

JOURNAL OF LAW AND MEDICINE

Volume 26, Number 1

October 2018

EDITORIAL – *Editor: Ian Freckelton QC*

Procedural Fairness and the Coroner

The hearing rule of procedural fairness applies to coroners’ investigations and the findings made by coroners. Decisions by Australian and New Zealand appellate courts starting from the 1980s and early 1990s suggest that this will require interested parties to be accorded the opportunity to respond to any adverse findings, and probably comments, which a coroner is minded to make by being alerted in advance to what is proposed by the coroner. This editorial scrutinises decisions by the Victorian Supreme Court and Court of Appeal on the issue between 2016 and 2018 against the backdrop of appellate decisions in South Australia and New Zealand, as well as in the context of the development of modern administrative law in both Australia and New Zealand. It identifies conceptual challenges that exist as a result of the recent case law for coroners’ courts, pointing to the uncertainty of what are “adverse” findings and comments for these purposes, a lack of clarity as to who is entitled to procedural fairness in the inquisitorial context of a coronial investigation, the uncertain parameters of reputation for such purposes, vagueness as to what is required for coroners to discharge their obligations, and the logistical difficulties that compliance with such obligations will pose for timeliness of coronial findings.

7

LEGAL ISSUES – *Editor: Danuta Mendelson*

The European Union General Data Protection Regulation (EU 2016/679) and the Australian My Health Record Scheme – A Comparative Study of Consent to Data Processing Provisions

As a general rule, lawfulness of data processing under the European Union General Data Protection Regulation (EU 2016/679) (GDPR) is based on affirmative, unambiguous, voluntary, informed, and specific or “granular” consent to processing of their data, including health data, by individuals referred to as data subjects. The GDPR grants data subjects the legal right to specifically agree to (or refuse) having their data processed in any of the ways statutorily defined as “processing”. Individuals also have the legal right to be fully informed about each and every intended use of their data by data processors and controllers, and the right to refuse such use. In Australia, once registered on the My Health Record (MHR) system, “healthcare recipients” as patients-cum-data subjects are called under the MHR scheme, have the right to remove documents from their MHR files and block some health care providers from accessing their data. However, this study demonstrates that the notion of “standing” consent that the MHR scheme appears to have created does not conform to any of the principles and rules governing data subjects’ consent rights under GDPR.

23

MEDICAL ISSUES – *Editor: David Ranson*

Geriatric Forensic Medicine – A Specialty that can no Longer Wait to be Realised – *David Ranson and Joseph Ibrahim*

The rise in the population and the growth in the proportion of the elderly in our population are changing the structure of many of our communities and placing increasing demands on

our social and health care services. “Scandals” regarding conditions and standards of care in residential aged care facilities have raised concerns about the regulation, assessment and auditing of these community services for the elderly. At the same time longer working lives change the age factors related to employment opportunities and the cadre of older employees presents a different range of human resource issues and occupational health and safety problems for employers. While there is evidence that an older workforce can bring a wider experience and understanding of critical issues to many work disciplines, ageing practitioners may pose professional regulatory issues for the community when considerations of cognitive and technical/physical ability arise. It is in these settings that the need for a forensic focus on gerontology and medical geriatrics arises.

39

BIOETHICAL ISSUES – *Editor: Hannah Maslen*

“A Steadying Hand”: Ascribing Speech Acts to Users of Predictive Speech Assistive Technologies – *Stephen Rainey*

Neuroprosthetic speech technologies are in development for patients suffering profound paralysis, such as can result from amyotrophic lateral sclerosis. These patients would be unable to speak without intervention, but with neurotechnology can be offered the chance to communicate. The nature of the technology introduces a neuroprosthesis that mediates neural activity to generate synthesised speech. How word prediction coheres with speaker intentions requires scrutiny. Some future forms of prostheses, using statistical language models to predict word patterns, could be thought of as participating with communicative intent – not merely channelling it. Concepts relating to vicarious liability, may serve to clarify these issues. This column shows how technology might interact with speaker intent in cases of delegated action, and how it should be seen as participating in the implementation of user “instructions”.

