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EDITORIAL – *Editor: Ian Freckelton AO KC*

**Spit Hoods: Reforms to Law and Practice** – *Ian Freckelton AO KC*

Spit hoods have been used for decades to reduce the ability of people to spit and bite police officers, corrective services officers, paramedics, doctors and nurses. However, historically and in public consciousness they have sinister resonances and often induce fear, panic and distress in persons to whom they are applied or in whose presence they are worn. Problematically frequently spit hoods have been used on detainees from ethnic minorities, including in Australia, on Indigenous persons, individuals with mental illnesses and children taken into custody. On a number of occasions spit hoods have been used with other forms of restraint and been associated with deaths in custody. This editorial reviews high profile cases internationally where spit hoods have played a role in precipitating deaths, important reports and reviews, including from coroners, ombudsmen and commissions of inquiry, into their abuse, and law reform in relation to spit hoods. It supports their abandonment and their replacement with other personal protective equipment options for maintaining custodians’ and carers’ occupational health and safety. ....

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HEALTH LAW REPORTER – *Editor: Cameron Stewart*

**Lessons from *Re Teo*: Unconventional Practice and the National Law** – *Cameron Stewart and Ian Freckelton AO KC*

This section explores the decision of the New South Wales Professional Standards in, *Re Teo* [2023] NSWMPSC 2. The case provides insights into how the *Health Practitioner Regulation National Law Act 2009* (Qld) regulates practitioners who practise outside of conventional practice. The section compares the decision to similar cases and then concludes with a proposal that an express policy on unconventional practice is needed in Australia. ....

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LEGAL ISSUES – *Editor: Charles Lawson*

**Is Intellectual Property the COVID-19 Bad Guy? Lessons We Could Learn from the Pandemic** – *Charles Lawson*

At the time the COVID-19 pandemic was declared there was no vaccine and other medical products were insufficient to meet demands. At the time intellectual property was considered a limitation to an effective pandemic response and the World Trade the WTO change Organisation to considered a waiver of intellectual property addressed by the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS). The lesson from the COVID-19 pandemic and TRIPS waiver is that, given enough time, sufficient medical products will be delivered, albeit there remain some complicated delivery challenges and vaccine hesitancy issues. This column addresses the moment before that medical product saturation and the inherent limitation imposed by industry policies. The column concludes that the private sectors’ motivating factors need to be integrated into the design of global public health pandemic responses from the start. ....

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**Gain of Function and Loss of Control: Genetic Modification of Microbial Agents – Viruses “On Steroids”** – Mike O’Connor

Gain of Function refers to genetic modification to enhance certain properties of a biological agent. “Dual use research” refers to experiments which have a primary goal of benefitting humanity, but which could produce harm if misapplied. So, for example, a virus which was being genetically modified (GM) for altruistic reasons might become more transmissible or resistant to vaccines or antimicrobial medications. Such a GM virus has bioterrorism potential. The UN *Biological Weapons Convention* has not been universally approved and 10 States are not signatories to the Convention. The control of such experiments is variously controlled in certain jurisdictions but in Australia these experiments are well regulated through the *Gene Technology Act 2000* (Cth), the *National Health Security Act 2007* (Cth) and the *Crimes (Biological Weapons) Act 1976* (Cth). The controls on such experiments in Europe and the United States are less precise. There are examples in the United States and Europe where the security provisions to contain microorganisms undergoing research including genetic modification have been breached. This threatens the health and safety of laboratory workers and the wider community. .... 555

**Interdisciplinary Collaboration in the Mental Health Sector: Legislating the Victorian Collaborative Centre for Mental Health and Wellbeing** – Bernadette McSherry

This column explores how the law might support interdisciplinary collaboration in research and practice in the mental health sector. It provides an overview of the Victorian Collaborative Centre for Mental Health and Wellbeing which was established by statute to support collaboration across multiple disciplines and services for the benefit of mental health consumers. It suggests that interdisciplinary collaboration, which has the lived experience and knowledge of mental health consumers at its heart, has the potential for transformative and beneficial systemic change. .... 566

ARTICLES

**Consumers or Patients? Medical Device Recipients under Australian Law Straddle Two Worlds** – Julia Symons and Marco Rizzi

This article analyses the status of medical device recipients under Australian law. The 2021 *Gill v Ethicon Sàrl* litigation in the Federal Court of Australia has brought the issue to the fore. Moving from the Court’s findings, the article dissects the specific vulnerability of medical device recipients and explores the under-researched distinction between patients and consumers under Australian law. The analysis spans the regulatory landscape for medical devices prior to marketing approval, the statutory protections and causes of actions available to consumers under the *Australian Consumer Law*, and the safeguards for patients developed under medical law (particularly medical negligence). In addition to doctrinal clarifications, the article provides a discussion of key policy considerations that frame the various regimes. Patients and consumers share characteristics, but their legal protections differ in terms of focus and objectives. Medical device recipients straddle both worlds, requiring the highest levels of care and disclosure. .... 572

