JOURNAL OF LAW AND MEDICINE

Volume 29, Number 3

2022

EDITORIAL

Vaccinating Children: The COVID-19 Family Law Jurisprudence – *Ian Freckelton AO QC*

Australian, New Zealand, English and Canadian courts have made a number of orders, often in the context of parenting disputes, requiring children to be vaccinated. Complementary therapy options have generally not been permitted as an alternative to mainstream vaccination. Debates about parental entitlements to make decisions about such matters have taken place in the context of contested family law litigation during the COVID-19 era. However, by contrast with Ontario Superior Court of Justice decisions in 2022, a series of Australian decisions, including the judgment of Sutherland CJ in *Clay & Dallas* [2022] FCWA 18, have developed the law further, having regard to both the capacity of a minor to consent to vaccination and reviewing a variety of factors going to children's best interests at different junctures during the pandemic, finding it generally to be in the best interests of children to receive COVID-19 vaccinations. This is likely to flow back into curial decision-making about vaccinations more broadly, as well as cognate matters. 645

LEGAL ISSUES – *Editor: Charles Lawson*

The COVID-19 Pandemic and the TRIPS Waiver: Patents and Flexibility – *Charles Lawson and Michelle Rourke*

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides for global minimum standard patents. These patents potentially limit access to products and processes for the surveillance, tracking, diagnosis and treatment of COVID-19. A possible solution currently under consideration is a TRIPS waiver of the implementation, application and enforcement for the prevention, containment or treatment of COVID-19. This article addresses the ways that TRIPS patents might be mediated including through TRIPS flexibilities. The article argues that there are sufficient means of derogating from patents (and potentially copyright, industrial designs and undisclosed information), although they alone will not resolve the access problems. The article concludes that the key patent problem is the transfer of know-how and that developing new ideas about addressing these patent know-how transfers is the presently unaddressed challenge. 663

MEDICO-LEGAL ISSUESMEDICO-LEGAL ISSUES – *Editor: Cameron Stewart*

A New Priority Pathway for Biologicals in Australia: Contextualising and Evaluating the Proposed Reforms – *Christopher Rudge, Sara Attinger, Ian Kerridge, Wendy Lipworth and Cameron Stewart*

This section examines recent reforms to the regulatory framework for biologicals contained in the *Therapeutic Goods Act 1989* (Cth) in the context of the "New Frontier" of reform envisioned in a report completed by the Commonwealth Government in 2021. It compares Australia's proposed reform of the approval processes for biologicals to similar reforms that have been made over the last three decades in the United States and the European Union. It places the Australian reforms in the context of the commercialisation of regenerative

medicine and identifies several potential shortcomings of the proposed reforms and reports on the current lack of data on the processes of expedited approvals in Australia more generally. 677

MEDICAL ISSUES – *Editor: Mike O'Connor*

Batting below Average: Failure to Manage Fatal Zoonotic Diseases – *Mike O'Connor*

Zoonotic diseases are those which originate in animals but are transmitted to humans often through an intermediate host such as a wild animal. In Australia Hendra virus (HeV) is a disease of horses with occasional human fatalities and which is spread by the fruit bat. This article explores the lessons learnt from managing the Queensland outbreak of HeV in 1994. The legal framework for the notification and management of prohibited matter including zoonotic diseases in Queensland and New South Wales has been strengthened by provisions in the *Biosecurity Act 2015* (NSW) which create strong penalties for failure to notify outbreaks and failure to isolate infected stock and prevent their removal from premises within 24 hours. The response of at least 20% of Queensland equine veterinarians to the new legal obligations has been to cease practising equine medicine. There may be scope for enhanced education of veterinary students in legal obligations under the biosecurity legislation. 700

MENTAL HEALTH LAW ISSUES – *Editor: Bernadette McSherry*

Seizures, Postictal States and Criminal Responsibility – *Bernadette McSherry and Mark Cook*

