

JOURNAL OF LAW AND MEDICINE

Volume 21, Number 2

December 2013

GUEST EDITORIAL – *Loane Skene, Imogen Goold and Jonathan Herring*

Regulating the use of human bodily material

The articles in this Special Issue consider recent developments in the law regulating the use of human bodily material and the wider implications of those developments. For some time, the law has accepted that a person who has undertaken “work and skill” on excised bodily material may obtain at least a possessory right; but the person from whom the material came did not have such a right. Now, however, the law has recognised that people may have some legal rights regarding their own bodily material. What is the nature and source of those rights? Should they be expanded? If so, what legal principles are best to do that? The most frequent suggestion is the law of property but many other areas of law are also relevant: the law of contract; tort (bailment and consent); criminal law (eg forensic testing); gifts; custodianship and others. These regulatory options are outlined in this Editorial and discussed by lawyers and other contributors in their articles in this Special Issue. There are also stimulating philosophical reflections on the nature of human bodily material. 245

LEGAL ISSUES – *Bernadette McSherry*

The legal regulation of seclusion and restraint in mental health facilities – Bernadette McSherry

A recent report submitted to the United Nations Human Rights Council by the United Nations Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, has called for “an absolute ban” on the use of seclusion and restraint in mental health facilities. In Australia, seclusion and some, but not all, forms of restraint are regulated either by legislation or guidelines. This column explores some of the issues raised by the lack of national reporting requirements for these practices and moves by the National Mental Health Commission towards their reduction or elimination. 251

MEDICAL ISSUES – *David Ranson*

Using existing information from medico-legal death investigations to improve care of older people in residential aged care services – Joseph Elias Ibrahim, Lyndal Bugeja and David Ranson

The care of older people in residential aged care services could be improved by optimising the use of existing information gathered for medico-legal death investigations. The authors address three myths contributing to underuse of this information: deaths are not preventable; public health gains are too small; and it is someone else’s charter or responsibility. A significant proportion of deaths are preventable, specifically those occurring prematurely from natural causes or due to injury and trauma. By addressing these preventable deaths, significant public health cost savings and better health outcomes for our growing ageing population can be achieved. Despite substantive monitoring of the provision of aged care, no single entity is explicitly responsible for systematically

analysing medico-legal death information. The data and skills for using information from medico-legal death investigations currently exist. Dispelling the myths removes one impediment to investing in this area of public health. 255

Sexual misbehaviour in the Australian Defence Force – *Angela Williams and David Ranson*

It is clear from recent media reporting that serious issues have come to light regarding sexual misbehaviour matters within the Australian Defence Force. Subsequent reviews have indicated that these behaviours appear to have been more widespread than the initial media reports suggested and a number of reviews have been undertaken to better understand the problem and address the concerns of victims, Defence command, government and the community. If these problems are not addressed, there is a risk that recruitment to the Defence Forces may become problematic. The strong command structures within the Defence Forces can both exacerbate these misbehaviours through entrenching secrecy and at the same time have the capacity to provide a powerful leadership message that can change attitudes and reduce such misbehaviours. 262

BIOETHICAL ISSUES – *Grant Gillett*

Consent, competence and lies to children: Veracity in paediatric care – *Maeve McMurdo, Nikki Kerruish and Grant Gillett*

Principles of consent and autonomy based on adult-oriented bioethics must be modified to take account of the cognitive development occurring in childhood. That development differentially affects executive and more theoretical intelligence and is greatly influenced by experience. Thus, a judgment about a matter of degree is required by clinicians dealing with children, particularly when children diverge from the choices that would be endorsed by the adults and clinicians surrounding them. If we accept that partnership and the evolution of consent away from a formal procedure are both indicative of current ethical and medico-legal thinking, then it follows that the involvement of a child in an open-ended conversation taking account of the realistic prospects and the subjective experiences associated with treatment is the right way to proceed and that it should reflect the ability of the child to understand what is at stake and how it will affect her or him. That carries implications for the child's access to adequate information about the condition, the treatment, and the decisions being made. 265

