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EDITORIAL – *Ian Freckelton SC*

**The Universal Declaration on Bioethics and Human Rights**

The steps toward the adoption by the United Nations Educational, Scientific and Cultural Organisation (UNESCO) of the *Universal Declaration on Bioethics and Human Rights* took a number of years and generated considerable controversy. This editorial reviews the principal provisions in the Declaration and argues that the Declaration constitutes an important formalisation on the basis of international consensus of the fundamental attributes of bioethical work undertaken by medical practitioners and scientists. However, the Declaration is only a beginning; many challenges lie ahead to ensure its effective implementation. .................................................................................................................. 187

LEGAL ISSUES – *Danuta Mendelson*

**The criminalisation of professional misconduct under the Health Professions Registration Act 2005 (Vic): How is a fine of $50,000 not punitive?** – *Ian Wheatley*

The purpose of medical boards is to protect patients and guide doctors. Courts and tribunals have constantly emphasised that their role is entirely protective and not punitive. By a huge increase in the fine that can be imposed on health professionals in Victoria to a level more commensurate with serious criminal activity, the regulatory environment has shifted from a simple and straightforward indication of disapproval to one where a medical practitioner can be sanctioned as a criminal without the protections afforded by the criminal jurisdiction. A standard of proof beyond reasonable doubt, double jeopardy and pleading remorse and contrition in mitigation are not available. No good reasons have been advanced for this change. .............................................................................................. 193

MEDICAL ISSUES – *Ian Freckelton*

**Apologies, medicine and the law** – *Penny Browne*

This column considers some of the imperatives and barriers which may impact on a medical practitioner who apologises to a patient following an adverse event in New South Wales. It also considers the inclusion of the apology provisions in ss 67-69 of the *Civil Liability Act 2002* (NSW) and the extent to which those provisions may protect apologising practitioners from liability. ................................................................................. 200

BIOETHICAL ISSUES – *Grant Gillett*

**Intent, the ethos of a caring society and justice** – *Grant Gillett* and *Matthew Gillett*

A paradoxical New Zealand case of a father who killed his five-month-old severely impaired daughter is discussed. The jury found the father not guilty of murder despite his confession that he acted so as to bring about her death. Standard constructions do not capture any reason for the jury to acquit him on the ground of lack of intent. The case also raises the issue of social mores in relation to difficult ethical decisions and the problems in trying to capture those in legislation or guidelines. The analysis discusses an alternative conception of intent according to a broader understanding of the patient's life story and the events surrounding the act in question and also the reasons why policy and legislative needs may distort bioethical analysis and argument in relation to difficult human situations. .......... 209

NURSING ISSUES – *Kim Forrester*

**Nursing in the aged care sector: Resident abuse and the reporting obligations** – *Kim Forrester*

Elder abuse is recognised in many countries as a significant social, medical and legal issue. In an attempt to address this issue the Australian Government has recently enacted legislative amendments to the *Aged Care Act 1997* (Cth). These amendments apply to providers in the residential aged care sector who are in receipt of Commonwealth Government subsidies. Among a range of obligations aimed at the protection of the elderly is the requirement for the mandatory reporting of sexual and serious assault in the aged care sector. This column considers some of the issues relevant to addressing the abuse of older Australians. .......... 216

MEDICAL LAW REPORTER – *Thomas Faunce*

**New forms of evergreening in Australia: Misleading advertising, enantiomers and data exclusivity: Apotex v Servier and Alphapharm v Lundbeck** – *Thomas Faunce*, *Tim Vines* and *Helen Gibbons*

