conscientious objection" and the requirement in both Acts of an "obligation to refer". The article concludes that ultimately, as a democratic society, it is important that both a woman's right to terminate a pregnancy and a doctor's right to freedom of conscience is respected. Where these rights conflict, as is the case when a doctor with a conscientious objection to abortion is confronted with a patient who seeks information about abortion, they must be balanced. The Victorian and Tasmanian Acts represent a considered and reasonable approach to balancing the rights at issue. 900

Regulating preimplantation genetic diagnosis in Australia: Disability and parental choice – Michelle de Souza

Preimplantation genetic diagnosis (PGD) is the process by which an early in vitro embryo is screened for a genetic condition. As the name suggests, the procedure is undertaken prior to the embryo being implanted into a woman and therefore affected embryos can be discarded. This article argues that the objections previously put forward opposing the use of PGD to select against disability are flawed. It also argues that permitting parents to act in a procreatively beneficent manner and to preserve their child's right to an open future are good reasons for parents to have the freedom to select against disability. In light of this, are there any sound reasons to limit the use of PGD to selection against serious disabilities? 915

End-of-life decisions in Malaysia: Adequacies of ethical codes and developing legal standards – Puteri Nemie Jahn Kassim and Fadhlin Alias

End-of-life decision-making is an area of medical practice in which ethical dilemmas and legal interventions have become increasingly prevalent. Decisions are no longer confined to clinical assessments; rather, they involve wider considerations such as a patient's religious and cultural beliefs, financial constraints, and the wishes and needs of family members. These decisions affect everyone concerned, including members of the community as a whole. Therefore it is imperative that clear ethical codes and legal standards are developed to help guide the medical profession on the best possible course of action for patients. This article considers the relevant ethical codes and legal provisions in Malaysia governing certain aspects of end-of-life decision-making. It highlights the lack of judicial decisions in this area as well as the limitations with the Malaysian regulatory system. The article recommends the development of comprehensive ethical codes and legal standards to guide end-of-life decision-making in Malaysia. 934

BOOK REVIEW

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