NURSING ISSUES – *Kim Forrester*

A new beginning for health complaints in Queensland: The Health Ombudsman Act 2013 (Qld) – *Kim Forrester*

The Queensland Government has recently passed the *Health Ombudsman Act 2013 (Qld)* which will render Queensland a co-regulatory jurisdiction for the purpose of complaints in relation to all regulated health practitioners. The Act also establishes a single entry complaints management system which will apply not only to regulated health practitioners but also unregulated practitioners and health service facilities and organisations. This column considers the legislatively created positions and processes aimed at strengthening the capacity of the health complaints system to protect the public, ensure safe and competent practice, maintain high standards of service delivery and public confidence in both the practitioners and the system. 273

Government control over health-related not-for-profit organisations: Agency for International Development v Alliance for Open Society International Inc 570 US __ (2013) – *Tim Vines, Angus M Donohoo and Thomas Faunce*

The relationship between government and the not-for-profit (NFP) sector has important implications for society, especially in relation to the delivery of public health measures and the protection of the environment. In key health-related areas such as provision of medical services, welfare, foreign aid and education, governments have traditionally preferred for the NFP sector to act as service partners, with the relationship mediated through grants or funding agreements. This service delivery arrangement is intended to provide a diversity of voices, and encourage volunteerism and altruism, in conjunction with the purposes and objectives of the relevant NGO. Under the pretence of “accountability”, however, governments increasingly are seeking to impose intrusive conditions on grantees, which limit their ability to fulfil their mission and advocate on behalf of their constituents. This column examines the United States Supreme Court decision, *Agency for International Development v Alliance for Open Society International Inc* 570 US __ (2013), and compares it to the removal of gag clauses in Australian federal funding rules. Recent national changes to the health-related NFP sector in Australia are then discussed, such as those found in the *Charities Act 2013* (Cth) and the *Not-for-Profit Sector Freedom to Advocate Act 2013* (Cth). These respectively include the establishment of the Australian Charities and Not-For-Profit Commission, the modernising of the definition of “charity” and statutory blocks on “gag” clauses. This analysis concludes with a survey of recent moves by Australian States to impose new restrictions on the ability of health-related NFPs to lobby against harmful government policy. Among the responses considered is the protection afforded by s 51(xxiiiA) of the Australian *Constitution*. This constitutional guarantee appears to have been focused historically on preventing medical and dental practitioners and related small businesses being practically coerced into government or large-scale private corporate operations. As such, it may prohibit civil conscription arising not only from “gag clauses” in managed care contracts, but also from “gag clauses” in governmental ideological controls over taxpayer-funded, health-related NFPs.

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ARTICLES

Relational bodies – *Jonathan Herring and P-L Chau*

This article argues that debates over the legal status of bodies reveal a much deeper dispute over the nature of the self. In these discussions lawyers and ethicists have much to learn from a more profound understanding of the biological nature of the body. Far from being a static entity, the body is constantly recreating itself. It contains parts that are organisms in their own right. Bodies are dependent upon other bodies and the external environment for survival. The complex biological picture reflects a philosophical truth that bodies are interdependent and “leaky”. We should not, therefore, expect a single legal regime, such as property, to capture the biological and ethical values that are at stake in relation to every part of the body. A more complex statutory regime is required to recognise the complexity of the interests in, and nature of, different body parts.

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Property or not property? The spectrum of approaches to regulating the use of human bodily material – *Imogen Goold*

This article presents the case for taking a property approach in regulating the use of human bodily material. It examines the current debates on the issue and outlines the various perspectives, ranging from the anti-property stance, through the spectrum of positions on

modified and semi-proprietary approaches, through to the “full-blooded” property approach advocated by some commentators. It elucidates why those approaches that allow some proprietary aspects into regulation are to be preferred. 299

“Thin” property and controversial subject matter: Yanner v Eaton and property rights in human tissue and embryos – Lyria Bennett Moses and Nicola Gollan

