



## Vaccine injury compensation

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Is it time for a vaccine injury compensation scheme in Australia?

The answer in part requires an assessment of how well the current ‘modified common law’ system serves to compensate those who suffer vaccine injuries. By considering the basic approach of the current common law<sup>1</sup> and looking at cases previously decided, it should become possible to reach an informed conclusion on the relative merits of the two approaches — common law and a ‘no fault’ scheme.

Making such a comparison in the absence of detail about a proposed vaccine injury compensation scheme makes it impossible to reach a definitive conclusion. Perhaps the most that can be concluded is that a properly constructed no fault vaccine injury scheme could assist some persons who fall within its ambit.

### Vaccine injuries

Vaccine injuries can occur in three relevant ways:

- defect through contamination, adulteration, improper configuration, other errors in the manufacturing process, inadequate testing or incorrect labeling;
- even if the vaccine itself is not defective, it may be administered improperly, an incorrect dosage may be used or it may be contraindicated because of allergy, illness, immune suppression or age; or
- non-defective vaccines properly administered can nevertheless produce idiosyncratic allergic reactions in individual cases.<sup>2</sup>

In Australia at least, recent data suggests only a very small number of adverse events following immunisation (AEFI). Professor David Isaacs, speaking at a recent Australian Health Policy Institute seminar,<sup>3</sup> summarised the 2000–04 findings of the Adverse Drug Reactions Unit<sup>4</sup> (ADRU) as showing definite or probable vaccination causes for four patients recovering with sequelae and one patient death. Five AEFI following immunisation over four years represents a small proportion even of the total reports to ADRU, some 5128, and a much smaller proportion of total immunisations.

### International comparisons

A significant number of developed countries have introduced vaccine injury compensation schemes,<sup>5</sup> the first being West Germany<sup>6</sup> in 1961, followed by Switzerland, France and Denmark. The US created a scheme in 1986 and England<sup>7</sup> in 1987. Japan, Taiwan, Singapore, NZ<sup>8</sup> and South Korea operate schemes in the Asia-Pacific region.<sup>9</sup>

However, simply to note the existence of a no fault scheme for vaccine injury compensation is not to say that all such schemes are equivalent. Some apply to compulsory vaccines only, and the compensation structures differ widely. England, for example, provides a single lump sum payment,<sup>10</sup> while Japan makes provision for medical allowances, care provision and a disability pension.



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**Legal options**

In Australia, even strong evidence that a vaccination has led to an adverse reaction will not necessarily lead to a viable legal claim for compensation. There are three hurdles to overcome.

For a legal claim to succeed, first negligence, breach of contract or some form of statutory liability must be proven on the balance of probabilities on the part of the vaccine manufacturer, distributor, medical practitioner administering the vaccine or some other relevant person or entity.

Second and most importantly, there must be evidence of a link between the negligence and the damage alleged — causation.

Third, there must of course be some measurable damage, otherwise there will be no entitlement to financial compensation.

Quite recently,<sup>11</sup> the High Court reminded us of the ambit of common law compensation:

A plaintiff who has suffered negligently caused personal injury is traditionally seen as able to recover three types of loss.

The first covers non-pecuniary losses such as pain and suffering, disfigurement, loss of limbs or organs, loss of the senses — sight, taste, hearing, smell and touch; and loss of the capacity to engage in hobbies, sport, work, marriage and child-bearing. Damages can be recovered in relation to these losses even if no actual financial loss is caused and even if the damage caused by them cannot be measured in money.

The second type of loss is loss of earning capacity both before the trial and after it. Although the damages recoverable in relation to reduced future income are damages for loss of earning capacity, not damages for loss of earnings simpliciter, those damages are awardable only to the extent that the loss has been or may be productive of financial loss. Hence 'the valuation of the loss of earning capacity involves the consideration of what moneys could have been produced by the exercise of the [plaintiff's] former earning capacity'.

The third type of recoverable loss is actual financial loss, for example, ambulance charges; charges for medical, hospital and professional nursing services; travel and accommodation

expenses incurred in obtaining those services; the costs of rehabilitation needs, special clothing and special equipment; the costs of modifying houses; the costs of funds management; and the costs of professionally supplied home maintenance services. It is not necessary for the costs actually to have been incurred by the time of the trial, but it is necessary that they will be incurred.

