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EDITORIAL – *Editor: Ian Freckelton QC*

Health Law: The Past and the Future

In the first 25 years of the *Journal of Law and Medicine* issues relating to abortion, euthanasia, turning off of life support, pandemics, cloning, surrogacy, technological change, patenting of DNA, regulation of health practitioners, health services in the Information and Genomic eras, mental health law, elder law, and medical negligence have figured prominently in the published scholarly contributions. This editorial reflects on the evolution of health law in its many aspects, contrasting issues that were contentious in 1993 with those that are in 2018 and reflecting on what is likely to continue to attract interdisciplinary analysis and the need for critical evaluation in the decades ahead. 869

LEGAL ISSUES – *Editor: Bernadette McSherry*

Computational Modelling, Social Media and Health-Related Datasets: Consent and Privacy Issues

Computational modelling is now being used to analyse posts on social media to predict the emergence of mental health conditions. While the aim is to develop tools for early detection and treatment of such conditions, computational modelling raises issues of user consent and privacy. The European Union has moved to regulate automated profiling of large databases and Australia has introduced a data breach notification scheme for cases where personal information held by an organisation is lost or subjected to unauthorised access or disclosure. There remains the question, however, of whether such regulation will be enough to prevent third-party access to social media and health-related datasets by those with less than benign motives. Opting out of using social media and schemes such as My Health Records may be one option to preserve privacy and avoid the use of personal data being used without consent, but that may be unattainable in a digital age. 894

MEDICAL ISSUES – *Editor: Ian Freckelton QC*

Responding Better to Desperate Parents: Warnings from the Alfie Evans Saga

The end-of-life litigation involving Alfie Evans (9 May 2016 – 28 April 2018) from Liverpool, England, who suffered from an incurable and degenerative neurological condition was extraordinary. It emerged in the shadow of comparable but not as extensive litigation enabled by crowdfunding in relation to Ashya King and Charlie Gard. Although Alfie's parents lost repeatedly in the High Court, the Court of Appeal and the Supreme Court of England, as well as before the European Court of Human Rights, they persisted in bringing more legal challenges. The public relations campaign on their behalf at times was threatening and accusatory of the clinicians and of Alder Hey Hospital. Both persons employed at the Christian Legal Centre, which represented the parents at times, and medical practitioners from Europe who participated in forensic assessments behaved unethically. There are many lessons to be learned from the Alfie Evans saga. If we are to maintain morale and commitment among those who provide paediatric clinical services to the very ill and the dying, they must be protected from the public relations and litigation

campaigns deployed by those purporting to represent the Alfie Evans family, and better non-adversarial methods need to be constructed as a matter of urgency to resolve matters involving disagreements about the treatment of terminally ill children. 899

BIOETHICAL ISSUES – *Editor: Julian Savulescu*

A New Ethical Model of Commercial Surrogacy Arrangements for Australia – *Jeremy Feiglin and Julian Savulescu*

The current regulation of altruistic surrogacy arrangements in Australia has resulted in a dearth of willing participants and is driving intending parents overseas to unregulated countries. This section contends that the current altruistic surrogacy arrangements in Australia violate a number of ethical principles and fail to protect the interests of all parties. This section then proposes a new ethical model for commercial surrogacy arrangements that includes: fair and just compensation; enforceability of surrogacy agreements; amended parentage presumptions and the ability to obtain pre-birth parenting orders; regulation of surrogacy agencies and brokers; recognition of approved international surrogacy arrangements; and review by a Patient Review Panel with legislative safeguards. Altruistic surrogacy arrangements would remain available to those parties who object to commercial surrogacy. This new ethical model better satisfies the four principles of respect for autonomy, beneficence, non-maleficence and justice than the current altruistic surrogacy model. 919

NURSING ISSUES – *Editor: Kim Forrester*

Codes of Conduct – A New Era for Nursing and Midwifery in Australia

The Nursing and Midwifery Board of Australia has developed and approved the new *Code of Conduct for Nurses* and *Code of Conduct for Midwives* which applies from 1 March 2018. The primary role of the Nursing and Midwifery Board of Australia (NMBA), is to protect the public by ensuring only those who are suitably qualified and trained to practise in a competent and ethical manner are registered. One mechanism by which this objective is achieved is the registration of practitioners who are required not only to meet the mandatory registration standards but also conduct their practice in accordance with the NMBA's standards, codes and guidelines. The language of these new codes clearly articulates the mandatory obligations imposed on nurses and midwives to establish and maintain specified standards of conduct that ensure safe practice. It is therefore important for nurses and midwives not only to read the codes, but incorporate the terms contained therein meaningfully into their practice. 929

