Holman Webb

Lawyers

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Contents

Introduction 2

GENERAL

Managing difficult employees 3

MEDICO-LEGAL

Update on Patel 6

Recent Case Provides Guidance on Causation under the Civil Liability Act – Paul v Cooke [2012] NSWSC 840 7

HEALTH

National Health Reform – Practical transitional issues 9

LIFE SCIENCES

Update on Clinical Trial Reform in Australia 10

Introduction

Welcome to the August 2012 edition of the Holman Webb Health Law Bulletin.

We are excited to announce the continued growth of our health, aged care and life sciences team with Sarah Perkins joining us as a Special Counsel in our Brisbane Office.

It continues to be a time of change for the Australian health care industry and arising from this there have been some interesting transitional issues. The changes have also brought workforce issues to the foreground. This edition of the Health Law Bulletin highlights some of these issues.

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, both in the "for profit" and the "not for profit" sector.

Our team includes lawyers who have held senior positions within the health industry.

Health, Aged Care and Life Sciences team.

Managing "difficult" employees

by Robin Young, Partner

Introduction

All health care organisations manage staff on a daily basis whether it be in relation to workload, business needs, clinical issues, time recording, efficiency or more personal matters such as leave and interpersonal relationships.

This article is not a human resources guide but rather a legal tool to identify and crystallise some of the relevant issues, the legal framework, the risks and what can be done to ensure compliance and minimise exposure to legal challenges to employer action.

Please note that this article focuses on the employment relationship and not credentialing of clinical privileges for medical practitioners.

What is a difficult employee?

This will depend upon perception. "Difficult" employees can include underperformers, serial complainers, high level absentees, bullies, those who don't take instruction well, those who disclose confidential information, those who fail to disclose conflicts of interest or engage in corrupt conduct, those with history, squeaky wheels, social butterflies, skylarkers, the dishonest and fraudulent.

Employers and HR managers must familiarise themselves with a wide regulatory framework. One incident can often give rise to issues which fall within the scope of multiple laws.

The Legislation

The legislation which regulates the employment relationship will depend upon whether or not the employer is a private sector employer or a public sector employer.

The *Fair Work Act 2009 (Cth)* (**FWA**) regulates "national system employers" such as private companies and some public health services, for example, in Victoria.

Many public sector health employees continue to be regulated under State law and policy, for example, the NSW public health sector employees are employed under the provisions of the *Public Sector Employment and Management Act 2002 (NSW)* and the *Health Services Act 1997 (NSW)* and are regulated by NSW Health policies and the *Industrial Relations Act 1986 (NSW)*.

These laws and relevant awards and enterprise agreements govern the employment relationship and contain provisions concerning remuneration, leave, termination, dismissal, redundancy, general protections, industrial action and other conditions of employment.

An employee exercising a legal right such as under an award, but not an employment contract, is exercising a workplace right when making a claim. Improper action by the employer may result in liability for the employer.

Performance Management

This is probably the hardest area to manage and involves multiple risks. Performance is necessarily subjective and the response will involve perceptions which if negative may result in conflict. Disputes concerning performance management and appraisal occupy a lot of time at Fair Work Australia, the NSW IRC, Workers' Compensation Commission, Human Rights Commission and Anti Discrimination Board to name a few. The policies and procedures adopted by organisations to manage staff are the rules which govern the process. They are intended to ensure fairness, consistency, statutory compliance and efficiency. Failure to properly apply the rules leads to internal disputes escalated to higher management levels and external disputes leading to litigation. This in turn leads to lost time, additional cost and even cultural damage.

The processes that govern performance must be sympathetic to the statutory framework that governs EEO, employment entitlements and work health and safety. Staff must be fully informed of the process, how it works, who does it, how it effects them and potential outcomes. Surprises are bad. Transparency, communication and good record keeping are crucial. Recent experience demonstrates that poor communication and uncertainty is likely to lead to cancelation of meetings and appointments being made with doctors and lawyers.

Leave and genuiness of illness

In addition to statutory and contractual entitlements to taking sick leave it is unlawful to terminate employment because of temporary absence/illness. Under the FWA, this is defined as 3 months. Paid sick leave has been interpreted to include periods of workers compensation.

