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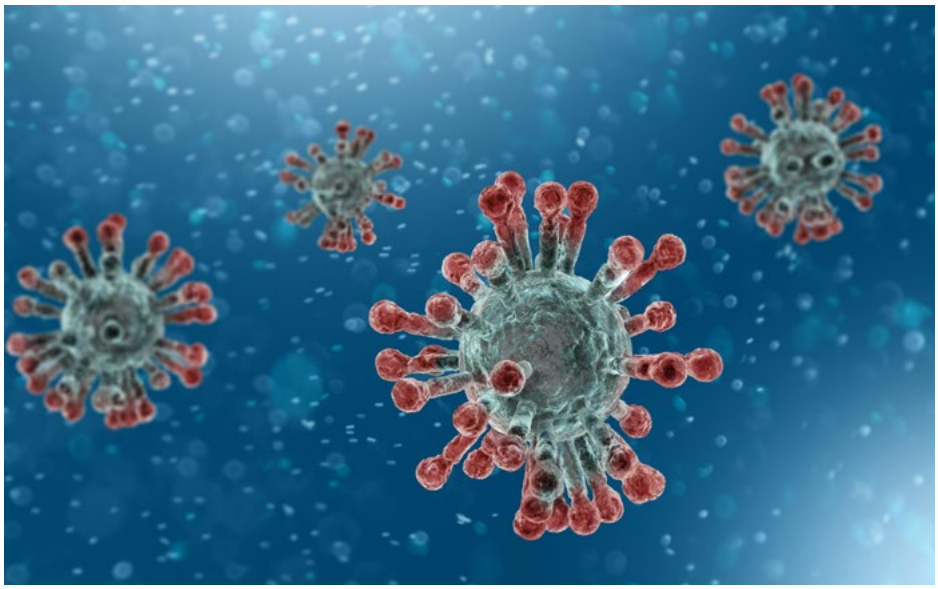
NOVEL CORONAVIRUS & INFECTIOUS DISEASES: WHAT HEALTH, DISABILITY AND AGED CARE PROVIDERS CAN DO

By Alison Choy Flannigan, Partner Leader, Health & Community, Hall & Wilcox

A Sydney residential aged care facility has placed 11 residents in isolation on 4 March 2020 after a staff member was diagnosed with coronavirus. The woman, who is in her 50s and has not travelled overseas recently, was working at the BaptistCare Dorothy Henderson Lodge aged care centre in Macquarie Park, northern Sydney. Eleven residents have been isolated. Two residents have displayed respiratory symptoms and are being tested, one has died. The cause of death was unknown at the time this article was published.

Update, 5 March: It has been confirmed that the woman's test results were positive for the COVID-19 virus.



The Australian Government triggered its emergency response plan to COVID-19 on Thursday, 27 February 2020. Four days later, the Government extended travel restrictions relating to COVID-19, on the advice of the Australian Health Protection Principal Committee (AHPPC) and the Australian Border Force.

COVID-19 is one of a number of infectious diseases for which health, disability and aged care providers should prepare for, including influenza.

WHAT ARE THE LEGAL OBLIGATIONS?

There are a number of legal obligations upon health and aged care providers in relation to infectious diseases. These include:

1. compliance with regulatory requirements, including licensing and/or registration or approval requirements;
2. duty of care; and
3. obligations under Work, Health and Safety Laws.

REGULATORY REQUIREMENTS

There are numerous regulatory requirements imposed upon health and aged care providers. These include standards which relate to sterilisation and infection control procedures, in addition to specific public health legislation.

The *Biosecurity Act 2015 (Cth)* authorises activities used to prevent the introduction and spread of target diseases into Australia. People reasonably suspected to have a listed human disease **(LHD)** specified under the Act are required to comply with a range of biosecurity measures and requests for information as directed by the Director of Human Biosecurity **(DHB)**, Australia's Chief Medical Officer **(CMO)**; Minister for Health; or a biosecurity official or human biosecurity officer as stipulated in the Act.

The Governor-General also has the power to declare a human biosecurity emergency, which authorises the Health Minister to implement a broad range of actions in response. These could be applied to respond to a serious infectious disease outbreak or a pandemic. 'Diseases can be added to the list of LHDs (as declared in the Biosecurity (Listed Human Diseases) Determination 2016) at any time by the DHB at short notice.

The *National Health Security Act 2007* (Cth) **(NHS Act)** authorises the exchange of public health surveillance information – including personal information – between the Australian Government, States and Territories and the World Health Organisation.

States and Territories have legislative powers that enable them to implement biosecurity arrangements within their borders and that complement Australian Government biosecurity arrangements. They also have a broad range of public health and emergency response powers available under public and emergency legislation for responding to public health emergencies.

For example, the Minister has wide powers under the *Public Health Act 2010 (NSW)*, including in a state of emergency the Minister:

(a) may take such action, and

(b) may by order give such directions, as the Minister considers necessary to deal with the risk and its possible consequences.

Without limiting the above, an order may direct—

(a) all persons in a specified group, or

(b) all persons residing in a specified area,

to submit themselves for medical examination in accordance with the order.

There are two policy directives issued by NSW Health – the Infection Prevention and Control Policy and the Health Influenza Pandemic Plan.

The policy directives refer to the NSW Infection Prevention and Control Handbook and the Australian Guidelines for the Prevention and Control of Infection in Healthcare.

The Aged Care Quality and Safety Commission has published a number of Influenza resources available at https://www.agedcarequality.gov.au/resources/influenza-resources

From 1 July 2019 the Commission will assess how organisations minimise infection-related risks under the Aged Care Quality Standards (Quality Standards). For example, under Standard 3 Requirement (3)(G), all aged care providers (to the extent relevant) will need to demonstrate the following:

- Minimisation of infection-related risks through implementing:
  - standard and transmission-based precautions to prevent and control infection; and
  - practices to promote appropriate antibiotic prescribing and use to support optimal care and reduce the risk of increasing resistance to antibiotics.
- All providers are expected to assess the risk of, and take steps to prevent, detect and control the spread of infections.
- All providers are expected to demonstrate that their approach to infection control aligns with best practice.

The Victoria Health website refers to the national standards[1] for guidance on which infectious agents require transmission-based precautions *(Australian Guidelines for the Prevention and Control of Infection in Healthcare)*[2]

DUTY OF CARE

Civil liability legislation in each Australian State and Territory imposes a duty upon professionals (including but not limited to medical practitioners and nurses) to act in accordance with peer professional practice, for example under section 5O of the *Civil Liability Act 2002 (NSW)*. There is similar legislation in each State and Territory of Australia.

While there are limited reported Australian cases on infection control, there are cases involving Salmonella and overseas cases.

DOWNEY V ST PAUL'S HOSPITAL [2007] B.C.J. NO. 700[3]

In the Canadian case of *Downey v St Paul's Hospital* [2007] BCJ 700, the plaintiff brought action in damages against St Paul's Hospital after contracting tuberculosis (TB) from his friend who was a patient.

The plaintiff was hit in the eye by phlegm produced by the patient when he was visiting.

When the plaintiff asked if his friend was contagious, a nurse assured him that the Hospital would not have allowed the plaintiff to visit if that was the case.

There were no warning signs on the door or in the ward concerning infectious diseases. A decision as to whether a patient needed to be isolated would be made at the time the patient was admitted to the HIV Service.

The admission form for patients to the HIV Service included a section that the admitting doctor must complete concerning whether or not a patient should be placed in isolation. The decision whether to isolate was constantly re-evaluated as more information became available. Less than 5% of the patients placed in isolation for TB turned out to have the disease.

