HOLMAN WEBB LAWYERS

Health Law Bulletin

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Contents

Introduction

Welcome to the August 2017 edition of the Holman Webb Health Law Bulletin.

Futurists predict that technology will be a major player in healthcare. Healthcare will shift its focus to preventive instead of reactive care. Genomic medicine will allow doctors to both treat illnesses based on your genes and work to prevent you from getting sick. Medical devices can already monitor our health. A program might direct you to run diagnostic tests on yourself and then send the results to your doctor, who would explain them and prescribe treatment via video. Consumers demand convenience and personal consultations may become a thing of the past, with people moving to on-line consultations using mobile devices. Regenerative medicine involves healing the body by replacing or regenerating cells, tissues or organs, including the use of stem cells. Hospitals will become more accountable and efficient by providing coordinated, standardised care.[1]

Personalised medicine may be used to make the use of medications more effective and reduce waste. Last but not least, the use of big data will facilitate better health outcomes through improved communication and record keeping and health service management, resourcing and planning.

There are a number of legal and ethical issues associated with all of these predictions. For example, big data raises privacy issues and the increased use of genomic testing raises issues in relation the standard of care and duty to warn.

What should be the rights of future consumers? The ACCC has recently announced that it will investigate Aveo over its contract terms and conduct, highlighting the need to have in place appropriate protections for consumers.

This Health Law Bulletin discusses issues such as:

- Legal and ethical issues with genomic testing;
- Lessons learnt from the Red Cross Blood Service Data Breach; and
- recent cases such as *Hunter v Hanson* [2017] NSWCA 164; *AAI Limited (t/as Vero Insurance) v GEO Group Australia Pty Limited* [2017] NSWCA 110; *Tinnock v Murrumbidgee Local Health District (No 6)* [2017] NSWSC 1003 and *ACCC v Reckitt Benckiser (Australia) Pty Ltd* [2016] FCAFC 181.

We trust that this edition of the Health Law Bulletin brings to you articles of relevance to the sector.

The health, aged care/retirement living and life science sectors form an important part of the Australian economy. They are economic growth areas, as more Australians retire with a significantly longer life expectancy and complex health care needs.

Against this background, Holman Webb's health, aged care and life sciences team provides advice that keeps pace with the latest developments. Our team has acted for health and aged care clients over a number of years, in the government, "for profit" and the "not for profit" sectors.

Some of our team members have held senior positions within the health industry.

Please do not hesitate to contact me or any member of our legal team should you have any questions about the Health Law Bulletin content and articles or if one of your colleagues would like to be added to our distribution list. ■

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[1] Shanna Freeman, *Futurist Predictions in the World of Health*, available at http://electronics.howstuffworks.com/future-tech/5-futurist-health-predictions.htm

Legal and Ethical Issues with Genomic Testing

By Alison Choy Flannigan, Partner and Zara Officer, Special Counsel

Introduction - Genome Testing – Genome.One

An Australia-first genomic testing service that combines whole genome sequencing and a comprehensive health assessment can offer individuals an unprecedented glimpse into their future health.[2]

Launched in June 2017, by Sydney's Garvan Institute's Genome. One lab and corporate clinic Life First, the service offers individuals the ability to predict how they would likely react to more than 220 medications, allowing clinicians to better tailor treatment to their patients.

People with a niggling curiosity and $6,400 can now find out if their genetics and lifestyle has left them prone to developing a suite of life-threatening conditions including 31 types of cancer and 13 heart conditions across 230 genes.

Blood samples provide the raw material needed to sequence a patient's genome. Individuals also undergo a physical examination as well as pathology testing and a review of lifestyle risks like smoking, diet and alcohol intake.

Genetic counsellors guide patients through the process, explaining how the testing works, managing expectations and interpreting the results.

Genome.One provides a number of services, namely:

- **Personal health genomics** - Personal health genomics analyses your genome (the entirety of a person's genetic material including all their genes) to provide you with a genomic profile. This profile can help you and your doctor to make personalised health decisions.
- **Disease diagnostics** - Genomic testing may identify the gene variant(s) that causes a genetic condition. This diagnosis can confirm the patient's condition, and can help with prognosis and management of their medical condition. The Whole Genome Sequencing (WGS) is used to produce information across the genome for analysis and clinical interpretation.
- **Discover genomics** - Discovery genomics services help position researchers at the forefront of genomic innovation for genomic exploration at scale.
- **Personal health applications** - Precision medicine relies on sophisticated algorithms, integrated data sharing networks and highly accessible software interfaces. Precision health platforms can reduce costs and improve health outcomes for patients.

Ethical Challenges[3]

Whilst genomic testing brings the prospect of real benefits for patients and the potential to revolutionise diagnosis, screening, prevention and treatment, it also raises a number of ethical challenges, including the following:

1. **Equity of access** – should access to genomic testing only be available to those who can afford to pay for it?
2. **Consent** – can a person consent without knowing the full implications of what they are consenting to? With genomic testing, the boundaries of the possibilities of testing are constantly expanding.
3. **Confidentiality** – the sharing of patient information is vital in order to assess the significance of individual genetic variants by comparing them to the norm. Genomic testing may test the boundaries of consent, particularly when information is known about one person, but could be of significant value to their family members and their health care providers.
4. **Availability for the greater good and adequate protection of genetic data** – what if something is discovered of clinical significance to humanity? The uniqueness of our genetic data means that it can never be truly anonymous. Protections need to be put in place to reduce the risk of discrimination based on genetic characterisations.
5. **Patient choice** – Many patients have suffered several years of delayed diagnosis. A genomic test may be able to provide information earlier so that treatment options can be introduced much earlier in the patient journey resulting in significant improvement of patient outcomes. In the future, should genomic testing be mandatory for the population to assist with health planning? However, people should have a right to privacy and many people may make the conscious choice not to be provided with information concerning their mortality. Ultimately, the challenge is to enable patients to have the choice. If they have the choice, then are they stealing from their family members their choice as well?
6. **Ownership** – what if a particular individual's genome are so unique as to unlock a key in medical discovery. Should pharmaceutical companies own intellectual property rights and therefore monopoly rights involving the fabric of a person's genome?

[2] Introduction sources: http://www.smh.com.au/national/health/australianfirst-whole-genome-sequencing-and-health-testing-open-to-public-20170619-gwtsgm.html; https://www.genome.one/

[3] Source information includes: http://www.phgfoundation.org/blog/ethical-challenges-for-generation-genome

Duty of care

Negligence means a failure to exercise care and skill. In an action for negligence, the plaintiff must prove that:

- the defendant owed him or her a duty to take reasonable care;
- the defendant breached that duty by failing to take reasonable care;
- the defendant's breach of duty caused the injury or damage suffered by the plaintiff; and
- the injury or damage suffered was not too remote as a consequence of the breach of duty.

The standard of care is now codified in Australia, for example under the *Civil Liability Act 2002 (NSW)* (**Civil Liability Act**). There is similar legislation in each State and Territory of Australia.

Section 5B of the Civil Liability Act states.

(1) A person is not negligent in failing to take precautions against a risk of harm unless:

(a) the risk was foreseeable (that is, it is a risk of which the person knew or ought to have known), and

(b) the risk was not insignificant, and

(c) in the circumstances, a reasonable person in the person's position would have taken those precautions.

(2) In determining whether a reasonable person would have taken precautions against a risk of harm, the court is to consider the following (amongst other relevant things):

(a) the probability that the harm would occur if care were not taken,

(b) the likely seriousness of the harm,

(c) the burden of taking precautions to avoid the risk of harm,

(d) the social utility of the activity that creates the risk of harm.

Does genomic testing expand what is reasonably foreseeable?

The standard of care for professionals is set out in section 5O of the Civil Liability Act:

(1) A person practising a profession (a professional) does not incur a liability in negligence arising from the provision of a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice.

(2) However, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational.

(3) The fact that there are differing peer professional opinions widely accepted in Australia concerning a matter does not prevent any one or more (or all) of those opinions being relied on for the purposes of this section.

(4) Peer professional opinion does not have to be universally accepted to be considered widely accepted.

This Division does not apply to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information in respect of the risk of death of or injury to a person associated with the provision by a professional of a professional service.

In future, will genomic testing become standard of care?

The duty to warn is identified as extending to "material risks" which may attend a proposed treatment. The risk is "material", relevantly for present purposes, if it is a risk to which a reasonable person in the position of the patient "would be likely to attach significance in choosing whether or not to undergo a proposed treatment".[4]

Except in cases of emergency or necessity, all medical treatment is preceded by the patient's choice to undergo it which choice is in reality, meaningless unless it is made on the basis of relevant information and advice.

Genomic testing may well influence the obligation of duty to warn for clinicians.