Legal authority has established that an employer has the right to establish the bona fides of an illness. Employee must provide evidence of illness and employers are entitled to be satisfied regarding the state of health but not necessarily a full medical analysis. It may be reasonable to seek additional information, a meeting with the employee and doctor and independent examination.

Work Health & Safety

The new *Work Health and Safety Act 2011 (NSW)* commenced on 1 January 2012. A knowledge of work health and safety laws is fundamental to every person conducting a business or undertaking (**PCBU**). Key points are a new primary duty of care qualified by reasonable practicability to safeguard the health and safety of workers, an end to the reverse onus of proof, obligations for company officers to exercise due diligence, obligations of notification, consultation, codes of practice and enforceable undertakings.

Work health and safety obligations are relevant to skylarkers and bullies and those who won't comply with safe work methods and organisational procedures. It is not possible to delegate or abdicate responsibility. However, policies and procedures and well communicated instruction and enforcement will lead to a reduced incidence of injuries.

Failure to comply with employment instructions may result in disciplinary action. Careful investigation and implementation of policies will ensure that an employer will not be hamstrung.

A new draft Code of Practice has been introduced on workplace bullying. An article on this was published in the June 2012 edition of the Holman Webb Health Law Bulletin.

Dishonesty

Employers should respond to dishonesty in the workplace notwithstanding the potential issues that may arise in relation to the disciplinary action and termination. The Corporations Act and the Crimes Act impose obligations on corporate conduct which may involve a serious offence or breach of an officer's or directors duties. It is an offence to conceal a serious indictable offence and to accept a benefit in return for not reporting such conduct.

Workers Compensation

Workers compensation legislation, such as the *Workers Compensation Act 1987 (NSW)* (**WCA**) imposes statutory obligations out of which parties may not contract and employers must be alert to ensure that premiums are controlled and that employee rights are not compromised.

Where an employee exercises a right by making a workers' compensation claim, employers must ensure that they comply with relevant laws, and for example, to provide suitable duties.

Under the WCA it is an offence to terminate employment because of incapacity/injury within 6 months. An employee may apply for reinstatement within 2 years.

No compensation is payable for psychological injury resulting from reasonable conduct in relation to a business decision. Employers who apply protocols in relation to performance management are far less likely to experience stress claims and can argue that injury resulted from reasonable conduct.

There are new reforms to workers compensation laws which will be dealt with in a separate article.

Previous History

Lack of due diligence or lack of disclosure at the commencement of the employment relationship may cause problems. This can be avoided by implementing pre-employment protocols such as checking qualifications, obtaining CVs, reference checks and documenting that the employment is based on the information provided being accurate or may be brought to an end.

An employee may hide a previous injury for fear of discrimination. It may not be unlawful discrimination on the grounds of disability if an employee is unable to perform the "inherent requirements" of the role.

Confidential Information

After employment ends an employee may not use or disclose confidential information based on an express or implied term or a duty of confidence.

All health care organisations should have policies and procedures in relation to confidentiality and privacy.

Conflicts of interest

Conducting a rival business whilst employed or not disclosing a material conflict of interest is a breach of duty to the employer. An employee may undertake steps in relation to plans *after* the employment terminates.

Public sector employees are also subject to anti-corruption laws.

Restraints

There is a legal presumption against post employment restraints and the employer must prove that a restraint is reasonable and valid. Enforceability depends upon a legitimate interest to protect the business of the employer and whether it is a reasonable protection of that interest. The position will be improved with express obligations concerning confidential information, intellectual property, conflicts of interest and restraints.

Anti Discrimination

Anti Discrimination Laws ensure that employers do not discriminate against employees on prescribed bases including race, sex, disability and age. Employers must not discriminate when selecting applicants for employment, in the terms and conditions on which they offer employment, against employees or particular classes of employees during the course of employment or when dismissing employees.

Policies

Implementation of policies for employment entitlements, investigation, discipline, grievance handling and the like are invaluable tools when dealing with employees. An employer must afford a reasonable, fair and transparent process and the decision of *Nikolic v Goldman Sachs J B Were Services Pty Limited [2006] SCA 784* demonstrates the importance of policies imputed into employment contracts

Employers should be aware that they also must comply with policies, so care is required when preparing them that they do not state practices which the employer is unable or unwilling to follow.

