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EDITORIAL – *Ian Freckelton*

Expert evidence accountability: New developments and challenges

A series of developments in relation to the accountability of expert witnesses and the admissibility of their opinions is taking place. This extends to encroachments in the United Kingdom on expert witness immunity, the imposition of disciplinary liability for registered health practitioners in Australia and the United Kingdom, and recommendations from the United Kingdom Law Commission for a systematised procedure for reliability determination as a prerequisite for admissibility rulings. This combination of measures is indicative of international concern about the contemporary role of expert witnesses. It highlights the need for both empirical information about whether the anecdotal and experiential concerns about expert evidence are well-founded and for the provision of better and clearer guidance to experts and litigators alike about the underpinnings and methodologies that are permissible for admissible and probative expert opinions. 209

LEGAL ISSUES – *Bernadette McSherry*

Laws to detain individuals with substance dependency: Breaching human rights or restoring health? – Bernadette McSherry and Sarah Lenthall

At the turn of the 20th century in the United Kingdom and Australia, legislation was introduced to detain and treat “inebriates”. Since that time, variations of such laws have continued to exist. This column examines current laws in Australia and New Zealand with a particular focus on recent law reform efforts in New South Wales and Victoria. The column raises some of the issues with these laws in relation to breaching human rights for the purpose of treatment. 225

MEDICAL ISSUES – *Danny Sullivan*

Access to expensive anti-cancer drugs – Linda Mileshekin and Danny Sullivan

Expensive anti-cancer drugs expose controversy underlying the process for resource allocation decisions, and intermittently result in marked publicity, emotive discussions about access to novel and expensive treatments, and political involvement which may override existing processes. This column outlines the methods of determining whether or not a treatment is considered appropriate to fund, and focuses upon the evidence of patient and doctor wishes. The existing research illustrates the complexity of patient and oncologist decision-making when these drugs are to be considered. Past litigation to obtain access to expensive treatments is discussed, along with the interactions between patients, pharmaceutical companies, health services and oncologists. This evolving field is being transformed by developments in molecular biology enabling targeted drugs, and amply demonstrates the complexity of funding decisions and how expensive treatments are considered by a range of stakeholders. 232

BIOETHICAL ISSUES – *Grant Gillett*

Living and learning during an ethical crisis in medicine – *Grant Gillett*

The Cartwright Report was released at a time of massive ethical change in New Zealand medicine, the shock waves spreading throughout the region as they caught the surge of interest in patient autonomy and patient rights. The mood was as revolutionary for health professionals as the late 1960s and 1970s were for society in general, with many established patterns of practice and everyday expectations about the nature of clinical care being challenged and disrupted. For some of us who witnessed the medico-legal impact of the report in Australasia, it revived memories of our time as medical students when the events reported on were being played out. Looking back now on a time of moral crisis in medicine has lessons to teach us which have a timeless quality about them as they recall the dim distant days of Semmelweis and other doctors struggling at a political fringe of the profession. 244

NURSING ISSUES – *Kim Forrester*

The growing role of carers in the administration of medications – *Kim Forrester*

The roles of registered nurses, enrolled nurses, nurse practitioners and midwives in the administration of medications are subject to the legislation and regulation in their respective States and Territories in Australia. Underpinning this regulatory framework is a presumption that health professionals who come under the relevant legislation and regulations have attained the levels of competency, skill and knowledge consistent with professional standards and the protection of the public. This column considers the provisions of the *Health (Drugs and Poisons) Regulation 1996* (Qld) addressing the administration of controlled and restricted drugs in light of a recent Queensland Civil and Administrative Tribunal decision. 250

MEDICAL LAW REPORTER – *Thomas Faunce*

Condliff v North Staffordshire Primary Care Trust: Can human rights redress inequities in United Kingdom and Australian cost-containment-driven health care reforms? – *Ruth Townsend and Thomas Faunce*