[Endnotes omitted.]<sup>12</sup>

The practical value of any legal rights arising must be assessed in the context of recent tort law changes in most States and Territories and under federal law, which generally speaking reduce the value of all claims and sometimes extinguish smaller claims entirely.<sup>13</sup>

**Negligence and breach of contract**

Of the three categories of potential AEFI noted above, the third — being non-defective vaccines properly administered producing idiosyncratic allergic reaction in an individual case — will not give rise to a viable compensation claim. However, the first two categories may give rise to a viable claim. First, there may be contamination, adulteration, improper configuration, other errors in the manufacturing process, inadequate testing or incorrect labeling. Second, a vaccine may be administered improperly, an incorrect dosage may be used or it may be administered despite contraindication because of allergy, illness, immune suppression or age.

The customary first port of call for a lawyer seeking to assess whether an AEFI could give rise to a compensable claim is 'negligence'. The multiple elements of the test for professional negligence are now contained in s 50 of the NSW *Civil Liability Act*.<sup>14</sup> For most purposes, claims for breach of contract are not distinguishably different.<sup>15</sup> The section provides:

50 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 that 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.

Among those elements, the key word is, arguably, ‘competent’. For practical purposes,<sup>16</sup> there may be little difference between the s 50 definition and the common law test for professional negligence previously applied by the courts and those that apply in most other Australian jurisdictions.<sup>17</sup>

A claim framed as a claim in negligence for a vaccination injury is perhaps most likely to be aimed at a medical practitioner for administering the vaccination — presumably in circumstances such that the vaccination administration was not in the circumstances one widely accepted in Australia as competent practice.

### Failure to warn

The NSW *Civil Liability Act* expressly excludes application of the s 50 test to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information in respect of the risk of death or injury to a person associated with the provision by a professional of a professional service.<sup>18</sup>

However, the *Civil Liability Act* deals with two matters that may be of particular significance in claims arising AEFI. First, s 5D(3) confirms the application of a subjective test, which may be helpful to a particular plaintiff with views or concerns differing from the majority of persons who might unquestioningly accept vaccination. Second, and perhaps less helpfully, s 5D(3) makes certain evidence of a

plaintiff inadmissible, by s 5D(3):<sup>19</sup>

- (3) If it is relevant to the determination of factual causation to determine what the person who suffered harm would have done if the negligent person had not been negligent:
  - (a) the matter is to be determined subjectively in the light of all relevant circumstances, subject to paragraph (b), and
  - (b) any statement made by the person after suffering the harm about what he or she would have done is inadmissible except to the extent (if any) that the statement is against his or her interest.

The correct approach is, with respect, that of Kirby J in the High Court decision of *Hoyts Pty Ltd v Burns* [2003] HCA 61; BC200305858, a case involving a claim for compensation by a woman who suffered injury in a cinema. Her seat had been constructed in such a way that the seat base lifted up when a person was not sitting upon it. It had lifted up when she left the seat temporarily and, while she was attempting to sit down again, the seat base fell to the ground and the woman injured herself on the underlying seat structure. The plaintiff alleged that she would not have suffered injury had a warning been given.

Justice Kirby delivered a separate judgment, which expressly considered the evidence given by Ms Burns as to what she would have done if a warning sign had been displayed. His Honour said (at [54]):

... trial counsel for the Appellant protested that the ‘evidence’ about what would have been done if a sign had been displayed was a matter of ‘speculation’. So indeed it was. Whether or not, strictly, such evidence is admissible, it is commonly received in Australian courts. Presumably, this practice emerged once it was established that the relevant test of causation applicable in Australia was a subjective one.<sup>20</sup> Nevertheless, the evidence of what a Claimant would have done if a non-existent warning had been given by a hypothetical sign is so hypothetical, self-serving and speculative as to deserve little (if any) weight, at least in most circumstances.

Helpfully, Justice Kirby goes on to foreshadow how the Court might

proceed in circumstances where such evidence is excluded (at [55]):

The evaluation of what the Respondent would have done, if a sign of the kind devised by the Court of Appeal had been displayed is truly a matter of hypothesis based upon an evaluation of circumstances that did not in fact occur rather than an assessment of whether the Respondent was telling the truth about her postulated belief in what she said in the additional evidence that the Judge allowed.