An action was brought under the British Columbia *Occupiers Liability Act* which imposes a duty on the occupier to take reasonable care to see that persons using the premises will be reasonably safe. There are similar public liability obligations on occupiers of premises in Australia.

The Supreme Court of British Columbia, Canada held:

- The Hospital did not breach its duty of care to the plaintiff by failing to isolate the patient.
- The decision on whether to order respiratory isolation is complex. The Hospital was entitled to rely on the medical judgment of health practitioners at the Hospital, who concluded that the patient did not require isolation.
- The Hospital did not breach its duty of care to the plaintiff by failing to warn him.
- The duty to warn is not divorced from the duty to isolate. Having decided that a patient did not require isolation, the Hospital was not required to warn visitors that the patient might have TB.
- The Hospital must be reasonably safe for visitors. However, the Hospital is not an insurer of the health of visitors.
- Hospitals contain sick people and visitors to hospitals know there are sick people present.

ELIZABETH MILLER V GREATER GLASGOW NHS BOARD [2010] CSIH 40[4]

In the UK case of *Miller v Greater Glasgow NHS Board* [2010] CSIH 40, the respondent was admitted to Glasgow Royal Infirmary for an aortic valve replacement and was diagnosed with a post-operative wound infection.

The infection was identified as being MRSA and the respondent argued that the infection was passed on to her by a staff member who had not followed the hospital's hand hygiene policy.

The respondent maintained that she had become infected because members of the hospital staff were involved in 'hands-on' treatment of her, increasing the risk of transmission.

Various hygiene preparations such as antiseptic soap were not available where they might have been appropriate.

The hospital's Infection Control Policy Manual, which contained a section on MRSA control, was not available to staff.

1 https://www2.health.vic.gov.au/public-health/infectious-diseases/infection-control-guidelines

2 https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-prevention-and-control-infection-healthcare-2019

3 https://www.bccourts.ca/Jdb-txt/SC/07/04/2007BCSC0478.htm

4 https://www.scotcourts.gov.uk/search-judgments/judgment?id=9d9286a6-8980-69d2-b500-ff0000d74aa7

The patient (respondent to the appeal) claimed on two bases:

1 The first of these, to be found in Condescendence 5, is based upon an alleged breach of the reclaimers' duty, directly incumbent upon them, to exercise reasonable care to look after the safety and welfare of patients, while being treated in the hospital.

   It is said that it was their duty to take reasonable care to ensure that adequate hygiene measures were instituted and enforced in the hospital by various detailed means, which have been specified.

2 The second of the respondent's common law cases, set out in Condescendence 7, is based upon the claim that her injury was caused by the fault of the hospital staff, for whose acts and omissions in the course of their employment the defenders are vicariously liable.

It was held:

- In exercising their duty to take reasonable care for patients, the hospital had a duty to ensure that adequate hygiene measures were instituted and enforced.
- At that time, it is said that there existed defects in the washing facilities, both as regards the plumbing system and the availability of soap. Towels were missing in some areas. Various hygiene preparations such as antiseptic soap and alcohol gel were not available where they might have been appropriate. Against that background it is claimed that there were management deficiencies. The hospital's Infection Control Policy Manual, which contained a section on MRSA control was said not to be available to staff, who did not know where to locate it.
- The respondent's loss, injury and damages arose from her contraction of the MRSA infection.

KIMBERLY F V MARY HITCHCOCK MEMORIAL HOSPITAL AND HITCHCOCK CLINICS (1993) U.S. APP. LEXIS 31541[5]

In the US case of *Kimberly F v Mary Hitchcock Memorial Hospital* and Hitchcock clinics (1993) U.S. App. LEXIS 31541, the plaintiff was admitted to the

obstetrical unit at the Mary Hitchcock Memorial Hospital to give birth.

One week later after being discharged, she was diagnosed as having an outbreak of genital herpes.

When admitted to the hospital, the plaintiff had no prior history of herpes. She was in hospital within the herpes incubation period.

A second patient with herpes was in the maternity ward at the time and occupied the same room as the plaintiff immediately prior to being put in the room.

The urine catch basin in the room contained urine from the other patient and some of the nurses did not wash their hands before examining the patient.

She subsequently sued the defendants alleging that she was infected with herpes while at the hospital and that the Hospital negligently failed to protect her from such an infection.

It was held:

- The probable cause of the infection was one or more acts of negligence by the hospital.
- This conclusion was sufficient to establish causation even though the doctor could not identify a single cause as the more-likely-than-not cause of the infection.

In this case, the jury awarded plaintiff US$125,000 and her husband $US25,000.

SAMAAN BHT SAMAAN V KENTUCKY FRIED CHICKEN PTY LTD [2012] NSWSC 381

The plaintiff, Monika Samaan (by her tutor), sued KFC for damages as a result of contracting Salmonella after consuming a chicken 'twister' purchased by her father.

As a result of being infected with salmonella, the plaintiff suffered serious injuries including severe brain injury and spastic quadriplegia.

The plaintiff and her family had consumed a number of suspect meals from KFC within the incubation period for Salmonella.

It was held:

(i) The meal purchased at KFC was the only common meal eaten in the relevant period by those members of the family who had fallen sick.

(ii) The standards set my KFC in relation to food handling and preparations were not met during the relevant period.

(i) The Court was of the view that the contamination occurred after cooking, by cross contamination with product (directly or indirectly) that was contaminated with the bacteria and, more probably than not, a clump of flour or other such material that was contaminated. That contact was a breach of the procedures mandated by KFC and was negligent, or the use of it after such contact (also a breach of KFC procedures) was negligent.

5 https://law.resource.org/pub/us/case/reporter/F3/009/9.F3d.1535.93-1438.html

6 https://www.caselaw.nsw.gov.au/decision/54a636e83004de94513d9799

(ii) Further, the duties imposed by the common law of contract and/or the Sale of Goods Act are such that this later discovered defect, which existed at the time of sale, renders the goods unmerchantable and/or not reasonably fit for the purpose required. The contract (including statutory warranties) has been breached and damages must flow.

(iii) Had the standard procedures been followed, it would have been almost impossible to contract salmonella from KFC products.

(iv) There was evidence of 'aberrant behaviour' by staff. It was likely that there had been cross-contamination of the chicken pieces after cooking.

(v) Ms Samaan was awarded $8 million in damages plus costs.

In the US in Missouri, a 69-year-old plaintiff was awarded a US$2.58 million verdict after contracting an infection through an IV that was administered in the ambulance following a heart attack: https://wislawjournal.com/2008/12/01/hospital-infections-spread-so-do-lawsuits/

WORK, HEALTH AND SAFETY

Employers or businesses, or anyone who falls under the definition of a 'person conducting a business or undertaking' (a PCBU), has legal obligations under work health and safety laws.

A 'person conducting a business or undertaking' is a broad term used throughout work health and safety legislation to describe all forms of modern working arrangements

As an employer and/or a PCBU, you have the main responsibility for the health and safety of everyone in your workplace, including visitors.

WHAT SHOULD PROVIDERS DO?

Health, disability and aged care providers should ensure that they comply with regulatory standards including sterilisation, and the standard precautions and monitor Government announcements and information provided to the sector in relation to infection control.

They should provide adequate orientation and training of staff on standard precautions.

