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EDITORIAL

Human Challenge Trials: Ethical and Legal Issues for COVID-19 Research – Ian Freckelton QC

COVID-19 has generated a new and distinctive focus on the use of human challenge studies, also known as controlled human infection trials. The first such trial was authorised in England in February 2021. Although vaccines are now available for COVID-19, there remain multiple deficits in knowledge in respect of treatment and prevention of the infection and a powerful impetus for solutions given the level of its global morbidity and mortality. Thus, there are potent incentives for unorthodox acceleration of medical knowledge but against these must be balanced ethical and pragmatic considerations. This editorial adds to the literature on such issues by reflecting on the ethical principles that are applicable and identifying the arguments that have been mustered for and against human challenge studies in relation to COVID-19. It argues that, given the limited state of knowledge about the diverse and longer term risks from contraction of COVID-19, considerable care needs to be devoted to any assessment of the appropriateness of human challenge trials to test treatments for the disease or measures to prevent contracting the virus. 311

LEGAL ISSUES – *Guest Editor: Ian Freckelton QC*

Sex Therapy as a Reasonable and Necessary Support for Persons with a Disability – Ian Freckelton QC

Historically, there has been inadequate recognition of the need for persons with disabilities to have the opportunity for meaningful sexual expression. Many impediments lie in the way of such recognition and, for some with a disability, professional assistance is required. In a precedent-setting decision by the Full Court of the Federal Court of Australia (*National Disability Insurance Agency v WRMF* (2020) 378 ALR 449; [2020] FCAFC 79) a woman with multiple sclerosis who had been accepted onto the National Disability Insurance Scheme was affirmed to be eligible for taxpayer-funded receipt of services from a sex worker, in spite of the National Disability Insurance Scheme having declined such services as not constituting a reasonable and necessary support. However, it may be that the decision will be overturned by a controversial legislative amendment. This section reviews the reasoning in the decision and the human rights and political issues raised by the decision that require consideration and engagement. 323

NURSING AND MIDWIFERY ISSUES – *Editor: Mary Chiarella*

Patients’ Access to Care During COVID-19 and the Role of Nurse Practitioners in Australia – Jane Currie

The anxiety piqued by the impact of the COVID-19 pandemic has motivated health planners to consider all options in attempting to ensure the delivery of effective health care. The response to the early stage of the pandemic offered both opportunity and hope for the removal of historic barriers to the effective utilisation of nurse practitioner (NP) services in Australia. This column discusses the utilisation of NP services to improve

access to care during the COVID-19 pandemic, and highlights the failures to optimise their impact. The intent of introducing the NP role into Australia 20 years ago was to enhance the flexibility of the workforce by expanding and increasing access to health services, particularly for underserved populations. Since implementation, NP services have been plagued by resistance from the medical profession in Australia and constrained by policy and legislation. 336

PUBLIC HEALTH LAW ISSUES – *Editor: Paula O’Brien*

COVID-19: Public Health Emergency Powers and Accountability Mechanisms in Australia – *Paula O’Brien and Eliza Waters*

During the COVID-19 pandemic in Australia, governments in all jurisdictions (except New South Wales) have declared states of emergency and exercised powers under their public health emergency legislation. Highly restrictive measures have been introduced pursuant to the exercise of such powers. Extraordinary government action demands strong accountability. This section piece reviews the public health emergency legislation in all Australian jurisdictions and finds that inadequate accountability mechanisms are embedded in the statutes. This section piece demonstrates that there is insufficient transparency around the decisions being made by the Executive under the public health emergency powers. The section piece also reveals that there are very few options built into the public health emergency legislation for review of executive action for its legality, meritoriousness and fairness. 346

GENOMIC LAW ISSUES – *Editor: Dianne Nicol*

Pathways, Processes and Protections: Australia’s Clinical and Direct-to-Consumer Genetic Testing Spaces – *Jan Charbonneau and Dianne Nicol*