A recent case from the English Court of Appeal (*R (on the application of Condliff) v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910, concerning denial by a regional health care rationing committee of laparoscopic gastric bypass surgery for morbid obesity) demonstrates the problems of attempting to rely post hoc on human rights protections to ameliorate inequities in health care reforms that emphasise institutional budgets rather than universal access. This column analyses the complexities of such an approach in relation to recent policy debates and legislative reform of the health systems in the United Kingdom and Australia. Enforceable human rights, such as those available in the United Kingdom to the patient Tom Condliff, appear insufficient to adequately redress issues of inequity promoted by such “reforms”. Equity may fare even worse under Australian cost-containment health care reforms, given the absence of relevant enforceable human rights in that jurisdiction. 255

LETTER TO THE EDITOR

Australian and New Zealand governments agree to proceed with the joint regulatory agency for therapeutic products – *Jennifer Moore* 272

ARTICLES

Global artificial photosynthesis project: A scientific and legal introduction – *Thomas Faunce*

With the global human population set to exceed 10 billion by 2050, its collective energy consumption to rise from 400 to over 500 EJ/yr and with the natural environment under increasing pressure from these sources as well as from anthropogenic climate change, political solutions such as the creation of an efficient carbon price and trading scheme may arrive too late. In this context, the scientific community is exploring technological remedies. Central to these options is artificial photosynthesis – the creation, particularly through nanotechnology, of devices capable to doing what plants have done for millions of years – transforming sunlight, water and carbon dioxide into food and fuel. This article argues that a Global Artificial Photosynthesis (GAP) project can raise the public profile and encourage the pace, complexity and funding of scientific collaborations in artificial photosynthesis research. The legal structure of a GAP project will be critical to prevent issues such as state sovereignty over energy and food resources and corporate intellectual monopoly privileges unduly inhibiting the important contribution of artificial photosynthesis to global public health and environmental sustainability. The article presents an introduction to the scientific and legal concepts behind a GAP project. 275

Is there still a place for gene patents in Australia? Implications of recent United States and European case law – *Alexandra Ridley and Dianne Nicol*

This article considers the ramifications of recent United States and European litigation relating to patents claiming rights to genes associated with hereditary forms of breast cancer (the so-called BRCA genes) for recently commenced Australian litigation relating to the same subject matter. The article is contextualised with brief summaries of the relevant patent law, the science of genetics, the history of the BRCA genes and an overview of the activities of the patent holder. The analysis of first instance and appeal decisions on the validity of the United States BRCA patents shows the final outcome is still highly uncertain in that jurisdiction, while the European litigation provides little assistance in predicting the outcome of the Australian action. This article concludes that the outcome of the Australian litigation is an issue that cannot be determined with any certainty due to the lack of specific, relevant precedents both in Australia and in other jurisdictions. 282

Legal impediments to data linkage – *V Xafis, C Thomson, AJ Braunack-Mayer, KM Duszynski and MS Gold*

Large numbers of electronic health data collections have been accumulated by both government and non-government agencies and organisations. Such collections primarily assist with the management of health services and the provision of health care programs, with only a minority of these data collections also intended for research purposes. A number of constraints are placed on access to such data for the purposes of research, including data linkage. This article examines those factors arising from the intricacies of Australia's privacy legislation landscape which impede access to such collections. The relevant issues discussed include issues relating to the existence of multiple privacy and health privacy Acts, the recommendations made by the Australian Law Reform Commission in relation to the *Privacy Act 1988* (Cth) and the constraints placed on the conduct of data-linkage research which arise from legislation that relates specifically to certain data collections. 300

Sub-Saharan African randomised clinical trials into male circumcision and HIV transmission: Methodological, ethical and legal concerns – Gregory J Boyle and George Hill

In 2007, WHO/UNAIDS recommended male circumcision as an HIV-preventive measure based on three sub-Saharan African randomised clinical trials (RCTs) into female-to-male sexual transmission. A related RCT investigated male-to-female transmission. However, the trials were compromised by inadequate equipoise; selection bias; inadequate blinding; problematic randomisation; trials stopped early with exaggerated treatment effects; and not investigating non-sexual transmission. Several questions remain unanswered. Why were the trials carried out in countries where more intact men were HIV-positive than in those where more circumcised men were HIV-positive? Why were men sampled from specific ethnic subgroups? Why were so many participants lost to follow-up? Why did men in the male circumcision groups receive additional counselling on safe sex practices? While the absolute reduction in HIV transmission associated with male circumcision across the three female-to-male trials was only about 1.3%, relative reduction was reported as 60%, but, after correction for lead-time bias, averaged 49%. In the Kenyan trial, male circumcision appears to have been associated with four new incident infections. In the Ugandan male-to-female trial, there appears to have been a 61% relative increase in HIV infection among female partners of HIV-positive circumcised men. Since male circumcision diverts resources from known preventive measures and increases risk-taking behaviours, any long-term benefit in reducing HIV transmission remains uncertain. 316