In our opinion, with genomic testing, three things will become critical:

- adequate confidentiality and privacy protection and the need to obtain adequate consent;
- the patient to be able to make an informed and conscientious choice as to the genetic information to be provided to him or her; and
- appropriate genetic counselling. ■

What Retirement Village Operators Need to Know About *Australian Consumer Law* & NSW Reforms

By Alison Choy Flannigan, Partner and Bill Lo, Solicitor

Background

The Australian Competition and Consumer Commission (**ACCC**) has recently announced that it will launch an investigation of the *"more serious matters being raised"* in the Aveo retirement village scandal.

ACCC Chairman Rod Sims said there also needs to be a wider review of the sector, which should involve the Australian Securities and Investment Commission (**ASIC**) and state regulators.

There are three main areas the ACCC will investigate: misleading conduct, unfair contract terms and unconscionable conduct.

We note that NSW Fair Trading has recently commenced auditing Retirement Village Operators. We recommend that all Retirement Village Operators review their Village Contracts to ensure that they comply with both retirement living laws and the *Australian Consumer Law*.

The *Australian Consumer Law* (**ACL**), is contained in Schedule 2 of the *Competition and Consumer Act 2010 (Cth)* and applies to consumer contracts including Village Contracts and also residential aged care and home care client agreements.

It is important to remember that if there is an inconsistency between the legislation and the contract, the legislation will prevail to the extent of the inconsistency.

Unfair Contract Terms

The ACL provides that a term of a consumer contract will be void if the term is unfair and the contract is a standard form contract.[5]

A consumer contract is a contract for the supply of goods or services or a sale or grant of an interest in land to an individual whose acquisition of the goods, services or interest is wholly or predominantly for personal, domestic or household use or consumption.

A consumer contract is a standard contract unless proven otherwise.[6] A standard form contract is offered on a "take it or leave it" basis.

[5] *Australian Consumer Law*, Section 23
[6] *Australian Consumer Law*, Section 27

A term will be unfair if it:

(a) causes a significant imbalance in the parties' rights and obligations under the contract;

(b) is not reasonably necessary to protect the legitimate interests of the party advantaged by the term; and

(c) causes financial or other detriment to the resident if it were relied on.[7]

However, the following terms are exempt from the unfair contract provisions of the ACL:

(a) terms that set out the price;

(b) terms that define the product or services being supplied; and

(c) terms that are required or permitted by another law (such as terms limiting liability permitted by the ACL).[8]

An example of an unfair term under a Village Contract would be one that allows the Village Operator to unilaterally terminate or amend the contract or a one-sided harsh indemnity.[9]

Unconscionable Conduct

Village Operators must not engage in conduct that is unconscionable.[10] Unconscionable conduct is generally understood to mean conduct which is so harsh that it goes against good conscience. Conduct may be unconscionable if it is particularly harsh or oppressive. To be considered unconscionable, the conduct must be more than simply unfair — it must be against conscience as judged against the norms of society.

Factors considered by the court include:

(a) the relative bargaining strength of the parties;

(b) whether any conditions were imposed on the weaker party that were not reasonably necessary to protect the legitimate interests of the stronger party;

(c) whether the weaker party could understand the documentation used;

(d) the use of undue influence, pressure or unfair tactics by the stronger party;

(e) the requirements of applicable industry codes;

(f) the willingness of the stronger party to negotiate;

(g) the extent to which the parties acted in good faith.

An example of unconscionable conduct is encouraging a resident to sign a Village Contract knowing that the resident does not have the skills to understand the terms of the Village Contract.

[7] *Australian Consumer Law*, Section 24
[8] *Australian Consumer Law*, Section 26(1)
[9] *Australian Consumer Law*, Section 25
[10] *Australian Consumer Law*, Section 20

Misleading and Deceptive Conduct

Village Operators must not engage in conduct that is misleading or deceptive or is likely to mislead or deceive.[11] Village Operators should ensure that any statements, including those used in their marketing materials, are true, accurate and able to be substantiated.

Contraventions of the ACL in respect to false or misleading conduct will attract a pecuniary penalty. The maximum penalty is $1.1 million for corporations and $220,000 for individuals.

Incorrect Representations

In addition to the ACL, retirement village legislation may also include prohibitions for making incorrect representations. For example, section 17 of the *Retirement Villages Act 1999 (NSW)* states that a retirement village operator is prohibited from making incorrect representations, including representations:

- which are knowingly inconsistent with the information contained in the disclosure statement provided to the prospective resident;
- which are knowingly about an existing or future service or facility which is/will be provided or available at the village unless the services or facility is provided; or
- which are prohibited by the regulations, for example, that the resident is likely to make a capital gain on vacating the premises or that residents of the village have priority access to residential care by an approved provider under the *Aged Care Act 1997 (Cth)*.

The penalty for making a false representation is 50 penalty units, that is $5,500.

[11] *Australian Consumer Law*, Section 18

NSW reforms and Retirement Villages Regulation 2017 (NSW)

The Retirement Villages Regulations 2017 (NSW) will commence on 1 September 2017.

The proposed changes are as follows:

- clarifying that re-painting of external surfaces once every 10 years is capital maintenance;
- requiring copies of a village's insurance policy documents be available to residents;
- a new 'average resident comparison figure' in the Disclosure Statement to facilitate more effective comparison between villages;
- reducing the maximum amount payable for an operator's legal and other expenses to $50;
- adding new matters for which village rules can be created, including smoking in communal areas;
- requiring clearer information in annual budgets around head office expenses;
- lowering the maximum amount allocated for contingencies to $1;
- prohibiting additional matters that cannot be financed by recurrent charges;
- simplifying the process for allowing residents to hold office on a residents committee for longer than three years; and
- allowing service of documents by electronic means. ■

The Importance of Understanding Your Medical Malpractice and Civil Liability Policy – Updated - *AAI Limited (t/as Vero Insurance) v GEO Group Australia Pty Limited* [2017] NSWCA 110

By Zara Officer, Special Counsel

A recent Court of Appeal decision confirms the need for healthcare providers to understand their medical malpractice and civil liability policy terms and conditions. The primary decision was the subject of our article in the May 2017 edition of the Health Law Bulletin.

Facts

Mr Mace was charged with armed robbery offences on 18 February 2010 and was refused bail. On 3 March 2010 Mr Mace was transferred to Parklea Correctional Centre (**Parklea**) on remand and remained in protective custody from 3 March to 7 March 2010. GEO Group Australia Pty Limited (**GEO**) was the new private operator of Parklea and was contractually required to provide psychological and counselling services to inmates at the prison. On 7 March 2010 Mr Mace jumped off a landing at Parklea and suffered serious injuries including brain injuries. It was common ground that no psychologist or counsellor employed by GEO had any contact at all with Mr Mace prior to the incident. Mr Mace sued the State of New South Wales, Justice Health and GEO in the Supreme Court. The case was settled by all three defendants.

GEO was insured under a Medical Malpractice Civil Liability Insurance Policy (**Policy**), and GEO made a claim under the Policy in May 2012 in respect of Mr Mace's claim. AAI Limited t/as Vero Insurance (**Vero**) resisted the claim, arguing that it did not fall within the terms of the Policy.

Primary proceedings

The essence of Mr Mace's claim against GEO was that it failed to conduct an appropriate risk assessment of Mr Mace on his arrival at Parklea or at all, failed to provide him with access to psychological services, and failed to refer him to Justice Health for treatment or further assessment.

Mr Mace claimed that GEO negligently failed to provide him with health care services as it ought to have done.

The claim in the Supreme Court made by GEO against Vero was expressly limited to the claim made against GEO by Mr Mace.

The trial judge considered that Mr Mace's claim against GEO was a claim "resulting from" GEO's conduct of the "Health Care Services" and therefore fell within the insuring clause of the Policy.

Vero appealed. Vero maintained that the non-provision of counselling and psychological services by GEO to Mr Mace did not fall within the cover provided by the Policy. Vero's argument was not accepted by the Court of Appeal, and the Court of Appeal upheld the primary decision.

Insuring clause

The insuring clause of the Policy provided:

> *"The Insurer will indemnify the Insured against civil liability for compensation and the claimant's costs and expenses in respect of any Claim or Claims first made against the Insured and notified to the Insurer during the Period of Insurance* ***resulting from the conduct of the Health Care Services"*** *(our emphasis).*

Health Care Services were defined as the *"provision of medical services and treatment including services and treatment provided by psychologists and counsellors"*. Those services involved inmate assessment. The cover extended to claims concerning acts and also omissions in the conduct of the Health Care Services.

Contractual obligations

GEO was required by its contractual obligations as the private operator of Parklea to assess, identify and manage inmates at risk of self-harm in custody when they entered Parklea. GEO employed psychologists and counsellors to meet those obligations. In the case of Mr Mace, GEO failed to undertake such an assessment and provide him with necessary mental health services. GEO failed to identify Mr Mace's risk of self-harm.

Court of Appeal findings

Mr Mace's claim against GEO was limited to the non-provision of the services. Vero argued that this was outside the insuring clause of the Policy because it related to the provision of GEO's operational custodial services (which it did not insure) rather than its health care services. The Court of Appeal did not agree.

