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GUEST EDITORIAL – *Jenni Millbank, Isabel Karpin and Anita Stuhmcke*

Towards facilitative regulation of assisted reproductive treatment in Australia

This editorial introduces four articles reporting on the results of a four-year ARC-funded research project undertaken at the University of Technology Sydney. The study explored how Australian laws and policies across States and Territories affected the decisions of assisted reproductive treatment users with respect to their frozen embryos. In this editorial we offer some conclusions about the impact of the law which we argue fundamentally fails to take account of the diversity of ways in which embryos have meaning for the women and men who created them. We believe that informed choice and autonomy in the area of reproduction is vital. This goes beyond “consent” to a particular outcome and involves an active and ongoing process of selection. State intervention in decisions about family formation should only occur in pursuit of legitimate objectives, justified by evidence, and intrude only to the extent that is absolutely necessary. Therefore, we conclude that there must be a fundamental rethinking of the role of the state in the regulation of assisted reproductive treatment towards one of facilitative regulation. Major reforms that follow from this reconceptualisation include the provision of external information-giving and dispute resolution body or bodies to assist genuinely informed decision-making. 701

LEGAL ISSUES – *Bernadette McSherry*

Torture and ill-treatment in health care settings: Lessons from the United Nations – *Bernadette McSherry and Piers Gooding*

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, raises a number of issues related to health care practice across all countries. The report analyses the nexus between the prevention of torture prevention, the right to health, and the framework of the *Convention on the Rights of Persons with Disabilities*. Particular attention is paid to involuntary detention for medical conditions, reproductive rights violations, denial of pain treatment, the involuntary treatment of persons with psychosocial disabilities, and marginalised groups. Overall, the report seeks to highlight how certain types of mistreatment in the health care context might be addressed through a torture and ill-treatment framework when these violations can be seen to extend beyond the scope of the right to health. This column summarises some of the findings of the report and considers certain issues raised following its submission to the Human Rights Council. 712

MEDICAL ISSUES – *David Ranson*

The Coroners Court and public communications: Delivering the prevention message – *David Ranson*

The unique position of the Coroners Court within the justice system is exemplified by the ongoing death and fire prevention activities undertaken by the court through the publication of coroners’ findings and recommendations. In Victoria, publication is mandated through legislation and serves to promote public health and safety activities

within the community. Public agencies and entities are also statutorily required to respond publicly and to demonstrate what, if any, actions they have taken to address the issues identified in the coroner's recommendations. The publication of these responses on a public website puts these agencies on notice that their actions have been officially noted and that the information is available to other potential parties to legal proceedings. Statistics from the Coroners Court of Victoria suggest that the use of the publication website is increasing and that significant numbers of responses to coroners' recommendations are being received and published. 719

BIOETHICAL ISSUES – *Grant Gillett*

Immunisation and minimally informed consent – *Grant Gillett and Simon Walker*

There is a fairly well formed doctrine of informed consent in Australasia that includes the kind of information that a reasonable doctor would impart, the information that a reasonable patient should expect to be given and any details of treatment that a particular patient would need to make a reasoned decision. Whereas this standard seems generally applicable in clinical practice, the situation is otherwise in public health. The ethical balance to be struck in public health-related choices is a little different due to several factors. These include the public interest in effective herd immunity, the practicalities of mass immunisation programs, the likelihood of subjective bias distorting an objectively reasonable choice, and the unreliability of anecdotal evidence regarding risks and benefits in this area. Four factors of ethical importance arise: a proper system of health governance and the trust it warrants; the likelihood that subjective assessments of risk and benefit may be misleading; the need for individual compliance in the service of a shared or public good; and the nature of adequate information for the relevant decision in relation to the objective best interests of members of a community. These combine to justify a less stringent standard for consent in certain public health settings. 723

