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EDITORIAL

COVID-19 as a Disruptor and a Catalyst for Change – Ian Freckelton AO QC

COVID-19 has profoundly and pervasively disrupted the world's health, economy, security and attitudes. It has caused us to rethink what is most important for us individually and collectively, what we must change to retain viability as a species and as a planet, and what values and public health infrastructures governments need to embrace to avoid the next pandemic. COVID-19 has given a fillip to "One Health", the "Global Virome Project" and other co-ordinated initiatives to address the risk of zoonotic spillovers of disease. We are challenged to become more responsible in our workplaces and in public spaces. We have learned to trust and mistrust our governments in times of crisis. Our awareness of public health and the importance of evidence-based foundations for treatment and disease-prevention has been changed. Remote health service provision has become part of the architecture of conventional health care. Hybrid-working will become standard. Masks have become conventional accessories in congregate environments. Our respect and compassion for our health practitioners has increased but at a terrible cost. We have been reminded of the importance of direct and tactile communication with those whom we love.

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LEGAL ISSUES – Guest Editor: Ian Freckelton AO QC

COVID-19 Denialism, Vaccine Scepticism and the Regulation of Health Practitioners – Ian Freckelton AO QC

During a pandemic such as COVID-19 fear, anxiety and paranoia can become prevalent within the community. Agnotology has taught us that in such times science denialism and vaccination scepticism can gain a foothold and discourage the undiscerning and the uninformed from receiving the treatment and prophylactic public health measures that are essential to community health and safety. When health practitioners endorse such attitudes they pose a serious risk to not only their patients but the whole community. This requires a robust response from health practitioner regulators, disciplinary tribunals and courts. This column identifies such a sensible and proportionate response from the Irish High Court in *Medical Council v Waters* [2021] IEHC 252 when a general practitioner's registration to practise was suspended for promoting such views. The decision, along with a comparable decision by the Victorian Civil and Administrative Tribunal in 2020 constitute potent international examples of a robust and commonsense regulatory endorsement of science during a time of public health crisis.

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MEDICAL ISSUES – Editor: David Ranson

Killing of Elderly Patients by Health Care Professionals: Insights From Coroners' Inquests and Inquiries in Three Cases – Jordyn Nelson, Joseph Ibrahim, Lyndal Bugeja and David Ranson

As the world's population ages, a question of who can be trusted to look after the increasing elderly population arises. Health care professionals are commonly considered

one of the group of people we entrust with our health care and maintenance of a good quality of life. Unfortunately, some abuse this trust. Harold Shipman, Elizabeth Wettlaufer and Roger Dean are three examples of health care professionals held responsible for multiple homicides of patients aged 65 years and older in their care. Harold Shipman, a United Kingdom doctor, is suspected of killing potentially 400 patients over 27 years. However, the true number may never be known. Elizabeth Wettlaufer, a Canadian nurse, admitted to killing eight patients over seven years and Roger Dean, an Australian nurse, killed 11 patients in one night by deliberately lighting a fire in a health care facility. The subsequent inquiry reports into their actions resulted in multiple recommendations which aimed to prevent similar occurrences and to protect the lives of this vulnerable cohort of people. These recommendations included restrictions on the hiring process of health care professionals and increasing the accountability of access to Schedule Eight drugs by doctors and registered nurses. The governments responsible for responding to the inquiry reports have done so in various ways, although not all recommendations have been implemented and some may not be practical with current residential care infrastructure provisions and requirements. More work is required to determine the types of countermeasures that could be implemented to protect the elderly from maverick health care professionals. 620

BIOETHICAL ISSUES – *Editor: Julian Savulescu*

Bell v Tavistock: Why the Assent Model Is Most Appropriate for Decisions Regarding Puberty Suppression for Transgender and Gender Diverse Youth – *Lauren Notini*

The decision of the High Court of England and Wales in *Bell v Tavistock* [2020] EWHC 3274 (*Admin*) raises important questions regarding best care for transgender and gender diverse (TGD) youth. In this section, I describe this case, its ruling, and its implications. The ruling is underpinned by the position that puberty suppression can only be ethically and legally permissible where the young person has not only provided their assent but has also been deemed capable to provide valid consent. I challenge this position on three grounds. First, it overlooks the key ethical question of whether puberty suppression is in the individual's best interests. Second, withholding puberty suppression until the young person can consent will likely result in harmful, irreversible consequences for them. Finally, puberty suppression is not sufficiently potentially harmful to justify the additional protection offered by requiring patient consent and court authorisation. For these reasons, I argue that an assent model should govern decisions about puberty suppression for TGD youth. 632

