‘Wrongful life’ claims rejected by NSW Court of Appeal

Senior Associate Luisa Uriarte looks at the first decision on ‘wrongful life’ claims by an appellate court in Australia, where it has been decided that there is no cause of action against medical practitioners for ‘wrongful life’ in New South Wales.

What is a ‘wrongful life’ claim?

A ‘wrongful life’ claim is brought by those who allege that, but for the negligence of the medical practitioner, they would not have been born. It is a claim brought by the child, not the parents. These claims differ from:

• ‘wrongful conception or pregnancy’ claims, which involve claims brought by parents of a healthy but unplanned child; and
• ‘wrongful birth’ claims, which involve claims by parents of a child born with congenital disabilities.

‘Wrongful life’ claims have been rejected by appellate courts in England, Canada and at least 23 states in the United States.

Harriton and Waller cases

The decision addresses appeals by two different people. Although the facts in each case differ, the appeals were heard together, as they involved similar questions of law. Each case concerned a plaintiff who had been born with severe disabilities:

• The first plaintiff, Alexia Harriton, was born in 1980 with severe congenital disabilities caused by the rubella virus that her mother had been infected with during the first trimester of her pregnancy. Alexia’s injuries included blindness, deafness, mental retardation, spasticity, an inability to care for herself and the need for 24-hour care.

The second plaintiff, Keedon Waller, was born in 2000 after a process of in vitro fertilisation. Keedon was born with a genetic deficiency (which is a permanent disability in itself). Shortly after birth, Keedon experienced cerebral thrombosis (arising from the deficiency), which resulted in permanent brain damage, cerebral palsy and uncontrolled seizures.

The disabilities in each case were caused by circumstances that occurred prior to birth and could not have been prevented by any medical practitioner. However, in each case, the particular circumstances giving rise to the risk of the plaintiff being born with a disability was capable of being discovered prior to birth. In each case, the medical practitioners involved failed to detect and advise the parents of the plaintiffs of the existence of those circumstances.

It was alleged that, if the medical practitioners had properly advised the parents, the parents would have taken steps to ensure that the plaintiffs would not have been born or, in the case of Keedon, not have been conceived.

The issues for determination by the Court of Appeal

In this case the Court of Appeal was asked to determine the following two questions:

1. Do the plaintiffs have a cause of action against the medical practitioners?
2. If so, what type of damages are available (eg general damages for pain, suffering and loss, economic loss and/or damages for gratuitous care)?

The court was aware that if the plaintiffs were successful, this would create a new type of negligence claim against medical practitioners.

For the purposes of both cases, it was accepted that the medical practitioners had failed to exercise reasonable care in the management of the plaintiffs’ parents and, except for that failure, the plaintiffs would not have been born.

**Question 1**

By a majority of 2-1, the Court of Appeal decided that the plaintiffs did not have a cause of action against the medical practitioners.

While the court unanimously accepted that a medical adviser to prospective parents does owe a duty of care to the prospective child, there was a difference of opinion on whether this duty to the child extends to encompass conduct that, if it had been properly performed without negligence, would have led to the termination of the pregnancy or would not have contemplated conception in the first place.

In reaching its decision, the majority said that not all harm caused by negligence is recoverable in law, and not all negligence gives rise to recoverable harm. For damage (or ‘harm’) to be actionable it must be capable of being calculated. In the present case, the majority considered that no such damage had been established. In particular, one judge, Justice Ipp, considered that it was impossible to assess the difference between life with a disability and non-existence. However, there was a strong dissenting judgment that leaves open the possibility that the plaintiffs will seek leave to appeal to the High Court.

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**Question 2**

Since it was decided that the plaintiffs do not have a cause of action against the medical practitioners, the second question did not need to be answered.

**Additional considerations**

The majority of the judges also stated that policy considerations dictated against a finding of a new cause of action of ‘wrongful life’ including because:

- the principle of ‘sanctity of life’ operates against recognition of the duty for which the plaintiffs contend;
- the law already provides a remedy for damage brought about by medical negligence resulting in the birth of disabled children (ie the action available for parents to claim financial expenses of raising and maintaining the children - see discussion below).