Health-related genetic testing, once exclusively within the medical space, is now available within the commercial space. This paradigm shift from medical to consumer presents challenges to regulators, health care professionals and individuals. This section reports on pathways, processes and protections afforded to Australians whether genetic test results are provided by medical professionals or commercial players. While a complex web of protections is available within Australia’s medical space, those accessing commercial testing rely on the same protections afforded all consumers in all marketplace transactions. There is also potential for these two initially bifurcated pathways to merge, either by business model or individual choice. Individuals pursuing commercial options obtain personal genetic information, which they self-interpret and, if they choose, share with family, medical professionals and online. While this section focuses on health-related genetic testing, it gives insight into what will undoubtedly be continued incursions into the medical space by commercial players. 370

HEALTH LAW REPORTER – *Editor: Cameron Stewart*

Supported Decision-Making for People Living with Dementia: An Examination of Four Australian Guardianship Laws – *Meredith Blake, Cameron Stewart, Pia Castelli-Arnold and Craig Sinclair*

Australia is obliged under the Convention on the Rights of Persons with Disabilities to provide decision-making support to people with cognitive impairment. While there has been considerable recent activity looking at how the law should respond to the challenges raised by the Convention, there has been little discussion in Australia of how these changes will impact upon the care of people with dementia (the largest class of person with cognitive impairment in Australia). This section examines current Australian legal

approaches to decision-making for people with dementia in four jurisdictions (New South Wales, South Australia, Victoria and Western Australia) through an analysis of reported tribunal decisions in each of these jurisdictions. It notes the scope for informal supported decision-making and the basis for the invocation of guardianship orders, including the new Victorian supportive guardianship order, and compares the new standards raised by the Convention. The section considers legal reforms which could improve the implementation of supported decision-making for people living with dementia. 389

ARTICLES

The Regulation and Governance of Clinical Trials: Past and Present Considerations to Ensure Ethical Treatment of Human Participants – *Grace Borsellino, Patrick Foong and Sonia Allan*

Clinical trials are crucial in determining whether novel medical interventions are effective and safe. The use of human participants in such trials is also vital, as animal testing and computer simulation are no substitutes for testing people. Regulation aimed to ensure ethical and safe practices when using human participants, had its beginnings at a global level in response to World War II atrocities. Since that time, there has been an exponential rise of clinical trials, driven mostly by large pharmaceutical companies and for-profit contract research organisations motivated to find preventions and cures for illness and disease, and profit. In turn, there is an ever-growing demand for clinical trial human participants. This article considers historical and contemporary instances of when such trials have gone wrong, and examines the development, and importance of comprehensive, robust, and responsive regulation and governance of clinical trials at both international and domestic levels of which researchers must be aware. 421

Scientific Uncertainty and Guarantee of Supply of Medicines and Healthcare Products during the Crisis Caused by the SARS-CoV-2 in Spain – *Carlos del Castillo-Rodríguez and Silvia Enriquez-Fernández*

The pandemic caused by the new SARS-CoV-2 coronavirus has created a climate of uncertainty. The application of the precautionary principle is therefore justified for some of the measures taken by the competent authorities. In Spain, these measures have been aimed, on the one hand, at stopping its spread by means of a state of alarm for the restriction of daily activities. On the other hand, they aimed at recommending the most appropriate treatment according to scientific research developments, as well as containment measures based on the use of health care products. These latest measures have led to an extraordinary increase in the use of medicines and health care products, which compromises their supply. Thus, authorities were forced to regulate certain actions in the legal supply chain of medicines and healthcare products, such as procurement and dispensing. 439

Parental Refusal of Treatment and Children’s Rights in Nigeria – *Titilayo Oyeniun Aderibigbe and Amarachi Chizaram Okonkoh*