44

MEDICAL LAW REPORTER – *Editor: Thomas Faunce*

Australia’s First Official Illicit Pill Testing at Canberra’s Groovin’ the Moo Music Festival: Legal Hurdles and Future Prospects – *Sarah Byrne, Angela Gock, Anne Cowling and Thomas Faunce*

The first official pill testing at an Australian music festival was conducted at Groovin’ The Moo in Canberra on 29 April 2018. As the trial was the first of its kind in Australia, it was not without legal hurdles and uncertainty. Primarily, there was concern over the legal consequences for patrons participating in the pill testing, as well as the legal liability of those facilitating and conducting the testing. This article will discuss the legal hurdles that were overcome in order to facilitate the trial, and the future consequences and position of pill testing at Australian festivals.

54

ARTICLES

Moritz Meyer and the Medical Board: Preventing Refugee Doctors from Practising Medicine in Victoria, Australia, 1937–1958 – *Gabrielle Wolf*

In 1937, the Medical Board of Victoria (the Board) declined to register Moritz Meyer to practise medicine in Victoria, Australia. Meyer was a Jewish doctor who had completed his medical degree in Germany and obtained postgraduate qualifications in Scotland. Meyer successfully challenged the Board’s decision in the Supreme Court of Victoria and the Board’s appeal against that decision to the High Court of Australia, which was dismissed. In response to Meyer’s victory, the Board, under the influence and together with the British Medical Association, successfully lobbied the Victorian Parliament to prevent doctors from practising medicine in Victoria unless they had completed their studies in Victoria or in a

country in which Victorian doctors, by virtue of their registration in Victoria, were entitled to practise medicine. Meyer’s case received substantial press coverage, but historians have referred to it only in passing. This article fills a notable gap in the historiography about this period by illuminating the significance of Meyer’s matter. It analyses the decisions in this case and considers their impact on European doctors who sought refuge in Victoria immediately before, during and after World War II, and on the medical profession and lay community. It then seeks to explain these reactions to Meyer’s matter. 61

Does Disciplinary Law Protect Us from False and Misleading Health Advertising? – Jordan Sacco

Health-related advertisements should not mislead prospective patients. To do so may deprive patients of their ability to give or withhold consent to treatment and in the case of terminally ill patients, of the opportunity to accept and come to terms with the dying process. Patients should be able to expect that claims in health-related advertising are based on the most recent scientific evidence and are not predatory or exploitative. However, internet advertising and social media continue to provide opportunities for unscrupulous health practitioners to peddle their wares. This article considers whether disciplinary law effectively deals with false, misleading or deceptive health-related advertising in the context of regulated and unregulated practitioners as well as complementary and alternative medicine. It argues that consideration should be given to amending disciplinary law to specify what evidence is required to substantiate claims made in advertising. 89

National Competition Policy and Australia’s Health Care System: A Look at the Policy Landscape with New Eyes – Jayne E Hewitt

Australia spends nearly 10% of its gross domestic product on health services. With such a substantial financial commitment, even relatively minor improvements in efficiency, effectiveness and productivity can increase community welfare. Competition is a well-recognised policy lever implemented to achieve these goals in market economies. However, it has for many years struggled to gain traction in the health care sector. This article traces recent attempts to promote competition principles in Australia’s health care sector. Highlighting where these attempts have stalled, it compares Australia’s recent health reforms with those instituted in the United Kingdom’s National Health Service where a sector-specific competition regulator has been in place for several years. It concludes that there is room in Australia’s regulatory landscape to improve public reporting and increased choice in health care. A sector-specific regulator is envisaged to support these important competition-based initiatives. 103

Dental Health Workforce Regulation – How Amendments to the Health Practitioner Regulation National Law Act May Shape the Future of the Dental Profession – Gillian Jean, Alexander Holden and Marc Tennant

Recent amendments to the *Health Practitioner Regulation National Law Act* adopt a number of recommendations published in the final report of the Independent review of the National Registration and Accreditation Scheme. The adopted recommendations are of interest because of their potential effect on the regulation of the dental profession and how they demonstrate the potential attenuation of the influence of the health professions in general in the arena of healthcare regulation. The wide-reaching effects of these changes and the impact they may have on the future direction of the dental profession in Australia are still uncertain, but are sure to be significant. This article will consider the changing role of the Dental Board in regulation and health workforce reform and show that the Dental Board is no longer the driver of dental workforce policy but plays a subordinate role to facilitate and implement health policy on direction from the AHWMC. 128