Accordingly, that would appear to be the approach required of a court under the NSW *Civil Liability Act* s 5D(3)(b) — the establishment of a hypothesis based upon the evaluation of circumstances, rather than an assessment of whether the injured person was telling the truth about his or her belief. That, in essence, seems to be the approach taken also by Hoeben J in his recent judgment in *Richards v Rabilly* [2005] NSWSC 352; BC200504607, when he said (at [256]–[257]):

Reliance was also placed upon the evidence of Mr Richards when he was recalled after the conclusion of the evidence (T.1226–1228). The evidence of Mr Richards was that had treatment options been explained to him, he would have chosen Vigabatrin. The evidence of Mr Richards to which I have referred, is of little value. He understood how important that answer was to Rhiannon’s case. Although his evidence on this question may well have been truthful, it suffers from the problem identified by McHugh J in *Chappel v Hart* (1998) 195 CLR 232 at 246 (note 64) and restated in *Rosenberg v Percival* [[2001] HCA 18; BC200101435] (p 443, para 25). The reliability of such evidence needs to be assessed by reference to other evidence.

### Product liability

Most commentators agree<sup>21</sup> that professionals in the practice of their profession — whether as corporations, hence under the *Trade Practices Act 1974* (Cth), or as individuals, hence under the *Fair Trading Act 1987* (NSW)<sup>22</sup> — may be liable for breaches of statutory obligations for misleading or deceptive conduct. Certainly, large corporations such as pharmaceutical



companies readily fall under those statutes.

Product liability is a broad topic in itself, and relatively untried in the area of medical litigation,<sup>23</sup> but for the purposes of this article it is sufficient to note some aspects briefly. An individual's idiosyncratic reaction to an otherwise 'safe' vaccine will not of itself make a doctor or manufacturer liable, as can be seen from litigation concerning a mitral valve implant, *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853; BC200404164, per Kieffel J. In that matter, the applicant had suffered from a heart condition since childhood. He underwent surgery for repair of his mitral valve. However, during surgery the repair of the valve was unsuccessful and so a mechanical mitral valve was implanted. The patient suffered infarcts to the spleen and kidney and a stroke. The mechanical valve was later removed and a porcine tissue valve implanted. The initial valve was returned to the manufacturer and found to be chipped.

Without attempting to summarise that complex decision in any real detail, the Court held that the failure to warn did not render the product defective under s 75AD of the *Trade Practices Act* and the applicant could not establish that the chip caused the thrombo-embolic events suffered. Evidence established that risks were advised to the applicant. The Court held that it was not reasonable for the applicant to expect no prospect that the valve would cause development of thrombi, hence his claim under s 74B of the *Trade Practices Act* was not established.

### Case law

There are comparatively few Australian reported decisions of vaccine injury compensation. The selected cases summarised below serve to reflect the approach of the courts to such claims.

#### *Denis Stepanovic v ACT*

*Denis Stepanovic v ACT* [1995] ACTSC 115 (13 November 1995) was a relatively small claim arising from the development of keloid scarring after immunisation against diphtheria and

tetanus. Miles CJ noted (at [2]) that there were two substantial issues for determination: Did the injection contribute to the formation of the keloid scar? If so, was the immunisation procedure carried out without reasonable care and skill?

Both questions turned on where it was exactly on the plaintiff's arm that the needle was inserted. The particulars of negligence alleged that the injection was given 'into the shoulder and not into the muscle'.

The Health Centre recommended to its nursing staff certain immunisation procedures in a document (at [6]). The Health Authority's own recommendations as to the administration of vaccines required the nurse to 'choose the appropriate site' and that 'for intramuscular injection the needle is inserted at 90 degree angle'. There was also some text appearing at the foot of an illustrated page, quoting an American publication. It stated that the 'injection site in deltoid muscle is approximately 1 1/2 to 2 inches below the acromion process'. The recommendations of the National Health and Medical Research Council provided that for children between two months and eight years, the immunisation should be carried out by 'deep subcutaneous or intramuscular injection'. There was no dispute at the trial that reasonable care on the part of a nurse administering the CDT vaccine required compliance with both sets of recommendations (at [7]).

