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EDITORIAL

Parkinson’s Disease and the Criminal Justice System – Ian Freckelton AO QC

Parkinson’s disease is the world’s second most common neurodegenerative disorder, and its incidence is growing. This editorial reviews the current state of knowledge about Parkinson’s disease, its causes, its treatment and the symptomatology that is particularly relevant to the administration of criminal justice. It identifies that, in conjunction with comorbidities, it can result in unfitness to stand trial, soundly based pleas of insanity/ mental impairment and, in particular, can have a significant effect on the sentencing of offenders. It argues that with the ageing of the modern jail population, the incidence of Parkinson’s disease provides a strong justification for the creation of alternative health care approaches that can provide suitable custodial services for those with conditions such as Parkinson’s disease, Alzheimer’s disease and a variety of forms of dementia.

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GENOMIC LAW ISSUES – *Editor: Dianne Nicol*

How Should We Regulate Heritable Human Genome Editing in Australia? – Dianne Nicol, Christopher Rudge, Rebecca Paxton and Simon Niemeyer

Heritable human genome editing is a form of modification of the human genome that will be inherited by progeny of the person whose DNA has been edited. Editing human genomes in ways that are heritable is currently prohibited in many countries throughout the world, including in Australia. This section starts with an examination of the historical backdrop to Australia’s current laws relating to heritable human genome editing, with particular focus on how technological advances and community responses have shaped our legislative environment for innovative artificial reproductive technologies. The section then examines how community responses to current developments in heritable human genome editing might shape future law reform. The aim is to provide a foundation for examining how the future regulatory environment for heritable human genome editing in Australia might be shaped in ways that are responsive both to technological developments and to contemporary ethical norms and social values.

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HEALTH LAW REPORTER – *Editor: Cameron Stewart*

Negligence and Health Innovation: Issues with the Standard of Care and the Need to Revisit the Voluntary Assumption of Risk – Cameron Stewart, Lisa Eckstein, Dianne Nicol and Jane Nielsen

This section examines current debates about the test for standards of care in negligence under the Civil Liability Acts in Australia, and how those debates may impact adversely on innovations in health care. It examines the recent history of attempts to define and regulate health innovation and compares them to judicial determinations from New South Wales that have potential to limit the protections otherwise afforded to competent professional practice. The section argues that, if those protections are eroded, alternative options to protect and encourage innovation should be explored, most especially a resuscitated defence of the voluntary assumption of risk.

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“A Nasty Bump”: Lessons from Refugee Doctors’ Defiance of Discrimination, 1937–1950 – *Gabrielle Wolf*

Prominent members of the Australian medical profession sought to prevent European doctors who immigrated to Australia in the late 1930s and 1940s from practising medicine. This article explores how these so-called “refugee doctors” contested the major strategies used by Victorian, New South Wales and Queensland statutory medical boards, influenced by the British Medical Association – Australian doctors’ peak body – to impede their medical practice. In Australia’s eastern States, refugee doctors challenged refusals to grant them registration to practise medicine, appealed decisions to deregister them, and practised medicine while unregistered. The article also considers lessons we might learn from this history, including the importance of reducing the potential for international medical graduates to whom Australia grants refuge to experience unfair obstacles both to practising their profession and challenging discrimination against them. Equally important is to remove temptations for them to practise medicine without registration and lower the risk of them doing so.

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Fitness to Stand Trial: Contemporary Clinical Issues – *Danny H Sullivan*

The assessment of fitness to stand trial in Australian jurisdictions has been grounded in the *R v Presser* criteria for more 60 years. However, a range of subsequent precedents has assisted expert witnesses to ensure that clinical assessments can inform the legal process more effectively, as have changes in legal process. Awareness of particularly vulnerable cohorts, and of contemporary approaches to disability, has led some jurisdictions to introduce supports for defendants. The lived experience of those found unfit to stand trial reminds all who participate in the legal process of the importance of access to justice, and the possible outcomes of being found unfit.