**Artificial Intelligence in Medicine: Issues When Determining Negligence** – Paul Nolan and Dr Rita Matulionyte

The introduction of novel medical technology, such as artificial intelligence (AI), into traditional clinical practice presents legal liability challenges that need to be squarely addressed by litigants and courts when something goes wrong. Some of the most promising applications for the use of AI in medicine will lead to vexed liability questions. As AI in health care is in its relative infancy, there is a paucity of case law globally upon which to draw. This article analyses medical malpractice where AI is involved, what problems arise when applying the tort of negligence – such as establishing the essential elements of breach of duty of care and causation – and how can these can be addressed. Product liability under Australian Consumer Law is beyond the scope of this article. In order to address this question, the article: (1) identifies the general problems that black box AI causes in the health care sector; (2) identifies the problems that will arise in establishing breach and causation due to the “black box” nature of AI, with reference to the *Civil Liability Act 2002* (NSW) and common law through two hypothetical examples; and (3) considers selected legal solutions to the problems caused by “black box” AI. .... 593

**They Can Have Our Cake – But Can We Eat It? Access to Raw Genomic Data under Australian Privacy Law** – Carolyn Johnston, Jane Nielsen, Mark J Cowley, Rebekah McWhirter and Margaret Otlowski

There is an increasing demand for the return of raw genomic data by research participants in translational genomic research. This article discusses the scope and application of privacy and freedom of information legislative provisions in Australia. Whether there is a right to access a copy of such data under Australian privacy legislation is contingent on whether raw genomic data can identify an individual and this article explores the opportunities for genomic data to be linked to individuals. We conclude that despite the complexity and overlapping nature of privacy laws in Australia, there is a clear right on the part of research participants to access their raw genomic data. .... 616

**Work Stress, Vicarious Trauma and the Public Mental Health Framework: *Kozarov v Victoria* [2022] HCA 12 and Its Aftermath** – Kay Wilson and Ian Freckelton AO KC

Research on the social determinants of health and mental health has revealed that work stress and sexual violence can have deleterious impacts on health and, in particular, mental health. A Public Mental Health Framework approach argues that law and policy are important in preventing mental ill-health and promoting wellbeing. Therefore, the 2022 decision of the Australian High Court in *Kozarov v Victoria* (*Kozarov*), in which a lawyer from the Office of Public Prosecutions (OPP) who worked in the Specialist Sex Offences Unit successfully claimed damages for vicarious trauma, has significant implications for the legal profession and those who are employed in emotionally demanding work. This article provides commentary on the *Kozarov* decision, within the context of other Australian case law including subsequent cases. It explores the significance of *Kozarov* and post-*Kozarov* authority for the development of (1) the law in “work stress” cases; (2) employers in the wake of the decision, including the OPP; and (3) the Public Mental Health Framework in relation to work stress and sexual violence as social determinants of health and mental health. .... 641

**Investigating Investigation Powers under the Health Practitioner Regulation National Law – Chris Corns**

Investigators and inspectors appointed under the *Australia Health Practitioner Regulation National Law* play important roles by gathering and assessing evidence used in disciplinary proceedings and/or criminal prosecutions. In performing these roles, investigators and inspectors exercise “police-like” powers including coercive questioning and entry onto private property with or without a search warrant. The investigation process can add additional stress and anxiety for health practitioners who are subject to disciplinary proceedings. It is difficult for an aggrieved party to challenge the lawfulness of the exercise of an investigation power in a tribunal as tribunals lack jurisdiction to rule on the legality of an investigation power or the admissibility of evidence. This article explores the range of powers possessed by investigators and inspectors under the *National Law* and a number of issues relating to the exercise of those powers. ....

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**Key Informant Perspectives on Barriers to Advance Personal Planning: Results from a Qualitative Interview Study – Briony Johnston, Nola M Ries and Amy Waller**

Advance Care Planning (ACP) relates to the process of thinking about, discussing, and potentially documenting future wishes and preferences relating to personal and health matters. Existing literature has explored ACP from the perspective of health care professionals and older people. However, data exploring the broader process of Advance Personal Planning (APP), which also accounts for plans relating to legal and financial matters, are limited. This article reports on an interview study that explored barriers to APP engagement, factors influencing the quality and future use of instruments, and opportunities for improving APP processes for older adults from the perspectives of key informants working in the fields of law, health, and aged care. Data were coded in NVivo and analysed thematically. Opportunities for improvement include education, normalising conversations, integration into usual practice, and reform. Recommendations are made at professional, community, and structural levels, with the aim of improving APP outcomes for all involved. ....