Conclusion

These are a number of the risks faced by employers when dealing with a workforce of individuals with different personalities, issues, histories, foibles and nuances.

Employers are entitled to manage the performance of underperforming employees. The appropriate action to be taken will depend upon whether or not the conduct of the employee should result in dismissal or not. If dismissal is not warranted, then the employer should explain to the employee what is expected of them and give them the opportunity to respond and improve. Adequate records should be taken of this process.

Understanding the laws is important. Understanding the employees is more important. Having good policies and procedures is important **but** implementing them properly is crucial.

Update on Patel

by Sarah Perkins, Special Counsel

On 29 June 2010 a Queensland jury found Dr. Jayant Patel guilty of three counts of manslaughter and one count of grievous bodily harm. Justice Byrne sentenced Patel to seven years imprisonment in respect of each manslaughter conviction and three years in respect of the grievous bodily harm conviction, to be served concurrently. He is ineligible to apply for parole until December 2013.

Whilst the families of the deceased patients expressed to the media their relief that the case was "all over", in fact the legal arguments were just beginning. The basis of the argument was:

- the Crown had begun the 58 day trial arguing that Patel had been criminally negligent in deciding to undertake the surgical procedures; and
- Dr. Patel had been criminally negligent in his performance of those procedures.

However, on day 43 of the trial, the second limb of the Crown's case was abandoned after the trial judge had characterized it as a "mud-slinging exercise", after:

- the jury had heard considerable evidence in relation to the allegedly negligent performance of the procedures; and
- legal argument in the absence of the jury had occurred as to the correct way for the Crown to proceed.

Patel applied for a mistrial on day 44 of the trial on the grounds that prejudicial evidence relating to the allegedly negligent performance of the surgical procedures had been heard by the jury. That application was refused.

Patel appealed to the Queensland Court of Appeal on the grounds that provisions of the Queensland Criminal Code had been incorrectly interpreted, resulting in errors in the trial judge's summing up and directions to the jury, resulting in a miscarriage of justice and that the amendment by the Crown of its case after the presentation of evidence rendered much of that evidence irrelevant and prejudicial. The Court of Appeal upheld the trial judge's view and dismissed Patel's appeal.

Leave was granted to appeal to the High Court on the grounds that Patel had been convicted under the wrong provision of the Criminal Code and that there had been a miscarriage of justice in the manner in which the trial was conducted.

Five justices of the High Court travelled to Brisbane to hear the arguments on the 6th and 7th June 2012. Patel's argument was:

- He had been convicted under s288 of the Criminal Code in circumstances where that section had no application, as it relates only to the actual performance of surgery, not to the decision to operate, which is addressed by s282 of the Criminal Code. In fact, s282 is an excusatory provision and the jury was never asked to consider it. Essentially, Patel was deprived of the opportunity to make out the excuse.
- A cumulative miscarriage of justice occurred during the trial, in that the judge allowed the hearing of evidence to continue in the absence of coherent particulars provided by the Crown. By the time the Crown had "pared down" its case, much of the evidence was irrelevant and prejudicial.