Denis's father gave evidence that he was present at the time of the immunisation and saw a nurse give the injection 'pretty high on the left shoulder'. He indicated the location of the injection as at the point of the shoulder. He noticed something wrong straightaway, or after a few days, and a lump like a blister formed 'exactly where the injection was'. In answers to interrogatories, Mr Stepanovic said that the scar was first noticed when Denis complained of itching around the area of the scar about three to six months after immunisation. In his evidence, he said that he thought that it was much earlier.

Dr Quach recorded that the plaintiff first presented with a keloid lump at the injection site in January 1983 and



that he referred the plaintiff to Dr James on 18 June 1984, with a view to having the keloid scar injected with cortisone in order to soften it. Dr James recorded that he first saw the plaintiff on 3 September 1984 for what appeared to be ‘an active scar on the point of the left shoulder’. Dr James said that this was at the site of an immunisation injection two years previously (at [18]–[20]).

As to causation, Dr James had no doubt that the scarring was in consequence of the injection in 1982 placed into tissue on the upper and outer aspect of the left shoulder in an area known to be of high risk for hypertrophic scarring in persons so susceptible. Dr James considered that the initial site of the scarring, just below the acromion process, would suggest that the injection was placed higher than the recommended site and that ‘even if this were not the case, injecting into an area so prone to hypertrophic scarring would seem to be an unacceptable practice’ (at [23]).

In an adversarial system, a court is usually presented with conflicting medical evidence as in this case, where the defendant called evidence from Dr Weedon. In material collected for his recent textbook, Dr Weedon was able to find no reference to keloid scarring occurring as a result of CDT immunisation. He made a further search online, including the main worldwide database held at the National Library of Medicine in Washington DC, and was unable to find any reference to such causal connection. Dr Weedon expressed the view based on his own experience that even subcutaneous injection does not give rise to keloid scarring but rather (and only very rarely) to a lump in the nature of aluminium granulomas, which can be removed surgically. In cross-examination Dr Weedon accepted that the plaintiff’s shoulder bore a large and obvious keloid scar.

Miles CJ observed that Dr Weedon conceded that the closer the injection is to the acromion process, the more likely it is that any abnormal state

caused by an injection or the entry of foreign bodies in tissue adjacent to the skin will continue and result ultimately in keloid scar formation, not so much because of the absence of muscle as the mobility of the acromion process tending to prevent healing (at [29]–[30]). Ultimately, the Court held that, on the balance of probabilities, the nurse who injected the plaintiff’s arm did so at a site so close to the acromion process that it put in train this process and that over a period of at least several months, the hypertrophic scarring developed and continued to develop (at [30]). Damages were assessed at a total of \$42,000.<sup>24</sup>

***Bonello v Lotzof***

In a 1997 NSW case, *Bonello v Lotzof* Matter No 11530/93 (23 September 1997, per Grove J), David

alternatively, would have given some warning of risks involved.

Evidence on behalf of the plaintiff was that he was brought to the surgery because he had been sick for about two weeks and he was presented to the defendant with a cough and congestion. Mrs Bonello used the expression ‘a little bit wheezy’ and her husband referred to flu-like symptoms. However, the Court ultimately held that when the plaintiff was brought to the surgery on 7 November 1978, he was not manifesting any symptoms which would contraindicate<sup>25</sup> immunisation, nor were there any matters of history that the defendant ought to have elicited which would have created such a contraindication. That finding appears to have been primarily based on an assessment of the somewhat inconsistent evidence of the parents, and the lack of supportive

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Bonello brought an unsuccessful action against a general practitioner, Dr Lotzof. David Bonello was born on 26 June 1978. Signs of disability were not manifest in the first months of life and the first noticed untoward event was a fit, which was observed on 7 November 1978. Previously on that day, he had been taken by his parents to the general medical practice of the defendant Dr Lotzof, where the second of an intended course of three triple antigen immunisations was administered. Triple antigen (DTP) consists of three vaccines to combat diphtheria, tetanus and pertussis (whooping cough).

The plaintiff sued the defendant, claiming that his brain damage was caused by negligent treatment in proceeding with the immunisation in the circumstances alleged to have been current, where a reasonably skilful general medical practitioner would not have then administered DTP or,

material in the records of Blacktown Hospital later that day.