NURSING ISSUES – *Kim Forrester*

Understanding law in clinical practice: Theory or reality? – *Debra Griffiths*

How do nursing and medical staff working in acute care environments deal with patients who decide to decline medical treatment? To understand current practices and investigate their sufficiency in addressing patient wishes, a qualitative study was undertaken in two public hospitals in Melbourne, Victoria. The aim was to ascertain how nurses and medical practitioners actually manage patients' decisions to refuse active treatment. In light of the existing legislative provisions, the study highlighted numerous responses, including areas that may limit patient autonomy and the subsequent right to self-determination in the acute care environment. This column concentrates on one facet of the findings relating to the participants' knowledge of the law and the recording of decisions. 728

COMPLEMENTARY HEALTH ISSUES – *Ian Freckelton SC*

Legal implications for complementary medicine practitioners of the New South Wales Health Practitioner Code of Conduct – *Michael Weir*

A number of recent cases in Australia of unprofessional practices by unregistered health practitioners resulting in injury to consumers have revealed the difficulty faced by regulators in not having the discipline provided by a registration board. New South Wales, in enacting a *Code of Conduct for Unregistered Health Practitioners* under the *Public Health Act 2010* (NSW), has applied negative licensing to specify the expectations for professional practice for unregistered health practitioners and, importantly, to provide the legislative basis for restraining practitioners who are non-compliant with the provisions of this Code. If applied sensitively to legitimate practice, this form of regulation will provide

cost-effective and not unduly restrictive regulation. South Australia has now applied a similar Code. This form of regulation is of national significance as it is one regulatory option currently being considered at a national level. 734

MEDICAL LAW REPORTER – *Thomas Faunce*

Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65: Should gene patent monopolies trump public health? – *Tim Vines and Thomas Faunce*

At a time when the double mastectomy of Angelina Jolie has highlighted the importance of genetic testing for breast cancer, the Federal Court’s decision in *Cancer Voices Australia v Myriad Genetics Inc* [2013] FCA 65 has clarified that, for now at least, isolated DNA and RNA can constitute a patentable invention under s 18(1)(a) of the *Patents Act 1990* (Cth). This is a significant decision for companies seeking to secure patents over DNA and genetic material, whether isolated or not. This column critically examines this case in the context of parallel legal action currently underway in the United States. It also reviews it with regard to political and bureaucratic inaction in Australia (much of which relies upon an overly restrictive interpretation of the High Court decision in *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252) that has compromised the setting of cost-effective public health limits on patentable subject matter concerning the human genome. 747

ARTICLES

Rethinking consent, information-giving and counselling concerning stored embryos within IVF treatment – *Eloise Chandler, Anita Stuhmcke, Jenni Millbank and Isabel Karpin*

This article presents findings on consent practices drawn from a larger research project about the impact of law, ethical guidelines and clinical policies and practices upon the decisions that people make about their stored embryos created during IVF. In exploring the process of decision-making about stored embryos, participants reflected upon their earlier experiences of clinic information-giving and counselling, particularly at the outset of treatment. The study found that the type and timing of the information given and the range of options presented by clinics in typical consent processes did not meet many participants’ needs. Informed consent processes in IVF involving the storage of embryos require a number of key changes. Consent to treatment and subsequent decisions about storage and further outcomes for stored embryos need to be addressed separately. To be effective, embryo directive forms should be accompanied by plain language explanations of their legal effects, including what elements are binding, the source of the rules governing decisions, and available formal and informal dispute resolution avenues. Consent and embryo directive forms should be made available on clinic websites to allow greater opportunity for reflection, as well as enabling patients to compare the options available at each clinic. Greater availability of ongoing counselling as well as other external sources of information are crucial to enable informed decision-making. 759

Use of stored embryos in IVF following separation or death of a partner – *Anita Stuhmcke, Isabel Karpin, Eloise Chandler and Jenni Millbank*