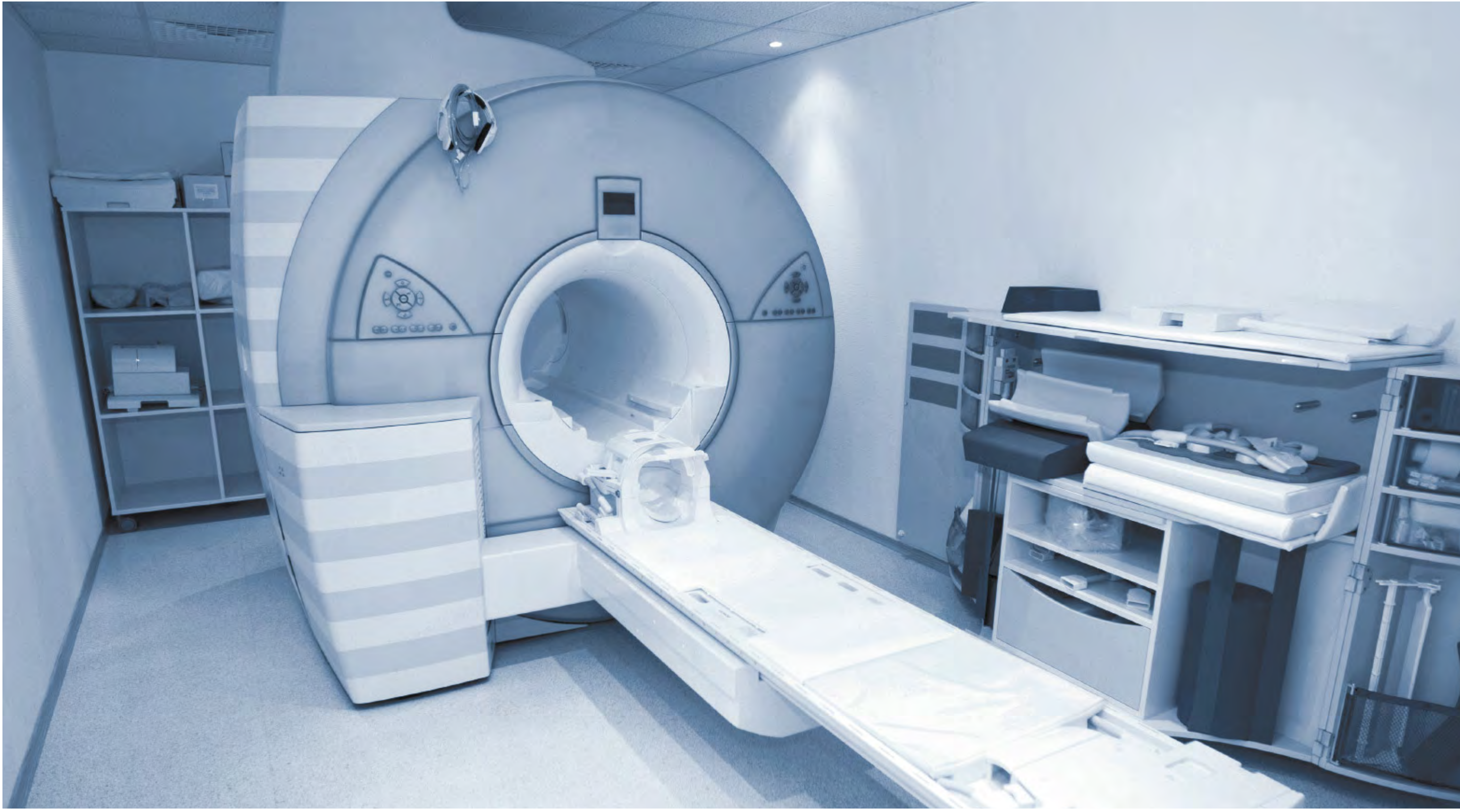
He asked that his convictions be quashed and a retrial ordered.

The Crown's response was that:

- The words "in doing such an act" in s288 of the Criminal Code encompass the decision to perform surgical procedures, as well as the actual performance of them.
- The evidence complained of remained relevant to other issues, such as the gravity of the offence, Patel's state of mind and the reasonableness of his actions.
- If the High Court decides against that interpretation of s288, no miscarriage of justice has occurred because the evidence supports Patel's guilt and the jury has found those facts necessary to support the Crown's case. Accordingly, the High Court ought to be convinced beyond a reasonable doubt that Patel is guilty of the offences with which he was charged.

If the High Court is minded to order the convictions quashed and a re-trial, the Crown could proceed on the basis of the usual manslaughter provisions without invoking s288. Patel would then rely on s282 to excuse his behavior and the trial would turn on whether his decisions to perform the surgical procedures which led to the deaths and the injury were "reasonable, having regard to the patient's state at the time and to all the circumstances of the case".

After almost ten years, a governmental review of the Queensland health system, two Commissions of Inquiry, proceedings in the Health Practitioners Tribunal, lengthy extradition proceedings, a 58 day criminal trial in the Queensland Supreme Court, a hearing before the Queensland Court of Appeal, an application for leave to appeal to the High Court and 2 days of hearing before the Full Bench of the High Court, all accompanied by extensive media attention, will this saga finally be "all over"? The High Court is expected to hand down its decision in the near future.