***Bryden v Health Department***

In *Bryden v Health Department* (1987) Aust Torts Reports 80-075, a 1986 decision of Vincent J of the Victorian Supreme Court, a schoolteacher was vaccinated with ‘BCG’ vaccine as part of a mass inoculation program at schools in Victoria designed to reduce the incidence of tuberculosis. The schoolteacher had suffered for a number of years from rheumatoid arthritis, and had been taking corticosteroid tablets, the combined effect of which was to suppress the efficiency of his immune system.

Several days after being vaccinated, the schoolteacher became severely weakened and developed malignant lymphoma and quadriplegia. He subsequently underwent several operations and chemotherapy, having



developed a rare form of cancer. He alleged that the defendant, chief general manager of the Victoria Health Department, had breached his duty of care by failing to provide him with a warning that there was a risk to persons with impaired immune systems in being vaccinated with BCG vaccine. This was a risk known to the defendant, as each package supplied by the vaccine's producer, the Commonwealth Serum Laboratories, contained a warning that the vaccine should not be given as part of a mass immunisation campaign to persons who were immune-suppressed or who were chronically ill.

The Court held that the defendant had breached his duty of care in allowing the vaccine to be administered to the plaintiff without any warning, and in failing to adopt an adequate screening process for the purpose of excluding immune-suppressed or chronically ill persons from the immunisation program. Further, the Court held that causation, which was disputed, had been proven, notwithstanding the short period of time between the date of the vaccination and the development of the malignant lymphoma. This was because the Court accepted that it would have been unlikely to have been coincidental for a lump to appear in

pertussis vaccination at age 20 months. However, legal aid was withdrawn when contradictions became apparent between the parents' testimony and hospital records.

*Loveday v Renton* [1990] Med LR 117 has been described as the final test case concerning pertussis vaccine; this case again concerned causation. There were in fact some nine cases; however, Stuart Smith J in March 1988 found the cases unconvincing, as none had symptoms in the first 48 hours and there appeared to be convincing alternate diagnoses such as viral encephalitis (at p 125):

In reaching my decision a number of processes have to be undertaken. The mere expression of opinion or belief by a witness, however eminent, that a vaccine can or cannot cause brain damage does not suffice. The court has to evaluate the witness and the soundness of his opinion. Most importantly this involves an examination of the reasons given for his opinions and the extent to which they are supported by the evidence ...

*Thompson v Bradford* [2004] EWHC 2424 was an October 2004 decision of Wilkie J. Similar to the above decision of *Bonello v Lotzof*, it focused on whether a 1997 immunisation (polio) ought to have been given when the health of the child, Hamish, was said to

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the lymph gland in the relevant drainage area to the injection site only several days after the injection.

### **International experience**

There are a number of US cases, but many relate to vaccine injury compensation scheme entitlements.<sup>26</sup> In England, there is an extensive, albeit older, history of claims concerning pertussis vaccination.<sup>27</sup> A key claim in 1985–86 was brought on behalf of Johnnie Kinnear, a 15 year old with cognitive deficits said to arise from

be uncertain. It appears that the parents elected to pursue a common law claim in order to obtain more generous compensation than available under the UK *Vaccine Damage Compensation Act 1987*.<sup>28</sup>

The mother, a nurse, gave evidence that she voiced her concern to the doctor as to whether the vaccination at age eight weeks ought be delayed because of the child's recent red spots on his buttocks. Contemporaneous records confirmed that the mother had before the vaccination spoken with a



health visitor and consulted an after hours medical service.

The general practitioner, Dr Bradford, diagnosed the perianal abscess and prescribed antibiotics, but reassured the mother that the vaccination need not be delayed. The child's perianal abscess became worse and four days later he was taken to a hospital, where a doctor lanced the abscess under general anaesthetic. A few weeks later, the child developed paralysis and was diagnosed as suffering polio.

Wilkie J ultimately held that the general practitioner's conclusion that there was no underlying systemic illness was a reasonable one.

However, he found that the doctor breached his duty to properly inform the parents, and also concluded that, if properly informed, the parents would have postponed the immunisation. The doctor had been dismissive of the parents' concerns; had used inappropriate wording in giving his advice; and had failed to mention issues which were relevant to their choice as to whether to go ahead with the vaccination. Specifically, the doctor had failed to mention the fact that surgery might be necessary in the near future, which might increase the risk of infection by the vaccine.