This article examines the definitions of “property” offered by the majority of the High Court of Australia in the case of *Yanner v Eaton* (1999) 201 CLR 351, which involved a statute giving the Crown “property” in fauna. It argues that the majority judges in that case endorsed a flexible or “thin” conception of property that is consistent with recognition of property in “things” such as excised human tissue and in vitro human embryos, despite the many differences between such “things” and ordinary chattels. A similar flexible conception of property was also an important factor in the United Kingdom case of *Yearworth v North Bristol NHS Trust* [2010] QB 1. 307

Making something into nothing: Reforming the “no property” rule for human tissue – Nicolas Rolf

Advances in medical science have redefined the use and worth of once useless human tissue. The Australian common law has not kept pace with these advances, perpetuating the “no property” rule in human tissue. This has led to a plethora of legal problems surrounding who owns human tissue. This article examines the Australian common law position in relation to regenerative tissue. It then compares it with approaches in the United States and the United Kingdom. With a focus on absurd or unethical outcomes in these jurisdictions, it illustrates how such situations will occur in Australia. Finally, it proposes a framework of property rights that could be adopted at common law to prevent these problems without the commodification of human tissue occurring. 312

Body ownership and research – Rebekah E McWhirter, Dianne Nicol, Don Chalmers and Joanne L Dickinson

This article questions whether recognition of property rights in human tissue would enhance protection of the interests of donors of tissue used for research purposes. Best practice already obliges researchers to comply with a range of legal and ethical obligations, with particular focus on informed consent and research transparency. A number of lawsuits relating to research use of human tissue emphasise the central importance of informed consent to donors. Informed consent of communities, as well as individuals, becomes essential when engaging in research with indigenous peoples. Increasingly, genetic researchers are adopting participatory governance as a model for working with communities to develop culturally appropriate genetic studies that address health problems that are priorities for the communities involved. The transparency of the participatory governance model means that participants feel that their autonomy is respected and that their interests are being represented throughout the research process. The question of ownership of samples becomes irrelevant as control is codified through alternative mechanisms. 323

Stepping back from the property line: A perspective from regulatory theory – Chris Dent

There are multiple populations affected by issues associated with the excision and use of human tissue, each with different interests. There are also multiple subject matters for regulation; multiple regulatory goals that inform the system; and multiple strategies that may contribute to the attainment of those goals. This article outlines a range of regulatory mechanisms and suggests that a property regime is only one method of regulation in this area. Others may need to be considered to take account of the interests of all who may be affected. 330

Establishing the offence of non-consensual genetic testing in Australia: A call for action – *Margaret Otłowski*

A criminal offence should be created in Australia for non-consensual genetic testing. This has been recommended in several law reform inquiries due to the sensitive and personal nature of genetic information, and the real potential for harm that non-consensual genetic testing can cause. Since those recommendations were made, the potential for misuse of genetic information has increased, with new methods to easily access large quantities of genetic material and information, such as whole genome sequencing and the increasing availability of direct-to-consumer genetic testing. Some countries have already created an offence of non-consensual genetic testing and their provisions are considered and compared. 335

Biobanking of blood and bone marrow: Emerging challenges for custodians of public resources – *Lorena Aparicio, Wendy Lipworth, Shih-Ning Then, Cameron Stewart, Patrick Coghlan, Ian Kerridge and Jennifer Fleming*

The Australian Bone Marrow Donor Registry (ABMDR) is a publicly funded company that is part of an international network that facilitates unrelated bone marrow transplantation. This role means that the ABMDR has access to a large biospecimen repository, therefore making it a highly valuable research resource. Recognising the potential value of these biospecimens for research purposes, the ABMDR is in the process of determining whether, and how, to share its biospecimens with other biobanks. While this would undoubtedly be of value to the scientific community, and ultimately to the wider community, it would also inevitably transform the role of an institution whose primary role is therapeutic, and would compromise the degree of control that a custodian has over donated material. This article describe the challenges confronting the ABMDR, and organisations like it, in balancing their duties to donors, patients, researchers and the general public. These problems have led inevitably to the use of “property” rights language in the discussion of these issues but notions of gift, ownership, trusteeship and transfer might also be considered. 343