When stored embryos are created through IVF, the individuals responsible for them are rarely contemplating what will happen to those embryos in the unexpected event of separation from their partner or death. This article draws upon the findings of a larger empirical study based upon interviews with people who have or have had embryos in storage. It explains the stark attitudinal difference of interviewees between what should happen to embryos following separation as opposed to the death of a partner and exposes confusion and uncertainty surrounding “consent” in these circumstances. In particular, on

the subject of the posthumous use of embryos, the present research highlights a dramatic mismatch between law, consent forms and the express wishes of participants. This article concludes that current legal approaches are insufficiently nuanced to effectively resolve disputes concerning what will happen to stored embryos in the event of separation or death and recommends changes to law, the NHMRC Ethical Guidelines, and clinical policies and practices. The present authors advocate for the development of both formal and informal dispute resolution mechanisms and propose that the current position of the NHMRC Ethical Guidelines and State legislation requiring express written consent to posthumous use by the deceased be reversed. 773

Embryo donation for reproductive use in Australia – Jenni Millbank, Eloise Chandler, Isabel Karpin and Anita Stuhmcke

This article presents empirical findings on embryo donation for the reproductive use of others in Australia, drawn from a larger research project about the impact of law, ethical guidelines and clinical policies and practices upon the decisions that people make about stored embryos created during IVF. The authors interviewed 10 people who had actually donated embryos for the reproductive use of others and four people who were recipients of donated embryos. In addition, another nine interviewees had attempted to donate, or had a strong desire to donate, but had been prevented from doing so. The article places the present findings in the context of Australian and international research on widespread unwillingness to donate for reproductive use of others. The article then examines why the donors interviewed here were willing and able to donate, and presents findings concerning the donation process and models in operation, including matching and counselling practices and the contentious question of “directed donation”. The article also reports the experiences of several “would-be” or thwarted donors and examines the rationales for some of the external barriers to donation identified in the course of the study. 789

Analysing IVF participant understanding of, involvement in, and control over embryo storage and destruction in Australia – Isabel Karpin, Jenni Millbank, Anita Stuhmcke and Eloise Chandler

This article examines the impact of laws regulating the storage and destruction of embryos on the people most affected by them: individuals and couples who have engaged in IVF treatment. It presents findings from a large empirical study examining the impact of law, ethical guidelines and clinical policies and practices on the decisions that people make about stored embryos created during IVF. The authors support the continued storage of embryos where this is desired by patients and, equally, the destruction of embryos where this is desired by patients. Based on this research, they have crafted a number of recommendations that aim to respect the deeply emotional dimension of decision-making concerning stored embryos and their disposition and to maximise the opportunity for informed choice. 811

Stem cells and regenerative medicine: From research regulation to clinical applications – Donald Chalmers, Peter Rathjen, Joy Rathjen and Dianne Nicol

Stem cell science has attracted widespread international interest in recent years. Stem cells are valuable tools for basic science. There are considerable hopes that stem cell technology may lead to treatments for degenerative diseases, such as Parkinson’s disease, and for ischemic events, such as stroke and heart attack. Stem cells may become sources for replacement and transplantation tissue for nerve, muscle, blood, liver, pancreatic and heart diseases. The science has accelerated over the last decade, especially since the discovery of pluripotent embryonic stem (ES) cells in humans in 1998. The term “regenerative medicine” is increasingly used as stem cell research moves towards clinical applications, such as trials to address macular degenerative disorders. This article examines the current state of the science of stem cell technology, the regulatory

frameworks established for the derivation of stem cells, particularly from human embryos, which has attracted the greatest ethical and legal controversy, and the translation of stem cell research to clinical applications. 831

Recent moves to compensate women who provide their eggs for research and implications for Australia – *Loane Skene*

In Australia, it is unlawful for women to be paid or otherwise rewarded for donating their eggs for use in medical research (or for treatment). The issue was considered and rejected in both reviews of the Australian federal legislation on human embryo research. However, compensation is permitted in some parts of the United States; and in the United Kingdom, women can gain fertility treatment more cheaply if they donate some eggs for research (a process called “egg sharing”). Recent policy reviews support some compensation for women who donate eggs for research. The collection of human eggs is invasive and may have risks. If women are compensated, it would not be for the eggs themselves. Women not undertaking fertility treatment would be compensated for the time, discomfort, inconvenience and potential health risks associated with egg collection. Women who are already having eggs collected for treatment would be compensated for the loss of a chance of pregnancy from an egg provided for research. The women would be compensated even if no eggs are collected, or the eggs are not suitable for research (but not if the women later change their minds and want to keep their eggs). This need not be a precedent for payment for the donation of organs or tissue, which can be distinguished from egg donation. 845