Of course, it was still necessary for the plaintiff to prove causation — that having the vaccination when he did, instead of on some postponed date, caused the polio. The medical evidence was complex and contradictory, but ultimately the Court found in the plaintiff's favour on the basis that the lancing of the abscess and consequent muscle damage allowed the virus to access his central nervous system.<sup>29</sup>

However, the decision was overturned on appeal in *Thompson v Bradford* [2005] EWCA Civ 1439. The Court of Appeal<sup>30</sup> considered as the important question whether there was a relevant breach of duty. That depended on what Dr Bradford could reasonably have foreseen as the consequences of his failure to explain. Neither he nor any competent GP could have foreseen that, if Dr

Bradford failed to explain the unusual nature of the perianal ulcer and the risk of surgery, and if that failure led to there not being a postponement, the result would be a contraction of vaccine associated paralytic poliomyelitis (VAPP) or even an increased risk in the contraction of

addition, provided sufficient individuals are immunised, it also provides a benefit to society as a whole by further reducing the risk of infection. One example provided by Professor Isaacs is for poliomyelitis:<sup>31</sup>

... the current risk of wild-type poliomyelitis in Australia is almost nil,

## At school entry, documentation of full vaccination is required in most Australian jurisdictions, with children who do not have such documentation or serological proof of immunity to specific diseases, such as measles, able to be excluded from school attendance if suspected cases occur.

VAPP. The maximum any competent GP could have foreseen was that if Hamish had an adverse reaction to the vaccination, he would have a greater degree of discomfort as a result of possible surgery (at [30]).

By reason of that conclusion, the question of whether the parents would have delayed the vaccination did not arise. However, the Court in passing expressed serious doubt as to whether the trial judge's conclusion was realistic. The parents were anxious, but they were seeking the advice of a medical professional as to whether they should go ahead with immunisation. They got the firm advice of Dr Bradford that they should go ahead. Unless what Dr Bradford was meant to indicate in providing information was that there could be a serious risk to Hamish's health, the Court found it difficult to conclude that the parents would not have accepted the advice (at [33]).

### Concluding remarks

There is arguably a sound policy argument for the establishment of a vaccine injury compensation scheme in Australia. Most other forms of medical treatment provide benefit to an individual, the resultant health or otherwise of whom is of no direct benefit to society as a whole other than perhaps in some indirect economic sense. However, while vaccination provides a benefit to an individual, in

because the very high rate of immunization means that wild-type poliomyelitis does not circulate. For any single child in Australia at present therefore, the risk of catching polio may actually be lower than the risk of developing vaccine associated paralytic poliomyelitis (VAPP). Of course, if all parents declined to give their children oral polio vaccine (OPV), then wild-type polio would circulate again and the benefits of OPV would outweigh the risk. But, when OPV immunization levels are high, each child who receives OPV is benefiting the community ...

The policy argument is stronger should vaccination be compulsory. In Australia, vaccination is not compulsory but various incentives and reminders aim to promote it.<sup>32</sup> Payment of the maternity allowance at 18 months and the childcare benefit require up-to-date vaccination, according to the Australian Childhood Immunisation Register (ACIR), unless a medical practitioner has notified the ACIR of a contraindication or serologically confirmed immunity, or has discussed conscientious objection with a parent. At school entry, documentation of full vaccination is required in most Australian jurisdictions, with children who do not have such documentation or serological proof of immunity to specific diseases, such as measles, able to be excluded from school attendance if suspected cases occur.<sup>33</sup>



The difficulty of bringing a successful compensation claim under current law is perhaps demonstrated by the historical data; there have been few successful claims arising from vaccination. Of course, the rarity of such claims may also simply confirm the rarity of vaccine related adverse events. But inevitably, at least for the third category referred to initially, non-defective vaccines properly administered producing idiosyncratic allergic reaction in an individual case, there will be no viable compensation claim.

The political potential is perhaps analogous with proposed<sup>34</sup> amendments to the NSW motor accident legislation, where compensation will be available to victims of what has been described in a shorthand way as 'inevitable accident' cases — such as where the driver of a motor vehicle suffers an unexpected cardiac arrest or epileptic seizure. Such cases are also rare but can be catastrophic for an individual.