The majority of the judges were also concerned that the discoveries and potential discoveries in the field of genetics should make courts extremely cautious in extending the law of negligence to wrongful life claims.
Implications for medical practitioners

This case is different to cases involving ‘wrongful conception’/‘wrongful birth’ claims. The court made a distinction between the law recognising the parents’ ‘wrongful birth/conception’ claim but not recognising the child’s ‘wrongful life’ claim because the loss or damage under consideration was different.

While this decision will be welcomed by medical practitioners in relation to ‘wrongful life’ claims, the strong dissenting judgment leaves open the possibility that the plaintiffs will seek leave to appeal to the High Court. Further, while influential, this case is not binding authority on courts outside of NSW. Until there is a decision by the High Court or legislation that clearly addresses the issue, uncertainty will remain in all Australian jurisdictions, except NSW.

Gene patenting and human health

Having engaged in widespread public consultation on the impact of patents law and practice, the Australian Law Reform Commission has now released Discussion Paper 68: Gene Patenting and Human Health, outlining 49 proposals for reform and 19 questions for consideration and comment. The final report is now under preparation and recommendations are due to be delivered to the Federal Attorney-General by 30 June 2004. Senior Associate, Caroline Ryan looks at the progress of the inquiry and its recommendations.

Gene patenting in Australia

As reported last year in Focus: Health February 2003, the Australian Law Reform Commission (ALRC) is conducting a major inquiry into the impact of current patent laws as applied to genetic material, research and technology, on the cost effective provision of healthcare in Australia.

Gene patents are identified in Discussion Paper 68 as being relevant to the provision of healthcare through medical genetic testing (including diagnostic, screening and prenatal testing) and in the application of novel therapies (such as gene therapy, the production of therapeutic proteins and the use of stem cells).

Australia’s Patents Act 1990 (Cth) (the Patents Act) expressly excludes certain subject matter from patentability, including human beings, and the biological processes for their generation. In practice, Australia’s patent system (as with most other jurisdictions) makes a distinction between the patentability of isolated genetic material, and genetic material in its natural state. A gene (or gene fragment) in its natural state is not patentable. A gene (or gene fragment) that has been extracted from an organism, isolated and purified may be patentable, provided it complies with the normal requirements for patentability under the Patents Act.

The ALRC inquiry has identified a range of concerns and assumptions regarding the future impact current practices of patenting genetic materials and technologies may have on the future development of associated healthcare services. This includes the concern that the existence of gene patents could either increase costs if healthcare providers are required to pay licensing fees for providing services, or possibly make services less accessible where patent holders license only a single service provider.

Despite the concerns surrounding the patenting of genetic material from some parts of the community, Discussion Paper 68 states that there is limited evidence to date that patents (and the cost of associated licences) have had any significant adverse impact on the provision of healthcare in Australia. However, as it was acknowledged that gene patents may have the potential to increase expenditure on medical genetic testing and novel therapies in the future, more detailed and ongoing consideration of these issues is proposed.

Significant issues

Part E of Discussion Paper 68 outlines the potential impact of gene patents on the provision of healthcare by presenting an analysis of the Australian healthcare system, its funding and how various technologies are accessed by healthcare providers and their patients.