Two recent decisions of the Federal Court of Australia have provided interesting insights into the ongoing struggle between originator drug manufacturers and the public interest in Australia. In *Apotex Pty Ltd (formerly GenRx Pty Ltd) v Les Laboratoires Servier (No 2)* [2008] FCA 607 the court held that an advertising campaign by an originator pharmaceutical company, which sought to persuade doctors to issue prescriptions prohibiting substitution of "a-flagged" generics, constituted misleading and deceptive conduct under s 52 of the *Trade Practices Act 1974* (Cth). The decision of the court in *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618; [2008] FCA 559 limits the ability of the manufacturer of a drug based on a purified racemate enantiomer to claim a later registration date on the Australian Register of Therapeutic Goods and subsequently obtain an extension of its intellectual monopoly privileges as well as an exclusivity period for the data it had submitted to safety regulators. Importantly, this case is one of the first to consider recent allegedly pro- and anti-"evergreening" changes to the *Therapeutic Goods Act 1989* (Cth) and *Patents Act 1990* (Cth) as impacted by the intellectual property chapter (Ch 17) of the *Australia–United States Free Trade Agreement.* .......... 220

ARTICLES

**The meaning of "serious disability" in the legal regulation of prenatal and neonatal decision-making** – *Kristin Savell* and *Isabel Karpin*

The concept of "serious disability" appears to play a significant role in circumscribing treatment-limiting decisions in neonatal care, prenatal counselling, preimplantation genetic diagnosis, and abortion following prenatal diagnosis. However, there is no legal definition for this concept and its meaning varies among members of the community and the medical profession. Legal and policy responses to "serious disability" consist of an assortment of ethical guidelines, specific legislative frameworks and longstanding provisions of the criminal law, some of which were neither enacted nor developed with modern medical practices and dilemmas in mind. In addition, many of these regulatory frameworks and prohibitions vary between State and Territory jurisdictions. This leaves service providers, families wishing to utilise (or avoid utilising) diagnostic technologies and the broader community uncertain about the legal limits. This uncertainty has implications for women's autonomy in reproductive decision-making. For instance, services may be withheld, or their use encouraged, depending on differing understandings of the concept of "serious disability". The time has arrived for governments to consider whether it is appropriate to introduce a uniform set of guidelines and/or regulations across Australia for guiding clinical determinations of "serious disability". .................................................................... 233

**The new regulation of non-consensual genetic analysis in New Zealand** – *Katie Elkin*

The *Human Tissue Act 2008* (NZ) makes it a criminal offence for human tissue to be collected for analysis, or to be analysed, without informed consent. The Ministry of Health has described the provisions of the Act as "clos[ing] a gap in current regulation" of such activities. This article questions whether the Act will have this effect, whether it is likely to achieve the other aims as stated by the government in championing it, and how the Act fits with existing regulation. ........................................................................................... 246

**Preimplantation genetic diagnosis for susceptibility conditions: A new frontier or a logical extension?** – *Jeanne Snelling*

A susceptibility or "lower penetrance" condition is a condition to which a person may be predisposed by virtue of a particular gene mutation they carry within their genetic code. Genetic testing for susceptibility to late-onset conditions, an increasingly available phenomenon, has recently been associated with preimplantation genetic diagnosis (PGD). Performing PGD for conditions that occur later in life and that may be preventable or, if not, may be treatable, or that may never even develop, is highly contentious. It constitutes a significant departure from traditional PGD, going beyond testing for serious heritable disorders that are apparent at birth or in very early childhood or late-onset diseases that are certain to manifest themselves. It is likely that, as technology advances, there will be a growing demand for PGD to detect these types of conditions. This article considers the issues raised by susceptibility testing. It questions whether embryonic testing for late-onset susceptibility conditions is more appropriately a matter for regulatory restraint or reproductive liberty. ........................................................................................................ 263

**Posthumous reproduction: Consent and its limitations** – *Sarah Jones* and *Grant Gillett*

The majority of the extensive debate surrounding posthumous sperm procurement (PSP) focuses on how to respect the deceased man and his autonomy. Policy and law also focus on the deceased's interests, specifying the level of consent required. This article argues (using four hypothetical fact situations) that consent should not be the sole focus of ethical debate. Instead, a fuller picture should be examined, including the wishes and values of the prospective sperm donor; the future life and prospects of the resultant child; the needs and motivations of the mother, and other pertinent factors. In practice, this means that a committee acting judicially should consider each case. This is a practical option for New Zealand and Australia where applications for posthumous sperm procurement are not common but it also enables us to consider the ethical arguments in relation to such determinations in other jurisdictions. ........................................................................... 279