The Court of Appeal held that an objective observer would conclude that the parties to the insurance policy intended that the "conduct" of the Health Care Services included an omission by GEO to provide health care services. The insuring clause was broad enough to provide cover to GEO in circumstances where, by reason of a failure of GEO's health care systems to identify Mr Mace as requiring assistance, he suffered loss and damage.

The conduct of Health Care Services by GEO involved more than acts and omissions of a particular counsellor or psychologist in the course of the consultation with a particular inmate. The "conduct" of Health Care Services extended to identifying and assessing inmates for the purpose of determining what health services were required.

The Court of Appeal was of the opinion that at the time of Mr Mace's admission to Parklea, GEO was engaged to provide health care services to inmates at Parklea and the failure to assess Mr Mace was an omission in the provision of health care services to inmates. The claim therefore resulted from the conduct of Health Care Services, as defined in the Policy. The primary judge had come to this conclusion, and the Court of Appeal upheld her decision. The policy cover applied.

This is a case in which the Court took a broad interpretation of the insuring clause in the Policy, so that the cover applied. Health care providers should regularly review their medical malpractice and civil liability policy terms and conditions to ensure that their ordinary activities, including the omission to provide their services, are covered.

Defamation - Absolute Privilege and the Good Faith Protection for Complaints to the NSW Medical Council and Health Care Complaints Commission *Hunter v Hanson* [2017] NSWCA 164

By Zara Officer, Special Counsel

A recent Court of Appeal decision in a defamation claim has considered the defence of absolute privilege under section 27(2)(d) and Schedule 1, clause 15 of the *Defamation Act 2005 (NSW)*, and the good faith protections for complainants under the *Health Care Complaints Act 1993 (NSW)* and the former *Medical Practice Act 1992 (NSW)*.

Facts

Mr Scott Hunter and Dr Benjamin Hanson were neighbours and the relationship was not amicable. The antagonism stemmed from a long-running dispute involving the use of a Crown Road running through Mr Hunter's property. Dr Hanson and his partner were entitled to and did use the road to access their property.[12] The catalyst for the defamation proceedings were two letters dated 5 February 2010 and 28 March 2010 (**the letters**) which Mr Hunter wrote and sent to the former NSW Medical Board (**Board**) and the NSW Health Care Complaints Commission (**HCCC**) concerning Dr Hanson.

It was common ground at the trial that the two letters conveyed defamatory imputations and that those imputations were false. Among the imputations conveyed in the first letter were that Dr Hanson was "*so unprofessional that he breached standards of professional practice, that he was so unethical that he deliberately misused and exaggerated a patient's medical condition for his own gain, that he was so mentally unstable that he was not competent to practice medicine, that he had committed perjury, a criminal offence, made false complaints to the police and was so delusional that he had a mental illness and/or a manic disorder*".[13] The second letter conveyed imputations that Dr Hanson was "*so vindictive that, in retaliation for the first letter he had made a false complaint to the NSW Police and that he was so unethical and unprofessional that he used his medical status to make a false diagnosis of [Mr Hunter].*"[14]

Primary defamation proceedings

Dr Hanson commenced defamation proceedings against Mr Hunter. At the District Court trial, Mr Hunter did not plead any positive defence and the only issue at trial was whether by virtue of the nature of the publications to the HCCC and the Board, Dr Hanson could not have suffered any loss or damage. Mr Hunter argued the HCCC and the Board were legally bound under statute to keep the letters confidential, and in any case the letters were not believed or given any credence by those bodies.

During the trial Mr Hunter obtained leave to plead a defence of triviality under section 33 of the *Defamation Act 2005 (NSW)* (**Defamation Act**). In making out the defence of triviality, it was submitted on behalf of Mr Hunter that it was clear the complaints to the HCCC and the Board lacked bona fides, and there was no objective factual support for the complaints. The majority of the matters complained about had "nothing whatsoever" to do with Dr Hanson's practice as a medical practitioner. The complaints were characterised as "*a self-evident case of abuse by a disgruntled neighbour about a dispute over access to neighbouring land…*" and "*…a vexatious complaint devoid of any substance in fact made by a disgruntled neighbour*".[15] The HCCC had dismissed the complaints within three months of them being made.

The defence of triviality was rejected and the trial judge awarded $50,000 damages plus aggravated damages in the sum of $10,000, and interest in the amount of $8,000. The total damages award was $68,000. In awarding aggravated damages, the trial judge said "*there can be no other view open to the Court except that [Mr Hunter's] conduct was lacking in bona fides, was improper and is unjustifiable*".[16]

Mr Hunter appealed. An application for leave to appeal was required because the damages were under $100,000.

Court of Appeal

In the Court of Appeal Mr Hunter attempted to raise two further defences to the defamation claim, that of absolute privilege under section 27 and Schedule 1, clause 15 of the Defamation Act, and the defence of good faith under section 47 of the *Medical Practice Act 1992 (NSW)*.

The Court of Appeal dismissed Mr Hunter's application for leave to appeal. The Court of Appeal refused to permit Mr Hunter to raise defences of absolute privilege or good faith on appeal, when these defences had not been raised at the trial. The Court of Appeal nevertheless made comment on each of the defences.

[12] *Hunter v Hanson* [2014] NSWCA 263 at [1]
[13] *Hunter v Hanson* [2017] NSWCA 164 at [14]
[14] *Ibid* at [15]
[15] *Ibid* at [18]
[16] *Ibid* at [19]

Absolute privilege defence

In *Lucire v Parmegiani*[17] the Court of Appeal held that the defence of absolute privilege under the Defamation Act, so far as it concerned complaints to the former Board, was confined to communications made for the purpose of dealing with a complaint once made, but not the complaint itself. The Court of Appeal decided that Mr Hunter should not be able to rely on the protection of absolute privilege under section 27 and Schedule 1 of the Defamation Act for the first time on appeal. The Court of Appeal then expressed the view that neither of the complaint letters would be protected by absolute privilege, based on the decision of *Lucire v Parmegiani*. A further, more pragmatic reason not to allow the absolute privilege defence to be raised, was that the matters in the letters largely were not within the remit of the HCCC. In large measure, the complaints related to the road issue rather than the professional conduct of Dr Hunter. The line as to what was or what was not within the remit of the HCCC was not a matter that should be addressed on appeal for the first time.

Good faith defence

The proposed good faith defences were also raised for the first time on appeal.[18] This was diametrically opposed as to how the trial was run by Mr Hunter, and inconsistent with the findings made by the trial judge. In support of the defence of triviality at the trial, Mr Hunter had submitted that his letters lacked any bona fides and his complaints had little to do with Dr Hanson's practice as a medical practitioner, were vexatious, and included false allegations.

Mr Hunter's counsel in the Court of Appeal submitted that honesty of purpose, or good faith is presumed and it was for Dr Hanson to displace that presumption. The Court of Appeal was not attracted by that submission. Though it was not necessary to decide the matter, the Court of Appeal said that Mr Hunter would bear the evidentiary burden to establish he had acted in good faith when making the complaints to the Board and to the HCCC, in order to attract the immunity. This had not been done at the trial, in fact, the opposite had been argued, to support the defence of triviality.

[17] [2012] NSWCA 86

[18] Those defences are contained in section 96 of the *Health Care Complaints Act 1993 (NSW)*, and section 47 of the former *Medical Practice Act 1992 (NSW)* (repealed). The good faith protection previously in the *Medical Practice Act 1992 (NSW)* is preserved in section 237 of the *Health Practitioner National Law 2010 (NSW)*.

Damages

With respect to the damages awarded, the Court of Appeal considered that they were not manifestly excessive. The trial judge was dealing with implications which attacked Dr Hanson at the core of his professional and personal reputation. Further, although the publication of the letters was limited, they were conveyed to persons responsible for Dr Hanson's future as a medical practitioner, and additionally Dr Hanson had had to disclose the letters to his professional association and possibly to his insurer.

Comment

The case is a clear illustration of a vexatious complaint which should never attract the good faith protections under section 96 of the *Health Care Complaints Act 1993 (NSW)*, or the current section 237 of the *Health Practitioner Regulation National Law 2010 (NSW)*. It provides clear guidance of the type of complaint which can easily be characterised as not made in good faith. The case also affirms previous authority of *Lucire v Parmegiani* that there is no defence of absolute privilege under the Defamation Act for individuals who make complaints to the Board. This principal is likely to apply to complaints made to the HCCC and to the NSW Medical Council.