MEDICAL LAW REPORTER – *Editor: Thomas Faunce*

Australian Senate Committee Report on Transvaginal Mesh Devices – *Chloe Thompson and Thomas Faunce*

On 28 March 2018 the Australian Senate Community Affairs References Committee issued its final report on transvaginal mesh devices. It found these devices have caused unnecessary physical and emotional pain and suffering to thousands of women who were not told by their doctors of the objective material risks associated with their use. The Senate Committee concurred with the description by the Public Health Association of Australia of the complications resulting from transvaginal mesh implants as constituting a serious public health issue requiring a response at both an individual and at a population level, including counselling, public education, clinical interventions and long-lasting protective mechanisms. The committee's inquiry highlighted significant shortcomings in Australia's reporting systems for medical devices, with flow-on consequences for the health system's

ability to respond in a timely and effective way. Among other recommendations, the Senate Committee backed the establishment on a cost recovery basis of a national registry of high-risk implantable devices linked to a system of mandatory reporting of adverse events. 934

ARTICLES

When Is It in a Child's Best Interests to Withhold or Withdraw Life-sustaining Treatment? An Evolving Australian Jurisprudence – *Lindy Willmott, Ben White and Neera Bhatia*

Decisions about whether to withdraw or withhold life-sustaining medical treatment from children give rise to complex and value-laden judgments. While recourse to the courts is uncommon, judicial decisions provide an important source of guidance for the children (where they can participate), families and health and medical professionals involved in these decisions. Yet, there has been remarkably little consideration of the Australian jurisprudence on this issue. This article addresses that gap by undertaking the first comprehensive analysis of all publicly available Australian cases that consider whether or not it is in a child's best interests to receive life-sustaining treatment. A total of 25 cases were located and the judicial consideration of best interests was thematically analysed. Key considerations (to varying degrees) when assessing best interests included the likelihood of treatment curing or improving the child's health, medical views about diagnosis, prognosis and treatment and the child's and parents' views and wishes. The article concludes that the law requires greater certainty and transparency in decision-making. Given the significance of these cases, judgments should describe the factors that the court considers relevant and important, and those that are less influential, as well as the weight ascribed to those various factors and the reasoning that underpins an assessment that treatment is or is not in a child's best interests. 944

Biosimilars: The Challenges of Novelty, Inventive Step and Sufficiency – *Teddy Henriksen and Jay Sanderson*

In order to understand the relationship between patents and biosimilars in Australia better, this article examines whether, and in what circumstances, biosimilars can be patented under the *Patents Act 1990* (Cth). Part II provides the necessary background in discussing the structure and function of biosimilars as well as the regulation of, and key arguments for, biosimilars in Australia. Part III explores the key challenges faced in patenting biosimilars in Australia, particularly the requirements of novelty, inventive step and sufficiency of description. In so doing, the recent case of *Pfizer Ireland Pharmaceuticals v Samsung Bioepis AU Pty Ltd* [2017] FCA 285 provides some guidance and is discussed. The article concludes in Part IV with consideration of the implications of biosimilar patents for manufacturers, as well as access and affordability of treatment to the community and the interaction between government subsidy through the Pharmaceutical Benefits Scheme, and biosimilars. 973

The Legal Doctrine of Informed Consent and Renal Dialysis – Do Patients Really Consent? – *Marina Wainstein, Anna Rose Menzies, Frank Patrick Brennan and Mark Ashley Brown*

A doctor has a legal duty to secure the informed consent of a patient prior to performing a medical or surgical procedure. The elements of the legal doctrine of informed consent include capacity, voluntariness and the provision and understanding of relevant information. This article examines the doctrine in the context of renal dialysis. Dialysis is a complex therapy that impacts upon quality of life and has limited survival advantage in some patients. It is likely that informed consent is often not fully integrated into the care of patients commencing dialysis. The article analyses the common law doctrine of

informed consent as it relates to dialysis and presents the findings of a retrospective study of the adequacy of the consent process based on interviews with dialysis patients who commenced dialysis in the previous 12 months. It concludes with recommendations for improvement in practice. 992

Building Public Confidence in Medical Registration Revalidation: Reform of Medical Registration Law in Australia, a New Risk-based Approach – David J Carter, Deborah J Street and Stephen Bush