Standard precautions are work practices required to achieve a basic level of infection control. They include:[7]

- hand hygiene and cough etiquette
- the use of personal protective equipment (PPE)
- the safe use and disposal of sharps
- routine environmental cleaning
- incorporation of safe practices for handling blood, body fluids and secretions as well as excretions

As necessary, providers should be prepared to isolate sick patients/residents and seek medical attention. It would be prudent to monitor the temperatures of sick patients/residents on a regular basis.

Providers should advise visitors who are unwell with potentially contagious diseases not to visit or interact with patients and residents. This may include self-isolating as per medical advice.

Providers should also advise staff not to come to work if unwell with a potentially contagious disease and to self-isolate. Many organisations are requesting staff to advise if they have or will be travelling overseas and minimising overseas travel for work.

If Providers are providing home care services, then there should be in place a communication protocol so that clients inform carers if they are feeling unwell.

Medical practices should be asking patients if they have travelled overseas recently and feel unwell and encourage those patients to be seen in their homes or attending hospitals rather than attending their clinics.

Organisations should implement appropriate corporate and clinical governance to monitor incidents and as necessary have a communications and media plan to communicate with stakeholders including shareholders/members, staff, patients/residents and their families.

This article was written with the assistance of Lauren Krejci, paralegal.

USEFUL RESOURCES:

- the Department of Health's *Australian Health Sector Emergency Response Plan for Novel Coronavirus* is useful for preparing an emergency plan, particularly with respect to pandemic infections https://www.health.gov.au/resources/publications/australian-health-sector-emergency-response-plan-for-novel-coronavirus-covid-19
- the Communicable Diseases Network Australia (CDNA) *National Guidelines for Public Health Units in the Series of National Guidelines (SoNGs)* has information on the public health management of COVID-19 https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm
- the Department of Health has produced factsheets and resources for aged care staff, residents and families with advice on measures to limit transmission of the virus: https://www.health.gov.au/resources/publications/coronavirus-covid-19-information-for-residents-of-residential-care-services-and-family-members
- the 24-hour national Coronavirus health information line 1800 020 080 provides health and situation information on the COVID-19 outbreak.
- Department of Health: Standard Precautions: https://www1.health.gov.au/internet/publications/publishing.nsf/Content/cda-cdna-norovirus.htm-l~cda-cdna-norovirus.htm-l-8
- Department of Health – Guidance for managing suspected norovirus outbreaks in aged-care facilities – https://www1.health.gov.au/internet/publications/publishing.nsf/Content/cda-cdna-norovirus.htm-l~cda-cdna-norovirus.htm-l-app5~cda-cdna-norovirus.htm-l-app5.2

7 https://www1.health.gov.au/internet/publications/publishing.nsf/Content/cda-cdna-norovirus.htm-l~cda-cdna-norovirus.htm-l-8

AGED CARE UPDATE: RECENT CHANGES TO AGED CARE REGULATION AND NOTIFICATION REQUIREMENTS

By Alison Choy Flannigan, Partner, and Lauren Krejci, Paralegal

A NEW REGULATORY FRAMEWORK FOR ENFORCEMENT AND SANCTIONS

On 1 January 2020, the *Aged Care Legislation Amendment (New Commissioner Functions) Act 2019* (the **Amending Act**) which amended the *Aged Care Quality and Safety Commission Act 2018 (Cth)* (the **Act**) transferred new aged care regulatory functions to the Aged Care Quality and Safety Commissioner (the **Commissioner**).

The Amending Act has established a new regulatory framework that enables the Commissioner to have a full suite of regulatory functions.

Changes to the *Aged Care Quality and Safety Commission Rules 2018* (**Commission Rules**) have been made to give operational effect to the new framework. These changes have affected accreditation and re-accreditation, timetables for improvement, assessment contacts, quality reviews, review audits and the 'serious risk' provisions.

Since the changes have come into effect, we have been seeing stronger regulatory action from the Aged Care Quality and Safety Commission and various providers who previously did not receive sanctions have received sanctions or unmets.

TRANSFERAL OF COMPLIANCE AND ENFORCEMENT POWERS

The sanctioning powers of the Secretary have been transferred to the Commissioner, along with the function of ensuring compliance with the aged care responsibilities of approved providers.

Part 7B of the Act (as amended) streamlines the procedures that must be followed by the Commissioner before imposing sanctions:

a. the Commissioner may impose sanctions for non-compliance with aged care responsibilities (section 65N);

b. in deciding whether it is appropriate to impose sanctions on an approved provider for non-compliance with one or more of the aged care responsibilities of the provider, the Commissioner must consider the following matters:

   i. whether the non-compliance is of a minor or serious nature;

   ii. whether the non-compliance has occurred previously and, if so, how many times it has previously occurred;

   iii. whether the non-compliance threatens the health, welfare or interests of the care recipients to whom the provider is providing care;

   iv. whether the non-compliance would threaten the health, welfare or interests of care recipients to whom the provider may provide care in the future;

   v. if the provider has given an undertaking as required by a notice given to the provider under section 63T – whether or not the provider has complied with the undertaking;

   vi. if the provider has agreed to do one or more things as required by a notice given to the provider under section 63U – whether or not the provider has complied with the agreement;

   vii. the desirability of deterring future non-compliance;

   viii. any other matters specified in the rules.

   However, the Commissioner must give paramount consideration to the health, welfare or interests of care recipients.

c. The Commissioner must notify an approved provider of its intention to impose sanctions, unless there is an immediate and severe risk to the safety, health and the well-being of care recipients to whom the provider is providing care as a result of the non-compliance (section 63S);

d. the notice must invite the provider to make submissions, in writing, to the Commissioner (section 63S (e));

e. if the provider's submissions are satisfactory, the Commissioner may require the provider to give an undertaking setting out a remedial course of action in response to the non-compliance (section 63T); and

f. failure to comply with the undertaking will result in a sanction (section 63N).

NO TFI REQUIREMENTS

The Commission Rules no longer require a timetable for improvement (TFI) to be issued to providers in order to meet Quality Standards.

Following a performance assessment, the Commission may identify areas of improvement to ensure that Quality Standards are met or may direct the provider to revise its continuous improvement plan.

CHANGE FROM 'SERIOUS RISK' TO 'IMMEDIATE AND SEVERE RISK'

The Commission Rules no longer require the Commission to consider whether the non-compliance placed or may have placed the safety, health or well-being of a care recipient at serious risk.

The Commissioner's new powers for monitoring and enforcing compliance involves identifying whether there is an immediate and severe risk to care recipients and considering whether to impose sanctions.

Assessment Teams will continue to identify any potential failure in standard or care that may place a care recipient's health or safety at risk.

Further information on the amendments since 1 January 2020 is available on the Australian Government's Aged Care Quality and Safety Commission website https://www.agedcarequality.gov.au/providers/commission-act-and-rules.

REPORTING MATERIAL CHANGES'

Updates to the 'Material Change Form' in October 2019 under section 9–1 of the *Aged Care Act 1997* now require aged care service providers to notify the Department of Health of any 'material changes' in business operations.

Aged care providers are required to notify the Department of any 'material change' within 28 days after the change occurs that will affect their ability to meet suitability criteria under the *Aged Care Act 1997*.

The nature of a 'material change' (that is substantial or considerable in nature) will be determined on a case-by-case basis. However, the Department published a non-exhaustive list of circumstances to be used as guidance. For example, if the provider:

a. is no longer an incorporated organisation;

b. is unable to meet any of the home, flexible or residential care standards in the Aged Care Quality standards;

c. is unable to manage its financial responsibilities, including subsidies and care recipient's fees and payments;

d. makes a change which may affect the rights of aged care recipients; and

e. makes substantial changes to its organisational or governance structure such as entering into a sub-contract arrangement for the delivery of clinical care or the use of a management company to manage the day-to-day operations of the organisation or a change to key personnel.