Dr Hanson was successful in bringing his defamation suit. The complaint made against him was not made in good faith. It can be expected that other examples of complaints that are dismissed by the HCCC may arise. Such complaints may well be made in good faith, but the complainant may nevertheless be subjected to a defamation suit. The complainant will bear the onus of proving they acted in good faith, as it will not be presumed. ■

Patient consent issues where the procedure is performed by another surgeon - *Tinnock v Murrumbidgee Local Health District (No 6)* [2017] NSWSC 1003

By John Van de Poll, Partner and Vahini Chetty, Senior Associate

Facts

Ms Tinnock initially underwent surgery for repair of an incisional hernia on 7 June 2010, under the care of Dr Justin Gundara, surgical registrar. The surgery was supervised by Dr Michael Payne, specialist general surgeon.

On 15 June 2010, Ms Tinnock underwent a second surgery to drain a seroma which had developed secondary to the first surgery. During the course of that surgery, a mesh dressing was applied.

Dr Payne performed a third procedure on 27 June 2010 to close the abdominal cavity which accommodated the mesh dressing.

Ms Tinnock presented to the Calvary Hospital in Canberra on 16 July 2010 with a severe infection associated with the surgical mesh. On this occasion, she required urgent surgical intervention.

Ms Tinnock subsequently commenced proceedings against the Murrumbidgee Local Health District in the New South Wales Supreme Court alleging battery. In particular, she alleged that she did not consent to Dr Gundara performing the first surgery. In the alternative, if unsuccessful in her claim for battery, Ms Tinnock relied on a claim in negligence alleging that an ordinary specialist general surgeon professing to have the special skill associated with that profession would have inserted a negative pressure surgical drain to reduce the risk of post-surgical infection. Ms Tinnock went on to claim that in relation to the second and third procedures, reasonable care on the part of her surgeons required that they diagnose the presence of infection and either remove the mesh as its probable source or treat her as an inpatient with intravenous antibiotics for a prolonged period.

To establish an action in battery, Ms Tinnock had to establish that she had not consented to the treatment performed, or that the consent she had provided was invalid.

In considering the question of consent, the Court emphasised that Ms Tinnock's case was not that she was mistaken as to the nature or quality of the procedure proposed or its intended therapeutic nature, but rather, she alleged that she was mistaken as to the identity of the person who would perform the surgery.

This gave rise to two questions for the Court to consider, first, whether Ms Tinnock believed the operation would be performed by Dr Payne and no one else, and if so, whether this led to a mistaken belief on her part as to the nature and character of the operation so as to vitiate her consent. Campbell J formed the view that even if she was mistaken as to who would perform her surgery, this would not have led to a vitiation of consent since the nature and character of the operation would remain the same.

Ms Tinnock signed a consent form at her first consultation with Dr Payne on 25 February 2010. The contents of that consent form indicated that Ms Tinnock had consented to an incisional hernia repair (post-caesarian section).

The twelfth line of that consent form contained the acknowledgement, *"I have been told that the procedure/treatment may be performed by another doctor"*.

During the course of cross-examination, Ms Tinnock identified her signature, and gave evidence that whilst she had read the form *"fairly closely"* before signing it, she was unaware of the content of that acknowledgement.

Whilst he did not recall the details of what he had told Ms Tinnock, Dr Payne gave evidence that it was his standard practice to inform patients that in the public system, consultant surgeons will not always personally perform the procedure, and that the procedure might be performed by one of his registrars.

Ms Tinnock denied receiving this information and stated that she would have requested further details regarding any other doctor who might perform the surgery if she had.

The clinical record nominated Dr Gundara as the surgeon and Dr Payne as the assistant. Dr Gundara was halfway through his surgical training at the time of Ms Tinnocks Surgery, and subsequently became a Fellow of the Royal Australasian College of Surgeons in March 2015. He gave evidence that all relevant decisions regarding the surgery were made by Dr Payne.

Findings

The Court accepted both surgeons' evidence regarding their standard practice and found that this was not an operation performed by Dr Gundara rather than Dr Payne, but that it was performed by both doctors although Dr Gundara was the designated surgeon. Both doctors were present and "scrubbed in". Dr Payne was not merely standing by and watching, but directed Dr Gundara fairly closely and took an active part in the procedure. Moreover, the evidence of the doctors accords with what is generally known about the practice of surgeons, that is to say that they very commonly work in pairs when performing surgery under general anaesthetic.

Ms Tinnock was found to be aware of the contents of the consent form, and she was found to have understood its terms when she signed it.

Accordingly, Ms Tinnock's claim in battery failed.

With respect to Ms Tinnock's claim in negligence, the Court found that Dr Payne's care fell short of the standards of the ordinary surgeon in that he failed to use negative pressure drains in the original repair of the incisional hernia, failed to identify the mesh infection by 3 July 2010, and failed to treat the mesh infection more aggressively by re-operating to remove the mesh for washing with topical antibiotics or removing it altogether.

Ms Tinnock succeeded in her claim in negligence and was awarded $1,005,509 in damages.

The Court's decision in relation to consent indicates that so long as the treatment rendered is consistent with the nature and character of the treatment to which a patient has consented, consent will not be vitiated where a different surgeon performs the procedure. However, that surgeon will need to possess the ordinary level of skill and competence. ■

Full Federal Court orders $6 million penalty for Nurofen Specific Pain products *Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Ltd* [2016] FCAFC 181; *Reckitt Benckiser (Australia) Pty Limited v Australian Competition and Consumer Commission* [2017] HCASL 86

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

In the September 2016 edition of our Health Law Bulletin we reported on Australian Competition and Consumer Commission's (**ACCC**) proceedings against Reckitt Benckiser (Australia) Pty Ltd (**RB**) and the judgment arising from the first substantive hearing. Since that judgment, there has been an appeal to the Full Federal Court and finally in April 2017, the dismissal of an application for special leave to appeal to the High Court of Australia by RB.

Facts

The cases concerned the marketing of the Nurofen specific pain range of products, that is, the four Nurofen specific packaged product range said to "target" migraine pain, period pain, back pain and tension headache. There was no difference in the therapeutic content of the four products, however, the products were sold with a recommended retail price of about double that of the standard Nurofen product which also provided a dose of 200mg of ibuprofen. The only difference was the packaging and the marketing. Contrary to the representations, ibuprofen does not "target" any particular kind of pain. Any representation to that fact was inherently misleading. The obvious and expected consequence of the contravening conduct was to entice consumers to pay more for the products.

Primary Judgement

The primary judge of the Federal Court imposed a civil penalty of $1.7 million on RB arising from contraventions of section 33 of the *Australia Consumer Law* (**ACL**), which is contained within Schedule 2 to the *Competition and Consumer Act 2010 (Cth)* (**CCA**).

Section 33 of the ACL states that:

> *"A person must not, in trade or commerce, engage in conduct that is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose or the quantity of any goods."*

The maximum penalty for each contravention of section 33 of the ACL is $1.1 million for corporations and $220,000 for individuals.

Full Court of the Federal Court Decision

The Full Federal Court in December 2016 set aside the $1.7 million penalty and in its place ordered a penalty of $6 million.

The Court limited the penalty to the amount sought by the ACCC, namely $6 million, which was based upon a characterisation of the conduct as involving 6 courses of contravening conduct. The ACCC submitted that the four different packages each amounted to a contravention and there were two web sites that amounted each to a contravention. The primary judge held that the conduct was characterised as amounting to two contraventions (namely publications on a web site and the representations on the packaging).

Interestingly, the appeal judges considered whether the characterisation of the contraventions as amounting to the number of times by which consumers may have been misled:

> *"Rather, the misleading character of the representations operated as contraventions each and every time a consumer saw the packaging"* [19]

Given there were 5.9 million products sold in the contravening packaging, the Court theoretically suggested the maximum penalty was a multiplier of 5.9 million by the maximum penalty per contravention of $1.1 million. However, the Court held that the assessment of the appropriate range for penalty in the circumstances of the case is best assessed by reference to other factors, as there is no meaningful overall maximum penalty given the very large number of contraventions over such a long period of time. Given this, the court considered that, to the extent that the course of conduct principle had any meaningful work to do, the better way to look at it was in terms of each of the four "types" of packaging, each with its own consumer target audience. This proceeding really involves four types of contravention, with many individual contraventions each over the five years. The webpage contraventions can be viewed as one or two serious courses of conduct. But ultimately, this discussion itself serves to demonstrate the limited utility of the course of conduct principle in the circumstances of a case such as the present, and why such characterisation could not properly have the significance which the primary judge gave to it.[20]

[19] *Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Ltd* [2016] FCAFC 181 at [145]
[20] Ibid at [157]

Overall, in the particular circumstances of the case, the Court considered that one useful guide to the appropriate penalty range is loss to consumers. In this case, loss may be assessed by reference to the extra amount paid by consumers as against a product that did not suffer from any of the impugned representations, such as ordinary Nurofen.

