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GUEST EDITORIAL – *Belinda Bennett*

## **Time for a national approach to donor conception in Australia**

There is a growing recognition of the interests and rights of individuals conceived using donated gametes in assisted reproductive technology to information about their biological parentage. In Australia these rights vary between jurisdictions according to differing statutory provisions. In February 2011 the Senate's Legal and Constitutional Affairs References Committee published its report on *Donor Conception Practices in Australia*. The report recommended the development of a nationally consistent approach to donor conception and recommended the enactment of legislation in those Australian jurisdictions without legislation regulating donor conception. This editorial reviews the Senate Committee report and its recommendations and supports calls for a nationally harmonised approach to donor conception in Australia. ....

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LEGAL ISSUES – *Danuta Mendelson*

## **Operation of guardianship laws in the emergency ward – *Danuta Mendelson and Anne Saunders***

Enduring and workable legislative schemes typically include (a) a balanced approach to the rights and duties of all parties under their purview; and (b) consideration of all major consequences that may flow from the codification of underpinning doctrines. This column examines the 1999 amendments to the *Guardianship and Administration Act 1986* (Vic) regulating patients' consent to medical treatment focusing on their application in modern emergency departments. The legislation needs to reconcile the human rights principle that humane and appropriate treatment is a fundamental right of all those who suffer from ill health and disease, with the principle that all patients (including those with impaired, but not totally absent, decisional capacity) have an absolute right to refuse life-saving treatment. Consent and refusal of treatment provisions should be based on the notion of reasonableness, including recognition that the mental and emotional states experienced by physically ill people may, in the short term, adversely affect their decision-making capacity. Unless the consent legislation factors in the realities of modern emergency practice and resources, statutory thresholds for decisional competence, instead of affording protection, may result in much worse outcomes for vulnerable patients. ....

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MEDICAL ISSUES – *David Ranson*

## **Sexual assault examinations and forensic medical samples – *David Ranson***

Recent studies and a review in the United States have identified that tens of thousands of used but untested sexual assault examination kits containing medical examination specimens are to be found in police station evidence rooms, forensic science laboratories, hospitals and rape crisis centres. A 2007 survey undertaken by the National Institute of Justice in the United States explored some of the reasons why forensic specimens are not tested by forensic science laboratories. Many of these relate to lack of knowledge on the part of investigators as to how scientific information can assist the investigation process, even if not used subsequently at trial. Cost factors and laboratory casework overload were

also identified as significant. For the medical practitioner, the lack of testing poses issues that include quality management of the forensic medical examination and informed consent in a setting requiring the balancing of public and private benefits for the examinee. Limiting scientific testing, even with intelligence-led triaging of sample testing, could have an adverse effect on both prosecution and defence decision-making and ultimately could adversely affect trial outcomes. .... 32

#### BIOETHICAL ISSUES – *Malcolm Parker*

##### **Not so great expectations: Why we should accept and respect hopelessness and futility** – *Malcolm Parker*

Medicine and health care attempt to prevent and cure disease, restore lost function, and relieve suffering. These are positive aspirations in the face of disvalued states of being. Part of the approach to countering illness can be to encourage or therapeutically increase such states as optimism, emotional wellbeing, peace and meaning, and to try to decrease mental and existential distress and despair, feelings of vulnerability, feelings of loss and loss of meaning. The column briefly examines examples from three fields – cancer, psychotherapy and end-of-life – and the relationships between therapeutic and social pressures for optimism and hope, on the one hand, and wellbeing, health and freedom, on the other. It suggests that in each field there are risks that arise from premature and/or excessive accentuation of the positive, and neglect of the presence and importance of what is conventionally regarded as the negative. .... 36

#### MEDICAL LAW REPORTER – *Thomas Faunce*

##### **Freedom of information applications as an “evergreening” tactic: Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd (2010) 191 FCR 573; [2010] FCA 1442** – *Tim Vines and Thomas Faunce*

