# JOURNAL OF LAW AND MEDICINE

Volume 26, Number 4

July 2019

EDITORIAL - Ian Freckelton QC

## **Encouraging and Rewarding the Whistleblower in Research Misconduct Cases**

There are many pressures that militate against work colleagues "blowing the whistle" or "ringing the bell" on each other in respect of research misconduct. These pressures result in a significant proportion of such conduct not coming to light at all or coming to light later or less straightforwardly than is desirable. There need to be meaningful incentives for colleagues to draw to the attention of authorities concerns that they have about adherence by others to their obligations in relation to research integrity. The United States has a distinctive process under the False Claims Act which provides significant financial encouragement to such persons, known as "relators" under the qui tam scheme, including in the context of proven research misconduct. This editorial reviews prominent occasions on which qui tam actions have been taken and considers the ramifications of a US\$112.5 million settlement arrived at in 2019 involving research misconduct at Duke University. It discusses the advantages and disadvantages of the incentives that lie at the heart of the United States False Claims Act and canvasses whether it should be emulated in other countries. 719

LEGAL ISSUES - Editor: Bernadette McSherry

## Electroconvulsive Therapy without Consent: The Influence of Human Rights Law – Bernadette McSherry

The use of electroconvulsive therapy (ECT) is highly regulated across Australia. Its use on those under compulsory mental health treatment orders remains controversial and the United Nations Special Rapporteur on Torture and Other Cruel and Inhuman Treatment or Punishment has called for a ban on its nonconsensual use. Mental health tribunals must consider whether or not the person concerned has capacity to consent to ECT and there have been different understandings of just what capacity means in this regard. This column discusses the influence of human rights law and a recent decision by Justice Bell of the Supreme Court of Victoria setting a low threshold for a person's capacity to consent to or refuse ECT. 732

MEDICAL ISSUES - Editor: David Ranson

## The Role of Patient-reported Outcome Measures in Post-operative Death Investigations - Anant Divyang Butala, Joseph Elias Ibrahim, Lyndal Bugeja and David Ranson

Coronial investigations of post-operative deaths can play an important role in improving the quality and safety of patient care. Correctly identifying reportable deaths in the postoperative period and reporting them to the coroner is a key responsibility of medical practitioners but may be challenging, particularly when determination of unexpectedness is problematic. Patient-reported outcome measures (PROMs) have a potential role to play in assisting clinicians with better identification of these reportable deaths. Moreover, the inclusion of PROMs within coronial investigations can assist in identifying systemic

failures and result in recommendations on public health and safety. In particular, PROMs could be effective in addressing the overuse of surgery which remains a major public health concern. While the role of PROMs in clinical practice has undergone extensive research, their potential use in death investigations has been overlooked. As medicine continues to transition towards a patient-centred model of care, the use of frameworks such as PROMs will become increasingly important and may also provide benefit to the process of medicolegal death investigations. 737

#### MEDICAL LAW REPORTER – Editor: Thomas Faunce

## Australian Medical Professionals, National Security and Administrative Offshore Punishment of Asylum-Seekers: Regulatory Update Including the Medevac Legislation - Sarah Miller and Thomas Faunce

This article updates how Australia's national security concerns have intersected with the regulation of Australian medical practitioners in the area of mandatory, indefinite, administrative offshore detention of asylum-seekers. It outlines relevant recent decisions of the High Court, including dissenting opinions that such detention represents unconstitutional extra-judicial punishment with a primary deterrence aim. It evaluates recent amendments to the Australian Border Force Act 2015 (Cth) as well as exploring recent relevant legislation and administrative, political and judicial decisions made in both Papua New Guinea and the Republic of Nauru. It considers the Medical Evacuation legislation and the Australian Government's attempts to challenge judicial authority to transfer people off Nauru for medical treatment. The article concludes with an analysis of prospects for further Australian asylum seeker and refugee policy and legislative reform more coherent with basic principles of medical ethics and international human rights. ..... 742

#### ARTICLES

# Social Responsibilities of the Global Pharmaceutical Companies: Towards an Ethical Health Care Paradigm – Abhay Vir Singh Kanwar and Mia Mahmudur Rahim