The potential for financial gain from the contravening conduct was in excess of $20 million (on the simple proposition that the total revenue was $45 million and the products were sold at twice that of the standard products).[21]

The Court also considered the need for deterrence both general and specific, was substantial. The notation of deterrence in the context of this case warrants some further elaboration. In the Court of Appeal's view, RB's conduct was towards the high end of the range for section 33 contraventions.[22]

In addition, the primary judge overlooked at least one readily apparent non-monetary effect of the contravening conduct, the loss or at least serious distortion of genuine consumer choice and created the risk of double-dosing.[23]

The Court noted that prohibited conduct under section 33 only needs to be "*liable to mislead the public*", it does not need to be misleading or deceptive, such as representations prohibited by sections 18 and 29 of the ACL.[24]

Overall, the judgment of the Full Federal Court suggests there was potential for the contravening conduct to have attracted penalties well exceeding the $6 million penalty sought by the ACCC and imposed by the Court. The Court noted that it could have been entitled to impose a considerably greater penalty, given the losses which it considered were occasioned by the conduct and these were serious contraventions even within the spectrum of the liable to mislead category. The Court in setting the penalty emphasised that an "*ordinary and natural consequence of the conduct was the real risk that some consumers did not buy an alternative product that was in fact formulated to treat their specific pain and of double-dosing by consumers suffering from more than one of the types of pain purported to be treated by the so-called Nurofen specific pain range*".

Pharmaceutical companies and medical device companies must continually assess their compliance measures in the packaging and promotion of their there therapeutic goods. The judgment of the Full Federal Court suggests that future action for non-compliance with the ACL in the marketing to consumers of therapeutic goods may result in significantly higher penalties than have historically been imposed. ■

[21] Ibid at [158]
[22] Ibid at [149]
[23] Ibid, para [114]
[24] Ibid at [177]

Matters to Consider when Advertising Therapeutic Goods – Consistency with the Accepted Indication/Accepted Intended Purpose

By Alison Choy Flannigan, Partner and Bill Lo, Solicitor

Sponsors of therapeutic goods must ensure that they advertise their products in accordance with the indications accepted in relation to inclusion on the Australian Register of Therapeutic Goods (**ARTG**).

A person commits an offence under section 22(5) of the *Therapeutic Goods Act 1989 (NSW)* (**Act**) if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

A person commits an offence under section 41ML of the Act if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion.

Contravention of either of the above provisions of the Act will incur a penalty of 60 penalty units, that is $12,600.

Sponsors of a registered/listed medicine/medical device must also hold evidence to support all the indications they make for their product at the time they register/list the medicine/medical device in the ARTG. The evidence they hold must adequately support all indications and demonstrate all claims made for the medicine/medical device are true, valid and not misleading.

If you advertise an indication other than as accepted for use in the ARTG which is also misleading and deceptive, then you will also be in breach of the *Australian Consumer Law (**ACL**)*.

Contraventions of the ACL in respect to false or misleading conduct will attract a pecuniary penalty. The maximum penalty for false or misleading and unconscionable conduct and breaches of relevant product safety provisions is $1.1 million for corporations and $220,000 for individuals.

In *ACCC v Reckitt Benckiser (Australia) Pty Ltd* [2016] FCAFC 181, the Full Federal Court has upheld an appeal by the Australian Competition and Consumer Commission against the penalty imposed on Reckitt Benckiser (Australia) Pty Ltd for contravening the ACL. The Full Court ordered Reckitt Benckiser to pay a revised penalty of $6 million (up from $1.7 million) for making misleading representations about its Nurofen Specific Pain products.

Set out below are a sample of relevant cases from the Therapeutic Goods Administration Complaints Resolution Panel (**Panel**). The cases indicate that the Panel will:

- review each advertisement in its context to ensure that the advertisement is consistent with the Accepted Indication/Accepted Intended Purpose in the ARTG;
- in checking for consistency, be quite strict in interpreting the wording of the advertisement against the Accepted Indication/ Accepted Intended Purpose in the ARTG; and
- not require perfect reproduction of the wording of an indication in advertising.

Caroline's Cream

In *2014/06/007 Caroline's Cream (Health Writer Hub and Caroline's Skincare Pty Limited)*, the advertisement included representations about the therapeutic use of the product that did not correlate to any of the indications stated on the ARTG entry for the product, for example, curing the 25 listed conditions, claims regarding the relief and management of frostbite and stretch marks and the management of haemorrhoids.

The Panel held that section 22(5) of the Act does not in the Panel's view amount to a requirement that the accepted indications for therapeutic goods must be reproduced in entirety in each advertisement for those goods. The question of whether an advertisement complies with section 22(5) of the Act must be decided for each advertisement in context.

XL(S) Medical

In *2016-02-011 XL(S) Medical (Orion Laboratories Pty Limited trading as Perrigo Australia)*, the complainant alleged that the advertisement, through the inclusion of the product label within it, breached section 22(5) of the Act because it used the words "*lose up to 3x more weight than with dieting alone*", while the indications on the ARTG for the advertised product were qualified with the word "*help*".

The Panel did not find this aspect of the complaint justified, for two reasons:

(a) the advertisement as a whole clearly qualified the indication, so that the complainant's allegation was not sound; and

(b) in any event, promoting the advertised product for weight loss, when an indication on the ARTG was for weight loss, did not breach section 22(5) of the Act. Section 22(5) of the Act does not require perfect reproduction of the wording of an indication in advertising; rather, it requires that therapeutic goods be advertised only for uses consistent with their indications and not for uses that are not indicated.

Caroline's Lip Balm

In *2015-04-003 Caroline's Lip Balm (Caroline's Skincare Pty Limited and Doward International Pty Limited)* the Panel found that the advertisement advertised the product for the prevention of cold sores because of the words "*the formula is especially useful for those who typically suffer from extremely dry skin which can often result in the onset of conditions such as Cold Sores*".

While the intended purpose for the product made some reference to cold sores, it did not in the Panel's view extend to the *prevention* of cold sores, only to the use of the product by sufferers of cold sores for *symptomatic relief*.

Cyber Security - Tips for Health Care Providers

By James Vickery, Managing Director, I Know IT

The Australian Signals Directorate's cyber security web page at: https://www.asd.gov.au/infosec/mitigationstrategies.htm provides useful guidelines for healthcare providers to minimise the threat of a hacking attempt or data breach.

Historically, hacking and virus creation might have been considered somewhat of a hobby for bored, tech savvy teenagers with too much time on their hands or disgruntled former employees looking to inflict some harm on their employer on the way out the door. These attacks, whilst disruptive for some, were often isolated and caused minimal disruption to the broader business community or the public.

Today, hacking and virus attacks are often initiated by crime organisations looking to extort money through ransomware or to target sensitive records for financial gain. These highly sophisticated, targeted attacks are carried out by organisations who reside overseas and out of reach of law enforcement.

The recent high profile "Petya" and "WannaCry" strikes were created to inflict the most damage to businesses. The cost to organisations in Australia alone stands at $4.5 billion this past year.[25] That's more than enough to prompt the Government to start educating businesses on preventing a major cyber security incident.

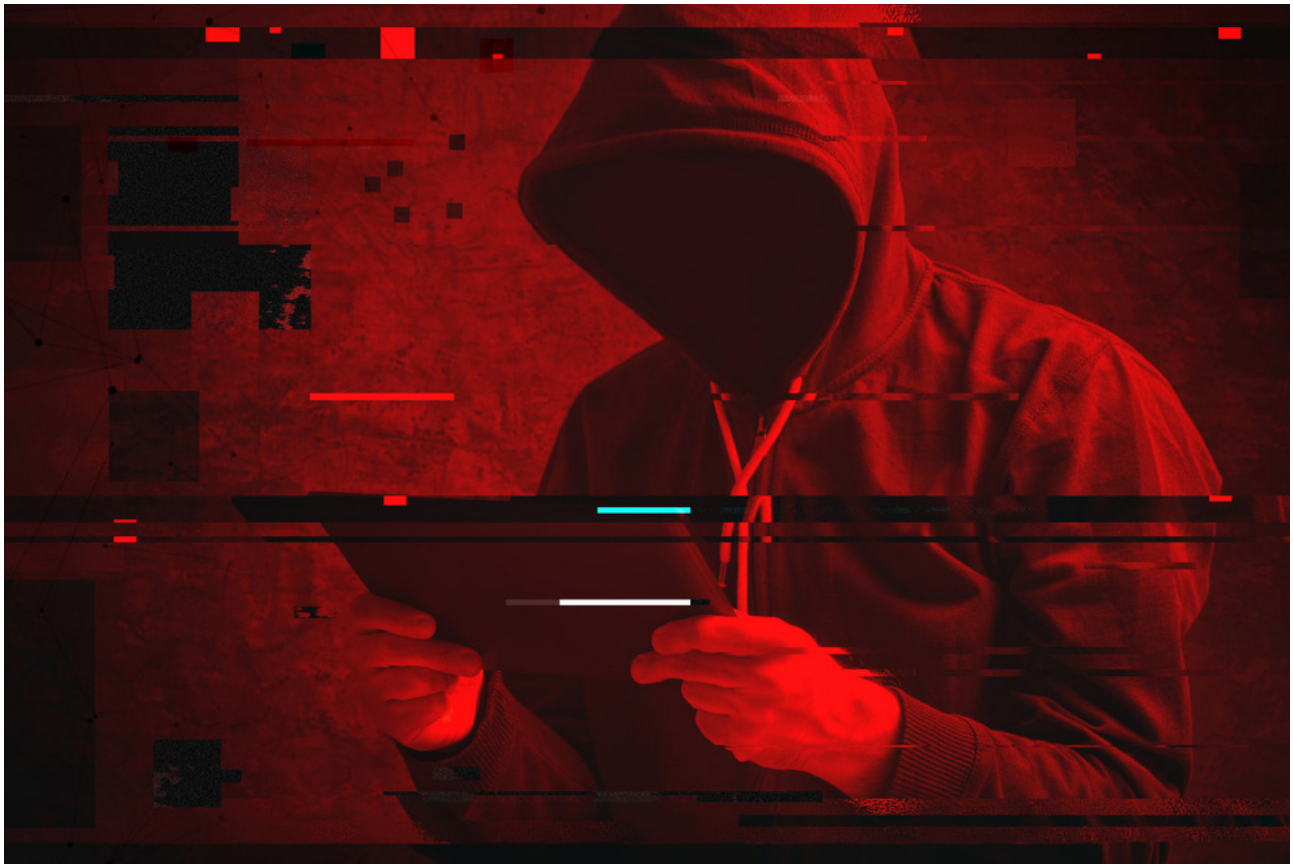
Organisations who hold health records, such as health and aged care providers are a particularly attractive target because of the sensitivity of the data that they hold. In many cases the attacks are not obvious to the victim for months or years after the fact while sensitive data is quietly sold off on the dark web.