Love and nurture constitute the overarching motivation that propel parents in the preservation of their child’s life when ill. Religious dogma, culture and tradition sometimes override this natural instinct making parents express love in ways contrary to law. This article examines parental consent practices over children. It focuses on parental withholding of consent to medical treatment on religious, spiritual, cultural/compassionate grounds, especially in cases of terminally ill children, children with congenital diseases and disabilities. It further explores the effects and implication of traditional African beliefs on parental consent. Nigeria’s bifocal legal system implies varying levels of children’s protection. These have implications for rights exercisable by parents/guardians. The autonomous rights of children above parents are discussed referring to specific cases. We conclude that children’s rights

to essential medical care can be usurped by parents' ethical/religious values, putting health care practitioners in a dilemma in emergency situations. We recommend legal enforcement of protective children's rights laws. 449

Guiding Genomic Research: Australia's *National Statement on Ethical Conduct in Human Research* – *Belinda Bennett, Elizabeth Dallaston, Fiona McDonald, Andrew McGee, Shih-Ning Then and Bethany Allen*

With advances in genomic research playing an important role in the development of clinical applications, it is important that ethical guidance for researchers is contemporary and relevant. In this article we analyse the relevant provisions in Australia's *National Statement on Ethical Conduct in Human Research* (revised in 2018) and consider the guidance it provides for contemporary genomics research. We analyse four key areas: genomic information; biobanking and use of human tissue; consent to participation in genomic research, including specific issues related to participation by children; and return of findings. We conclude that Australia's *National Statement* is well-placed to provide guidance to Australian researchers on issues relating to genomics, although there is scope for additional guidance on some issues related to consent. 462

Australia after Bawa-Garba: Does Reflective Learning Remain Tenable for Health Care Practitioners? – *Christopher D Mills*

Should a written reflection about regrets be part of the private life of a doctor – or of any health care practitioner – or something that can be used in the public domain when things do go wrong? This article examines the tenability of reflective practice in Australia after the Bawa-Garba cases, outlining the options for the future of reflective practice, and assessing the options ranging from maintaining the current status quo to protecting the use of reflections via absolute legal privilege. In particular, this article explores the value of reflective practice in the broader context, weighing up which of the options for change to reflective practice bring with it the greatest enhancement to public safety. This work concludes by suggesting a potential method for allowing the continued safe implementation of reflective practice by stakeholder groups: briefly considering the novel proposition in the Williams Review that could be adopted in Australia. 475

Epidemiology of Offences against Health in the Republic of Kazakhstan: 2015–2019 – *Oxana Tsigengagel, Nataliya Glushkova, Vugar Mammadov, Zaituna Khismetova, Meruert Gazaliyeva, Zhanara Ibrayeva and Yuliya Semenova*

The epidemiology of offences against health is a subject of debate in developed nations but it is poorly studied in former socialist economies, to which the countries of Central Asia belong. This study investigated the epidemiology of medical errors and associated compensation payments, pre-trial settlements and court hearings in the Republic of Kazakhstan over a period of five years (2015–2019). We performed the analysis of nationwide data on offences against health and associated mortality. There was a decrease in the rate of offences against health from 4,024 per 100,000 population in 2015 to 2,533 per 100,000 population in 2019. Likewise, the mortality rate from offences against health has gradually declined. Over the study period there were significant variations in the numbers of adverse events, compensation payments, patient victims and health care providers involved. Understanding the scope of unsafe care in Kazakhstan and solutions to be adopted is critical for delivering safe and effective medical care to the country's citizens. Decisions made on the safety of medical services should be evidence-based. It is necessary to construct a State program focused on monitoring of medical errors and their consequences in order to protect patients and strengthen legal protection of health care workers. 492

The Doctrine of Double Effect and Potential Criminal Liability of Medical Practitioners in Australia – Scott Davison

Recent parliamentary inquiries into end-of-life choices identify the need to provide legal certainty for health practitioners working in end-of-life care. A concern identified is the lack of clarity surrounding the operation, status and application of the doctrine of double effect. This discussion clarifies these concerns. Although the doctrine is judicially recognised in several overseas jurisdictions, in Australia the doctrine of precedent means that it does not form part of the common law. In most jurisdictions, the fault element for murder includes recklessness, and application of the doctrine does not avoid criminal liability being established against orthodox criminal law principles. Although the prosecution of a medical practitioner who incidentally causes death in the proper course of medical treatment is a rare event, it remains a live issue. Legislative protection of medical practitioners, as has occurred in Queensland, South Australia and Western Australia, is the means to achieve the certainty sought.