The law of gifts, conditional donation and biobanking – *Cameron Stewart, Jennifer Fleming and Ian Kerridge*

Tissue banks are critical to research efforts into the causes and treatment of many diseases. Biobanks are created from donated tissue but property concepts have not played a major role in understanding methods of the collection and use of tissue. Little work has been done to study the proprietary dimensions of these gifts primarily because of the influence of the *res nullius* rule. Instead, the primary focus of studies has been the concept of informed consent, but this has proven to be problematic. This article examines how the law of gifts can help to resolve these difficulties. It argues that the concept of conditional donation is a more useful way to understand and explain how tissue can be donated to biobanks. The article also suggests ways that conditional donation could be regulated so as to balance the needs of researchers and the concerns of donors. 351

Property in recyclable artificial implants – *Jamie Glister and Tony Glister*

This article discusses property rights in recyclable artificial implants such as pacemakers. These implants can remain useful and valuable after the death of the first user, but it is not clear who owns the devices when they are removed. The article explains how property rights are transferred consensually and by the operation of law. It then applies these principles to the problem of recyclable implants and argues that the central question is whether the device in any given case accedes to its host human body. If it does not, then on removal the device is owned by the same person who owned it when it was first

implanted: this may be the first user or their estate, or a hospital, or even a manufacturer. On the other hand, if the device does accede to the host body, then it ceases to exist as an independent object. The thing into which it has merged, a living human body, cannot be the subject of property rights. This means that any earlier rights in the implant are lost, and would not revive on removal. Instead, new property rights may attach to an explanted device. 357

Extra-bodily DNA sampling by the police – Jeremy Gans

Forensic investigators have statutory powers to take DNA samples directly from suspects' bodies in certain circumstances but sometimes the powers fall short, legally or practically. Police may then look for samples that have become separated from their suspects for one reason or another. No jurisdiction currently bars or even regulates this practice, which is instead loosely governed by laws on property, consent and evidence. This article argues that this lack of regulation undermines the entire system of forensic procedure laws. 364

Who owns your body? Patricia Piccinini and the future of bioethics – Matthew Rimmer

This article analyses some popular cultural representations of biotechnology, especially the artistic work of the Australian artist Patricia Piccinini to reflect on the role of law, technology and ethics in relation to bodily material. Her view that “with creation ... comes an obligation to care for the result”, so evident in her poignant pictures, is a sober reminder to us of our responsibilities in regulating new technologies. 370

How are pharmaceutical patent term extensions justified? Australia’s evolving scheme – Charles Lawson

This article examines the evolving patent term extension schemes under the *Patents Act 1903* (Cth), the *Patents Act 1952* (Cth) and the *Patents Act 1990* (Cth). The analysis traces the change from “inadequate remuneration” to a scheme directed specifically at certain pharmaceuticals. An examination of the policy justification shows there are legitimate questions about the desirability of any extension. The article concludes that key information provisions in the *Patents Act 1990* (Cth) that might assist a better policy analysis are presently not working and that any justification needs evidence demonstrating that the benefits of patent term extensions to the community as a whole outweigh the costs and that the objectives of extensions can only be achieved by restricting competition. 379

Plagiarism and registered health professionals: Navigating the borderlands between scholarly and professional misconduct – Jon Wardle

As access to published materials becomes more readily available, the ability to plagiarise material, deliberately or unwittingly, has become easier than ever. This article explores important recent decisions in Australia and the United Kingdom regarding registered health practitioners who have engaged in plagiarism, both related and unrelated to their clinical practice, and explores the ways in which regulatory authorities in these countries have viewed scholarly misconduct committed by registered health professionals. This article also examines the implications of plagiarism for the registered health professions, and makes suggestions for strategies to reduce its influence and incidence in modern clinical practice. 399

Destination death: A review of Australian legal regulation around international travel to end life – Sarah Steele and David Worswick