Australian Signals Directorate Guidelines

The Australian Security Directorate (**ASD**) guidelines are available at https://www.asd.gov.au/infosec/mitigationstrategies.htm.

The ASD guidelines include several recommendations ranging from firewall security, implementing more complex passwords or using 2-Factor verification services (similar to those used for internet banking) as a first step in the prevention of cyber-crime.

Health care providers should conduct a full review or audit of their IT and backup systems as their current IT infrastructure may not be designed to withstand or recover from a cyber-attack.



[25] Acumen Insurance Broker, *Cybercrime costs the Australian Economy over $4.5 billion annually 14 March 2017*, available at http://acumeninsurance.com.au/2017/03/14/cybercrime-costs-the-australian-economy-over-4-5-billion-annually-and-is-now-in-the-top-5-risks-faced-by-businesses/

The reason that these modern intrusions have been so successful is that most organisations lack the knowledge or resources to implement the recommendations set out by the ASD.

The ASD states that no single mitigation strategy is guaranteed to prevent cyber security incidents. At least 85% of the adversary techniques used in targeted cyber intrusions which ASD has visibility of could be mitigated by implementing the following mitigation strategies, referred to as the "Top 4", namely:

- use application whitelisting to help prevent malicious software and unapproved programs from running;
- patch applications such as Flash, web browsers, Microsoft Office, Java and PDF viewers;
- patch operating systems; and
- restrict administrative privileges to operating systems and applications based on user duties.

These Top 4 mitigation strategies for targeted cyber intrusions were mandatory for Australian Government organisations as of April 2013.

Before implementing the strategies, organisations need to identify their assets and perform a risk assessment to identify the level of protection required from cyber threats. Organisations need to:

- identify which assets require protection – do they hold important, sensitive or other information with a need for immediate and continuous access?
- identify which adversaries are most likely to compromise their information – cyber criminals, nation-states or malicious insiders?
- identify what level of protection is required – use the Essential Eight (see guidelines) strategies as a baseline and then select other relevant strategies based on the risks to their business.

Where to from here?

In order to prevent or minimise the threat of cyber crime, you should:

1. review the ASD guidelines;
2. discuss the guidelines with your internal IT department or IT service provider;
3. assess that your staff and contractors have the required skills and experience in cyber security mitigation;
4. conduct an IT security audit. A contractor with a background in cyber-security prevention techniques specific to the health care sector can identify flaws within your organisation's IT systems and advise on specific actions to take; and
5. educate staff on basic security precautions such as password protection, not opening suspect attachments or memory devices and set their devices to lock within a certain period of time.

As the cyber landscape continues to change it's also important to stay up to date with the latest developments and recommendations.

Lessons learnt from the Red Cross Blood Service Data Breach Investigation

By Alison Choy Flannigan, Partner and Nicholas Heinecke, Special Counsel

Introduction

On 7 August 2017, the Office of the Australian Information Commissioner (**OAIC**) released the following investigation reports into the major data breach that occurred on 5 September 2016 through the Australian Red Cross Blood Service's (**Blood Service**) website:

- *DonateBlood.com.au data breach (Australian Red Cross Blood Service) Investigation Report; and*
- *DonateBlood.com.au data breach (Precedent Communications Pty Limited) Investigation Report.*

This incident highlights the need for Commonwealth Government and private sector healthcare providers to:

1. implement processes and policies to ensure that personal information which is collected by that entity is periodically destroyed or de-identified in accordance with Australian Privacy Principle (**APP**) 11.2 of the *Privacy Act 1998 (Cth)* (**Privacy Act**); and
2. when engaging third party contractors, including specific contractual obligations about the handling of personal information and mechanisms to ensure the obligations are being fulfilled.

In addition, healthcare providers should also be reviewing and updating their contracts to ensure that contractors notify the healthcare provider of relevant data breaches. Mandatory notification of serious data breaches will commence in February 2018. Please refer to our previous article, avaiable at: http://www.holmanwebb.com.au/blog/mandatory-data-breach-notification-to-commence-privacy-amendment-notifiable-data-breaches-act-2017-cth.

Facts

On or about 5 September 2016 a database containing files relating to approximately 550,000 prospective blood donors was moved to a public-facing web server. The file was inadvertently placed on the web server by an employee of a third party contractor providing services for the management of the Blood Service's website, Precedent Communications Pty Ltd (**Precedent**). The data file was discovered and accessed by an unknown individual on 25 October 2016. On the same day, the individual notified the Blood Service via a number of intermediaries. The Blood Service immediately took steps to contain the breach.

The Blood Service responded on 26 October 2016 and in the following days, took a number of steps to immediately contain the breach, including temporarily closing the website. It engaged a consultant to undertake an independent risk assessment and notified individuals whose personal information was involved and provided assistance to those individuals. The Blood Service accepted full responsibility for the incident.

The Blood Service

The OAIC concluded that:

"The data breach occurred without the authorisation or direct involvement of the Blood Service, and was outside the scope of Precedent's contractual obligations to the Blood Service. There was no 'disclosure' by the Blood Service of the data file within the meaning of (APP) 6." [26]

The Blood Service had in place policies and procedures to protect personal information as required by APP11.1, including documented information security policies and regular staff training.

However, there were two matters within the Blood Service's control that were a contributing factor to the data breach and which constituted breaches of the Privacy Act, namely:

- the absence of contractual measures or other reasonable steps on the part of the Blood Service to ensure adequate safety measures for personal information held for it by the relevant third party contractor, in breach of APP 11.1; and
- the retention of data on the website for a longer period than was required, in breach of APP 11.2.

Although the Blood Service had not met all of the requirements under the Privacy Act in relation to the data breach, the Blood Service acted appropriately and in a timely manner to rectify the data breach, and its response to the data breach provides a model of good practice.

All copies of the database backup had been destroyed and the Blood Service has enhanced its information handling processes.

It does not appear that the Blood Service assessed the adequacy of Precedent's security measures and practices when the decision to award Precedent the contract for the development and application support, ongoing management, consulting and testing, maintenance and upgrade of the Donate Blood website in 2015.

The contractual arrangements between the Blood Service and Precedent focussed on service level agreements and were absent control to mitigate the corresponding privacy risks of a third party provider. The Blood Service's requirements of Precedent in relation to information security were not clearly articulated or proportional to the scale and sensitivity of the information held by the Blood Service and Precedent. A reasonable step in the circumstances may have been to include specific contractual requirements for how Precedent would handle and store the personal information of blood donor on the Donate Blood website, and a reporting mechanism for the Blood Service to ensure these contractual requirements were being met.

The Blood Service failed to implement the appropriate contractual requirements or control measure in order to protect personal information that is handled by a third party provider.

A contract addressing data management or IT related services may contain a clause requiring the parties to comply with Privacy Laws and at the conclusion of the arrangement to return or destroy all confidential information. The data breach that affected the Blood Service highlights the need to periodically assess and manage collected personal information, to ensure that your contracts with contractors comply with privacy laws and requires the contractor to notify you of any data breaches.