Recent Case Provides Guidance on Causation under the Civil Liability Act – Paul v Cooke [2012] NSWSC 840

by Sarah Perkins, Special Counsel

In 2003 Dr Cooke, a radiologist, reviewed an angiogram taken of Mrs Paul and failed to diagnose a berry aneurysm in her right anterior cerebral artery. It was admitted that this was a breach of his duty to her. Had Mrs Paul suffered a spontaneous rupture of the undiagnosed aneurysm, there is no doubt that Dr Cooke would have been held liable for her damage.

However, Mrs Paul's aneurysm was subsequently diagnosed in 2006 and she elected to undergo a surgical procedure known as coiling in order to rectify the problem. The aneurysm ruptured intra-operatively, which led to a stroke. It was common ground that the rupture was not due to any negligence on the part of the surgeon, who was not a party to the proceedings, and rupture was a known risk of the procedure.

Mrs Paul initially argued that the passage of time had allowed the walls of the aneurysm to thin, making it more susceptible to rupture, but this was not borne out by the medical evidence and was abandoned.

She then argued that had her condition been appropriately diagnosed in 2003, she would not have undergone coiling, but instead would have chosen to undergo a more invasive procedure known as clipping. She contended that the risk of intra-operative rupture was smaller for clipping than it was for coiling.

Mrs Paul argued that the reasoning in *Chappel* v *Hart* (1998) 195 CLR 232 allowed her to recover damages on the basis that the risk of intra-operative rupture was small and that had she undergone the procedure at an earlier time (as she would have done had Dr Cooke correctly diagnosed her condition in 2003) it would not have occurred.

Dr Cooke argued that the scope of his duty to Mrs Paul did not extend to the prevention of a known risk of treatment, in which he was not involved. However, Brereton J held that once breach of duty was established (and it was admitted in this case) then the question became one of causation.

Turning then to the causation issue, His Honour noted that it was governed by section 5D of the *Civil Liability Act* 2002 (NSW) (Section 11 of the *Civil Liability Act* 2003 (Qld) contains almost identical wording). His Honour considered that section 5D requires the Plaintiff to prove, on the balance of probabilities, both factual causation and scope of liability (not to be confused with scope of duty).

He found that factual causation was established on the basis that had Dr Cooke correctly diagnosed her condition, Mrs Paul would have undergone a clipping procedure in 2003 and the rupture and subsequent stroke would not have occurred.

His Honour then turned to the scope of liability, which is a policy judgement as to whether it is appropriate for liability to extend to the harm in question in the circumstances of the case. He considered that *"harm from the very treatment that prompt and proper diagnosis was intended to enable is not harm of the kind against which the relevant rule of responsibility was intended to protect a patient".*

Mrs Paul argued that the fact of the rupture was sufficient, whether it occurred spontaneously or intra-operatively. His Honour disagreed on the basis that a spontaneous rupture would be a consequence of the failure to diagnose, while an intra-operative rupture was a consequence of treatment which would have been necessary whenever the diagnosis was made.

His Honour was satisfied that the delay had *"no meaningful causal relationship to the harm"*.

He distinguished failure to warn cases on the grounds that this was not a case in which the Plaintiff would have refused to run the risk of the procedure, had she been appropriately warned. To the contrary, the risk would not have been avoided – it would simply have been hazarded on another occasion, whether by way of clipping or coiling. His Honour was of the view that the level of risk was not, in fact, materially different as between the two procedures.

Judgement was entered for Dr Cooke.

This case illustrates the requirement for plaintiffs to clearly show that the breach of duty caused damage. It is no longer enough to argue that damage *might* have been avoided, but that, on the balance of probabilities and in a meaningful way, that it *would* have been avoided.

National Health Reform – Practical transitional issues

by Dr Tim Smyth, Special Counsel

With implementation of the *National Health Reform Agreement* underway around Australia, legislation and associated administrative instruments have rearranged public sector health services. In times of governance and organizational restructuring, it is important that Boards and Chief Executives do a periodic check to make sure that nothing has been "lost" in the transition.