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Putting People First: The Importance of Recommending Minimum Staffing Levels and Skills Mix – *Micah DJ Peters, Casey Marnie and Annie Butler*

Australia’s Royal Commission into Aged Care Quality and Safety has concluded. The Commission’s final report described a sector failing to deliver care that older Australians deserve despite the best efforts of many staff. Throughout the Commission, staffing was a frequent concern, with the size and composition of the direct care workforce a prominent focus. Throughout the Commission, many stakeholders campaigned for mandated staffing levels in skills mix in nursing homes and the Commission’s report and Commonwealth Government response included recommendations for these. While this is a necessary step toward wider reform, the Royal Commission’s recommendation and the Australian Government’s response must support the delivery of best practice care more strongly. This column argues that the minimum standard for nursing home staff care time must be higher, and that higher minimum staffing levels and more clearly defined skills mix are critical to the delivery of safe, respectful, dignified person-centred care.

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Health Technology and Big Data: Social Licence, Trust and the Law –
Bernadette Richards and James Scheibner

Technology is empowering advances in health care, extending beyond the clinical interface to the collection, collation and use of personal data. While this advance has the potential for population-wide benefits, there are legal and ethical challenges which carry the risk of both individual and collective harms. This section critically appraises the existing approach to the governance of health data in Australia. This approach is grounded in the principles of autonomy, privacy and respect for individual choice. This section then identifies the broader imperatives of social good, public health, improvement of outcomes and advancement of knowledge and the importance of balancing individual and collective interests. Central to this discussion are the concepts of social licence and avoiding ethical debt. A significant challenge to the appropriate sharing and use of health data are the existing regulatory barriers (both perceived and actual) and these are explored in some detail. 388

ARTICLES

Death by Choking or Dysphagia: A Review of Coronial Findings (Australia and Canada): A Picture of Preventable Death, Non-adherence to Written Recommendations, and Lack of Appropriate Supervision –
Shaun McCarthy, Bronwyn Hemsley, Fiona Given, Hannah Williams and Susan Balandin

Choking and aspiration pneumonia are a leading cause of preventable death for people in residential care in Australia. In Victoria, in 2018–2019, 59% of deaths of persons in residential care that were referred to the coroner were from aspiration pneumonia. In 2016–2017, in New South Wales, the leading cause of death in people with disability living in residential care was pneumonitis caused by solids and fluids in the lungs. Such deaths are closely linked with swallowing problems (dysphagia) and people with cognitive impairments and multiple health issues, including mental health issues, are most at risk. This commentary focuses on coronial inquests where coroners’ findings have identified dysphagia or aspiration pneumonia as a cause of death or a contributor to a person’s death. It also includes a summary of the recommendations by coroners which highlight processes that should be implemented to improve the safety of people with dysphagia. 400

The Perils of Cosmetic Surgery Tourism: Evolving Knowledge, Awareness, and Challenges –
Dale Jobson and Ian Freckelton AO QC

Concern has been ventilated for some years about the risks of complications and the need for revision procedures after cosmetic surgery tourism. Such tourism is large and growing. Recent literature and coroners’ inquests have provided a new evidence base for evaluating the extent of the dangers posed by a variety of overseas cosmetic surgery procedures. This article reviews such literature and identifies reason for considerable concern about cosmetic surgery tourism as well as about the deficits in regulatory and legal liability that might otherwise inhibit substandard practice. Provision of carefully drafted information about risk issues which patients can factor into their decision-making before embarking on overseas trips for the purpose of cosmetic surgery is a constructive initiative deserving of further attention by relevant Colleges, professional association and health advocacy groups. 406

Participant Selection for Inpatient Physical Rehabilitation – Brent Hyslop

Intensive, inpatient physical rehabilitation in a dedicated unit can have a hugely positive influence on a person’s life after a major injury or illness. This resource, however, is scarce and not every participant will benefit. Appropriate and fair participant selection for inpatient rehabilitation is therefore vital. This article considers challenges in these selection decisions, including the potential for inconsistency, bias and controversy, and the limits of evidence-based selection criteria. To provide best care in this setting, this article suggests that a clear process of decision-making is also important, alongside the use of objective selection criteria. One possible framework for this selection process is New Zealand’s Health and Disability Commissioner Code of Patients’ Rights, which is informative for clinicians and health authorities in rehabilitation selection in all jurisdictions, and which supports appropriate and fair participant selection. 421