3 To view article go to: www.aar.com.au/pubs/bio/fofeb03
Key proposals and questions for consideration include:

- whether the *Patents Act* should be amended to specifically exclude genetic materials or technologies, methods of diagnostic, therapeutic or surgical treatment from patentable subject matter;
- establishing processes for an economic evaluation of the financial impact of gene patents on the delivery of healthcare services and the possible use of government funding to control the cost of services that are the subject of gene patents (to be done through the Australian Health Minister’s Advisory Council);
- establishing the Human Genetics Commission of Australia as an independent statutory authority to monitor and advise health departments and other relevant stakeholders about the application of intellectual property laws to genetic materials and technologies;
- establishing special offices at both Commonwealth and State health department levels to monitor and manage intellectual property issues, including intervening where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on research or the provision of healthcare;
- reviewing the Australian Research Council and the National Health and Medical Research Council’s current principles and guidelines to ensure that results from publicly funded research being placed in the public domain, or that any patented inventions are widely licensed;
- increasing the role of the Australian Consumer & Competition Commission (ACCC) in monitoring uncompetitive conduct, including conducting informal price monitoring of medical genetic tests and other genetic inventions involved in the provision of healthcare services;
- amending the *Patents Act* to clarify the provisions relating to Crown use or Crown acquisition to ensure that an invention is exploited for the services of the Commonwealth or the State if exploitation is for the provision of healthcare services or products to the members of the public; and
- amending the *Patents Act* to include a new defence to patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment, similar to the medical treatment defence in the United States.

**Next step**

The ALRC is currently considering comments and submissions from national and international experts in the fields of gene patenting and human health, with the final report and recommendations due to be delivered to the Attorney-General by 30 June 2004.

AAR will continue to keep you up-to-date of the inquiry’s progress, and the associated legal developments in this area.

**Proposed changes to Disability Discrimination Act:** how will it affect the health industry?

Proposed amendments to the *Disability Discrimination Act 1992* may dramatically alter the employment practices of health organisations and the way such organisations interact on a day-to-day basis with people with a drug addiction. Lawyer Alison Yong examines the implications of the proposed amendments for the health industry, as well as potential problems with the current drafting of the Disability Discrimination Amendment Bill 2003.

**Background to the Disability Discrimination Act 1992**

The *Disability Discrimination Act 1992* (Cth) (*DDA*) protects people with disabilities from receiving less favourable treatment in the provision of
accommodation, employment and goods and services, in circumstances where that treatment is unjustified or unreasonable. That is, if a decision is made against a person with a disability on the basis of prejudices, stereotypes or stigmas attached to the disability, then the DDA will provide a basis for redress. The DDA does not confer any extra rights or benefits on people with disabilities; it simply ensures that they are treated the same as everyone else.

**Proposed amendments to the DDA in respect of drug addiction**

The Disability Discrimination Amendment Bill 2003 (the *Bill*) seeks to amend the DDA so that a person who is addicted to a prohibited drug will not be covered by the DDA (and therefore can be subject to lawful discrimination in relation to housing, employment or accessing goods and services) unless they are seeking ‘treatment’ for their addiction. The Federal Government, by way of this Bill, aims to pressure people with a drug addiction to seek treatment.

**The Bill’s effect on the health sector**

If the Bill is enacted, its effect on employers, including the health sector, will be far-reaching.

For example, the amendments under the Bill will make it lawful for employers to discriminate against a person with a drug addiction on the sole basis of that addiction, regardless of whether or not the addiction adversely affects the person’s ability to perform their job. Currently, the DDA provides substantial protection in the employment context: an employer can refuse to employ someone who is addicted to a prohibited drug, or dismiss an employee upon learning that the employee is addicted to a prohibited drug, only if that person is unable to perform the ‘inherent requirements’ of a particular job. The Bill, if enacted, will remove the current protections available to employees under the DDA.

However, it is important to bear in mind that, in addition to the Federal DDA, each state also has specific legislation dealing with disability discrimination, and that employers may not have the same rights under state legislation as they do under the proposed amendments to the DDA.

The amendments under the Bill will also make it lawful for medical staff (both in the private and public sectors), pharmacists and other health professionals to refuse people with a drug addiction access to health care and services. In the past, only a very small number of people have made complaints under the DDA alleging discrimination in relation to accessing health services on the basis of their addictive disorders.

**Criticisms of the Bill’s drafting**

Medical associations, such as the Royal Australian and New Zealand College of Psychiatrists, the Royal Australasian College of Physicians and the Royal Australian College of General Practitioners, have strongly criticised the Bill’s poor drafting, which, they argue, would make it difficult to apply in practice.