This column provides an overview of how courts have taken into account seizures and postictal states in terms of assigning criminal responsibility. In England, New Zealand and Australia, courts have generally treated evidence of epileptic seizures and postictal states as raising the defence of mental impairment which often results in indefinite detention. In comparison, there is a series of Canadian cases that have resulted in acquittals after evidence of seizures has been accepted as negating voluntariness or the fault element of the offence. It appears that policy issues have been influential in the Canadian cases, particularly a reluctance to equate epilepsy with "mental disorder". 707

ARTICLES

A Survey of Australian Hospital Pharmacy Staff Knowledge, Practices, and Assessment of Animal-derived Medications – *Jeanie Misko and Emma Fox*

This study aims to determine the knowledge and practices of Australian hospital pharmacy staff regarding animal-derived ingredients in medications and reviewing whether commonly used medications contain animal-derived ingredients. The study surveyed 67 pharmacy staff and reviewed 20 medications. Ninety-eight percent of staff were aware patients may have religious or cultural restrictions on ingesting animal-derived products; 33% discussed this issue with patients. Information on animal-derived ingredients was readily accessible for 1.6% of medications, with information unavailable for 14%. Staff demonstrated awareness that medications may contain animal-derived ingredients, but challenges exist in discussion with patients and in accessing information on animal-derived ingredients. ... 714

Uniquely You, Uniquely Yours? Applying the Current Property Law Regime to Human DNA Samples – *Estelle Sah*

Rapid developments in biotechnology have brought questions regarding ownership of human genetic material to the forefront of the public conscience. This article aims to determine the current approach of Australian and United Kingdom courts to property

disputes regarding human biological material and adjudicate its relevance in the context of human deoxyribonucleic acid (DNA) ownership. Following initial exploration of the question of whether DNA ought to be considered an object of property, it argues that the dominant approach established by the landmark decision of *Doodeward v Spence* (1908) 6 CLR 406 is weaker than the newer "guided discretion" basis in the DNA context. It concludes this latter approach is far better equipped to respond to key policy concerns associated with recognising property rights in DNA. 725

How Australia's Policymakers Can Ethically Approach Human Germline Genome Editing Technology – *Matthew Mangiapane and Patrick Foong*

This article undertakes an analysis of Australia's laws affecting human germline genome editing (HGGE). It draws on research from various ethical frameworks to analyse the values underpinning existing policy and which could underpin future approaches on HGGE. The article emphasises the importance of protecting egalitarianism, mitigating inequality risks, and ensuring stigmas around people with genetic conditions targeted by HGGE are not perpetuated. Doing so makes the philosophical case for a policy allowing HGGE for research use and considers the potential for limited clinical uses as we advance. The article recommends law reform in Australia in the form of an ongoing legislative review every three years, with the first review considering research and informed consent. The second considers appropriate clinical uses based on medical risk and what is agreed upon to be a list of considerations of a severe enough disease to be treated by HGGE. It gives examples of what the reform might look like, pending public engagement methodologies advocated. Finally, this article recommends considering ancillary legal issues raised by HGGE, including anti-discrimination and potential protections from liability. 740

Justice for Our Genes: The Case for Genetic Non-discrimination Regulations in the New Zealand Life Insurance Industry – *Emily Buckenham Boyle*

While most comparable jurisdictions have adopted more restrictive positions, life insurers in New Zealand remain permitted to request the disclosure of predictive genetic test results from applicants, driving up the cost to obtain life insurance for those with known susceptibilities to genetic disease. The permissive approach is now an outlier, and risks disincentivising health care and research innovation, facilitating irrational discrimination, and compounding existing health inequities. This article examines the New Zealand position through a consequentialist lens. It analyses justifications for the status quo, as well as international approaches, before concluding that genetic non-discrimination regulations governing New Zealand's life insurance industry should be introduced to enhance public wellbeing. 760

Mapping the Legal Regulation of Voluntary Assisted Dying in Victoria: The Coherence of a New Practice within the Wider Legal System – *Ben P White, Katrine Del Villar, Lindy Willmott, Eliana Close and Ruthie Jeanneret*