A recent decision of the Federal Court of Australia illustrates how patent-holding pharmaceutical companies are attempting to use Australia’s *Freedom of Information Act 1982* (Cth) to force Australian safety, quality and efficacy regulators to disclose whether generic competitors are attempting to enter the market. In *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd* (2010) 191 FCR 573; [2010] FCA 1442 a single judge of the Federal Court overturned a decision of the Administrative Appeals Tribunal (AAT) that would have compelled the Australian Therapeutic Goods Administration (TGA) to reveal whether they were in possession of an application to register generic versions of two iNova products: imiquimod and phentermine. In its justification to the AAT for refusing to confirm or deny the existence of any application, the TGA argued that to reveal the existence of such a document would prejudice the proper administration of the *National Health Act 1953* (Cth) as it could compromise the listing of a generic on the Pharmaceutical Benefits Scheme. The AAT failed to appreciate the extent to which this revelation to a competitor would have undercut 2004 amendments to the *Therapeutic Goods Act 1989* (Cth) that provided penalties for evergreening tactics involving TGA notifications to drug patent-holders and 2006 amendments to the *Patents Act 1990* (Cth) which protected the right of generic manufacturers to “springboard”. The decision of the Federal Court is one of the first to explore the use of freedom of information legislation by patent-holders as a potential “evergreening” technique to prolong royalties by marginalising generic competition. Because of the significant amounts of money involved in ensuring rapid market entry of low-cost generic products, the issue has considerable public health significance. .... 43

## ARTICLES

### **“Permanent discharge”: Deaths of people under 50 years of age in residential aged care in Victoria – *Liz Dearn***

In June 2007 there were 210 people under 50 years of age living in residential aged care in Victoria, Australia, most of whom had acquired brain injuries. There are an average of 21 deaths per year in this group yet very little is known about the causes of such deaths. While the *Coroners Act 2008* (Vic) requires mandatory reporting of “unexpected” and “accidental” deaths, anecdotal evidence and data from the Coroner’s Office suggest that most deaths of people under 50 years of age in residential aged care are not reported. This research presents the cases of three “preventable” deaths, none of which was reported to the coroner and all of which have implications for systemic reform. It concludes that cross-sectoral solutions to meet the complex needs of people under 50 years of age with disabilities in residential aged care are urgently needed as well as monitoring to help us to understand better the needs of young people in residential aged care. ....

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### **“Mummy beerest”: A study of fetal alcohol spectrum disorder, a mother’s duty of care and strategies for intervention – *Elise Jane Nolan***

Fetal alcohol spectrum disorder can occur in children when a mother consumes alcohol while pregnant. It can manifest in a range of both physical and mental impairments and in varying degrees of seriousness. The act of consuming alcohol while pregnant arguably constitutes a breach of the duty of care that a mother owes to her unborn child and may lead to an award of damages for children with the disorder. However, to conclude that a duty is owed to an unborn child may be legally problematic. Further, an award of compensation may be of little utility to the child. It is therefore suggested that intervention strategies should instead be implemented which target relevant population groups and which prevent and assist in the management of the disorder. ....

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### **Reliance on internal autopsies in coronial investigations: A review of the issues – *Michael Barnes and Belinda Carpenter***

Internal autopsies are invasive and result in the mutilation of the deceased person’s body. They are expensive and pose occupational health and safety risks. Accordingly, they should only be done for good cause. However, until recently, “full” internal autopsies have usually been undertaken in most coroners’ cases. There is a growing trend against this practice but it is meeting resistance from some pathologists who argue that any decision as to the extent of the autopsy should rest with them. This article examines the origins of the coronial system to place in context the current approach to a death investigation and to review the debate about the role of an internal autopsy in the coronial system. ....

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### **Disability and the legal profession in the United States – *Frances Gibson***

There are more people with disabilities than any other minority group in the United States. However, little attention is paid to lawyers and potential lawyers with disabilities. This article examines difficulties faced by people with a disability as law students through to participation in the legal profession. Aspects of discrimination and issues relating to discipline of lawyers and disabilities are canvassed. The legal profession in the United States is taking steps to increase representation of people with a disability in its ranks but it is a slow process. ....