In Sickness and in Prison: The Case for Removing the Medicare Exclusion for Australian Prisoners – *Craig Cumming, Stuart A Kinner, David B Preen and Ann-Claire Larsen*

Many current and former prisoners experience significantly higher rates of physical and mental health problems than others in the community, and are among the most marginalised and disadvantaged people in society. This article argues that granting prison health services an exemption under s 19(2) of the *Health Insurance Act 1973* (Cth) would make the Medicare Benefits Schedule and the Pharmaceutical Benefits Scheme-funded services available to prisoners who meet the eligibility criteria. Australian prisoners would then receive a level of care at least equivalent to that offered by community health services. Reducing health inequities that prisoners experience, particularly Indigenous prisoners, is essential for them continuing to receive health care following release and successfully reintegrating into the community. Further, granting the exemption would assist the Australian Government to meet its international human rights obligations to provide equitable health care for all Australians.

140

“Mental Disorder” and Sentencing: Resolving the Definitional Problem – *Jamie Walvisch*

Mental health problems affect the majority of people who face the sentencing process. The fact that a convicted offender has mental health problems may be taken into account in various ways: it may mitigate or aggravate the penalty, or may affect the type of sanction that is imposed or its conditions. At present, sentencing judges use a two-stage process to determine the effect (if any) that an offender’s mental health problems should have on the sentencing determination. First, they ascertain whether the offender has a relevant mental health problem. If they find that he or she does, they then decide what effect that mental health problem should have on the sentencing determination. This article compares recent approaches that have been taken to the first stage of this process in Australia and Canada. It highlights difficulties with both approaches, and recommends replacing the current two-stage process with an integrated, single-stage approach.

159

Biologics and Public Health: Prospects and Challenges – *Olasupo Owoeye and Oluwabusayo Owoeye*

Biotechnology has been used by humankind for thousands of years and it remains a very important part of human medicine. Biotechnology is particularly relevant to the creation of new medicines and vaccines. Biotechnology drugs or biologics are becoming increasingly popular in the life sciences sector. Biologics were estimated to account for US\$289 billion pharmaceutical sales in 2014 and are projected to reach US\$445 billion in 2019. It is also anticipated that biologics’ share of global prescription and over-the-counter pharmaceutical sales will rise to 26% by 2019. Biological medicines are capable of being developed to cure life-threatening diseases that used to be completely incurable. While biologics have unprecedented therapeutic effects, though, they also raise significant quality and patient safety issues. This article discusses some of the regulatory challenges relating to biologics. It also explores mechanisms that may be adopted to promote the development of new biologics and access to biological drugs especially in low income countries.

170

The Privacy-Related Challenges Facing Medical Research in an Era of Big Data Analytics: A Critical Analysis of Australian Legal and Regulatory Frameworks – *Moira Paterson and Normann Witzleb*

This article examines the Australian approach to handling the complex privacy issues raised by Big Data analytics in health research. It analyses the privacy challenges posed by Big Data analytics and considers the privacy-related issues pertaining to the secondary use of health data for research purposes. It also examines the Australian regulatory regimes governing secondary uses of health data for research purposes contained in privacy

legislation and human research guidelines, and includes a critique of a new criminal offence for re-identification of de-identified datasets proposed by the Australian Government. The article concludes with suggestions for a reform process that enables responsible research into big health data while properly addressing the protection of privacy and confidentiality of such data. 188

Australian Public Attitudes on Gene Editing of the Human Embryo – Tamara Treleaven and Bernard E Tuch

Technology is now available which facilitates gene editing and has recently been applied internationally to embryos in the laboratory. A 2002 law in Australia prohibits making heritable changes in embryos, regardless of whether the treated embryo is discarded thereafter. We sought to begin to understand public opinion in Australia about this matter, using a questionnaire given to the audience attending a Q and A panel of experts. We found majority support for allowing heritable changes for health purposes. If this is confirmed in a larger survey of the population, we suggest the existing law should be reviewed. 204

Regulating RNA Research and CRISPR Gene Drives to Combat Biosecurity Threats – Thomas Faunce, Andrew Ray, Christie Gardiner, Thomas Preiss and Gaetan Burgio