Although the pharmaceutical industry is a multi-billion-dollar business, it fails to save the lives of millions. Astronomical drug prices are not just an economic problem that can be settled through clever marketing strategies but a significant ethical issue. This article delves into the ethical health care paradigm, which can supplant the present economistic paradigm. Grounded in the ethical-philosophical argument for recognising an individual's right to be healthy, it asserts the practical proposal of cost rationalisation and universal availability of essential and lifesaving drugs. This is achievable by supporting research and development funding for drug innovation by the business establishment, and as such falls 

# Legislative Capture: A Critical Consideration in the Commercial Determinants of **Public Health** – *Tony Brown*

Contemporary public health literature contains an increasing emphasis on the commercial determinants of health including the influence of unhealthy food, beverage and tobacco industries on government harm prevention policy agendas and global sustainable development goals. Effective capture by the industries of the crucial legislative process associated with the harm prevention initiatives would have a detrimental impact on public health. This article proposes a qualitative multi-spectrum prototype legislative capture test with broad application to a range of industries and jurisdictions at all levels of government where legislative capture may be suspected. It is predicated on a finding of significant encroachment of the public interest (PI) by special interest groups and reciprocating beneficial conduct between the lawmakers and the group. The test is populated from a

critical case study of key New South Wales (NSW) alcohol industry statutory amendments within a doctrinal and social inquiry/power framework. It relies upon parliamentary records and secondary data to analyse critically the 2015 "fit for purpose" (FFP) reforms to NSW alcohol supply laws and their consistency with the PI and other constitutional safeguards. It aligns the reforms with other research relating to the magnitude of alcohol and gambling industry political donations and the operation of the alcohol outlet post reform approval process. The application of the test to the case study finds that the 2015 FFP amendments are indicative of legislative capture and associated clientele corruption critical new considerations in the commercial determination of health. It also identifies the 

## Rational Social Impact Assessment of Alcohol Outlets: Slip Sliding Away – Alison Ziller and Tony Brown

In 2004 legislators in New South Wales relied on Australia's National Competition Policy to change the reason for determining alcohol outlet approvals from a "needs" to a "harm minimisation" basis. This was predicated on the application of a rational social impact assessment (SIA) process. Within a short time, however, the volume of liquor licence applications began to erode that intention and the delays that applicants encountered placed politicians under pressure to fast-track the process. Subsequent liquor legislation retained the statutory obligation on decision-makers to ensure no overall detrimental social impact associated with the approval of an alcohol outlet licence. However, legislative amendments to the approval process reduced the number and kinds of licences and authorisations to which the social impact test applied and encouraged other shortcuts which undermine the validity of these assessments. The resulting statutory approval system in practice relegates SIA to an exception rather than the rule and has revealed the relative weakness of SIA as a public health safeguard. 786

## Mandatory Welfare Drug Treatment in Australia – Allan Ardill

In 2017 and 2018 Australia almost implemented laws to require unemployed people to undertake mandatory drug testing and treatment. Debate about linking welfare with mandatory drug treatment suffers from the complexity and paucity of research specifically about the efficacy of mandatory welfare drug treatment. This allows the possibility for mandatory welfare drug treatment to remain on the political horizon. This article situates the Australian proposal to introduce mandatory drug treatment for the unemployed within the relevant research literature. It concludes that the literature shows there is little chance of efficacy if welfare is linked with mandatory drug treatment. Instead, cost ineffectiveness and perverse outcomes are more probable than treatment efficacy. 800

# A Cross-sectional Survey of Health Professionals' Attitudes toward Medicinal Cannabis Use as Part of Cancer Management – Denesh Hewa-Gamage, Sarah Blaschke, Allison Drosdowsky, Trista Koproski, Anna Braun and Steve Ellen