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**The Legal Needs of People Living with a Sexually Transmissible Infection or Blood-Borne Virus: Perspectives From a Sample of the Australian Sexual Health and Blood Borne Virus Workforce – David J Carter, Benjamin Riley, Rhys Evans, Adel Rahmani, Anthea Vogl, Alexandra Stratigos, James J Brown, Hamish Robertson and Joanne Travaglia**

Law and the legal environment are important factors in the epidemiology and prevention of sexually transmissible infections (STIs) and blood-borne viruses (BBVs). However, there has been no sustained effort to monitor the legal environment surrounding STIs and BBVs. This article presents the first data on the incidence and impacts of unmet legal needs for those affected by an STI or BBV in Australia using a survey administered to a sample of the Australian sexual health and BBV workforce. Migration, Housing, Money/Debt, Health (including complaints about health services), and Crime (accused/offender) were reported as the five most common legal need areas, with 60% of respondents describing these legal problems as generating a “severe” impact on health. These results indicate that unmet legal needs generate significant negative impacts in terms of individual health, on public health, and the ability to provide sustainable services such as testing and treatment to those facing unmet legal needs. ....

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**Comparing Voluntary Assisted Dying Laws in Victoria and Western Australia: Western Australian Stakeholders’ Perspectives** – Casey M Haining, Lindy Willmott and Ben P White

In 2021, two years after voluntary assisted dying (VAD) laws commenced in Victoria, Western Australia (WA) was the second Australian jurisdiction to permit VAD. While the two regimes are broadly similar, key differences exist. This article reports on findings from a qualitative study of WA participants with VAD experience across four stakeholder groups (patients and families; health practitioners; regulators and VAD system personnel; and health and professional organisation representatives), focusing particularly on participants’ reflections on aspects of the WA VAD regime which differs from that in Victoria and the practical implications of those differences. Globally, participants viewed VAD as operating smoothly in Western Australia and, despite identifying some areas for improvement, that WA’s model was more functional and accessible than Victoria’s. By comparing two different VAD models, this article’s findings add to growing empirical evidence about VAD in Australia and can inform future VAD reforms and reviews. .... 716

**When Will Death Be? Legal Considerations and Regulatory Safeguards in Predictive Modelling Applications for End-of-Life Care** – Hui Yun Chan and Bernadette Richards

Advance care planning (ACP) is generally considered as valuable in guiding treatments that are aligned with patients’ preferences. Despite its benefits, there are some practical and legal difficulties in its implementation. Predictive modelling is increasingly used in clinical decision-making, for example, in predicting patients’ life expectancy, thus enabling clinicians to initiate timely ACP conversations. This development could transform the way end-of-life conversations are implemented. In this article we advocate for the use of predictive modelling in assisting clinicians to initiate ACP conversations provided several safeguards are in place to address ethical concerns that arise. Predictive modelling applications resolve several practical and legal difficulties in conducting end-of-life conversations. Ethical concerns such as explicability, accountability, trustworthiness and reliability of these models in clinical settings are important considerations. However, safeguards are needed to address these ethical concerns to ensure the models are appropriately supportive of patient needs and interests. .... 745

**“Missing Persons”: Absent Voices of People with Dementia in the Australian Royal Commission into Aged Care** – Kristina Chelberg and Kate Swaffer

This article argues the voice of people with dementia was missing from the Australian Royal Commission into Aged Care Quality and Safety (RCAC) Final Report. This absence was notwithstanding that the RCAC was explicitly tasked to inquire into dementia care. The RCAC Final Report is shown to marginalise the perspective and experience of people with dementia in the aged care system at the same time as prioritising substitute voices of experts, advocates, family and care partners. This absence of voice repeats and re-inscribes framing of people with dementia as “missing persons”. Where people with dementia face practical and legal barriers to participate in civic and legal processes, the RCAC failed to adjust its methodologies to ensure their voices were “heard”. The RCAC’s re-inscription of marginalisation of people with dementia raises concerns for the legitimacy and success of its recommendations for dementia aged care reform. .... 761

**BOOK REVIEW**

**Law at the Frontiers of Biomedicine: Creating, Enhancing and Extending Human Life**, by SD Pattinson – Reviewed by Ian Freckelton AO KC ..... 777