TECHNOLOGY HEALTH LAW ISSUES – *Editor: Bernadette Richards*

Regulation of AI in Health Care: A Cautionary Tale Considering Horses and Zebras – *Bernadette Richards, Susannah Sage Jacobson and Yves Saint James Aquino*

The introduction of Artificial Intelligence (AI) into health care has been accompanied by uncertainties and regulatory challenges. The establishment of a regulatory framework around AI in health is in its infancy and the way forward is unclear. There are those who argue that this represents a concerning regulatory gap, while others assert that existing regulatory frameworks, policies and guidelines are sufficient. We argue that perhaps the reality is somewhere in between, but that there is a need for engagement with principles and guidelines to inform future regulation. However, this cannot be done effectively until there is more clarity around the reality of AI in health and common misconceptions are addressed. This paper explores some of these misconceptions and argues for a principled approach to the regulation of AI in health. 645

Advance Planning in Mental Health Care: The Trouble with Terminology – Vrinda Edan, Bridget Hamilton and Lisa Brophy

Advance planning is increasingly being used in mental health care, particularly in the context of potential compulsory treatment. A variety of advance planning instruments may be used in health care settings and there has been confusion about the most appropriate language to describe them. This adds to confusion about whether an instrument is binding on health professionals or consumers and how the instrument might be disseminated. This column provides an overview and critique of current provisions in Australian law and of the key terms used. 655

HEALTH LAW REPORTER – Editor: Cameron Stewart

Posthumous Reproduction and the Law: Tissue Transplantation, Property Rights and the Reproductive Relational Autonomy – Cameron Stewart, Kelton Tremellen and Julian Savulescu

This paper examines the history of Australian superior court decisions on the retrieval of gametic material from deceased men. It examines the history of case law and legislation on the issue and then provides a summary of the current operative principles. The paper concludes with some reflections on the harms caused by posthumous retrieval of gametes, the role of property rights and the nature of reproductive autonomy. 663

ARTICLES

COVID-19 Tests the Limits of Biodiversity Laws in a Health Crisis: Rethinking “Country of Origin” for Virus Access and Benefit-sharing – Fran Humphries, Michelle Rourke, Todd Berry, Elizabeth Englezos and Charles Lawson

The COVID-19 pandemic raises serious questions about the operation of international agreements for accessing and sharing viruses potentially delaying emergency responses. The access and benefit-sharing (ABS) frameworks under the United Nations’ *Convention on Biological Diversity* and its Nagoya Protocol apply to the collection and use of the COVID-19 pathogen SARS-CoV-2. These frameworks aim to ensure countries of origin reap some of the benefits from the use of their resources. Using real-world examples, we demonstrate conceptual and definitional ambiguities relating to “country of origin” that make not only operationalising the ABS scheme for biodiversity conservation and sustainable use objectives difficult but may also undermine public health emergency responses. Understanding how COVID-19 fits (or does not fit) within ABS laws is a valuable exercise for international policy-makers trying to determine how best to operationalise pathogen ABS, an issue currently under examination at the World Health Organization and critical to responding to pandemics. 684

The Impact of COVID-19 on Fertility Treatment in Australia – Ronli Sifris and Karinne Ludlow

On 25 March 2020, as part of the Australian response to the coronavirus pandemic, all non-essential elective surgery was indefinitely suspended. This had an immediate impact on the provision of fertility treatment because the vast majority of fertility treatments were classified as non-essential. The suspension ended on 27 April 2020, although other restrictions continued. Between June and August 2020, we conducted semi-structured interviews to determine the impact of these initial regulatory responses to the pandemic on the provision of fertility treatment in Australia during two key periods: the suspension of non-essential surgery and the re-opening. Changes to the practice of fertility treatment

demonstrate the importance of planning for prioritisation and other matters to be addressed in preparation for possible future pandemics. 707

Chasing Immunity: How Viable Is a Mandatory COVID-19 Vaccination Scheme for Australia? – *Madeline Rohini Fisher*