This study aimed to evaluate the attitudes of health professionals toward the use of medicinal cannabis as part of the management of patients with cancer. A prospective, cross-sectional study was conducted using an anonymous survey, emailed out to health professionals at a public metropolitan hospital in Australia. One hundred and thirty-five responses were received. 62% of survey respondents reported that patients inquire about medicinal cannabis. More than half of the health professionals stated being insufficiently informed about access to medicinal cannabis (74%), about its evidence base (59%), and about potential drug interactions (65%). Thirty-four percent would recommend medicinal cannabis to their patients with cancer, 20% would not, and 46% were unsure. Comments indicated concerns about lack of clinician knowledge, drug efficacy, side effects and drug interactions. The results show that health professionals feel insufficiently informed about

and education are required for health professionals to consider medicinal cannabis as part of care provided to their patients with cancer.	815
Outcome Bias in Clinical Negligence Medico-legal Cases – Thom Petty, Lucy Stephenson, Pierre Campbell and Terence Stephenson	
Independent medical experts provide reports in clinical negligence claims brought against doctors and other health care professionals. They are asked to provide an opinion on whether the doctor has breached their duty of care to the patient, commonly described as the "Bolam Principle". By the time a patient litigates against a health care professional, the clinical sequence and outcome are known. Experts provide their opinions with the benefit of this knowledge. To determine whether knowledge of the outcome affects the expert's opinion, 42 independent general practice experts were asked to indicate whether a general practitioner had breached their duty of care in six clinical case scenarios. 21 were told the clinical outcome. Experts who knew the outcome were less likely to support the general practitioner's course of action, although this did not reach statistical significance. General practitioners demonstrated considerable "dove" or "hawk" variability when giving opinions on the same scenario.	825
Occupational Therapy Domestic Needs Assessment: Lawyer Perspectives – Susan Arnold, Lynette Mackenzie, Michael Millington and Carole James	
Occupational therapists are experts in understanding the impact an injury has on a claimant's capacity to perform their pre-injury level of domestic activities. Lawyers use this information when litigating claims for domestic assistance support. This is the first study exploring lawyers' experiences with occupational therapy domestic assistance reports using an online survey. The online survey was completed by 20 lawyers who practise in New South Wales, Australia. Results indicated occupational therapy reports were used to determine the amount of gratuitous domestic care the claimant received, the impact injury has on daily function and tasks requiring assistance. Lawyers used therapists with medicolegal experience although the timeframe for receiving the report was also influential. A high-quality report uses supportive evidence linking function and recommendations for care. Therapists require a clear understanding of the legislation and transparent reasoning while lawyers need to provide sufficient information to assist therapists' conclusions	831
Retained Surgical Items: Lessons from Australian Case Law of Items Unintentionally Left Behind in Patients after Surgery – Tina Cockburn, Juliet Davis, and Sonya Osborne	
The retention of items within a patient after surgery is considered to be a serious issue within the health care community. Termed a "sentinel event", a retained surgical item (RSI) is one of eight reportable adverse events deemed to have the potential to seriously undermine the health care system in the eyes of the public. Yet despite the gravity of these events, there has been little opportunity for the courts to examine the liability issues surrounding RSIs. This article reviews the limited case law in this area and analyses the key legal issues which arise in claims for redress, including civil, criminal and disciplinary liability, involving those who have suffered harm from RSIs.	841
Understanding Client Vulnerability in the Disciplining of Legal Professionals in New South Wales – Jennifer Schulz-Moore, Kate Diesfeld and Christine Forster	
Despite the increasing use of "vulnerability" in policy and legal documents, and the emerging scholarly literature about vulnerability and the law, there is little research focused on vulnerability from clients' perspectives. To address this gap, we analysed the	

access to, and use of, medicinal cannabis as part of cancer management. More information

New South Wales Civil and Administrative Tribunal (NCAT) and appellate court cases involving vulnerable clients and disciplined lawyers in NSW from 1 January 2011 to 30 January 2019. Our analysis of the cases draws from the "vulnerability theory" literature. We identified the following characteristics of clients for analysis: older age, gender, health impairment, and immigrant status. Twenty-eight tribunal cases and two appellate court cases involved vulnerable clients. Overall, the cases revealed that the relationship between public protection and vulnerability is not expressly discussed by NCAT. To optimise the legislative intent to safeguard the public, the NSW legislation should explicitly include vulnerability as a relevant feature of the disciplinary regime. 849

# Dealing with Patent Fragmentation in Genetics: Can Patent Pools Facilitate the Development of CRISPR Gene-Editing Technology? - Alessandro Stasi and Isabel Pereira Rodrigues