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The Strategy of Evaluation Automatism for Disability Assessment: A Pragmatic Choice to Simplify the Decision-making Process in the Italian Welfare System – Giuseppe Consolazio

The first instance assessment of all disability sectors in Italy takes place in most parts of the country in two stages. The first step is the applicant’s examination and judgment performed by the Local Health Authority (ASL). The second phase is the verification of the National Social Security Institute (INPS) on the ASL report, which ends with its confirmation or suspension and repetition. Disability examination strategies can fluctuate between the evaluation automatism and the personalised approach. Evaluation automatism implies a necessary and shared prediction of the judgment due to a specific diagnosis. The personalised approach favours a rigorously individualised, unrepeatably assessment, specifically adapted to the case examined. In both perspectives, the criteria for defining disability belong to a medical model that measures the disease-related impairment. The degree of sharing of judgments between ASL and INPS can often imply and express the contribution of the evaluation automatism to the procedure.

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Australian Medicare Benefits – Bachier Mawassi

The *Health Insurance Act 1973* (Cth) and Medicare Benefits Schedule regulate the Medicare benefits payable in Australia for the professional services provided by medical practitioners who are regularly required to make prompt decisions with respect to the interpretation and billing of Medicare items. If a medical practitioner engages in unacceptable practice by inappropriately billing Medicare items, subsequent professional review, disciplinary action and criminal proceedings can follow. Despite the explanatory notes provided for each Medicare item, disagreements between practitioners, professional bodies/associations and the relevant authorities can arise with respect to the meaning and scope of a particular Medicare item. This article explores the anterior question involved in resolving such disagreements, namely, what principles of statutory interpretation do the courts apply in the civil and criminal jurisdictions to determine the meaning and scope of a Medicare item.

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Workers’ Compensation, Return to Work, Behavioural Health and COVID-19 in Australia – Robert Guthrie, Robert Aurbach and Marina Ciccarelli

The COVID-19 pandemic has highlighted a range of challenges for the participants in Australian workers’ compensation schemes. Although there are some jurisdictional differences in legislation operating at sub-national levels, this article addresses some common themes that have emerged since the outbreak of the pandemic in Australia in early

2020. One of the major concerns which has emerged is the issue of proving the causal link between COVID-19 and work. In some jurisdictions, legislation has specifically addressed these causation concerns. While the number of workers' compensation claims overall is low, there are specific industries which have been heavily affected by the pandemic which may result in a spike in claims in areas such as aged care and the medical and allied professions. We speculate that a number of legal and practical concerns will emerge that may in time contribute to some new jurisprudence in the workers' compensation arena. ... 546

“Equality”, the “Capability Approach” and the Ethical Health Care Paradigm: The Interface – *Abhay Vir Singh Kanwar and Mia Mahmudur Rahim*

As a means of abating the crises of society, the idea of equality has long been a progressive, universal, moral and legal principle to seek justice. However, equality is open to a broad spectrum of meanings and practical applications, mainly due to its endorsement of different interpretations and concepts that give rise to complementary and competing interests. Likewise, the “capability approach”, which is proposed as an alternative to the “ideal of equality”, is not only contentious but also insufficient to build the theoretical basis of an ethical health care paradigm. This article aims to expand the discussion on the ambiguity around the concept of equality, particularly how it interacts with the diversities in human capabilities in a given context. 567

BOOK REVIEW

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