When he first announced Australia’s acquisition strategy for the COVID-19 vaccine, Prime Minister Scott Morrison alluded to the possibility of a mandatory vaccination scheme. The statement was met with significant backlash and Mr Morrison promptly rescinded the statement focusing instead on his desire to reach high levels of voluntary vaccine coverage. Nevertheless, interesting legal questions about the possibility of mandatory COVID-19 vaccination arose. This article explores the possible legal frameworks for implementing a mandatory vaccination scheme in Australia as well as the associated ethical dilemmas. Furthermore, it argues that a mandatory vaccination scheme, while possible and arguably ethical, would have undesirable implications resulting in popular opposition and decreased compliance with other voluntary vaccines such as childhood vaccination and seasonal influenza. Consequently, a voluntary scheme based on incentives and transparent provision of information is much more likely to achieve the desired uptake. 718

Adolescent Gender Dysphoria and the Informed Consent Model of Care – *Patrick Parkinson AM*

The informed consent model of care for people who identify as transgender is predicated on the idea that a careful mental health assessment and a formal diagnosis of gender dysphoria are not necessary preconditions before starting a person on cross-sex hormones. This article considers the legality of the informed consent model in relation to adolescents under 18 in Australia in the light of the decisions of the Family Court in *Re Kelvin* (2017) 327 FLR 15; [2017] FamCAFC 258 (*Re Kelvin*) and *Re Imogen (No 6)* (2020) 61 Fam LR 344; [2020] FamCA 761. The approach taken by the Family Court is predicated on the treatment being a response to a clinically diagnosed disorder, diagnosed after proper assessment. *Re Kelvin* indicates that assessment and treatment should be conducted by a multidisciplinary team in accordance with internationally recognised standards and guidelines. For these reasons, practising under an informed consent model of care without a mental health assessment or working within a multidisciplinary team, is unlawful. 734

Australian Medical Device Regulation during COVID-19: Has the Australian Regulatory Framework for Medical Devices Been Effective during the COVID-19 Pandemic? – *Jeffrey J Brownscombe*

Medical device regulation was an important element of Australia’s response to COVID-19. Early policy initiatives included expedited assessments of COVID-19 diagnostic tests and enhanced communications and information provision. Emergency exemptions enabled continuity of supply of diagnostic tests and personal protective equipment including face masks, and formed part of contingency planning regarding ventilator capacity. A post-market review of face masks improved the quality of face masks included on the Australian Register of Therapeutic Goods, and prompted broader reforms for low risk (Class I) medical devices. Increased compliance activities and infringement notices focused particularly on importation and advertising issues. Medical device regulatory initiatives effectively aligned with broader public policy objectives and helped achieve crucial collaboration between government and industry. Australia’s principles-based regulatory framework adapted well to the challenges of COVID-19. 745

Concussion, Chronic Traumatic Encephalopathy, and the Legal Obligation of Sporting Organisations to be Informed of the Scientific Knowledge of the Day and to Warn of Material Risks – David Thorpe

Athletes, many comparatively young, are reported to have initiated legal action claiming their sporting organisation negligently failed to inform itself of the risk of chronic traumatic encephalopathy (CTE) and to warn its athletes of that risk when sufficient information to do so was available. This article considers the legal obligation of sporting organisations, perhaps through their medical staff, “to be informed” of the risk of CTE, to assess the risk, and to warn their athletes of that risk. The law pertaining to the “medical model”, adjusted as to expertise, is proposed as the most suitable test of liability for failure to be informed and to warn. On the basis that CTE is a malady caused by repetitive head trauma, this article argues that delays in acquiring knowledge and warning of the risk of CTE deny athletes the opportunity to make a timely response to the risk of cognitive harm. 760

Use of Personal Health Information under Consent – Exempt Circumstances for Research: Views of the Australian General Public – David J Carter

Many human research regulatory systems permit human research to be undertaken without first gaining informed consent. In the Australian context, a “waiver of the consent requirement” may be granted by a Human Research Ethics Committee where research would be otherwise “impracticable” and there is “no known or likely reason” for thinking participants would not have consented. In this article, results of a national survey of Australian adults are presented to illustrate the general public’s view of such “consent-exempt” research. The results show that despite strong support for medical research, the general public is deeply reticent regarding consent exemption. Moreover, the results indicate that members of the general public do not believe there is a general obligation to participate in research, that the threshold for accepting consent exemption on the basis of “impracticability” is very high, and presumed consent can only be relied upon safely as a justification in very limited circumstances. 780

The Role of Medical Evidence in Determining the Outcome of Medical Negligence Cases When Peer Professional Opinion Is Used – Hugh Platt

