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EDITORIAL – *Editor: Ian Freckelton AO KC*

Cystic Fibrosis and the Law: The Ramifications of New Treatments – *Ian Freckelton AO KC*

Until the discovery of the gene for cystic fibrosis (CF) in 1989, diagnostic developments were limited, and treatment focused on symptom alleviation. However, following the genetic breakthrough, some 2,000 mutations of the gene have been identified. More recently CF transmembrane conductance regulator modulator triple therapy (CFTRm) has been introduced in the form of triple therapy with ivacaftor, lumacaftor and tezacaftor (ETI), in the United States from 2019, Europe from 2020 and then Australia from 2021. The new treatment option has revolutionised both the quality of life and life expectancy of many persons diagnosed with CF. This editorial reviews major developments in the clinical care that can now be provided to patients, and reflects on the legal and ethical ramifications of the improved situation for many patients in the contexts of medical negligence, damages assessment, family law and criminal law. It also considers the difficult issues of access and equity caused by the limited availability of the triple therapy in low- and middle-income countries. 217

HEALTH LAW REPORTER – *Editor: Cameron Stewart*

Challenging Pandemic Law: From Vaccine Mandates to Judicial Review of Vaccine Approvals – *Christopher Rudge*

Over recent years, dozens of legal challenges have been instituted in response to government action during the COVID-19 pandemic. While public health orders have been challenged on several grounds, few cases have succeeded. Fewer cases still have called into question decisions made by the Therapeutic Goods Administration (TGA) to approve the COVID-19 vaccines. This section provides a brief update on one recent, partially successful COVID-19 health directions case before examining two applications in the Federal Court of Australia seeking judicial review of the TGA's approval of the COVID-19 vaccines. The section argues that, while both TGA applications were dismissed for lack of standing, they illustrate how and why third parties will ordinarily not be entitled to challenge administrative decisions about therapeutic goods. 225

LEGAL ISSUES – *Editor: Malcolm Smith*

Recent Australian Legislative Developments in the Regulation of Assisted Reproductive Technology – *Malcolm Smith*

This section considers the recent resurgence of regulatory interest in the field of assisted reproductive technology (ART) practices focusing on the new legislative framework in the Australian Capital Territory (ACT). It provides an overview of the Australian regulatory framework in this field and considers how the new legislation in the ACT sits alongside this framework. A detailed overview of the key provisions of the ACT legislation is provided, before considering whether the legislation goes far enough in addressing some of the more controversial issues in the field of ART. 244

GENOMIC LAW ISSUES – *Editor: Dianne Nicol*

Moving Genomics into the Clinic: Platforms for Implementing Clinical Genomic Data-Sharing in Ways That Address Ethical, Legal and Social Implications – *Dianne Nicol, Margaret Otlowski, Keeley Reade, Natalie Thorne and Clara Gaff*

This section explores the challenges involved in translating genomic research into genomic medicine. A number of priorities have been identified in the Australian National Health Genomics Framework for addressing these challenges. Responsible collection, storage, use and management of genomic data is one of these priorities, and is the primary theme of this section. The recent release of Genomical, an Australian data-sharing platform, is used as a case study to illustrate the type of assistance that can be provided to the health care sector in addressing this priority. The section first describes the National Framework and other drivers involved in the move towards genomic medicine. The section then examines key ethical, legal and social factors at play in genomics, with particular focus on privacy and consent. Finally, the section examines how Genomical is being used to help ensure that the move towards genomic medicine is ethically, legally and socially sound and that it optimises advances in both genomic and information technology. 258

ARTICLES

Insight and the Capacity to Refuse Treatment with Electroconvulsive Therapy – *Russ Scott and Steve Prowacki*

All Australian jurisdictions have statutory provisions governing the use of electroconvulsive therapy. Cases in which the patient lacks insight into their psychotic illness and need for treatment and refuses to have ECT are particularly poignant. In *Re ICO* [2023] QMHC 1, the Queensland Mental Health Court considered whether a patient with a treatment-resistant psychotic illness had decision-making capacity to refuse ECT. The Court also considered whether the patient had been provided with an adequate explanation of the proposed treatment including the expected benefits, risks and adverse effects of ECT. As well as deciding whether ECT was appropriate in the circumstances, the Court considered whether there were alternative treatments including another trial of the oral antipsychotic clozapine. This article reviews issues relating to lack of insight in persons with psychotic illness and relevant considerations for determining ability to decline ECT. 273

Informed Consent and the Duty to Warn: More than the Mere Provision of Information – *Rajesh Gounder*

Before providing any form of medical treatment, medical practitioners are generally required to discharge their duty to warn. It is argued in this article that the duty to warn, at least as it relates to frail and elderly patients, requires the principles of shared decision-making to be adopted. Doing so will ensure a comprehensive biopsychosocial understanding of the patient and assist in identifying material risks that may not be readily apparent. Such risks include risks that threaten the patient's values, preferences, treatment aims and long-term outcomes. Once such risks are identified, in discharging the duty to warn, they should be contextualised in a manner that makes clear how that risk will manifest in that particular patient. These risks should then also be synthesised within the context of their other medical issues and longer-term interests. Finally, it is suggested that the traditional consent process may need restructuring. 324