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For example, in the health industry context, the lack of definitions for ‘addiction’ and ‘treatment’ would lead to significant uncertainty for employers and health care professionals when making daily operational decisions regarding people with a drug addiction. For example, it may be difficult to accurately distinguish ‘addiction’ from episodic drug use or to know whether a person is addicted ‘at the time of discrimination’. Also, the establishment of the bona fides of any ‘treatment’ program for that addiction may be difficult, given the broad definition of treatment under the Bill (ie even regular visits to a counsellor, priest or doctor are covered). Similarly, it may be difficult to know whether a person is undergoing treatment at the relevant time of discrimination.

Another concern is that the Bill has been drafted without consultation from medical, scientific or health experts and, hence, the Bill, according to some medical associations, does not recognise that the demand for drug treatment in Australia outstrips supply because of a lack of government funding.

These concerns about the Bill, as well as many others, have led a Senate committee inquiry to recommend that the Bill be referred to the Ministerial Council on Drugs Strategy for further consideration before the Bill is reintroduced into Parliament.
Conclusion
With the Federal Government’s ‘Tough on Drugs’ policy (which the Bill is a part of) still high on the agenda, it is possible that the Government will seek to reintroduce an amended form of the Bill for debate in the Senate before the next Federal election.

Australia-US Free Trade Agreement – impact on health

This year, agreement was reached on the text of a free trade agreement between Australia and the United States (AUSFTA). AUSFTA will not come into effect until the ‘agreed text’ passes through the legislative processes required by the Australian and US domestic legislatures. The final step in these processes is the passing of the domestic legislation necessary to bring the terms of the agreement into effect. It is intended that AUSFTA will take effect from 1 January 2005. Lawyer Cynthia Cochrane looks the issues involved.

This article focuses on two important changes proposed by the AUSFTA: the issue of generic drugs and the impact of the ‘early warning system’; and PBS listing – increased transparency and a mechanism for review.

Generic drugs: impact of the ‘early warning system’

In Australia all therapeutic goods (including prescription and non-prescription drugs) must be registered or listed on the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported, manufactured or supplied. The Therapeutic Goods Administration (TGA) is the body responsible for the evaluation and approval of therapeutic goods in Australia. A company wishing to market a new drug in Australia must apply to the TGA for approval.

Patents cover many of the drugs available in Australia. If a company, without the authorisation of the patentee, imports, exports, manufactures or supplies a patented drug (generic drug), the patentee has the right to sue the company for patent infringement. If successful, the patentee may obtain an injunction restraining the company from importing, exporting, manufacturing or supplying the generic drug in Australia. In some circumstances, courts have the discretion to grant such an injunction before the patent infringement case is decided (an interlocutory injunction). For a generic drug already on the market, this could involve its recall. To date courts have been reluctant to grant interlocutory injunctions in relation to generic drugs that are already on the Australian market.

There is no current legislative requirement for the TGA to inform the patentee that it has received an application for marketing approval of a generic version of an already-listed patented drug. Therefore, the first time patentees are likely to find out about a generic version of the patented drug is when it is first listed on the ARTG. This makes it difficult for the patentee to apply to the court for an interlocutory injunction before the generic product appears on the market.

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Under the AUSFTA-proposed system, a patentee will be notified when a generic manufacturer seeks approval to market its product before the patent’s expiration. It is likely the TGA will be required to keep a register for manufacturers to record any patents relating to their drugs (similar to the ‘Orange Book’ in the United States). This ‘early warning system’ will increase the patentee’s ability to enforce its patent before the generic product reaches the market. In particular, it will enable the patentee to apply to the court for an interlocutory injunction before the generic drug reaches the market. Since such an injunction will not involve the inconvenience of recalling a generic drug already on the market, the injunction should be easier to obtain than under the current system. Accordingly, if these proposed changes take effect, it will be more difficult for generic drugs that infringe a valid patent to reach the Australian market before patent expiration.
**PBS listing: increased transparency and mechanism for review**

The AUSFTA proposes the following changes to the approval process for admitting new drugs to the Pharmaceutical Benefits Scheme (PBS):

- the rules and procedures of the Pharmaceutical Benefits Advisory Committee (PBAC) will be published;
- the PBAC will publish reasons for accepting or rejecting an application;
- a mechanism will be established for review of the PBAC’s decisions;
- decisions of the Pharmaceutical Benefits Pricing Authority regarding the price of drugs listed on the PBS will be appealable to the PBAC.