Important changes in civil liability laws arose from the *Review of the Law of Negligence in Australia* undertaken in 2002 (the Ipp Report). One key recommendation of this review was the introduction of a modification of the Bolam Principle: “Medical Practitioners will not be found negligent if the treatment provided is in accordance with a significant body of opinion in the medical profession.” This article examines the concept of practitioner competence in medical negligence cases. It also examines the diverse forms of medical evidence used and evaluates whether the changes in laws have altered the legal approach to the use of medical evidence in cases utilising peer professional opinion. This article argues that, despite the amendments in 2002, regulatory concepts of medical competence are little used by the courts. Peer professional opinion utilising medical evidence has played only a minor role in determining the outcome of medical negligence cases. 798

Role of Law in End-of-Life Decision-Making: Perspectives of Patients, Substitute Decision-Makers and Families – Lindy Willmott, Ben White, Rachel Feeney, Cheryl Tilse, Jill Wilson and Joanne Aitken

The law regulating medical end-of-life decisions aims to support patients to receive high-quality health care. It does so through ensuring treatment received reflects the person’s wishes and values and protecting health professionals who provide adequate pain and symptom relief even if that treatment may coincidentally hasten death. However, good decision-making is predicated by those involved, including patients themselves and those

supporting patients, being familiar with the law and the role it plays in the decision-making process. This article reports on a study exploring the role that law plays in end-of-life decision-making from the perspective of terminally-ill patients, their substitute decision-makers and family members. While participants' decision-making practices were often underpinned by a legal framework, the role of the law was largely invisible. Community education is needed for the public to know their legal rights and responsibilities, and to understand that the law plays a role in supporting end-of-life decision-making. 813

New Challenges to the Legal Definition and Medical Determination of Brain Death: A Multi-jurisdictional Approach – Cases from the United States, the United Kingdom, Canada and Australia – James Tibballs and Neera Bhatia

Legal definitions of death and its medical determination have been challenged in high-profile cases in several jurisdictions which define death as either cessation of all functions of the brain or only of the brain stem. Several patients diagnosed brain dead have recovered some vestigial brain activity. Plaintiffs, seeking to prevent withdrawal of life-sustaining treatment, have sought to prevent performance of the key test, the apnoeic-oxygenation test, because it can cause harm and as a medical procedure requires informed consent. Reform of the *American Uniform Determination of Death Act*, which resembles Australian legislation, has been proposed to include specification of the medical determination of death and lack of requirement of consent to conduct testing. In this article we consider cases and proposals for law reform, concluding that the Australian definition of brain death ought to be retained but that the apnoeic-oxygenation test should be abandoned in lieu of testing brain blood flow and that religious accommodation should be considered. 831

Murder (Infanticide) in Post-partum Depression: The Case of Akon Guode – Joseph Briggs and Russ Scott

In 2015, 35-year-old Sudanese refugee Akon Guode had post-traumatic stress disorder and a post-partum depression when she drove her vehicle into a lake in a murder (infanticide, filicide)–suicide attempt. In 2017, Ms Guode pleaded guilty to two counts of murder, one count of attempted murder and one count of infanticide and was sentenced to 26 years' imprisonment. In August 2019, the Victorian Court of Appeal found the original sentence was "manifestly excessive". In March 2020, a majority of the High Court found that the Court of Appeal erred by taking into account that the Crown had accepted Ms Guode's plea of guilty to the charge of infanticide. The High Court quashed the sentence. In September 2020, the Court of Appeal imposed the same 18-year sentence and the same non-parole period as in August 2019. This commentary considers the application of the defences of "infanticide" and "mental impairment" and 'fitness for trial' in post-partum depression and PTSD. 855

Causes of the Obesity Epidemic and Economic Rationales to Support Taxation as a Population-based Policy Response – Lidia Xynas

This article examines the diverse and sometimes debatable underpinning causes of the growing obesity epidemic both in Australia and globally in order to provide a background that supports and legitimises the implementation of population-based strategies to address the associated negative impacts. Particular focus is given to the consumption of Highly Processed Foods, and Sweetened Sugary Beverages, and the impact that the over-consumption of these products has on obesity and overweight issues for individuals and broader society. In order to address and mitigate against the negative consequences that emanate from the consumption of such products for both individuals and for broader

society, taxation, as one population-based initiative that policymakers can implement is explored by reference to economic based theories. These include the Consumer Choice Constraint Theory, the Indifference Curve approach and the Pigouvian Theory of taxation. These economic theories provide a supportive basis upon which policymakers can effectively implement such an approach. 883

BOOK REVIEW

The Lost Lovelies Foundation, by Beth Wilson 905