Travel for euthanasia or assisted suicide – so-called “death tourism” – is a controversial emerging subset of medical travel. Both anecdotal reports and research indicate that individuals from around the world, including Australians, are travelling abroad to source

medications or procedures that hasten death. This article surveys the laws that govern these markets, and asks – using the Australian framework as a case study – whether current criminal laws are themselves facilitating, even driving, this new form of medical travel. It is suggested that the complex, uncertain and often problematic nature of provisions around assisting death in Australia is making euthanasia travel increasingly desirable for those wishing to end their lives. 415

Regulating impaired doctors: A snapshot from New South Wales – Helen Kiel

This article examines the regulation of impaired doctors in Australia and explores the inherent tensions in the new *Health Practitioner Regulation National Law* in attempting to both treat the doctor and protect the public. It discusses both informal and formal mechanisms of regulation with particular reference to therapeutic jurisprudence and mandatory notification. It focuses particularly on New South Wales and examines all the impairment cases which resulted in disciplinary proceedings in the Medical Tribunal of New South Wales in 2010. It identifies the most common forms of impairment and discusses the particular challenges that impaired doctors pose for regulators. 429

Responsibility for reporting patient death due to hospital error in Japan when an error occurred at a referring institution – Shoichi Maeda, Jay Starkey, Etsuko Kamishiraki and Noriaki Ikeda

In Japan, physicians are required to report unexpected health care-associated patient deaths to the police. Patients needing to be transferred to another institution often have complex medical problems. If a medical error occurs, it may be either at the final or the referring institution. Some fear that liability will fall on the final institution regardless of where the error occurred or that the referring facility may oppose such reporting, leading to a failure to report to police or to recommend an autopsy. Little is known about the actual opinions of physicians and risk managers in this regard. The authors sent standardised, self-administered questionnaires to all hospitals in Japan that participate in the national general residency program. Most physicians and risk managers in Japan indicated that they would report a patient’s death to the police where the patient has been transferred. Of those who indicated they would not report to the police, the majority still indicated they would recommend an autopsy. 441

Paradoxical justice: The case of Ian Tomlinson – Rebecca Scott Bray

On 1 April 2009, 47-year-old London newspaper vendor Ian Tomlinson collapsed and died during the G20 protests in central London. The initial autopsy found death consistent with “natural causes”. However, that finding was disputed after the public release of mobile phone video footage showing a police officer striking and pushing Tomlinson to the ground. The release of this footage changed the course of events in the case: further post-mortem examinations found blunt force trauma to Tomlinson’s body; the Independent Police Complaints Commission launched a criminal investigation; and a coronial inquest opened that was presided over by public order policing expert Judge Peter Thornton QC. On 3 May 2011, a coronial jury delivered a verdict of “unlawful killing”, finding police actions against Tomlinson “excessive and unreasonable”. The Crown Prosecution Service then revised its decision not to prosecute the officer filmed striking and pushing Tomlinson, and on 19 July 2012 the officer was acquitted of manslaughter. This case highlights a number of key issues discussed in this article, including the symbolic and practical importance of open inquests in allaying suspicion and rumour; the ordeal of death investigation proceedings as obstacles to justice; and the seeming contra-indications for justice thrown up by divergent legal outcomes. In high-profile matters such as the Tomlinson case, these issues are further underscored by the “new publicity” around inquests in a multi-media digital age. 447

Privacy protectionism and health information: Is there any redress for harms to health? – *Judy Allen, C D’Arcy J Holman, Eric M Meslin and Fiona Stanley*

Health information collected by governments can be a valuable resource for researchers seeking to improve diagnostics, treatments and public health outcomes. Responsible use requires close attention to privacy concerns and to the ethical acceptability of using personal health information without explicit consent. Less well appreciated are the legal and ethical issues that are implicated when privacy protection is extended to the point where the potential benefits to the public from research are lost. Balancing these issues is a delicate matter for data custodians. This article examines the legal, ethical and structural context in which data custodians make decisions about the release of data for research. It considers the impact of those decisions on individuals. While there is strong protection against risks to privacy and multiple avenues of redress, there is no redress where harms result from a failure to release data for research. 473

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