THE NEW MATERIAL CHANGE FORM

In October 2019, the Department revised the form that is used to report material changes. These include:

a. removing the direction to not report changes in key personnel;

b. new fields to collect third party information;

c. revised privacy notice; and

d. updates on existing fields to make them more specific.

REPORTING KEY PERSONNEL

An important change to the Material Change Form is the requirement to report changes in key personnel. This reversed an earlier direction in 2016 to not report key personnel.

Aged care providers are encouraged to review the definition of 'key personnel' under section 8B of the Act in order to accurately report material changes.

WHAT SHOULD AGED CARE PROVIDERS DO?

Following this update, aged care providers are encouraged to:

- reassess their current circumstances in order to identify any material changes, particularly in relation to third party organisations and key personnel;
- notify the Department of any material changes within 28 days after the change occurs as per section 9–1 of the Act; and
- notify the department of current key personnel as at 1 November 2019.

AGED CARE PROVIDERS ARE REQUIRED TO NOTIFY THE DEPARTMENT OF ANY 'MATERIAL CHANGE' WITHIN 28 DAYS AFTER THE CHANGE OCCURS THAT WILL AFFECT THEIR ABILITY TO MEET SUITABILITY CRITERIA UNDER THE *AGED CARE ACT 1997*

WHEN IS THE FAILURE TO DISCLOSE A FINANCIAL INTEREST UNPROFESSIONAL CONDUCT?

HEALTH CARE COMPLAINTS COMMISSION V PETROS [2019] NSWCATOD 83

By Alison Choy Flannigan, Partner, and Ashlee Johnson, Solicitor

The case of *Health Care Complaints Commission v Petros* [2019] NSWCATOD 83 concerned a complaint brought by the Health Care Complaints Commission (the Applicant) against Peter Petros (the Respondent), a gynaecologist specialising in pelvic floor reconstruction, for alleged misconduct in relation to the Tissue Fixation System device (TFS). Specifically, the Applicant alleged that the Respondent:

1. failed to disclose his financial interest in the TFS device to clients undergoing TFS surgery;
2. failed to conduct a proper handover of a patient when the patient was admitted to emergency as a result of post TFS surgery complications; and
3. as a consequence of Complaints 1 and 2, is guilty of unsatisfactory professional misconduct or professional misconduct.

COMPLAINT 1: FAILURE TO DISCLOSE FINANCIAL INTEREST

The first complaint was that the Respondent failed to disclose his financial interest in the TFS device to various stakeholders, including patients, the Applicant and the Medical Advisory Committee of Sydney Private Hospital.

A patent for the TFS was held by one of the Respondent's family companies, Kvinno Pty Ltd (**Kvinno**). In 2002, the Respondent, sponsored by Kvinno, obtained Australian Register of Therapeutic Goods (**ARTG**) approval for the registration of the 'Petros Pelvic Ligament Anchor' to be used in pelvic floor reconstructive surgeries.

CORPORATE STRUCTURE

The Respondent was involved in varying capacities in several family corporate structures, which were linked, either directly or indirectly to the TFS device, namely, the Respondent was a:

1. director of the family company Kvinno from 1972 until 2005.
2. residual beneficiary of the Petros Family Trust from 1 April 2005 to 7 July 2014 (**Trust**).
3. director of Sappho Pty Ltd from 1976 until 7 July 2014 (**Sappho**). Sappho held 100% of the shares in Kvinno and was trustee of the Trust.
4. director of TFS Manufacturing Pty Ltd from 2005 to 19 July 2011 (**TFS Manufacturing**).

FINANCIAL INTEREST

The NSW Civil and Administrative Tribunal (**NCAT**) determined that there were two of the four financial interests needed to be disclosed by the Respondent.

First, the Respondent had a financial interest in the TFS device as a residual beneficiary of the Trust for whose indirect benefit Kvinno was acting. Kvinno derived a financial interest from a 'fee-free, royalty-free, sole and exclusive licence to use, exploit and commercialise' the intellectual property in the TFS device which was granted to TFS Manufacturing in 2008. Further, under the licence Kvinno was entitled to 75–100% of the sale proceeds.

Second, the Respondent had a financial interest in the unsecured loans by Sappho to TFS Manufacturing as both director and residual beneficiary of the Trust for which Sappho was trustee. Sappho lent TFS Manufacturing unsecured loans to the amount of $1.6 million by 2016.

NON-DISCLOSURE

Between the period of 4 June 2013 and 24 October 2014, the Respondent completed TFS surgery on 108 patients. At no point did the Respondent disclose his personal or familial financial interest in the TFS device to either the patients or the lead surgeon.

On 5 November 2014, the ARTG cancelled the registration of the TFS device. After this date, the Respondent conducted nine more surgeries without disclosing the cancellation or financial interests.

The Respondent conceded his failure to disclose his financial interests; however, he maintained he was not under any obligation to do so as he derived no direct benefit from the corporate structures.

NCAT found that the Respondent did have an obligation to disclose both the financial interest and the cancellation of the ARTG registration.

MISLEADING INFORMATION

The Applicant also alleged that the Respondent deliberately sought to mislead the HCCC by omitting ownership information from documents relating to the intellectual property in the TFS device, failing to disclose full loan details and failing to disclose the fact that he had divested himself of financial interests just four days before asserting that he had no financial interest.

NCAT held that this conduct was sufficient to constitute misleading behaviour.

IMPROPER/UNETHICAL CONDUCT

NCAT held that the failure to disclose financial interests and misleading conduct of the Respondent satisfied the requirements for "unsatisfactory professional conduct" under section 139B of the National Law.[1]

COMPLAINT 2: FAILURE TO CONDUCT PROPER HANDOVER OF PATIENT

The second complaint alleged that the Respondent did not properly conduct a handover of his TFS patient who had deteriorated post-surgery. On 11 June 2013, one of the Respondent's patients experienced severe bleeding after the TFS surgery. After a failed attempt to stop the bleeding, the Respondent took the patient to St George Public Hospital via ambulance where the Respondent provided a handover to hospital staff.

NCAT made two findings:

1. that the handover conducted by the Respondent was improper as the Respondent failed to advise attending staff that the bleeding arose from TFS surgery and that he had downplayed the severity of the complications; and
2. the Respondent's decision to send the patient to St George Public Hospital when Royal Prince Alfred Hospital was half the distance was improper.

COMPLAINT 3: UNSATISFACTORY PROFESSIONAL CONDUCT OR PROFESSIONAL MISCONDUCT

NCAT concluded that, as a consequence of being guilty of Complaints 1 and 2, the Respondent was guilty of professional misconduct. This was because the unsatisfactory professional misconduct established in Complaint 2 was to such a serious degree.

DISQUALIFICATION

At the time the judgment was delivered, the Respondent no longer practiced or intends to practice ever again. Nonetheless, NCAT held that if he were still practising, the Respondent's registration would have been cancelled, the Respondent would be disqualified from registration as a practitioner for a period of two years and a record of the cancellation is to be kept by the Australian Health Practitioner Regulation Agency's Register of Practitioners.

TGA RECALL

The TGA decided on 28 November 2017 to remove transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the ARTG.