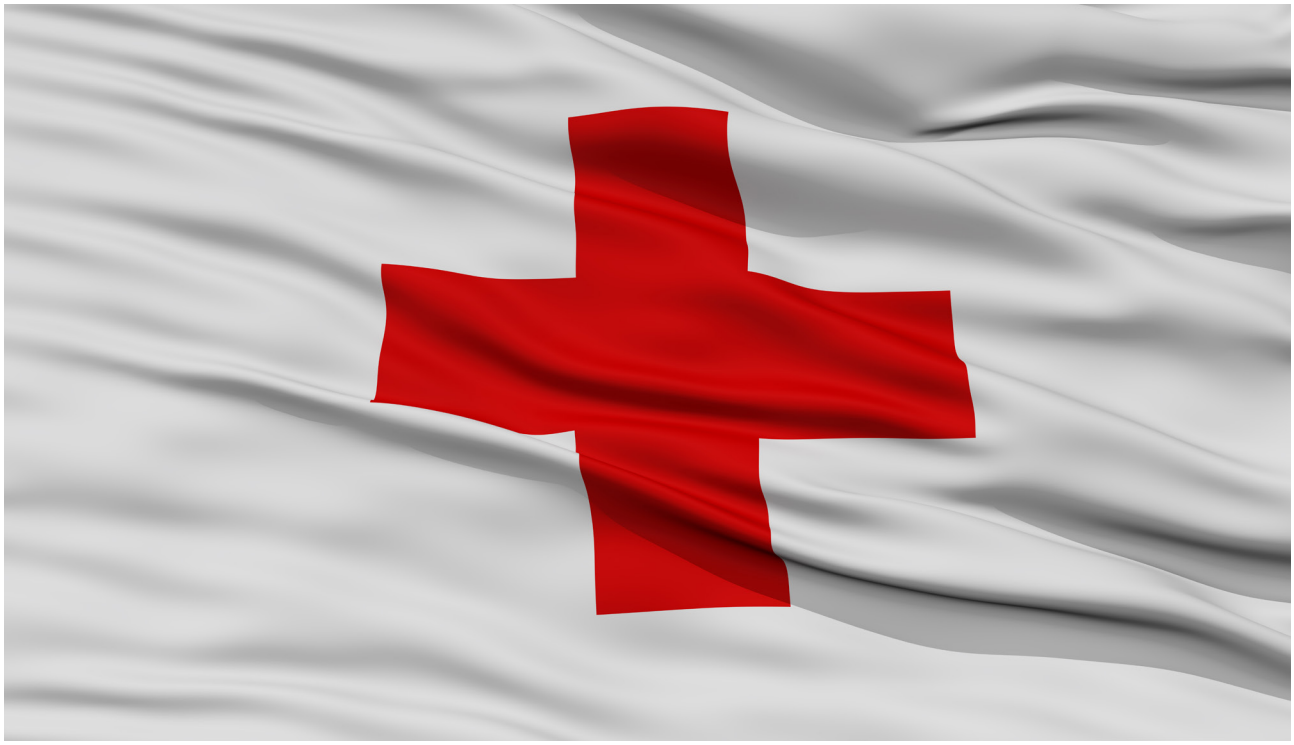
The OAIC found that the *"Blood Service failed to implement the appropriate contractual requirements or control measures in order to protect personal information that is handled by a third party provider"* giving rise to a breach of APP 11.1.

APP 11.1 states:

> *"11.1 If an APP entity holds personal information, the entity must take such steps as are reasonable in the circumstances to protect the information:*
>
> *(a) from misuse, interference and loss; and*
>
> *(b) from unauthorised access, modification or disclosure."*

APP 11.2 requires an entity to take such steps as are reasonable in the circumstances to destroy or de-identify personal information after it is no longer needed for any purpose for which the information was used or disclosed by the entity and the entity is not required by or under an Australian Law or a court/tribunal lawyer to retain the information.

[26] OAIC, *DonateBlood.com.au data breach (Australian Red Cross Blood Service) Investigation Report 7 August 2017*, page 2 available at https://www.oaic.gov.au/privacy-law/commissioner-initiated-investigation-reports/donateblood-com-au-data-breach-precedent-communications-pty-ltd



Matters which you should consider include:

- conducting appropriate due diligence on the services to be provided;
- considering the scope of the personal information handling services to be provided;
- considering what security controls and personal information handling measures the third party provider is expected to use; and
- including terms in the contract to deal with specific obligations about the handling of personal information and mechanisms to ensure the obligations are being fulfilled, such as regular reporting requirements.

A contract with a third party service provider who holds sensitive personal information should provide for *"specific obligations about the handling of personal information and mechanisms to ensure"* compliance. It is insufficient to include in such a contract (without more) a general obligation to comply with your policies. We would add that the specific obligations in the contract need to be both enforceable and give rise to consequences if not complied with. It is insufficient for a clause to only state that the parties will generally comply with Privacy Laws. For example, a third party contractor may not know what actions you must take to comply with the APPs, such as when and how frequently you will destroy personal information.

Precedent Communications Pty Limited

The root cause of the data breach was an unforeseen one-off human error on the part of a Precedent employee, such that the data breach was a "disclosure" within the meaning of APP6.

Precedent breached the Privacy Act in respect of APP6 and APP11, by:

- disclosing the personal information of individuals who had made an appointment on the Donate Blood website, in breach of APP 6; and
- failing to take reasonable steps to adequately mitigate against the risk of a data breach, and to protect the personal information it held from unauthorised disclosure, in contravention of APP 11.1.[27]

The case highlights how a number of security deficiencies can create a situation in which human error can trigger a data breach. Organisations should have sufficient protection in place to ensure that even if there is a failure at one point, other levels of protection will prevent the breach from occurring.

The Commission acknowledged that in response to the date breach, Precedent had invested significant effort to improve its information handling practices, strengthened its information security and ensure its compliance.

[27] OAIC, *DonateBlood.com.au data breach (Precedent Communications Pty Ltd) Investigation Report 7 August 2017*, page 2 available at https://www.oaic.gov.au/privacy-law/commissioner-initiated-investigation-reports/donateblood-com-au-data-breach-precedent-communications-pty-ltd

Work Health and Safety Update - Combustible Cladding

By Rachael Suttton, Partner

In the wake of the Grenfell Tower inferno in London, governments across Australia have been engaged in a review of rules and regulations relating to:

- the use of cladding in the construction of buildings;
- fire protection; and
- audits of buildings to determine how widespread combustible cladding has been used.

In July this year, cladding on Brisbane's Princess Alexandra Hospital was found to be combustible after tests were conducted on some of the 24,000 square metres of material which was installed on the outside of the hospital in 1998.

Cladding

Cladding is a type of "skin" or extra layer on the outside of a building.

It can be attached to a building's framework or an intermediate layer of battens or spaces.

It is mainly used to stop wind and rain from entering the building.

It can also provide sound and thermal insulation as well as fire resistance.

It is often used to make a building's exterior look more attractive.

It is made from wood, metal, brick, vinyl, composite materials that can include aluminium, wood, blends of cement and recycled polystyrene, wheat/rice straw fibres.

Issues with Aluminium Composite Cladding Panels

Issues with Aluminium Composite Cladding Panels include:

- there is potential for fire to spread quickly upwards in a building if inappropriate products are used;
- the panels consist of two aluminium faces and a core material such as polyethylene, a mineral-based material, or a combination of both;
- panels are between 3mm and 5mm thick;
- they may look similar on the outside, but their core materials may differ and affect their fire resistance; and
- panels with a higher proportion mineral core are considered to withstand fire better, but can still be considered combustible.

Building and Construction Codes in Australia[28]

In NSW it is a requirement under the *Environmental Planning and Assessment Act 1979 (NSW)* and Regulation that building work is carried out in accordance with the Building Code of Australia (**BCA**). The BCA is a performance based document, and as such, either the prescriptive deemed-to-satisfy provisions may be used, an alternative solution developed, or a combination of both. The issues with external wall construction, including aluminium composite panels, primarily relate to Volume One of the BCA (which pertains to Class 2 to 9 buildings) and to buildings of Type A or B construction. The BCA provides for materials used in the construction of external walls and attachments to external walls. External walls of buildings required to be of Type A or B construction must be non-combustible, under Clauses 3.1 and 4.1 of Specification C1.1, irrespective of whether or not that wall also requires a fire resistance level (**FRL**). External walls may be required to achieve an FRL if exposed to a fire source feature or otherwise required to be fire resisting under the BCA.

"Non-combustible" in the BCA is determined by testing to AS 1530.1 – *Methods for fire tests on building materials, components and structures - Combustibility test for materials*, or using materials that are deemed acceptable for use under C1.12 where non-combustible materials are required.

It is important to note that the BCA is a holistic document, and that an external wall may need to meet a number of requirements, such as fire performance, weatherproofing and energy efficiency.

BCA permits the use of combustible materials as a finish, lining or attachment to a wall required to have an FRL, if certain requirements are met under Clause 2.4 of Specification C1.1. Importantly one of these requirements is that the material or attachment must not constitute an undue risk of fire spread via the façade of the building.