This article examines the reform of the Health Practitioner National Law to introduce a form of medical registration revalidation. Revalidation is a regulatory performance management practice designed to confirm the competence of medical practitioners regularly and proactively. Its implementation will shift the law’s current contribution to constraining dangerous practice from a largely reactive stance onto a more proactive footing. In aid of advancing the case for registration revalidation, we describe the recent history of the National Law, provide analysis of the proposed revalidation reforms and then apply a novel empirical method of a discrete choice experiment to determine the Australian general public’s acceptance of and preferred approach to medical registration revalidation regulation. We argue that the reform represents a potentially effective and, importantly, acceptable reform to existing regulatory performance management and disciplinary systems. 1009

Holding Out and Protected Titles – Issues for Non-registrant Complementary and Alternative Health Practitioners – Michael Weir

The regulation of registered health practitioners in Australia focuses upon “holding out” provisions rather than statutory “scope of practice” provisions. One concern for non-registrant complementary and alternative medicine practitioners and other non-registrants is whether these holding out provisions are breached by simply providing a modality which may also be applied by a registered health practitioner (such as the use of Chinese Massage) and when does a breach of the holding out occur when they use particular words that might in the context of when they are used may be deemed to constitute a holding out. This article will analyse the relevant provisions of the National Law and case law to determine some guidelines for practitioners to avoid liability. 1033

Legal and Ethical Issues Surrounding the Use of Older Children’s Electronic Personal Health Records – Jacqueline Meredith, Shaun McCarthy and Bronwyn Hemsley

This article explores the legal and ethical issues surrounding the production, storage, retrieval and use of electronic personal health records of children aged 14 years and over. Specifically, we explore: (1) the capacity, consent and competence issues; (2) privacy and confidentiality concerns; (3) the tension between a child’s right to autonomy and his or her parent’s or guardian’s rights and responsibilities; and (4) outline implications of this for the implementation of Australia’s My Health Record system, particularly for children with communication disability who are high users of health systems and have high health information exchange needs. 1042

Changing Law Students’ Ideas about Dis/ability: Can We? Should We? How Would We? – Anna Cody

Access to the law, and effective justice for people with disability is a growing area of concern for lawyers and law teachers. In clinical legal education, where students work with real clients, working effectively and sensitively with people with disability is crucial. The founding principle in any design process of clinical legal education programs with people with disability is “nothing about us without us”. Students must also be taught specific skills when working with clients with disability, including the appropriate language to use,

communication skills, and the connections between sexism, racism and stigma attached to people with disability. Reflection skills and the ability to analyse and critique the law are all essential elements of a program working with people with disability. This article explores key elements drawing on the experience of clinics in Mexico and Australia to recommend the essential elements of a clinic which works with clients with disability. 1056

Best Interests and Non-consensual Research – Brent Hyslop

The issue of clinical research on adults who are unable to provide consent (non-consensual research – NCR) is a challenging area of law, which has gained prominence in New Zealand and elsewhere. In New Zealand, the legality of such research depends on a “best interests” test. It has been claimed, however, that a best interests test cannot be satisfied in NCR, and that a new legal standard is required to allow valuable research to appropriately proceed. This article argues that a best interests test can be satisfied in NCR and should be reconsidered as a suitable benefit–harm standard. Furthermore, there is a possibility of maintaining a best interests test as well as adopting a new, more specific standard and other recommendations for reform. These two components could be seen as consistent, or even synergistic, and this dual approach should be considered in current discussion. 1070

How Do Coroners’ Findings in Australian Jurisdictions Apply to Health Care Practitioners within Safety-I and Safety-II Paradigms? – Nicola Cunningham

The modern-day coroner sits uniquely at the interface between health care provision, patient safety and the law, playing an important role in informing health care practices to improve patient safety. In the 21st century, the health care system has rapidly developed in the field of patient safety. First came the Safety-I approach of “looking at what went wrong”, then the Safety-II approach of “understanding why things go right”. The advent of Safety-II has flipped the way some health care organisations view their systems and it is now time for the coronial jurisdiction to do the same. By applying the Safety-I/Safety-II Model for coronial investigations into health care-related deaths, coroners can address both the positive and negative factors in each case and refine the lessons in their findings. A Safety-II approach allows their role to evolve even further, firmly entrenching their preventive ethos as they become architects of resilience for the health care system. 1079