This article undertakes the first comprehensive mapping exercise of the legal regulation of voluntary assisted dying (VAD) in Victoria. Despite the detailed nature of the *Voluntary Assisted Dying Act 2017* (Vic), this analysis reveals that VAD is also regulated by a diverse array of other law: a further 20 pieces of legislation and 27 broad areas of law. In some instances, this legal regulation beyond the principal VAD legislation is significant for how the VAD system operates in practice. The article then identifies the implications of this mapping exercise for the coherence of the law, focusing in particular on the domains of consistency, comprehensiveness, and completeness. Findings include identifying areas of significant incoherence and the implications of this for law reformers, policymakers, and users of the law, including patients, families, health practitioners, and health service providers. 783

Assisted Deaths Prior to the Voluntary Assisted Dying Act 2017 (Vic): Would Patients Have Met the Eligibility Criteria to Request Voluntary Assisted Dying? – *Lindy Willmott, Rachel Feeney, Katrine Del Villar, Kenneth Chambaere, Patsy Yates, Geoffrey Mitchell and Ben White*

Unlawful assisted dying practices have been reported in Australia for decades. Voluntary assisted dying (VAD) is now lawful in Victoria and Western Australia in limited circumstances and will soon be lawful in a further four Australian States. This article examines nine cases involving unlawful assisted dying practices in Victoria in the 12 months prior to the commencement of the *Voluntary Assisted Dying Act 2017* (Vic) in 2019. It explores whether, if that Act had been in operation at the relevant time, these patients would have been eligible to request VAD, having regard to their decision-making capacity and their disease, illness or medical condition. Many of these patients would not have been eligible to request VAD had the legislation been operational, primarily because they lacked decision-making capacity. As VAD is lawful only in a narrow set of circumstances, unlawful assisted deaths may continue to occur in those States where voluntary assisted dying is legal. 811

Personal Importation and the Law: Protecting Patients Who Import Medicines for Legitimate Health Care Needs – *Narcyz Ghinea*

Australians who cannot access medicines locally are able to find most medicines for sale online. Australia's therapeutic goods legal regime permits individuals to purchase medicines directly from overseas suppliers via the Personal Importation Scheme. Individuals can either import medicines for their own use or that of an immediate family member. For some patients, importing medicines is the only way they can access the medicines they need due to lack of availability or affordability in Australia. This article analyses the therapeutic goods law to clarify offences that may apply to those who import medicines for their own use or that of an immediate family member. Considering the findings, legislative amendments are recommended for the purpose of protecting patients who import medicines for legitimate health care needs. 829

Regulating Health Care Safety: Enforcement and Responsibility Attribution in Response to Iatrogenic Harm – *David J Carter, Adel Rahmani and James J Brown*

The regulation of health care safety is undertaken in the name of the public and is motivated and justified by their protection. This regulatory action generates debate concerning the proper limits of responsibility attribution and enforcement, while the actions and opinion – both imagined and real – of the public loom large in this field. However, there exists limited knowledge of public opinion on key aspects of health care safety enforcement and responsibility attribution following iatrogenic harm. This article reports on the results of a survey-administered experimental study to determine how the Australian general public attributes responsibility, moral censure and enforcement actions in the event of health care safety failures in hospital and outpatient settings. The study provide evidence that the general public are sensitive to corporate and individual sources of error; attribute responsibility in a pluralistic manner; differentiate between recklessness and negligence; and will attempt both formal and social enforcement actions in response to harm. 847

Digital Colonialism and the Fourth Industrial Revolution – Preventing Exploitative Bio-economies – *Alessandra Marshall*

As the traditional use of non-human genetic resources in research and development is increasingly ceded to computerised research activities, current frameworks for access and benefit-sharing face an impending identity crisis. The absence of international consensus on the regulation of digital sequence information presents a critical point of social division

between the Global North and Global South, whereby a culture of "open data" promises immeasurable opportunity in high-income nations and threatens a wave of digital bio-piracy for vulnerable communities. This article critically evaluates these problems and considers solutions which draw on Indigenous Data Sovereignty principles. To do so, it uses the recent experience in Queensland to explore how the law might reconcile and balance these competing interests. Insofar as Queensland is one of the most mega biodiverse regions on earth, boasts a globally competitive life sciences sector, and has a vibrant and longstanding Indigenous population, it offers a unique case study. 866