**ACCC keeps a watchful eye on health funds**

The ACCC continues to keep a watchful eye on the actions of health funds to ensure that the rights of consumers using the funds are protected. Last year, the ACCC released its fifth Report to the Australian Senate on anti-competitive and other practices by health funds and providers in relation to private health insurance. Lawyer Alice Hume looks at the report and its ramifications.

The report outlined ACCC enforcement action and a number of the ACCC’s concerns about the private health sector, including:

- lack of accuracy and completeness of information provided by funds to consumers about health insurance products;
- lack of signatories in the private hospital/day hospital facility sector to the industry code of practice that addresses contract negotiation processes with health funds;
- doctors failing to make consumers aware of expected out-of-pocket costs for medical services; and
- the need for agents who are intermediaries between consumers and health funds to more accurately convey information to consumers about health insurance policies.

The ACCC has been disappointed with the accuracy and completeness of health insurance information provided to consumers by some health funds believing that many health funds do not pay sufficient attention to their obligations under the Trade Practices Act 1974 when making representations about health insurance products to their members or future members. In fact, the past two years has seen a number of cases instituted by the ACCC against health insurance companies in which allegations of misleading or deceptive conduct were made.

**Misleading or deceptive conduct by health insurance funds**

Consumers have a right to complete, honest and accurate information on which to base their decisions when purchasing health insurance or transferring between health funds. The ACCC has made it clear that health funds need to ensure they do not mislead or deceive consumers about premium levels payable for their health insurance products, the criteria for eligibility, waiting periods, or the benefits that consumers are entitled to when making a claim with the fund. This includes representations made to consumers by health fund staff or information contained in fund brochures, letters to members, TV or print advertisements and the fine print contained in membership application forms and advertisements.

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Importantly, although other legislation may affect prices payable by consumers for their health insurance, there is nothing in the Trade Practices Act that regulates the premiums charged by health funds.

How is the Trade Practices Act enforced against health funds?
Legal proceedings: general

Individuals, health practitioners, professional associations or other organisations can take providers of health services to court for breaching the consumer protection, fair trading or restrictive trade provisions of the Trade Practices Act. In fact, a large amount of litigation under the consumer protection provisions of the Trade Practices Act is private litigation and does not involve public agencies such as the ACCC. These cases can range from individuals taking legal action to recover loss or claim damages, to class actions on behalf of a group of consumers affected by similar unlawful conduct.

Legal proceedings: ACCC

The ACCC can also institute proceedings for a breach of the Trade Practices Act. If a court decides that the law has been breached, it may make orders including:

- fines or penalties
- damages
- injunctions
- refunds and/or
- corrective advertising

Enforceable undertakings

Rather then instituting legal proceedings, the ACCC, and the party engaging in the conduct, may choose to settle a matter administratively. This can be done by accepting enforceable undertakings from an organisation or person who the ACCC alleges has breached the Trade Practices Act. Once entered into, the party engaging in the conduct must adhere to an enforceable undertaking. If the undertakings are not honoured, the ACCC will ask the court for an order instructing the organisation or individual to comply with the undertaking. Ignoring such a court order would be contempt of court, and this, in turn, may lead to fines or imprisonment.

Enforceable undertakings may include requirements that involve:

- compensating consumers;
- running corrective advertisements; and
- introducing a trade practices compliance program.

Conclusion

Health cover is a significant decision for consumers in terms of cost, level of cover and risk assessment. It is also an area where consumers have a number of pressing issues to consider with the introduction of lifetime ratings, the availability of government rebates and taxation considerations. As a result, the ACCC continues to give health cover issues a high priority and will continue to watch health insurance advertising closely to ensure that consumers are not at risk of being misinformed.