An Analysis of Medico-legal Claims against Dermatologists in Australia from a Single Medical Indemnity Insurer – Paul Stevenson

Risk mitigation practices are essential to protecting patients from harm and reducing medical practitioner exposure to unnecessary reputational damage and economic loss. Despite traditionally being perceived as a “low-risk” specialty, published data on medico-legal claims against dermatologists in Australia are currently lacking. This article reviews the sources of medico-legal claims against dermatologists in Australia from a single medical indemnity insurer over the most recent three years. The failure to meet patient expectations was the largest source of claims against dermatologists, followed by adverse outcomes. Improved communication from practitioner to patient remains the most effective step to preventing medico-legal claims. Medico-legal claims, when they occur, are more successfully defended when thorough documentation processes are in place. 1100

Reproductive Autonomy and Social Sex Selection: A Chance of a Choice? – Kathryn Boyd

Through preimplantation genetic diagnosis (PGD), individuals can now reliably choose the sex of their baby. However, PGD is largely prohibited for individuals seeking to sex select for non-medical reasons. This article argues that to protect reproductive autonomy, individuals should be allowed to make reproductive choices, regardless of their motivations, unless those choices would cause serious harms to others. It follows that social sex selection should not be prohibited on the basis of moral objections, only

when it will cause serious harm. This article considers the opposing ethical framework of parental virtues. A reproductive autonomy framework is preferred, given the challenges of determining and applying parental virtues to social sex selection. This article examines three potential harms identified by opponents to sex selection, and argues that while these remain speculative they do not justify the curtailing of reproductive autonomy. 1106

Freedom of Expression, Belief and Assembly: The Banning of Protests Outside of Abortion Clinics in Australia – Anna Walsh

This article considers the phenomenon of “safe access” zone laws in Australia that seek to prohibit certain activities that occur outside abortion facilities during protests. While they are characterised as a reasonable reaction to concerns that certain activities may harm women and infringe their rights to privacy and security, such laws do so at the expense of the protesters’ right to freedom of political communication and cover activities such as sidewalk counselling and praying. This article critically examines the content and scope of these laws in each jurisdiction, identifies recent cases involving prosecutions for violations of safe access zone laws and considers the impact of the implied freedom of political communication on their constitutional validity in light of recent High Court decisions. 1119

Two Problems of Unburied Bodies – Robert Shiels

No aspect of the law should be neglected, yet it is probably not often within the practice of lawyers or medical doctors that they become involved in litigation over human remains. Yet, within a short period of time, the courts in Britain have been required to adjudicate on such sensitive issues. In two cases public anxiety about the disposal of remains led to litigation and judicial decisions which are likely to remain illustrative of the unique facts and circumstances surrounding such problems. 1129

A Whiter Shade of Grey: Comparisons of the Legal and Professional Status of Tooth Whitening in Three Jurisdictions – Alexander C L Holden

This article seeks to examine and compare the legal and professional positions of tooth whitening of three jurisdictions: the United Kingdom, Australia and New Zealand. Within each jurisdiction, a differing formula of legislation, case law and professional guidance dictates how tooth whitening is regulated and practised. Tooth whitening still holds curiosity as a procedure with regards to whether it does indeed warrant status as a professional activity and whether its practice should be limited to dental professionals. Through exploration of the differing positions of three different jurisdictions, it is possible to demonstrate that this issue is far greater than the common view within the profession that for reasons of public protection, access to tooth whitening should be controlled by the dental profession. The monopoly upon tooth whitening procedures that the dental profession often celebrates, where it exists, should be viewed to be fragile and not taken as an unending status quo. 1134

Infection Control Standards in Private Dental Practice – The Role of Accreditation – Gillian Jean, Alexander C L Holden, Marc Tennant and Estie Kruger

There are established standards for the management of infection control in private dental practices, but there is currently no proactive legislation to oversee correct adherence to those standards. The Australian Health Service Safety and Quality Accreditation Scheme (Scheme) promotes a quality and safety management program that includes attention to the prevention of healthcare acquired infections, but adoption of the Scheme is not compulsory for all. A recent case brought before the NSW Civil and Administrative Tribunal demonstrated the seriousness of breaches of infection control standards and the considerable costs of managing the consequences. This article discusses the role of quality

and safety assurance programs in the context of private dental practice regulation; compares the different quality and safety assurance schemes operating in Australia, Canada, and the United Kingdom; and argues that the compulsory adoption of an appropriate scheme which focuses on infection control would be in the public interest..... 1146

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