This follows a review by the TGA of the latest published international studies and an examination of the clinical evidence for each product included in the ARTG and supplied in Australia.[2]

1. Health Practitioner Regulation National Law Act (NSW) 2009 s 139B.

2. Therapeutic Goods Administration, 'Results of review into urogynaecological surgical mesh implants', Department of Health (online, 20 August 2014).

UPDATE ON VAGINAL MESH CLASS ACTION AGAINST MEDICAL DEVICES GIANT JOHNSON & JOHNSON –

GILL V ETHICON SARL & ORS [NO 5] [2019] FCA 1905; GILL V ETHICON SARL [NO 6] 2020 279

By Alison Choy Flannigan, Partner, and Lauren Krejci, Paralegal

On November 21st 2019, the Federal Court handed down its decision that Ethicon, a subsidiary of the medical devices giant Johnson & Johnson, contravened several sections of the *Trade Practices Act 1974* (Cth) ('the **Act**') as well *Australian Consumer Law* (**ACL**) in its promotion and distribution of vaginal mesh products. The products were advertised to treat urinary incontinence and pelvic prolapse. The Applicants made statutory and common law claims against the medical giant. Katzmann J of the Federal Court upheld both claims.

1. STATUTORY CLAIMS: *TRADE PRACTICES ACT 1974* (CTH) (NOW THE COMPETITION AND CONSUMER ACT 2010)

The Applicants made two central statutory claims against the Respondent.

1.1 SAFETY DEFECT

First, the Applicants alleged that the vaginal mesh devices had a defect, which contravened s75AD of the Act (liability for defective goods causing injuries).[1] It was argued that the lack of clinical evidence supporting the medical purpose of the Ethicon products and non-compliance with post-market regulatory requirements resulted in the devices having an inherent 'safety defect'. The Respondent had been informed of the 'high risk' of complications such as mesh erosion, however failed to ensure adequate pre-market clinical trials for the devices.

The Federal Court held that the conduct of the Respondent, amongst a culmination of other factors, rendered the devices defective. The finding of a defect enabled the Applicants to succeed on two additional statutory counts. These were:

1. section 74B of the Act, the devices are 'unfit for purpose'

2. section 74D of the Act, the devices are not of 'merchantable quality'

1.2 DECEPTIVE AND MISLEADING CONDUCT

Second, the Applicants argued that the Respondent had marketed the devices in a manner that was misleading and deceptive under s52 of the Act and s18 of the Australian Consumer Law.[2] Ethicon either significantly minimised or completely excluded certain known risks from instructions and promotional material for the devices. Examples include describing the risk of an inflammatory response to the mesh as "mild" and "transient"[3] in brochures. Earlier versions of the brochure failed to identify mesh erosion as a risk entirely. Additionally, the Applicants argued that the materials greatly exaggerated the benefits of the devices and "told a story of simple fixes for stress urinary incontinence that would restore the patient to a life free from social embarrassment" .

As such, the Federal Court held that by minimising the risks and exaggerating the benefits of the devices, Ethicon had been deceptive and misleading under s52 of the Act and s18 of the ACL.

2. COMMON LAW CLAIM: NEGLIGENCE

The Applicants also made a common law claim in negligence.

2.1 DUTY OF CARE

The Applicants alleged that the Respondent had breached its duty of care, which extended to providing accurate risk information pertaining to the Ethicon devices. Johnson & Johnson had failed to conduct accurate pre and post-market risk evaluation of the devices. The mesh products were inappropriately given a "CE" mark, indicating that they had met safety requirements in the European Union. Further, the Respondent failed to capture all known risks in the product's instructions and promotional material.

The Federal Court held that this conduct fell short of the standard of care expected from a reasonably prudent supplier of medical devices. As such, the Applicants also succeeded in this claim.

3. DAMAGES

On 6 March 2020, the Federal Court in *Gill v Ethicon Sarl [No 6]* [2020] FCA 279 ordered Ethicon Sarl (Johnson & Johnson) to pay $2.6 million to three women with faulty pelvic mesh implants. Individual damages awarded ranged from $555,555 to $1,276,113.

The plaintiffs also sought injunctive relief in relation to specified product warnings in relation to the supply, distribution, marketing and promotion of the products.

The court held pursuant to s 232 of the Australian Consumer Law, being Schedule 2 to the *Competition and Consumer Act 2010* (Cth), after 20 March 2020 the respondents may not supply, distribute, market or promote any of the medical devices identified in Schedule B to the orders anywhere in Australia without including in the patient information leaflets and any promotional material relating to those devices advice in the following terms or to the following effect:

'Prolene mesh is designed to, and will invariably elicit in all patients, an acute inflammatory reaction followed by a chronic inflammatory response. The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant remains in the body. The scar tissue will cause the mesh to contract to some degree in all patients. It is not possible to predict the severity of the chronic inflammatory response in any individual patient. In some patients the chronic inflammatory response will have adverse effects. It is not possible to identify in advance the patients who will experience those effects, although some patients are at greater risk than others. At-risk patients include healthy patients. The severity of a patient's chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It can also be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor may influence the compatibility and function of the implant.

1. *Trade Practices Act 1974* (Cth) s 75AD.

2. *Competition and Consumer Act 2010* (Cth) sch 2.

3. *Gill v Ethicon Sarl & Ors* [2019] FCA 1905.

The adverse events which may result include:

a. *infection;*
b. *erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain;*
c. *erosion of the mesh into surrounding organs such as the bladder, urethra or rectum which may cause pain and damage those organs;*
d. *damage to nerves in the scar tissue surrounding the implant or elsewhere;*
e. *chronic pain, which may be severe;*
f. *dyspareunia, which may be severe and may become chronic;*
g. *apareunia;*
h. *leg weakness;*
i. *de novo or recurrent urinary incontinence;*
j. *difficulty voiding; and*
k. *vaginal discharge.*

Adverse events may occur years after implantation. The risk will endure for as long as the implant remains in the patient.

Each of these events may occur regardless of the skill of the surgeon.

While the true incidence of these complications is unknown, they are not rare.

Removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms. Removal of part of the implant can be difficult. Removal of the whole of the implant may be practically impossible. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of stress urinary incontinence.

Removal of the eroded mesh will not necessarily prevent further erosions or other adverse events.'

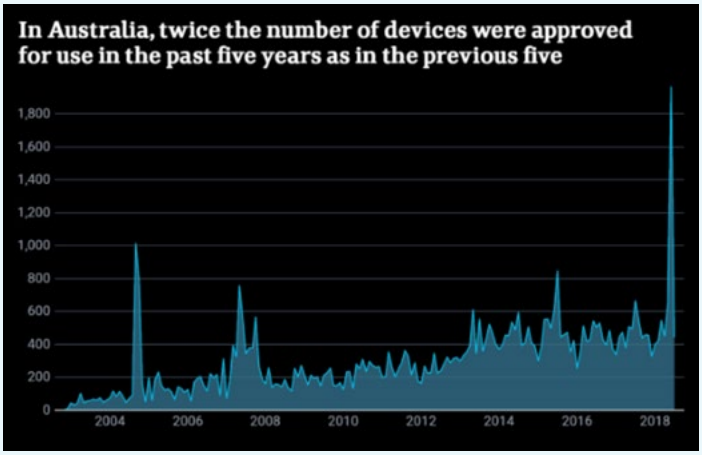
The Court held that pursuant to s 232 of the Australian Consumer Law, being Schedule 2 to the *Competition and Consumer Act 2010* (Cth), after 30 June 2020 the respondents may not supply, distribute, market or promote any of the medical devices identified in Schedule B to the orders anywhere in Australia without including in the instructions for use the above advice or advice to the same effect.