The Intersection of Law and Medicine in Full Skin Examination in Screening for Cutaneous Malignancy – Annika Smith

Full skin examination (FSE) is a vital practice in the diagnosis of cutaneous malignancy. Precisely what the FSE entails, however, with respect to concealed site examination (CSE), in particular sensitive sites including the anogenital region, breasts, scalp and oral mucosa, remains poorly elucidated. While the incidence of skin cancer at these sites is low, it carries a poor prognosis. A standardised approach is proposed to FSE with respect to inclusion of CSE to provide: an optimised and uniform approach to patient care, guidance to clinicians performing FSE routinely, and in doing so to protect them medico legally. This article analyses the medico-legal issues pertinent to this issue. 428

Misconduct in the Alcohol and Other Drug Treatment Sector in Australia – Simone Henriksen

This article examines the nature and level of misconduct occurring in the alcohol and other drug (AOD) treatment sector in Australia between 2015 and 2020. Data were drawn from disciplinary decisions of statutory compliance bodies, Australian Health Practitioner Regulation Authority, Consumer Law and coronial findings in all Australian jurisdictions. The data indicate that the current regulatory framework for unregistered health practitioners is unsuitable to protect the public from future acts of misconduct. The response to misconduct varies between registered and unregistered health practitioners. This suggests that unregistered health practitioners pose a greater risk of harm to the public than registered health practitioners, yet the former are subject to the least rigorous regulation. Further, systemic issues within organisations related to poor adherence or lack of sound policies and procedures were found to contribute to the misconduct and the risk of harm within the AOD treatment sector. 437

Biologics, Patents and Regulatory Exclusivities: Incentivising the Development of Future Pharmaceuticals – Jade Luci Andrews

The term “pharmaceuticals” has traditionally been understood as a reference to small molecule therapeutics. However, over the last several years there has been exponential growth in the development of large molecule therapeutics, more commonly known as biologics. Biologics are a sub-category of pharmaceuticals which utilise naturally occurring phenomena to treat maladies as opposed to chemically manufactured compounds. In Australia the development of pharmaceuticals is primarily incentivised by the patent system and regulatory exclusivities. While these systems incentivise the development of small molecule therapeutics, it should not be assumed that they will have the same effect for biologics. This article analyses the application of the patent system and

regulatory exclusivities to biologics to determine whether the unique character of these pharmaceuticals affects the operation of development incentives. 456

The New Serious Incident Response Scheme and the Responsive Regulation of Abuse in Aged Care – Lise Barry and Patrick Hughes

In response to criticisms of the reporting criteria for abuse in aged care that were aired in the Australian Law Reform Commission’s Report into Elder Abuse and more recently, the Royal Commission into Aged Care Quality and Safety, a new Serious Incident Response Scheme (SIRS) came into effect in April 2021. The new SIRS expands the definition of elder abuse and removes the exemption for reporting resident on resident abuse where the perpetrator has a diagnosed cognitive impairment. The Aged Care Quality Commission has outlined a comprehensive plan for the new SIRS in line with their model of responsive regulation. This article questions the extent to which the new scheme will improve regulation of reporting and management of resident-to-resident assaults, and reduce abuse in the aged care sector if not accompanied by improvements in the staffing levels and working conditions for the aged care workforce. 465

Wrongful Birth Cases: The Filters of Scope of Duty and of Normative Causation – Bill Madden

Wrongful birth cases were initially brought most often for failed contraception, sterilisation or termination of pregnancy. Claims have since arisen from alleged failures in the provision of pre-conception and antenatal advice leading to a loss of opportunity to commence or terminate a pregnancy, or for failures in assisted reproduction. Within that second category, breach of duty leading to the birth of a child with disabilities has not always been enough for the claimant parent/s to recover compensation or at least for all of the child’s disabilities. Two key cases show the courts’ focus on scope of duty issues – *Waller v James and Khan v Meadows*. Arguably the same outcomes could have been arrived at by consideration of normative causation. This article examines the two cases, but emphasises the fact-sensitive nature of those judgments in which scope of duty and normative causation filters may or may not apply. 481