Under a vaccine injury scheme, there will remain the challenge of discerning which are 'valid' AEFI, as opposed to disabilities arising from other causes or for no ascertainable reason. Hence the various US cases referred to above.<sup>35</sup>

Such a scheme need not deprive victims of medical negligence of their current legal rights.<sup>36</sup> Indeed, the preservation of that alternative avenue of compensation would assuage concerns about what probably would be lesser levels of compensation available under a scheme compared to the modified common law.<sup>37</sup>

Of course, Australia already has a 'no fault' compensation system. It is variously called the Department of Social Security or Centrelink and it funds wage loss by the disability support pension, and care costs by a carer's pension. The treatment side of the equation is met by the public health system. Admittedly, compensation for pain, suffering and emotional distress is missing.

Finally, such a scheme may provide some easier framework for victims should a vaccine manufacturer be granted legal immunity or indemnity in certain unusual circumstances, such as has been raised in the context of rapid

and perhaps less rigorously tested avian influenza vaccine production.<sup>38</sup>

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## Endnotes

1. The common law across Australia has now been modified by statute to varying extents, not consistently. This article refers to the *Civil Liability Act 2002* (NSW).

2. Mariner W K 'Compensation programs for vaccine related injury abroad — a comparative analysis' (1986–87) 31 *St Louis University Law Journal* 599.

3. At the University of Sydney in November 2005 (see paragraph above these endnotes).

4. See <[www.tga.gov.au/adr/](http://www.tga.gov.au/adr/)>.

5. Drawn from the summary prepared by Professor T Adams at the Australian Health Policy Institute seminar, above note 3.

6. As it then was.

7. The *Vaccine Damage Compensation Act 1987* (UK).

8. The NZ scheme arose under that country's no fault accident compensation scheme in 1974. In 1992, a 'fault' component was introduced for medical misadventure, but as from 1 July 2005 the scheme was further amended; see s 32 of the



*Injury Prevention, Rehabilitation and Compensation Act 2001* (NZ).

9. For a more comprehensive listing, see Isaacs D 'Should Australia introduce a vaccine injury compensation scheme?' (2004) 40 *Journal of Paediatric Child Health* 247–300.

10. Presently to a maximum of £100,000.

11. 21 October 2005.

12. *CSR Ltd v Eddy* [2005] HCA 64; BC200507889 at [28]–[31].

13. See, for example, the *Civil Liability Act 2002* (NSW). In the context of a claim arising from a childhood immunisation, s 16 creates a significant threshold for non-economic loss (general damages), and s 15 creates thresholds and reduces the quantum of compensation awarded to a parent of a child requiring care. According to s 16, for example, no damages may be awarded for non-economic loss unless the severity of the non-economic loss is at least 15 per cent of a most extreme case and the maximum amount of damages that may be awarded for non-economic loss is \$416,000, but that maximum amount is to be awarded only in a most extreme case.

14. Slightly, but not materially, different definitions apply elsewhere in Australia.

15. See, for example, the discussion in Christensen S and Duncan W *Professional Liability and Property Transactions* Federation Press Sydney 2004 p 39.

16. In the sense of deciding whether a claim is viable to pursue through the courts.

17. See comments of Hoeben J at [230] in *Richards v Rabilly* [2005] NSWSC 352; BC200504607.

18. *Civil Liability Act 2002* (NSW) s 5P. Similar provisions exist in some other States and Territories in Australia.

19. Section 5D(3)(b).

20. As is made clear now in s 5D(3)(a) of the NSW *Civil Liability Act*.

21. Christensen S and Duncan W *Professional Liability and Property Transactions* Federation Press Sydney 2004 p 52.

22. Similar legislation exists in other States.

23. Walmsley S, Abadee A and Zipser B *Professional Liability in Australia* Thomson Lawbook Co Sydney p 174.

24. At [40]. The plaintiff, then 19 years old, worked at two part-time jobs

as a cleaner at night. The harness of the cleaning equipment irritated the scar. He was probably unfit for full-time work in this capacity unless the scar was made less tender. There was no evidence of any actual loss of earning capacity in the past. Allowing for a likely operation in two or three years, the success of which could not be guaranteed and which would leave the plaintiff with some cosmetic blemish, he was awarded \$25,000 for pain and suffering and loss of enjoyment of life (\$15,000 for the past); \$10,000 as a buffer for the range of occupations for which the plaintiff is likely to be unfit (jobs requiring repeated heavy lifting and carrying loads on the left shoulder, jobs in which there is a risk of bumping the left shoulder or upper arm); and \$1000 for the cost of the possible future operation.