RESPONSES TO THE INCREASE IN THE PRODUCTION OF MEDICAL DEVICES

By Kelli Stallard, Partner, Alison Choy Flannigan, Partner, and Benjamin Wilson, Paralegal

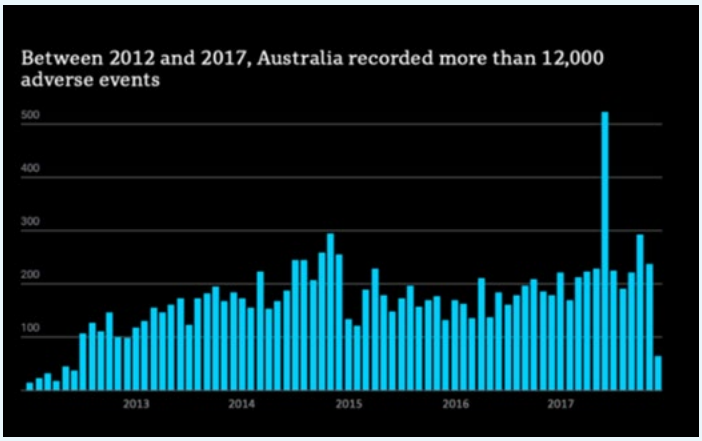
MEDICAL DEVICES PRODUCTION GROWTH

The approval of medical devices globally has increased significantly. The following graph shows that Australia is included in the trend.



(ABC, 26 November 2018)

The proponents argue that competition is the main reason for increased approvals, as manufacturers seek to meet the demand for more cost-effective devices. The RAND Corporation has published a paper which found that the market for medical products is beginning to open up to a wider market, from what was originally a narrow and wealthy segment. Medical device companies have had to adapt their business models towards frugal innovation, which takes the form of simpler products with lower unit cost. The largest medical device producer, Medtronic, is developing a cardiac pacemaker that will be five to 10 times cheaper than the classic models.[1]



(ABC, 26 November 2018)

1. Soeren Mattke et al, 'Medical Device Innovation in the Era of the Affordable Care Act', RAND Corporation (Web-only Perspective, 2016).

REGULATORY RESPONSE

In response to the increase in medical devices, countries across the world have increased regulation.

On 5 April 2017, two new regulations on medical devices and in vitro diagnostic medical devices were adopted in the European Union. They entered into force on 25 May 2017 and will progressively replace the existing directives. The new regulations will be fully applicable in May 2020 for medical devices and May 2022 for in vitro diagnostic medical devices.

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

The new regulations contain a series of extremely important improvements to modernise the current system.

Among them are:

- stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level;
- reinforcement of the criteria for designation and processes for oversight of notified bodies;
- inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations;
- a new risk classification system for in vitro diagnostic medical devices in line with international guidance;
- improved transparency through a comprehensive EU database on medical devices and a device traceability system based on unique device identification;
- introduction of an 'implant card' for patients containing information about implanted medical devices;
- reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations;
- strengthening of post-market surveillance requirements for manufacturers; and
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.

Australian companies exporting medical devices to the EU should be aware of these changes. It is important that all medical device companies are fully aware of the changes and start preparing for the implementation of the new regulations as soon as possible.

More information is available on the European Commission website. https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

In Australia, on 4 April 2019, the 'Action Plan for Medical Devices' was released by the TGA.

The Action Plan is a three-part strategy to:

- improve how new devices get on the market in Australia;
- strengthen monitoring and follow up of devices already in use; and
- provide more information to patients about the devices they use.

The Therapeutic Goods (Medical Devices) Regulations 2002 (**the Regulations**) were amended on 12 December 2019.

The changes relate to:

- software – the new software regulations will commence on 25 August 2020 for new applications for inclusion;
- personalised medical devices – the new personalised medical device regulations will commence on 25 August 2020;
- IVD companion diagnostics – for IVD companion Diagnostics seeking inclusion and a new application is received on or after 1 February 2020 the new rules apply; and
- the reclassification of certain devices – new classification rules will apply to all new applications for ARTG inclusion from 25 August 2020.

More information is available on the Therapeutic Goods Administration website. https://www.tga.gov.au/therapeutic-goods-legislation-amendment-2019-measures-no1-regulations-2019

A top priority of the Australian Competition and Consumer Commission (**ACCC**) is the introduction of a general safety provision which would have real impact on manufacturers. The provision would place the onus on manufacturers to ensure their products are safe before sale, with the risk of liability where they can be found not to meet the standard. While therapeutic goods are covered by the *Therapeutic Goods Act 1989 (Cth)*, in some cases, therapeutic goods can also be considered a consumer good, which allows either the ACCC or TGA to carry out a recall. The recent amendments to the *Australian Consumer Law* penalties for misleading and deceptive conduct, which are now far more severe, shows that Parliament is open to supporting an ACCC argument for severe penalties regarding a general safety provision.

Hall & Wilcox's industry leading health practice believes that competition is the main reason for increased approvals, as manufacturers seek to meet increasing demand.

AUSTRALIAN COMPANIES EXPORTING MEDICAL DEVICES TO THE EU SHOULD BE AWARE OF THESE CHANGES. IT IS IMPORTANT THAT ALL ACTORS ARE FULLY AWARE OF THE CHANGES AND START PREPARING FOR THE IMPLEMENTATION OF THE NEW REGULATIONS AS SOON AS POSSIBLE.

WHAT IS THE STANDARD OF CARE FOR AMBULANCE OFFICERS?

***MASSON V STATE OF QUEENSLAND* [2019] QCA 80**

By Rachael Arnold, Partner, and Catherine Blair, Senior Associate

The Queensland Court of Appeal's decision is illustrative of a position that ambulance officers should not depart from any guidelines available to them unless a more qualified medical specialist is present to make a more informed clinical assessment.

On 10 May 2019, the Queensland Court of Appeal delivered a judgment in which it overturned the Supreme Court's earlier finding that the Queensland Ambulance Service **(QAS)** was not negligent when it attended and provided treatment to Jennifer Masson in 2002.

FACTS

25-year-old Jennifer Masson was a chronic asthmatic and had been admitted to hospital for asthma many times during her life. She carried puffer medication, which administered salbutamol, and an EpiPen, which administered adrenaline.

On 21 July 2002, Ms Masson suffered a severe asthma attack and collapsed. QAS officers were arrived six minutes later and were informed of Ms Masson's immediate and more long-term medical history, including that she had taken salbutamol prior to collapsing.

Ambulance officers observed that Ms Masson had a Glasgow Coma Scale (**GCS**) of six (meaning she was effectively unconscious), she was cyanosed (her face was blue) and her respiratory rate was low at two breaths per minute. Her blood pressure was 155/100 and her heartbeat was 150 beats per minute; she was tachycardic. Ambulance officers ventilated Ms Masson and administered two milligrams of salbutamol in eight portions intravenously over the next 21 minutes. This was twice the recommended dosage in the clinical practice manual (**CPM**) carried by ambulance officers.

During transportation, Ms Masson became bradycardic as her heartbeat was less than 60 beats per minute. A minute later adrenaline was administered in three dosages of 100 micrograms, 60 seconds apart. At hospital, Ms Masson's condition was recorded as cyanosed, no respiratory effort and no carotid pulse. Three further doses of adrenaline was administered and provoked an immediate response with the pulse becoming discernible and increasing. By this time, however, Ms Masson had suffered irreversible brain damage by oxygen deprivation. Ms Masson lived in a vegetative state until 2016 and her claim for damages against QAS survived in the hands of her estate.