Practitioners, including certifying authorities, need to be satisfied that suitable evidence is provided to demonstrate that the products proposed for use in the construction of external walls comply with the relevant requirements of the BCA. Various forms of evidence may be relied upon to demonstrate compliance with the BCA.

[28] NSW Department of Planning and Environment, *Building System Circular BS 15-001 3 August 2015*, available at http://www.planning.nsw.gov.au/Policy-and-Legislation/Building-Systems-Circulars

Acceptable forms of evidence are given in A2.2 of the BCA. Where consideration needs to be given to the fire performance of a product, it is considered that the most suitable forms of evidence would be a report issued by a Registered Testing Authority, or a CodeMark Certificate of Conformity.

The National Construction Code (**NCC**) also requires buildings to have elements such as non-combustible external walls to stop fire spreading.

The Commonwealth Government is currently investigating non-conforming building products used locally. The Senate Economics Reference Committee (**Committee**) into Non-Conforming Building Products (**NCBPs**) is scheduled to hand down its final report on the issue in October 2017.

Evidence given in the hearings of the Committee revealed not only issues with the use of combustible cladding but also that it would appear that sufficient care has not been taken by:

- builders and installers to ensure that materials or products being installed during construction are the same as those specified in the approved building documentation; and
- at the completion of work, appropriate evidence is sought by the principal certifying authority to confirm that materials and products installed are the same as specified in the approval documentation and that they have been installed in the approved manner.

Inter-government agencies in New South Wales, Queensland and Victoria have also been established to fast-track the investigation.

New South Wales

In July 2017, the NSW Government announced a 10-point action plan[29] to ensure unsafe building products are no longer sold, buildings with cladding are identified and owners are notified, and that only people with the necessary skills and experience certify buildings and certify fire safety.

The plan includes:

- a comprehensive building product safety scheme which would prevent the use of dangerous products on buildings;
- identifying buildings which might have aluminum or other cladding;
- writing to the building/strata managers or owners of those buildings to encourage them to inspect the cladding and installation of cladding, if it exists;
- NSW Fire and Rescue visiting all buildings on the list, as part of a fire safety education program, to gather information to prepare for a potential fire at that building and provide additional information to building owners;
- creating a new fire safety declaration that will require high-rise residential buildings to inform state and local governments as well as NSW Fire and Rescue if their building has cladding;
- speeding up reforms to toughen the regulation of building certifiers;
- creating an industry-based accreditation to ensure only skilled and experienced people can carry out fire safety inspections;
- establishing a whole-of-government taskforce to coordinate and roll out the reforms;
- instructing all government departments to audit their buildings and determine if they have aluminum cladding, with an initial focus on social housing; and
- following up with local councils on correspondence they received in 2016 from the NSW Government after Melbourne's Lacrosse Tower fire.

Many of the elements of the 10-point plan are already underway, including the establishment of a taskforce.

In August 2017, the NSW Government published the results of an audit of NSW buildings revealing that 1011 buildings out of the (approximately) 178,000 audited across the state are potentially at risk from dangerous cladding.

The NSW Government has enacted the *Environmental Planning and Assessment Amendment (Fire Safety and Building Certification) Regulation 2017 (NSW)*. The regulation is due to commence on 1 October 2017. The main changes include:

- mandatory involvement of "competent fire safety practitioners" in specific functions. These practitioners will eventually be required to be accredited;
- mandatory submission of endorsed plans and specifications for complex fire safety systems to the certifying authority before those systems are installed;
- new and changed requirements for the documenting, endorsing and checking of non-standard fire safety designs (referred to as performance solutions / alternative solutions under the Building Code of Australia);
- limited exceptions from compliance with technical standards for minor safety system works;
- new critical stage inspections targeting apartments and other buildings where people sleep;
- new Fire and Rescue NSW inspection power for multi-unit residential buildings; and
- assessment of the ongoing performance of essential fire safety measures must now be undertaken by "competent fire safety practitioners".

The details of other reforms, such as a building product safety scheme and tougher regulation for building certifiers, have yet to be established.

The plan gives little insight into how the NSW Government proposes to deal with the 1100 buildings clad with potentially combustible materials. The plan suggests that owners will be encouraged to replace the cladding rather than requiring it to be rectified (for example under a rectification order).

[29] NSW Department of Planning and Environment, *A new fire safety package will help keep NSW families safer in their homes 31 July 2017*, available at https://www.nsw.gov.au/news-and-events/news/ten-point-plan-for-fire-safety-reforms/

Queensland

On 24th August 2017 the Queensland Government passed the *Building and Construction Legislation (Non-conforming Building Products – Chain of Responsibility and Other Matters) Amendment Act 2017 (QLD)* which requires designers, manufacturers, importers, suppliers and installers to ensure building products are safe and fit for purpose. The legislation:

- requires Queensland Building and Construction Commission (**QBCC**) licensees to notify the QBCC of site activities that could present a WHS issue;
- requires the QBCC to report safety issues that could cause serious injuries and deaths to regulatory agencies like Workplace Health and Safety Queensland;
- enables WHS information sharing arrangements between the QBCC and other agencies;
- extends the grounds for taking disciplinary action against QBCC licensees to include health or safety-related convictions and incidents where a licensee's work on a building site might have caused a death, grievous bodily harm or a serious safety risk to a person;
- allows inspectors to enter existing buildings, take samples for testing and direct rectifications; and
- the QLD Government to recall products that are non-conforming, and issue warnings about them.

Implications for owners and workplaces with suspect cladding in buildings

The question of how to deal with non-conforming cladding, whether existing regulatory frameworks can be utilised and who will be liable for the substantial costs that may be incurred if rectification is required remains a live issue for governments, councils, and property owners.

Despite the lack of a firm direction in all states for owners to undertake rectification works under the plan, owners or controllers of premises and/or persons conducting a business or undertaking (**PCBUs**) under the work health and safety legislation across all states and territories are required to ensure, so far as is reasonably practicable, the provision and maintenance of a work environment without risks to health and safety. Owners, controllers of premises and PCBUs have a legal obligation to rectify, replace or manage risk to safety or workers and others under work health and safety legislation and their common law duties of care.

Whilst owners and PCBUs occupying premises potentially may have recourse to legal avenues (under contract, statute and duties of care under the common law) to recover the costs of rectification as between, developers, builders, suppliers, installers, architects, fire safety engineers or building certifiers (and of course insurers) the obligation to eliminate and control the risk in the meantime must be appreciated and a management plan put into action.

If you are an owner and/or PCBU and your place of work is impacted by the use of combustible cladding you should consider what steps you should take to manage the risks to the health and safety to those in the work environment. Whilst it may be premature in some states such as NSW to arrange for a formal independent building audit when the appropriate experts are yet to be accredited under the new regulations, a risk assessment by appropriately qualified consultants of the premises should be conducted which takes into account the safety risks presented by the premises and the effectiveness of the fire safety and emergency management systems available at the premises. Owners, controllers of premises and PCBUs should review and ensure their fire safety procedures are compliant and working properly and that all those present at the place of work are provided with adequate induction and education in emergency plans. ■

Holman Webb are delighted to announce **Alison Choy Flannigan**, Partner, has been listed in the **Doyles Guide** as one of the top 3 preeminent lawyers in Health and Aged Care in NSW.

Alison was once again included in Best Lawyers – Australia (Health and Aged Care Law) for 2017 and was named a Finalist in the **Lawyers Weekly Partner of the Year Award for Health 2017**.

Our Insurance team been named as a finalist in the **Lawyers Weekly Australian Law Awards 2017 – Insurance Team of the Year** category.

Holman Webb recently bolstered the firm's property and construction practices with the recent merger with boutique Sydney law firm Bruce and Stewart.

With over three decades of expertise in land subdivision, joint ventures, construction and development work, partner Robert Gorczyca, and his team have now joined our Sydney office.

We welcome them to the firm.

MEET THE TEAM

John Van de Poll

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John has over 20 years' experience as a litigator specialising in all areas of insurance including medical indemnity and disciplinary matters on behalf of health practitioners, including registered medical practitioners. His team handles a broad range of claims including catastrophic claims, multi-party disputes, discrimination claims made by patients, defending defamation claims against practitioners and acting for practitioners in coronial enquiries.

John is an Accredited Specialist in Commercial Litigation (Insurance). He was named **Law Partner of the Year: Insurance** at the 2016 Lawyer Weekly Partner of the Year Awards and selected for the prestigious '**Best Lawyers International**' – Insurance 2017 & 2018.

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Heath has over ten years' experience in all aspects of property law, from assisting first-home buyers, families and investors with their purchase or sale of residential property to acting for major commercial and retail landlords as well as in the acquisition and development of residential and major mixed use projects, including retirement villages and aged care facilities, layered body corporate arrangements and harbour developments.

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