25. There was considerable exploration of available (in 1978) advice concerning contraindications and precautions when contemplating immunisation. That advice was not all precisely uniform. A general medical practitioner might commonly have had available references to publications such as *MIMS*, the *Prescription Proprietaries Guide* and the Commonwealth Serum Laboratories leaflet accompanying supplies of the vaccine. By way of example:

*MIMS* (1977) Contraindications  
 Concurrent illness or ill-health (including allergic disorders) in the child, familial neurological disease, history of convulsions or evidence of other abnormality of the central nervous system, a history of a severe constitutional reaction to a previous dose of pertussis-containing vaccine. It is important that an accurate and detailed history be sought about the child's reaction to a previous dose of Triple Antigen.

The advice contained in Nelson's *Textbook of Pediatrics* (1975 edn) is less rigid:

It is usually unwise to give any immunization during an acute illness, because the fever from the injection may confuse the picture of the illness. Some children who have frequent upper respiratory tract infections may have long delays in completion of immunizations if this policy is over rigidly followed; mild convalescent or

healing infections should not be an absolute contraindication to immunization.

26. A website at <[www.whale.to/vaccine/law7.html](http://www.whale.to/vaccine/law7.html)> provides links to a number of such cases; the primary website appears to be one that opposes vaccination.

27. The cases referred to below are drawn from Baker J P 'The pertussis vaccine controversy in Great Britain 1974–1986' (2003) 21 *Vaccine* 4003; available online at <[www.sciencedirect.com](http://www.sciencedirect.com)>.

28. The Act provides for a one-off payment of £100,000; however, recipients remain entitled to social security benefits and the like.

29. Some commentators have queried whether the Court's conclusion 'stretched the boundaries' of the evidence, given the heart rending condition of the child. Barr R 'Polio vaccines' (22 April 2005) *Solicitors Journal* 463.

30. The judgment of the Court of Appeal was that of Lord Justice Waller, with whom Lord Justice Jonathan Parker and Sir Christopher Staughton agreed.

31. See Isaacs, note 9 above, p 247.

32. Apparently with some success. Of a large sample of 1779 Melbourne children in child care in 1997, only 13 (0.7 per cent) had not received any vaccines. Bond L, Nolan T and Lester R 'Immunisation uptake, services required and government incentives for users of formal day care' (1999) 23 *Australian and New Zealand Journal of Public Health* 368–76.

33. McIntyre P B, Williams A H and Leask J E 'Refusal of parents to vaccinate: dereliction of duty or legitimate personal choice?' (2003) 178(4) *Medical Journal of Australia* 150–51.

34. Announced by the NSW Roads Minister following a car accident in which the driver suffered an unexpected epileptic seizure, lost control and injured two children in a child care centre. Referred to also by Bowen D in the NSW Parliament's General Purpose Standing Committee #1 *Enquiry into Personal Injury Compensation* 14 October 2005.

35. The website at <[www.whale.to/vaccine/law7.html](http://www.whale.to/vaccine/law7.html)> provides links to a number of such cases.



36. Isaacs, above note 9, at 247–300 notes that of the 13 schemes he identified, three countries made it contingent that claimants not seek damages through the courts and five imposed limits, the remaining five apparently imposing no restriction.

37. Although the proposed NSW no fault Lifetime Care and Support Plan for catastrophic injury motor accident victims suggests this need not be inevitable.

38. Some precedent exists for such indemnity by the Australian Government. On 12 December 2002, the Government took possession of an initial shipment of 50,000 doses of smallpox vaccine. This vaccine, to be used only in emergency situations, was the only type available for large-scale purchase and was manufactured using older style technology. The Government granted an indemnity to the manufacturer covering possible adverse events that could result from the use of the vaccine.

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