From Medical Diagnosis to Legal Personhood: The Unfinished Journey to Legal Consciousness for Intersex Australians – Alice de Jonge

This article explores the intersex experience in Australian law and society through the lens of hermeneutical (in)justice – a form of injustice in knowing that prevents a person from making sense of their own lived experience due to a lacuna in social understanding. It makes an original contribution to legal scholarship first by tracking the advances towards understanding reflected in recent legal and social reform; second by highlighting the shortcomings of these advances; and third by examining new questions and possibilities for moving forward, including through the deliberate creation of a stronger sense of shared identity between different intersex community sub-groups. 489

Trends and Characteristics in Health Care-related Deaths Investigated through Medico-legal Autopsies after System Changes in Japan – Rutsuko Yamaguchi, Yohsuke Makino, Go Inokuchi, Kenji Ishihara, Suguru Torimitsu, Fumiko Chiba, Yumi Hoshioka, Syumari Urabe, Yukiko Oya, Ayumi Motomura, Daisuke Yajima and Hirotarō Iwase

In Japan, a new cause-of-death investigation system and related new laws were enacted in the mid-2010s. These laws provided for an autopsy system for non-criminal unnatural deaths and a medical accident investigation system outside the criminal justice process for health care-related deaths. We retrospectively explored changes in the number and

characteristics of medico-legal autopsy cases of health care-related deaths in Chiba Prefecture, Japan, and examined trends over time during these reforms. We found that the percentage of forensic autopsies based on the Code of Criminal Procedure for health care-related deaths had decreased significantly. The number of autopsies of accidental and unintentional deaths in nursing homes, which are not covered by the newly established medical accident investigation system, has been increasing, reflecting the ageing of society. The trend toward decriminalisation of health care-related deaths was expected to contribute more to medical safety if the scope was expanded and a system for disclosure of autopsy information was established. 509

Superannuation Access for IVF Purposes: Time for Reform? – Rami Hanegbi

Australia’s superannuation system permits the early withdrawal of funds from superannuation accounts in limited circumstances. There has been a trend towards increasing use of the early withdrawal provisions to fund in vitro fertilisation (IVF) treatment through the broad “compassionate release” ground. A 2018 government report recommended tightening the relevant criteria for release, which would restrict release for IVF purposes to those suffering from a mental illness related to their childlessness. This article examines the impact of childlessness in those wishing to have children and concludes that the current release criteria should not be tightened in such a manner. However, the article suggests positive changes in the law to achieve greater compliance with the current law, which restricts early superannuation release to when a lack of alternative funding is unavailable. 522

Dismantling Obstacles to Gender Affirmation: Reimagining Consent to Medical Treatment by Transgender, Gender Diverse and Non-binary Minors – LM Shirley

Gender-affirming treatment is currently inaccessible for many transgender, gender diverse and non-binary minors in Australia, with significant implications for these minors’ physical and mental wellbeing. Existing legal frameworks create obstacles to treatment by requiring that minors either be supported by their guardians or be able to apply to court, as well as having access to medical and psychological experts. Such requirements do not consider the lived realities, and disproportionate vulnerabilities, experienced by these minors. This article argues that legislative intervention is needed to create a mechanism that renders these treatments more accessible. This argument is supported by findings from recent psychological and statistical studies and is further illustrated by facts from the recent case of Re Imogen. 545

Regulating Obesity in Australia: Current Frameworks, Reflections upon the Impact of COVID-19 and Future Reform – Meredith Blake, Marilyn Bromberg and Stephanie Parnell

This article considers the legal and policy regulatory frameworks in Australia relevant to two of the key areas identified as central to managing and preventing obesity, namely, food labelling and junk food advertising. It does so against the backdrop of a global pandemic which resulted in a perfect storm: a global virus colliding with an obesity epidemic. The aetiology of the COVID-19 virus, and the isolation and shut down restrictions associated with combatting it, mean that introducing reforms in these key areas is, more than ever, a public health priority. This article provides important practical recommendations to modify legal and regulatory policy frameworks in the two key areas to address the obesity epidemic in Australia. 560