Best interests of neonates: Time for a fundamental re-think – *Neera Bhatia* and *Mirko Bagaric*

This article examines the operation of the “best interests” test in relation to life and death decisions involving very young children. It is in this context that the best interests standard operates most acutely because it is not clouded by other considerations, especially individual autonomy. It argues that the standard is too obscure to provide an acceptable legal, medical and moral framework to inform life and death decisions. In particular, it argues that the basal assumption that underpins the test – that some lives are so pitiable that they should not continue – is conceptually flawed. This should prompt a fundamental reassessment of the test, whereby the legislature establishes concrete criteria regarding the application, scope and content of the standard. 852

Adult guardianship: Law, autonomy and sexuality – *The Hon Michael Kirby AC CMG*

The history of the law governing adults considered incompetent to make decisions for themselves originated in England in the *parens patriae* powers of the King. Subsequently, legislation revealed repeated competition between due process objectives and help and care models. Recent law reform inquiries in Australia, partly influenced by the new United Nations Disabilities Convention, have tended to favour enhancement of personal autonomy, to the highest degree feasible. In 1993, the author, in *Holt v Protective Commissioner* (1993) 31 NSWLR 227, foreshadowed and encouraged this approach, to which he adheres. However, new challenges are arising in respect of sexual relations and activities by persons with diminished capacity. The author suggests that these issues too must be resolved with high respect for the subject’s personal autonomy. Particular questions arise in attempted denial of that autonomy affecting sexual minorities and these are described and some conclusions drawn. 866

Rights, risks and the value of life: A critical analysis of the right to life under the European Convention on Human Rights – Alexander Green

The right to life has become increasingly debated in recent years and is of particular interest and importance to the medical profession. As it is enshrined under Art 2 of the *European Convention on Human Rights*, it is one of the most clearly developed provisions of that treaty. This article argues that courts assume the sanctity of life in their judgments and that judicial treatment of Art 2 constitutes an instrumental policy approach based on risk, rather than an attempt to remain loyal to rights-based reasoning. These two elements are criticised as antithetical to the concept of rights and a return to a rights-based approach is argued for.

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Contemporary practices in dementia research: Should the legal governance processes catch up to the clinical realities? – Richard Polkinghorn

Research involving people with dementia has grown exponentially in recent years as a result of the ageing population and the growing interest in research in this area. Many subjects cannot give informed consent to take part in the research, by virtue of their age and mental capacity, and are extremely vulnerable. It is ethically and legally unacceptable to exploit such people. However, it is argued that, in practice, researchers and members of ethics committees have difficulty applying the existing NHMRC and other guidelines because there is a “disconnect” between what is evident in theory and what happens in the reality of practice. This is demonstrated through an examination of the various procedures including informed consent, dual consent and the practice of both researchers and ethics committees. The article also recognises that researchers, clinicians and regulatory authorities must work collaboratively to achieve workable solutions that address the legal and ethical needs of this very vulnerable group of patients.

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Withholding and withdrawal of “futile” life-sustaining treatment: Unilateral medical decision-making in Australia and New Zealand – Lindy Willmott, Ben White and Jocelyn Downie

This article examines the law in Australia and New Zealand that governs the withholding and withdrawal of “futile” life-sustaining treatment. Although doctors have both civil and criminal law duties to treat patients, those general duties do not require the provision of treatment that is deemed to be futile. This is either because futile treatment is not in a patient’s best interests or because stopping such treatment does not breach the criminal law. This means, in the absence of a duty to treat, that doctors may unilaterally withdraw or withhold treatment that is futile; consent is not required. The article then examines whether this general position has been altered by statute. It considers a range of suggested possible legislation but concludes it is likely that only Queensland’s adult guardianship legislation imposes a requirement to obtain consent to withhold or withdraw such treatment.

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BOOK REVIEW

Stress, Trauma and Wellbeing in the Legal System by Monica Miller and Brian Bornstein

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