Reflecting history and the relative degrees of centralisation, each State and Territory has done things differently to create their local variant of Local Health Networks. In New South Wales, the former large Area Health Services were abolished and Local Health Networks were created on 1 January 2011. Following the State election in March 2011, the Networks were revised and Local Health Districts commenced on 1 July 2011.

Some functions and services of the former Area Health Services were transferred to one of three Health Reform Transition Organisations (**HRTOs**) as a holding measure pending further implementation of the 2011 Governance Review. Other functions and services transferred to new statutory health corporations.

In May 2012 the HRTOs were abolished and their functions and services transferred to either a Local Health District or to a division of the Health Administration Corporation.

The majority of these transfers have occurred under the provisions of the *Health Services Act 1997* (NSW) (the "**Act**"). Under sections 20, 43, 64 and 111 of the Act, the Governor may make wide ranging orders dissolving, amalgamating and/or transferring services and functions. Schedule 4 of the Act sets out more detailed provisions in relation to the nature and effect of these orders.

With the many changes made under these orders over the past 18 months, health executives should do a "stocktake" to ensure that ownership, control and accountability align with the legal effect of the Governor's Orders and other administrative instruments made by the Minister and/or Director-General.

Most public sector health services in NSW are now hosting, receiving and/or providing services and staff from a varied mix of separate legal entities. While all part of what is colloquially known as "NSW Health", NSW Health is a brand and not a legal entity.

Particular points of focus might include:

- Leases, subleases and licences – while in most cases, the provisions of the Act ensure that the transferee has the legal interest, notwithstanding provisions requiring consent to transfers and assignments, it would be appropriate that the other parties to these agreements are advised of the change in status. If the instrument is registered with LPI updating the registration may be required.
- Statutory licences under Commonwealth legislation – whether a statutory licence is effectively transferred under an order of the Governor may depend on the legislative framework for eligibility and approval of the licence. If holding a valid licence is a pre-requisite to receiving payment or other funding, confirmation of the licence validity may need to be sought.
- Right of private practice and other Special Purpose and Trust Funds formerly held by an Area Health Service or HRTO – particular attention may need to be given to accounts and funds that are not exclusive to one Local Health District in terms of source of funds or purpose.
- Clinical appointments for clinicians (both salaried and visiting) with roles across more than one Local Health District and/or Specialty Health Network – clarification of clinical governance, compliance with by-laws, criminal record and other checks, credentialing, delegated authority and rights of private practice may be required.
- Cross District and/or Network services – clarification of authority to bill, compliance with Tax Invoice requirements, delegations to incur expenditure and delegated employer may be required.
- Compliance with the *Work Health and Safety Act 2011* – especially the duties of "persons conducting a business or undertaking".

Another point to note is that the Health Administration Corporation is not a public health organisation for the purposes of the Act and other instruments.

Health services need to ensure that they are able to exercise appropriate control over all core functions and services required for the effective operation of their service. Clarity around the legal nature of each entity is an important part of achieving this.

Holman Webb is able to advise health services and organisations who engage with public sector health services on these interesting aspects of national health reform and organisational restructuring. ■

Update on clinical trial reform in Australia

by Alison Choy Flannigan, Partner, Health, Aged Care & Life Sciences

Traditionally, Australia has been at the forefront of clinical research due to the high calibre of our researchers and healthcare professionals, our health care facilities and our regulatory environment, including but not limited to laws which regulate therapeutic goods and human tissue and which protect intellectual property rights.

With the global financial crisis and the growth of the Chinese and Indian economies, more and more research and clinical trials are being undertaken offshore by large pharmaceutical and medical device companies.

In 2010 the Clinical Trials Action Group published its report "Clinically Competitive: Boosting the Business of Clinical Trials in Australia". The report made the following recommendations:

Recommendation A

- The implementation of the Human Research and Medical Research Canal (**NHMRC**) Harmonisation of Multi-centre Ethical Review (**HoMER**) through acceptance of a single ethical review for multi-centre human health and medical research and adoption of common policies, procedures and forms.
- The adoption of the NHMRC best practice governance research handbook for human health and medical research.
- The introduction of policy on clinical trials that supports the timely ethics and governance review of clinical trials.
- The monitoring of progress of these initiatives through jurisdictions publicly reporting annual data on the timeliness of ethics and governance review for both the types and numbers of clinical trials, in a consistent format.
- The inclusion of clinical trial activity and timeliness of approvals for clinical trials as a key performance indicator "KPI" when jurisdictions negotiate new agreements with public hospital Chief Executive Officers.