Legal Implications of Stroke Biobanking and Genomics Research in Sub-Saharan Africa – *Muyiwa Adigun, Babatunde Raphael Ojebuyi, Joshua Akinyemi, Kolawole Wahab, Albert Akpalu, Fred S Sarfo, Lukman F Owolabi, Rabiu Musbahu, Abiodun Bello, Reginald Obiako, Mayowa Ogunronbi, Arti Singh, Michelle Nichols, Carolyn Jenkins, Ayodele Jegede, Rajesh Kalaria, Mayowa Owolabi, Bruce Ovbiagele, Oyedunni Arulogun and Rufus Akinyemi*

Stroke is a major cause of death in Sub-Saharan Africa (SSA) and genetic factors appear to play a part. This has led to stroke biobanking and genomics research in SSA. Existing stroke studies have focused on causes, incidence rates, fatalities and effects. However, scant attention has been paid to the legal issues in stroke biobanking and genomics research in the sub-region. Therefore, this article examines the legal implications of stroke biobanking and genomics research in SSA. The article adopts a textual analysis of primary and secondary sources in law. It reports that there are laws from the perspectives of human right, the common law, and intellectual property. However, there are gaps to be filled. The article therefore argues for legislative intervention. It concludes that pending the time the statute will be enacted, genomics researchers in Africa should adopt the ethical guidelines prepared by Human Heredity and Health in Africa (H3 Africa). 579

A Review of Regulations Applicable to Human Germline Cell Editing in Australia and around the World – *Melissa de Zwart and Claudia Floreani*

This article argues that it is time for a more comprehensive review of Australian law relating to human germline cell genetic engineering. We do not aim to take an ethical stance. Rather, we argue that broader reform and review are necessary in order to come to a suitable ethical stance, and for legislation to reflect that ethical stance adequately rather than inhabiting the corridors of vagary. The need for this has arisen gradually over the past decade, as around the world more countries are developing their capabilities in this field. As such, regulation is of increasing importance either to facilitate further research, or adequately block inappropriate research. Australia's current regulation in comparison contains uncertainty and lacks conviction. We argue that in order to ensure this area is governed primarily by what is in the public interest a review is in order. 599

Genocide and the Oppression of Indigenous Peoples: The Extermination of the 19th Century Aboriginal Tasmanians – *Bruce Short AM RFD*

This article provides a brief outline of the genocides committed during the 20th century, examines the derivation of the appellation and concept of acts of genocide by the lawyer and activist Raphael Lemkin and the development of the United Nations Convention on the Prevention and Punishment of Genocide. The narrative describes the extant socio-economic characteristics of global Indigenous peoples and their vulnerabilities to imposed violence. The work includes a succinct review of the contemporary continuing crimes against humanity perpetrated by the Chinese and Myanmar governments and concludes with the 19th century flawed British colonial administration of the Tasmanian Indigenous tribes between 1803 and 1876 and examines the causes contributing to the genocidal demise of the Tasmanian Aborigines. 610

Assessment Team Recommendations on the Continuation of Involuntary Commitment in Poland – *Justyna Ziółkowska, Dariusz Galasiński, Tomasz Grzyb and Dariusz Doliński*

This study explores explicit justifications for recommendations regarding patients' continuing detention in forensic psychiatric wards. We are interested in what arguments are used in recommendations for the continuing detention of involuntarily committed

patients made by assessment teams for legal proceedings. Our frequency analysis shows that assessment teams refer predominantly to arguments related to the mental state of the detainee. When recommending a change of security level, the assessment teams frequently refer to behavioural factors. However, very rarely does such argumentation appear in recommendations for continuation of detention at the same security level. Additionally, our qualitative analysis shows a very high level of certainty with which pronouncements about patients' behaviour are made, typically in the absence of any social/institutional context. Our study shows that assessment teams tend to opt for safe decisions that are unlikely to be challenged by legal proceedings and that allow them full control over the patient. 622

BOOK REVIEW

The Chloroformist, by Christine Ball 635