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### **Is New Zealand’s regulation of nanomedical products adequate? – *Jennifer Moore***

This article investigates the adequacy of New Zealand’s regulation of medical products produced by nanotechnology and containing nanomaterials. There is concern that the

novel and unique properties of some nanoscale chemical substances will bring unforeseen human and environmental health and safety risks. Given the possible market for nanomedicines and the growing evidence of their potential risks, it is important to have adequate regulation of nanomedicines in order to prevent adverse public health ramifications. This article argues that nanoparticles, invisible to the human eye, are illuminating and exacerbating legislative imperfections in the *Medicines Act 1981* (NZ). This Act does not include a pre-market approval process for medical devices, nor does it include provisions for combination products. This approach is inconsistent with international norms. The article proposes amendment of the *Medicines Act 1981* (NZ) to address these weaknesses and the novel challenges posed by nanomedicines. .... 112

**The regulatory pyramid meets the food pyramid: Can regulatory theory improve controls on television food advertising to Australian children? – Belinda Reeve**

This article examines whether responsive regulation has potential to improve the regulatory framework which controls free-to-air television advertising to children, so that the regulatory scheme can be used more effectively as a tool for obesity prevention. It presents two apparently conflicting arguments, the first being that responsive regulation, particularly monitoring and enforcement measures, can be used to refine the regulation of children’s food advertising. The second argument is that there are limits to the improvements that responsive regulation can achieve, since it is trying to achieve the wrong goal, namely placing controls on misleading or deceptive advertising techniques rather than diminishing the sheer volume of advertisements to which children are exposed. These two positions reflect a conflict between public health experts and governments regarding the role of industry in chronic disease prevention, as well as a broader debate about how best to regulate industry. .... 128

**The regulation of pharmacy ownership in Australia: The potential impact of changes to the health landscape – H Laetitia Hattingh**

Australian community pharmacy ownership restrictions have been in place for many years. However, it is timely to review these structures in terms of the Commonwealth Government’s proposed changes to the health care system and the need for flexibility to ensure access of vital medicines to the community. Careful consideration has to be given to the advantages and disadvantages of regulatory structures that limit ownership to pharmacists, compared to non-pharmacist ownership. Other ownership aspects that need to be evaluated include the number of pharmacies one pharmacist should be allowed to own or co-own and the extent of control required on the location of pharmacies. .... 147

**The ethical obligations of the military medical practitioner – Grant Niemann**

International humanitarian law requires medical practitioners to be given “respect and protection” when serving as medical practitioners in the military. A component of this legal assurance is that when military medical personnel base their decisions on their medical code of ethics, that decision will be respected and protected. Although the “respect” that has been afforded by international humanitarian law has been part of the law for a considerable period of time, it is not always clear that military command or the courts are sufficiently aware of the ambit of this prescription. .... 155

**Young children as regenerative tissue donors: Considering the need for legal reform in light of divergent ethical approaches – Shih-Ning Then**

In Australia, young children who lack decision-making capacity can have regenerative tissue removed to treat another person suffering from a severe or life-threatening disease. While great good can potentially result from this as the recipient’s life may be saved, ethical unease remains over the “use” of young children in this way. This article examines the ethical approaches that have featured in the debate over the acceptability and limits of

this practice, and how these are reflected in Australia’s legal regime governing removal of tissue from young children. This analysis demonstrates a troubling dichotomy within Australia’s laws that requires decision-makers to adopt inconsistent ethical approaches depending on where a donor child is situated. It is argued that this inconsistency in approach warrants legal reform of this ethically sensitive issue. .... 172

**The need for a regulatory response to diagnosis fraud in mesothelioma cases – Rohan Price**

Australian courts and tribunals allow claimants with pleural plaques to “piggy back” compensation claims for mental health problems. This article contends that Australia is open to an era of diagnosis fraud by psychologists similar to that which has been experienced in the United States with radiologists. The courts will continue to reflect Australia’s “compensation culture” unless legislation squarely addresses the compensability of pleural plaques and clarifies when, if at all, the courts should allow mental health claims for asymptomatic “marker” conditions such as pleural plaques. .... 196

**BOOK REVIEW**

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