Is PTSD a Bodily Injury? – *Jacqueline Condon, Cameron Stewart and Cherrie Galletly*

Post-traumatic stress disorder (PTSD) is unique among psychiatric disorders in that the cause, a traumatic event (or events), is known. PTSD is often the subject of legal proceedings, seeking with persons compensation from the agency considered responsible for the trauma. While PTSD is clearly a psychiatric disorder, there is less agreement about whether PTSD can also be categorised as a bodily injury, as defined by the Montreal Convention 1999. This article describes *Pel-Air Pty Ltd v Casey*, a case involving physical and psychiatric injuries resulting from the forced landing of a plane. It was ruled that PTSD was not a bodily injury under the Convention. While psychiatric expert evidence demonstrated that PTSD causes neurochemical changes, it was ruled that neurochemical changes do not indicate a bodily injury. We describe evidence of neuroanatomical changes and neurochemical changes in PTSD, proposing that the structure of the brain in PTSD support the argument that PTSD is a bodily injury. 888

Professional Discipline for Vaccine Misinformation Posts on Social Media: Issues and Controversies for the Legal Profession – *Marta Rychert, Kate Diesfeld and Ian Freckelton AO QC*

Misinformation has challenged the rollout of COVID-19 vaccination around the world. In 2021, professional bodies for several regulated occupations (including doctors and lawyers) initiated investigations into the conduct of members who engaged in vaccine misinformation, including on social media. This commentary discusses key controversies surrounding this novel disciplinary issue, with the focus on the legal profession in New Zealand and Australia. We consider the difficulties of defining "vaccine misinformation", differentiating between public and private social media use, giving proper scope to rights of free speech, and challenges in identifying financial conflicts of interest and unethical client solicitation practices (eg, profiting from spreading vaccine misinformation). The chilling effect upon freedom of expression when lawyers are disciplined for their social media posts that are deemed unscientific is discussed. 895

Prolonged Solitary Confinement (Administrative Segregation) and the Human Rights of a Serving Prisoner – *Joseph Briggs and Russ Scott*

Solitary confinement is the harshest method of social control that can be applied to a prisoner. There is considerable research which establishes that prolonged solitary confinement may have profoundly negative effects. The United Nations Standard Minimum Rules for the Treatment of Prisoners (the "Mandela Rules") stipulate that solitary confinement should only be used "in exceptional circumstances as a last resort for as short a time as possible" and that solitary confinement should be "subject to independent review and only pursuant to the authorization by a competent authority". In *Owen-D'Arcy v Chief Executive, Queensland Corrective Services* [2021] QSC 273, a prisoner had spent over six and a half years in continuous solitary confinement. The Queensland Supreme Court held that the decision to continue the solitary confinement was not compatible with the prisoner's human rights pursuant to s 30 (humane treatment when deprived of liberty) of the *Human Rights Act 2019* (Qld). 904

Climatic, Environmental and Health Impacts of Disused Coronavirus Protective Equipment: Towards Effective Regulatory and Containment Measures – *Cosmos Nike Nwedu*

Though global health care delivery systems have been under inevitable pressure and risks from the ongoing coronavirus disease (COVID-19) pandemic, our natural human environment is also increasingly threatened. The reason is that efforts to contain the pandemic have resulted in a vast generation of medical waste from disused personal protective equipment, such as facemasks, face-shields, hand-gloves, hand-sanitisers, and related single-use products. Unprofessional management of medical waste can result in environmental contagion. This article, adopting an analytical approach, argues that COVID-19 waste represents a mode of contagion, and hence demands special regulatory attention, management, and disposal procedures at all levels of governance. The article offers an epidemiological perspective on COVID-19 waste and its place in medical waste. It provides insights into the best practices for managing COVID-19 waste and examines how global objectives and frameworks visibly support COVID-19 medical waste management globally. 943

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