The discovery of CRISPR systems has been one of the most exciting developments in the field of genetics in the past decade. The recent proliferation of intellectual property rights for CRISPR genome editing technology carries the risk of potential bottlenecks for further basic biological research and development of commercial products. To make CRISPRbased technology widely available, the reliance by the industry on efficient methods of collective management of intellectual property rights through patent pools seems inevitable. A packager of patent pools could be used as a mechanism to facilitate transactions in the market for technology and allow interested parties to deal with a single entity. This article argues that, while a global licensing platform could be effectively achieved in nontherapeutic applications of genome editing, it is questionable whether patent pooling would provide the ideal balance of incentive and reward for CRISPR genome editing technologies for human gene therapy. 866

# Considering the Provision of Growth Attenuation Treatment to Profoundly Disabled Children in Light of the Family Court's Welfare Jurisdiction – Elpitha (Peta) Lee Spyrou

Internationally, profoundly disabled children have received growth attenuation treatment to allow their parents to continue to care for them as they mature into adulthood. This article considers how the Family Court of Australia might approach this topic. It assumes that parents wishing to attenuate the linear growth of their child require an order from the Family Court under its welfare jurisdiction. This assumption is made because of the parents' conflict of interests; the treatment's irreversible nature; and the fact that it is sought for non-Gillick competent children. This article highlights the view that there are concerns about how the Court, given its adversarial nature and current approach to medical decisions, will determine whether this treatment is in a child's best interests. It concludes that a federally funded interdisciplinary administrative panel is better positioned to assess and decide each application on a case-by-case basis. 874

#### Advance Care Planning: A Communitarian Approach? – Tracey Evans Chan

This article examines the evolution of advance care planning (ACP) in Singapore through the development of a less-formal, communications-based model – the Living Matters program – and its experience with local cultural and community responses to the process and its outcomes. Living Matters is, in practice, arguably a communitarian approach to ACP. The article then examines the challenges Living Matters poses to the overarching legal framework for ACP and suggests improvements to the proxy decision-making framework under the Mental Capacity Act (Singapore, cap 177A, 2010 rev ed), offering more flexible legal tools for ACP, and more regulatory support for the means to implement ACP outcomes effectively. 896

Teachers' Health, Wellbeing and Professional Misconduct. An Exploratory Analysis of Cases from New Zealand's Teachers Disciplinary Tribunal 2017–2018 – Marta Rychert and Kate Diesfeld

Teachers' professional misconduct is rarely researched but of great public concern, given the potential impact upon students. Further, international concern has been expressed regarding teachers' wellbeing, including their working conditions. This study investigates the relationship between teachers' wellbeing and professional misconduct. We conducted a thematic analysis of disciplinary cases from the New Zealand Teachers Disciplinary Tribunal (NZTDT) between 2017 and 2018. Of the 41 disciplinary decisions from this period, 34 included references to teachers' health and wellbeing, including psychological stress at work and in their personal lives; psychiatric diagnoses; use of alcohol and other drugs; and emotional maturity. Breach of professional boundaries and inappropriate use of force were the leading reasons for discipline. The analysis illuminates a complex relationship between teachers' wellbeing and discipline, whereby diminished wellbeing may contribute to misconduct and be further affected by the disciplinary proceedings. Preventive strategies could include health-based interventions as part of professional development. 922

#### Decisional Competence and Fitness to Stand Trial in New Zealand – Brent Hyslop

New Zealand courts are increasingly finding people unfit to stand trial. It is therefore important that the topic is carefully explored. For instance, should an assessment of fitness to stand trial include an assessment of a person's ability to make autonomous decisions about how to conduct their defence? This ability is referred to as "decisional competence". A pivotal case on this issue is Solicitor-General v Dougherty [2012] NZCA 405. In this case, the Court of Appeal decided that an assessment of decisional competence should not be part of an assessment of fitness to stand trial, but in doing so, appeared to misunderstand the concept. This article aims to discuss a correct understanding of decisional competence, in particular by contrasting it with the notion of "acting in one's best interests". This will aid further discussion on this important and relevant issue. 943

#### **OBITUARY**

Thomas Alured Faunce (1958–2019	)	949

#### **BOOK REVIEW**

Defeating the Ministers of Death; The	Compelling History of Vaccination, by David	
<b>Isaacs</b> – Reviewed by Ian Freckelton QC		951

**VOLUME 26 – 2018–2019** 

Table of Authors	957
Table of Cases	969
Table of Statutes	983
Index	007