Is it lawful to use Medicaid to pay for circumcision? – Peter W Adler

Since 1965, tens of millions of boys have been circumcised under the Medicaid program, most at birth, at a cost to the United States Federal Government, the States and taxpayers of billions of dollars. Although 18 States have ended coverage since 1982, the United States Government and 32 States continue to pay for non-therapeutic circumcision, even though no medical association in the world recommends it. Many cite American medical association policy that the procedure has potential medical benefits as well as disadvantages, and that the circumcision decision should be left to parents. This article shows that Medicaid coverage of circumcision is not a policy issue because it is prohibited by federal and State law. As American medical associations concede, non-therapeutic circumcision is unnecessary, elective, cosmetic surgery on healthy boys, usually performed for cultural, personal or religious reasons. The fundamental principle of Medicaid law is that Medicaid only covers necessary medical treatments after the diagnosis of a current medical condition. Physicians and hospitals face severe penalties for charging Medicaid for circumcisions. Medicaid officials and the Federal and State Governments are also required to end coverage. It is unlawful to circumcise and to allow the circumcision of healthy boys at the expense of the government and taxpayers. 335

Psycho-social, ethical and legal arguments for and against the retrospective release of information about donors to donor-conceived individuals in Australia – Sonia Allan

In the February 2011 report on its inquiry into the past and present practices of donor conception in Australia, the Australian Senate Legal and Constitutional Affairs References Committee called for the introduction of legislation to regulate donor conception in all jurisdictions that do not have it in place “as a matter of priority”. It further called for the establishment, “as a matter of priority”, of a national register of donors to enable donor-conceived individuals to access identifying information about their donor. The Senate Committee left open the question as to whether the legislation and central register should have retrospective effect. This article focuses upon that question. It shows that arguments concerning the privacy, confidentiality and anonymity of some donors who may

wish to remain anonymous are outweighed by the manifest injustice faced by donor-conceived individuals who are denied access to such information, as well as their families and donors who wish to exchange this information. 354

Balancing public health and practitioner accountability in cases of medical manslaughter: Reconsidering the tests for criminal negligence-related offences in Australia after *R v Patel* – Nikita Tuckett

In 2010 Dr Jayant Patel was convicted of several offences on the basis of criminal negligence. Following the Queensland Court of Appeal's 2011 endorsement of the trial judge's decision, the case provides a timely opportunity to review prosecutions for medical negligence criminal offences throughout Australia and to critically examine the tests in assessing whether the balance has been correctly struck. The author argues that the thresholds required for prosecutions for criminal negligence for medical manslaughter are problematic and unduly onerous, and do not adequately strike the balance between the utilitarian value in health care and patient safety, on the one hand, and practitioner accountability and deterrence, on the other. This article considers reforms to remedy the imbalance, including a reformulation of the *Criminal Code* (Qld) and common law thresholds, proposals for the enactment of a separate offence of criminally negligent manslaughter and the utilisation of corporate prosecutions for manslaughter liability to broaden accountability in health care and promote patient safety on a systemic level. 377

Trafficking in persons and victim health in Australia – Andreas Schloenhardt and Benjamin Klug

This article explores the health problems experienced by victims of trafficking in persons in Australia and analyses the domestic support schemes established to assist these victims. It focuses specifically on the health of adult, female victims who constitute the majority of identified victims, and who are the principal recipients of government support services. Domestic experiences and support schemes are reviewed in the light of international law and best practice guidelines. Recommendations are made to improve the health services available to victims of trafficking in persons in Australia. 397

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