Recent technological breakthroughs in ribonucleic acid (RNA) research and the creation of synthetic gene drives using CRISPR/Cas9 have increased attention on the ethical and legal regulation of this field. RNA is now perceived as not merely a passive carrier of DNA information but especially through its propensity to mutate as a computation engine of cell biology, developmental biology and evolution. Synthetic Gene drives have been hailed as a potential strategy to reduce climate-change-mediated biosecurity threats such as spreading malaria and have attracted significant investment, with the Gates Foundation pledging US\$75 million and the Defense Advanced Research Projects Agency awarding US\$65 million. Calls for a global moratorium on RNA-mediated genetic engineering may overstate the potential risks of the developing technology, but form a background to the contest between “process”- and “product”-based approaches to regulation, the former purportedly favoured by the public and regulatory agencies and the latter favoured by the broad scientific community and corporate investors. At stake may be the democratic legitimacy of and equitable access to a technology that could be important to reduce the incidence of biosecurity threats both globally and in Australia. 208

Providing Palliative Care at the End of Life: Should Health Professionals Fear Regulation? – Lindy Willmott, Ben White, Donella Piper, Patsy Yates, Geoffrey Mitchell and David Currow

Anecdotal evidence from Australia and abroad suggests that health professionals may fear potential legal and/or professional repercussions if their patient dies after receiving pain relieving medication at the end of life. As a result, patients may be under-medicated and their pain and other symptoms not adequately relieved. The regulatory repercussions from inappropriate administration of medications are potentially broad and include criminal charges, civil negligence claims, coronial investigations and disciplinary proceedings. But despite these potentially serious repercussions, a review of publicly available cases in Australia reveals there has been comparatively little judicial or quasi-judicial scrutiny where over-medication is alleged to have resulted in a patient’s death. In this article, we describe the regulatory framework that governs this field of medical practice and analyse the extent to which the actions of health professionals have been scrutinised, and the consequences of that scrutiny. We identify a number of themes arising from this analysis and conclude that fears of legal or professional repercussions are largely unfounded, and that existing laws and other forms of regulation should not inhibit the prescription and administration of adequate pain and other symptom relief to people at the end of life. 214

The Role of the Medical Profession in Victorian Assisted Dying Law Reform – Jodhi Rutherford

The *Voluntary Assisted Dying Act (Vic)* will commence operation on 19 June 2019. Doctors were highly visible in the debate which informed the recent law reform process, and Victorian legislators relied considerably on the diverse views of the medical profession. It is important to pay attention to the role played by doctors in the legalisation of assisted dying in Victoria, not only because the current political environment suggests that further reforms may be likely in other Australian jurisdictions, but also because doctors' knowledge and expertise visibly contributed to the outcome of that process in Victoria. This article aims to map the participation of doctors in the recent law reform process to analyse how their professional attributes positioned them in the Victorian assisted dying space. It is suggested that doctors were afforded a place in law reform because of the routine acceptance of doctors as knowledge keepers in matters of life and death and an acknowledgment of the integral role of medical expertise in the legislation. A textual analysis of the Hansard record of the Victorian debate reflects that individual practitioner advocacy for legalisation prevailed over opposition by the national branch of the Australian Medical Association in the deliberations of parliamentarians.

246

Sexual Assault Examination of the Unconscious Patient: A Legal, Ethical and Professional Grey-area for the Forensic Physician – Justine E Rogers, Morris S Odell and Jason R Schreiber

When treating unconscious patients believed to have been victims of sexual assault, forensic physicians must decide whether to conduct physical examinations in order to collect evidence while patients are unconscious and cannot consent. The choice is urgent: potential evidence may be lost before the patient regains the ability to consent. The physician's choice affects not only the patient's bodily integrity, but also their ability to pursue criminal and potentially civil justice remedies if they were assaulted. This article bases its discussion on one such real-life situation. It first examines ethical models relevant to deciding whether to take evidence and finds that no one approach produces morally satisfactory outcomes in every case. It then examines the legal framework guiding these decisions, finding that while collecting evidence without consent may well be permissible under New South Wales (NSW) legislation, relevant guidelines disallow it, placing physicians in a legal grey-area. The article concludes with practical recommendations to address these ethical, professional and legal challenges.

265

BOOK REVIEW

Diamonds and Stones in an Era of Gold, by Brian Collopy – Reviewed by Ian Freckelton QC.....

274