The Commonwealth Criminal Code: Will It Restrict Access to Voluntary Assisted Dying in South Australia And Is There a Way Forward? – *Julia Matteo and Michaela Okninski*

South Australia's Voluntary Assisted Dying Act 2021 commenced operation on 31 January 2023. However, ss 474.29A and 474.29B of the *Criminal Code Act 1995* (Cth) prohibit the use of "carriage services" to promote or provide instructions about suicide and may impede access to voluntary assisted dying (VAD). Attempts to clarify whether VAD is suicide have been unsuccessful and doctors risk prosecution if they use telehealth to participate in VAD. This article examines specific steps in the VAD pathway that are likely to breach the federal law. Although there have been attempts to clarify what information can permissibly be discussed using a carriage service, doctors risk breaching the federal law at multiple stages of the VAD process. This article concludes arguing that this conflict of laws must be resolved and calls upon the Commonwealth Government to amend the Criminal Code to exclude VAD from the definition of suicide. 343

Virtual Labs and Designer Bugs – Generative AI, Synthetic Biology and National Security – *Brendan Walker-Munro*

AI technologies can pose a major national security concern. AI programs could be used to develop chemical and biological agents which circumvent existing protective measures or medical treatments, or to design pathogens with capabilities they do not naturally possess (gain-of-function research). Although Australia has a strong legislative framework relating to research into genetically modified organisms, the framework requires the interaction of more than 10 different government departments, universities and funding agencies. Further, there are few guidelines about the responsible use of AI in biological research where existing laws and policies do not apply to research that is conducted "virtually", even where that research may have national security implications. This article explores these under-scrutinised concepts in Australia's biological security frameworks. 353

Safe Access Zone Legislation and Its Compliance with the Human Rights of Anti-Abortion Protesters in Australia – *Kerstin Braun and Sarah Butcher*

Terminating a pregnancy is now lawful in all Australian jurisdictions, although on diverse bases. While abortions have not been subject to the same degree of heated debate in Australia as elsewhere, protests aimed at persuading women not to have a termination of their pregnancy have occurred outside abortion service providers in the past. Over the last decade, this has led to the introduction of laws setting out so-called safe access zones around provider premises. Anti-abortion protests are prohibited within a specific distance from abortion services and infringements attract criminal liability. As safe access zone laws prevent protesters from expressing their views in certain spaces, the question arises as to the laws' compliance with protesters' human rights. This article analyses this by considering the human rights compliance of the Queensland ban in light of Queensland human rights legislation. It concludes that the imposed prohibition of anti-abortion protests near abortion clinics is compatible with human rights. 370

Denial of Desire for Death in Dementia: Why Is Dementia Excluded from Australian Voluntary Assisted Dying Legislation? – *Amee Baird*

Euthanasia in the form of Voluntary Assisted Dying (VAD) is legal in all Australian States, but current eligibility criteria preclude access to people with dementia. This article discusses Australian VAD eligibility criteria that are problematic for people with dementia: (1) time until death within 12 months, (2) decision-making capacity for VAD,

and (3) determination of intolerable suffering. Legislation in the Netherlands allows VAD for people with dementia. The challenges and philosophical issues raised by such cases are explored. It is proposed that the unique nature of dementia in its various forms warrants the formulation of dementia-specific VAD eligibility criteria. A case could be brought to challenge the denial of access to VAD of people with dementia on the basis that their exclusion is discriminatory and an abuse of human rights. If such a challenge was successful, it could form a common law precedent to allow people with dementia access to VAD. 386

Media, Advertising and Inventing (Anna)rexia – *Rojina Parchizadeh and Marilyn Bromberg*

Too many Australians suffer from poor body image and eating disorders. The Israeli, French and Norwegian Governments have created body image legislation to try to address this: it responds to concerns that the countless images of thin women people see can contribute to poor body image. By contrast, Australia does not have a Body Image Law: it has a voluntary code that the advertising industry generally does not follow. This article argues that Australia should enact a Body Image Law that reflects health evidence that body image needs to be improved. The Body Image Law would require disclaimers on images that were not retouched, create a specialised government body to evaluate images and attract civil penalties for breaching it. The authors believe that this is the first Australian article to suggest an Australian Body Image Law of this kind. 403

Neurocognitive Disorders: Medical Illness or Mental Disorder: Examining the Mental Health and Wellbeing Act 2022 (Vic) Using Neurocognitive Disorders – *Rohan Wee*

Victoria has new legislation, the *Mental Health and Wellbeing Act 2022* (Vic) (MHWA) to govern the care and treatment of people with mental illness that came into effect on 1 September 2023. It takes a human rights approach with a focus on person-centred care. The definition of mental illness encompasses conditions such as dementia even though it is rarely used to manage such conditions. How would the management of dementia and associated conditions change if these conditions were managed under the MHWA? This article uses dementia to examine the differences between the new MHWA, the *Medical Treatment Planning and Decisions Act 2016* (Vic) and the *Guardianship and Administration Act 2019* (Vic) and how the human rights approach taken by the MHWA might inform future directions in managing dementia. 421

BOOK REVIEW

In Bad Faith, by Dassi Erlich – *Reviewed by Professor Ian Freckelton AO KC* 438