Recommendation B

- The Parliamentary Secretaries for Health and Innovation progress reforms, as outlined in Recommendation A, with the university and private hospital sector through Universities Australia and the Australian Private Hospitals Association.

Recommendation C

- The adoption of a table of standard costs associated with conducting efficient clinical trials.

Recommendation D

- To ensure that clinical trials can take advantage of the developing e-health system.

Recommendation E

- That the NHMRC develop a consumer-friendly web portal that includes information on all current clinical trials in Australia.

Recommendation F

- The investigation of the feasibility of a comprehensive and searchable web portal in relation to clinical trials.

Recommendation G

- The examination of ways in which existing general practitioner software can be used to enhance patient recruitment.

Recommendation H

- The development and distribution of consumer information through GPs and specialist offices designed to encourage consumers to talk to their doctors about suitable clinical trial options. The Consumers Health Forum of Australia has released a Consumer Guide to Clinical Trials, available at https://www.chf.org.au.

Recommendation I

- That greater support for clinical trials networks in priority health areas be provided through the NHMRC. A Clinical Trials Networks List was created, and is available at http://www.nhmrc.gov.au.

Recommendation J

- The collation of available material about the value and performance of Australian clinical trials.

Recommendation K

- That the Pharmaceutical Industry Working Group become a mechanism for relevant stakeholders to continue to have input into clinical trials policy and coordinate implementation of improvements.

Since that report there have been a number of developments, some of which are stated below:

Greater consistency and collaboration in clinical trial research agreements

The public health systems in New South Wales, Queensland and Victoria have adopted a more standardised approach to clinical trial agreements, evidenced in their policies.

They have adopted variations of the Medicines Australia clinical trials research agreements available at www.medicinesaustralia.com.au:

- Standard Clinical Research Trials Research Agreement for Commercially Sponsored Trials;
- Standard Clinical Research Trials Research Agreement for Contract Research Organisations;
- Standard Clinical Research Trials Research Agreement for Collaborative Research Group Studies;
- Standard Medicines Australia Form of Indemnity for Clinical Trials;
- Medicines Australia Form of Indemnity for Clinical Trials (Human Research Ethics Committee Review); and
- Guidelines for Compensation for Injury Resulting from Participation in a Company Sponsored Clinical Trial.

The Medical Technology Association of Australia has also released a standard Clinical Investigation Research Agreement, Standard and HREC Forms of Indemnity for Investigations and Compensation Guidelines available at www.mtaa.org.au.

Registry

On 29 March 2012, the Hon Tanya Plibersek, MP announced $2.9 million to increase access to clinical trials of new drugs, treatments and medical procedures. The funding will support the administration of the National Health and Medical Research Council Clinical Trials Centre and the expansion of the centre's Australian New Zealand Clinical Trial Registry.

The expanded registry is designed to assist people in remote and regional locations to have access to the latest information making it easier for them to enrol as well as to reduce duplication of trials by encouraging research collaboration.

HoMER

The Harmonisation of Multi-centre Ethical Review (**HoMER**) initiative aims to provide a single scientific and ethical review of a multicentre clinical trial taking place in the publicly funded health sector, across jurisdictions.

At present, the States and Territories are at different stages of implementing their processes to accept the single ethical review of clinical trials. Some sites are currently going through the accreditation process.

Commentary

Pharmaceutical companies should familiarise themselves with the reforms to clinical trials in the public sector as they are likely to assist them to streamline their involvement in Australian clinical trials and save administration costs.

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Sarah has over 12 years practical experience in medicolegal and other insurance litigation, with a focus on the health sector. She has acted on behalf of public health entities, private medical indemnity insurers, private hospital operators and their insurers, uninsured health professionals, as well as health professional disciplinary bodies. She is familiar with the civil claims process in Queensland, as well as disciplinary proceedings under the National Health Practioner Regulation Law. Sarah has a particular interest in coronial inquests and applications involving issues of consent, capacity and end of life decision making.

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