**Queensland nurses' attitudes towards and knowledge of the legislative duty to report child abuse and neglect: Results of a State-wide survey** – *Ben Mathews*, *Jenny Fraser*, *Kerryann Walsh*, *Michael Dunne*, *Sam Kilby* and *Linping Chen*

In 2005, legislation commenced requiring Queensland nurses to make reports of suspected child abuse and neglect to government child protection authorities. This development further harmonised Australian mandatory reporting laws and their application to the nursing profession, although inconsistencies still exist between States and Territories. As indicated by research published in 2006, little is known about nurses and the reporting of child abuse and neglect. The legislative change in Queensland provided a new opportunity to study nurses' attitudes to reporting, knowledge of the legal reporting duty, and reporting practice, all of which provides much-needed evidence about the reporting of child abuse and neglect, and about the laws themselves. This article describes results from a State-wide survey of Queensland nurses. Findings have implications for law reform, nursing practice, and nurses' training in child abuse and neglect reporting. ....................... 288

**Not-for-resuscitation orders: The medical, legal and ethical rationale behind letting patients die** – *Richard Cavell*

A doctor who is treating a patient in an Australian hospital may make a pre-emptive decision not to attempt to resuscitate that patient in the event of the patient's sudden demise. This decision is commonly referred to as a not-for-resuscitation (NFR) order. This article examines what resuscitation is, and what it means to withhold attempts at resuscitation from a patient. The medical, legal and ethical doctrines relating to death and dying are synthesised into a set of robust guidelines for making NFR decisions. ............. 305

**The non-compliance of clinical guidelines for organ donation with Australian statute law** – *James Tibballs*

Organ procurement is possible under statutes defining death as either irreversible cessation of all functions of the brain or irreversible cessation of the circulation, thus fulfilling the "dead donor rule". However, present practice does not conform strictly to these conditions. Clinical guidelines for the diagnosis of whole-brain death are equated, with coma, to absence of brain-stem reflexes which essentially means the absence of spontaneous respiration which is clinically interpreted as "dead enough" or "as good as dead" for the purpose. Moreover, *Krommydas v Sydney West Area Health Service* [2006] NSWSC 901 suggests public distrust of brain-stem reflexes as tests to diagnose whole-brain death. Mandatory adoption of a test of brain blood circulation, at present optional, would strengthen reliability of the diagnosis. Organ procurement is performed after cessation of the circulation following orchestrated withdrawal of futile life-support and is commenced when the heart fails to "auto-resuscitate" two minutes after it stops, rather than proven irreversible cessation. Ante-mortem procedures are performed on the donor to increase organ availability and viability but may contribute to or cause death. State and national ethical guidelines on this practice conflict and it appears proscribed under State guardianship legislation which requires actions in the best interests of the donor, not the recipient. Considerations should be given to organ procurement in situations where the donor is dying or in which survival is impossible. Simple abandonment of the "dead donor rule", however, is not feasible since organ procurement would be the direct cause of death. .................................................................................................................................... 335

**Democratic discussion in newspaper reporting of the Australia–United States Free Trade Agreement** – *Robbie Sykes*

This article presents a Habermasian analysis of newspaper reporting of the debate surrounding the effect of the *Australia–United States Free Trade Agreement* (the FTA) on access to medicines through Australian patent law. Habermas's concept of the public sphere is utilised in determining whether discussion within the print media adequately conveyed complex legal issues to the public and facilitated democratic discussion. It was found that newspaper reporting generally failed to meet this standard. .............................. 356

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