EVIDENCE

At trial, the plaintiff's (Ms Masson) medical experts gave evidence that adrenaline was, in 2002, and is the preferred treatment of an asthmatic in extremis. The plaintiff's expert in emergency medicine said that had adrenaline been administered early hypoxic brain damage would have been avoided. The trial judge accepted this opinion.

The defendant's (QAS) experts were concerned that adrenaline posed a risk because Ms Masson was hypoxic (deprived of oxygen), tachycardic and high blood pressure.

The principal ambulance officer gave evidence that he believed he was prohibited from administering adrenaline until the time that he did because of the vital signs Ms Masson was exhibiting, including that she was tachycardic and hypertensive. From his training and the CPM the principal ambulance officer understood that he was precluded from administering adrenaline until Ms Masson became bradycardic.

THE COURT OBSERVED THAT THERE WAS A 'SIGNIFICANT' DIFFERENCE IN THE CARE AND SKILL EXPECTED BY AN AMBULANCE OFFICER COMPARED TO THAT OF A SPECIALIST IN EMERGENCY MEDICINE.

FINDINGS BY THE TRIAL JUDGE

It was alleged by the plaintiff that the principal ambulance officer was negligent in administering salbutamol in favour of adrenaline in the first 20 minutes of Ms Masson's treatment. At the trial, the following questions were considered:

1. whether adrenaline was the preferred drug to treat an asthmatic in extremis in 2002;
2. whether Ms Masson's symptoms in the first 20 minutes of treatment meant that salbutamol was preferred, or equally acceptable, to adrenaline; and
3. whether the non-administration of adrenaline in the first 20 minutes was contrary to the guideline in the CPM.

The trial judge found that had adrenaline been administered to Ms Masson in the first few minutes of treatment, brain damage would have been avoided. He also found that there was a reasonable inference that the predominant view of the medical profession in 2002 was that the administration of adrenaline for a patient in asthma extremis was preferred.

However, the care given to Ms Masson did not fall below the standard expected of an ambulance officer because:

1. there was 'a responsible body of opinion in the medical profession in support of the view that Ms Masson's tachycardia and hypertension, in the context of her overall condition, provided a medically sound basis to prefer the administration of adrenaline.' Adrenaline could make a patient in Ms Masson's condition worse, for instance, by causing the heart to stop.
2. the principal ambulance officer demonstrated in his evidence that he had complied with the CPM by considering the administration of adrenaline; however, he concluded that Ms Masson's tachycardia and hypertension 'mitigated against' its administration.

ON APPEAL

On appeal, the Court reviewed the evidence given by the principal ambulance officer and rejected the trial judge's findings that the principal ambulance officer had made a clinical assessment and considered the administration adrenaline in accordance with the CPM. Instead, it was found that the principal ambulance officer excluded any consideration of the use of adrenaline based on a misunderstanding that adrenaline could not be administered on a patient who was not bradycardic.

Therefore, the principal ambulance officer had departed from the CPM in two ways:

1. by administering twice the recommended dosage of salbutamol; and
2. by failing to consider the administration of adrenaline.

The Court found that the CPM was not relevantly ambiguous.

The Court observed that there was a 'significant' difference in the care and skill expected by an ambulance officer compared to that of a specialist in emergency medicine. It was noted that the former lacks the education, training and experience of a medical specialist and the provision of guidelines such as the CPM illustrates that fact. Therefore, it was inconsistent with the exercise of reasonable skill and care for the principal ambulance officer to depart from the CPM.

Furthermore, the Court of Appeal disagreed with the trial judge that there was a responsible body of opinion in the medical profession to support the administration of salbutamol with Ms Masson's symptoms. While the Court of Appeal accepted that there were 'credible views' to support the same utility of salbutamol, the evidence did not amount to a 'credible body' of professional opinion to that effect.

ARE DAMAGES PAYABLE FOR THE FUTURE CARE OF AN ANIMAL?

***MAKAROFF V NEPEAN BLUE MOUNTAINS HOSPITAL HEALTH DISTRICT* [2019] NSWSC 715**

By Rachael Arnold, Partner, and Holly Turner, Lawyer

On 14 June 2019, the Supreme Court of NSW awarded judgment in favour of the defendants in *Makaroff* v *Nepean Blue Mountains Hospital Health District* [2019] NSWSC 715.

While this is a medical negligence claim, the findings in respect to quantum are useful for wider application, as the Supreme Court held that no damages are recoverable for the future care of a pet or the cost of a hobby.

BACKGROUND

The 67-year-old plaintiff, Diana Makaroff, has had a passion for horses her whole life. At the time of the trial, she resided in a horse float on a five-acre property owned by a friend, with 20 horses and 15 cats.

On 19 September 2010, while the plaintiff was reaching through a gate to feed her horses, one of her horses bit her right arm causing her right shoulder to become dislocated. The plaintiff was taken via ambulance to the nearest hospital to relocate the shoulder, and then to the Nepean Hospital (the first defendant) for plastic surgery. Following discharge, the plaintiff attended five appointments with her general practitioner, Dr Paul Percy (the second defendant), between 14 October 2010 and 5 April 2011.

The plaintiff brought a damages claim for chronic right shoulder injuries suffered as a result of alleged medical negligence on the part of the first and second defendants. The plaintiff's claim totalled $910,372.12, which included $412,750 for non-economic loss, based on 65% of the 'most extreme case'.

MEDICAL NEGLIGENCE CLAIM

The plaintiff's main allegations against the defendants related to failing to advise the plaintiff as to the likelihood of a rotator cuff injury and the follow-up treatment required, failing to ensure the plaintiff was referred to an orthopaedic surgeon, and failing to identify a rotator cuff tear and arrange for it to be repaired in a timely manner.

The defendants relied on Section 5O of the *Civil Liability Act 2002* (NSW) which provides:

'5O Standard of care for professionals

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.'

The Court was satisfied, on the balance of probabilities, that the first and second defendants' each acted in a manner that was widely accepted in Australia by peer professional opinion as competent professional practice, and that no negligence arose from the respective professional services provided. Accordingly, the plaintiff's claim against both defendants failed at the breach of duty stage.

For abundant caution, the Court considered causation.

The plaintiff did not prove, on the balance of probabilities, that '*but for*' the defendants' alleged negligence, she would not have suffered ongoing injury to her right shoulder. In making this determination, the Court took into account evidence that the plaintiff continued to perform manual work in her stables after the injury (despite the second defendant's warning); the fact that, even if she had been referred to an orthopaedic surgeon promptly and referred for surgery, she would have been put on a long public waiting list; and, lastly, that the plaintiff was unlikely to have ever undergone the surgery, given that she had no one to care for her 20 horses and 15 cats.

DAMAGES CLAIM

The plaintiff emphasised that she had been committed to the raising and training of horses for almost her whole life and that, at the time of the accident, she was running a stud business selling horses.

The Court noted that she was a difficult and unreliable witness whose evidence was to be treated with caution unless corroborated by other witnesses or objective contemporaneous material.

The plaintiff claimed a weekly sum for horse maintenance, including for watering and feeding horses, for the remainder of her life expectancy. The plaintiff later alleged that the keep of horses was not a hobby (but rather, a part of her business) and claimed a buffer amount of $100,000 for future economic loss. This was primarily on the basis that the plaintiff alleged she intended to grow her stud business to actively take

part in the artificial insemination, training and selling of horses.

The Court stated that if the horses are to be characterised as pets, or their care as a hobby, it is settled law that the plaintiff is not entitled to recover with respect to their future care.[1] However, if the purpose of maintaining the plaintiff's 20 horses is to sustain her business, then any flowing losses are correctly categorised as a loss of earning capacity.

On the evidence, the Court held that the plaintiff's view of any earning capacity deriving from the selling of horses was 'at best aspirational' as her business in the preceding years had consistently suffered a loss. The Court held that the plaintiff had no real earning capacity prior to her injury in 2010[2], and accordingly, there could be no diminishing of her earning capacity attributed to the defendants' negligence.[3]

Therefore, the plaintiff was not entitled to recoup damages for either future horse husbandry or economic loss associated with the keep of horses.

In the event that negligence was proven, the Court assessed the plaintiff's total entitlement to damages as $325,082.30. This comprised of $254,000 for non-economic loss (40% of the 'most extreme case'), future care of $52,850, and future treatment/medication/personal expenses of $18,232.30.

THE PLAINTIFF WAS NOT ENTITLED TO RECOUP DAMAGES FOR EITHER FUTURE HORSE HUSBANDRY OR ECONOMIC LOSS ASSOCIATED WITH THE KEEP OF HORSES.

1. *Geaghan v D'Aubert* [2002] NSWCA 260.
2. *Schofield v Hopman* [2017] QSE 297.
3. *Civil Liability Act 2002* (NSW) s 13.

MODERN SLAVERY LAWS HAVE COMMENCED

By Karl Rozenbergs, Partner, Faye Calderone, Partner, and Gemma Hallett, Lawyer

In Australia, it's estimated around 15,000 people may live in conditions of modern slavery, forced labour, wage exploitation, human trafficking or debt bondage.[1] The introduction of the *Modern Slavery Act 2018* (Cth), which commenced on 1 January 2019, aims to minimise modern slavery practices in the Australian market by requiring large businesses to report on modern slavery risks in their operations and supply chains, and actions taken to address these risks.

New mandatory reporting requirements will be imposed on Australian entities (including Commonwealth government entities), and foreign entities carrying on business in Australia, with an annual consolidated revenue of at least $100 million. Other entities may choose to report voluntarily.

The first Modern Slavery Statement required under the Act must be submitted by 30 June 2020 (for calendar-year-reporting entities) or 31 December 2020 (for financial-year-reporting entities). After that, entities will be required to report annually. Modern Slavery Statements will be kept in a public online repository.

Modern Slavery Statements must detail information about:

- the entity's structure, operations and supply chains;
- the potential modern slavery risks associated with the entity's structures, operations and supply chains (plus those of any entities it owns or controls);
- actions that were taken by the entity (or any entities it owns or controls) to assess and address those risks;
- how the entity assesses the effectiveness of those actions; and
- the process of consultation of the entity with any entities it owns or controls.

In April 2019, the Department of Home Affairs released its *Draft Guidance for Reporting Entities* https://www.homeaffairs.gov.au/how-to-engage-us-subsite/files/draft-modern-slavery-act-reporting-entity-guidance.pdf which details the practical steps entities should follow to comply with the reporting requirement. In summary, an entity must:

1. identify whether it is required to report;
2. prepare a Modern Slavery Statement which responds to each mandatory criterion;
3. have the Modern Slavery Statement approved by the entity's Board or other principal governing body, and signed by a responsible member of the entity; and
4. provide the Modern Slavery Statement to the Department to be published online.

Accordingly, entities who are required to report should commence a risk analysis, and update policies, procedures and contracts with subcontractors to ensure that risks are identified and ideally eliminated. Hall & Wilcox would be pleased to assist.

NSW employers should also be aware that similar is awaiting commencement. The *Modern Slavery Act 2018* (NSW) applies to commercial entities with an annual turnover of at least $50 million and at least one employee in NSW who supply goods and services for profit. This represents a much lower threshold than the Act. In further contrast to the Act, the NSW Act provides for penalties in circumstances where an entity fails to comply with its reporting obligations with penalties of up to 10,000 penalty points (currently $1.1 million).

1. Global Slavery Index,'Australia' https://www.globalslaveryindex.org/2018/findings/country-studies/australia/ (Minderoo Foundation, 2018).

VOLUNTEERING FOR THE PUBLIC GOOD

By Nathan Kennedy, Partner & Head of Pro Bono and Community

Hall & Wilcox is committed to giving back to our communities by doing work for the public good. Our pro bono practice embraces our ethical responsibility as a firm to help those in need, and enriches the personal and professional lives of the Hall & Wilcox lawyers who get involved.

Hall & Wilcox has entered into a partnership with the Centre for Volunteering, as well as other volunteering peak bodies around Australia, to provide pro bono legal services to them and their members who meet our pro bono eligibility criteria.

Volunteering Australia defines 'volunteering' as time willingly given for the common good and without financial gain. This definition is a natural fit with our pro bono practice philosophy, which provides pro bono legal services on a no fee basis to assist the disadvantaged or those organisations working to assist the disadvantaged or in the public good.

Organisations assisting these people often could not survive or provide sufficient levels of care without a volunteer workforce. So many organisations working for the disadvantaged or for the public good rely heavily on volunteers and rely on volunteering peak bodies around the country for guidance and resources on how best to manage this volunteer workforce. This is often a challenging and overwhelming responsibility for these volunteer peak bodies.

Our pro bono practice provides legal advice on issues such as governance, reviews of constitutions, contracts, agreements, employment, insurance, property matters and more to ensure that these organisations can continue to flourish and serve those most disadvantaged in our community.

With their legal issues taken care of the peak bodies and their member organisations can focus their time and resources on helping the disadvantaged and working for the public good.

Organisations working for the disadvantaged or for the public good that rely on volunteers and need pro bono assistance are invited to contact their local peak bodies or our Head of Pro Bono and Community, Nathan Kennedy on nathan.**kennedy@hallandwilcox.com.au** to discuss whether the Hall & Wilcox pro bono team can assist.

MEET **KITTY VO**

We are pleased to introduce Kitty Vo, who recently joined us as a partner in our Property and Projects practice in Sydney.

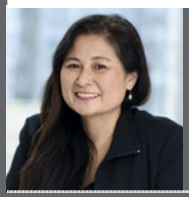
Kitty advises on all aspects of real estate transactions for both public and private sector clients, across a range of industries and sectors. Kitty has extensive experience acting in relation to leases, licences, and sales and acquisition of property.

Kitty has proudly acted for the Royal Flying Doctor Service of Australia in respect of the organisation's property requirements in New South Wales, and previously assisted Mid North Coast Local Health District regarding preparation of easements in connection with construction works at Port Macquarie Base Hospital. She has also acted in relation to pathology services and premises licensing arrangements.

With many of her friends and family members working in the healthcare industry, Kitty understands the health sector's pivotal role in our community and has maintained a keen interest in this sector.

Hall&Wilcox
smarter law

Key contacts



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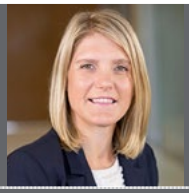

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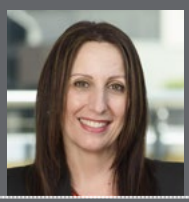

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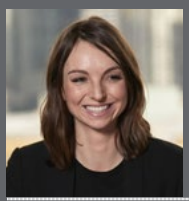

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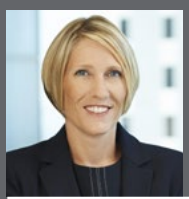

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