

Vaccination Adverse Events – Legal Liability

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1 Introduction

Is it 'time for a vaccine injury compensation scheme' in Australia? If it is, should that conclusion extend to a broader 'no fault' compensation scheme for adverse medical outcomes?

Answers to those questions require a consideration of how well the current 'modified common law' system serves to compensate those who suffer vaccine injuries. By considering the basic approach of the common law² and looking at cases previously made, it should become possible to reach an informed conclusion on the relative merits of the two approaches – fault and no fault.

Making such a comparison the absence of detail about a proposed vaccine injury compensation scheme makes it difficult 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 can occur in a number of ways. 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 used or is contraindicated because

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² The common law now has across Australia been modified by statute to varying extents, not consistently. This paper refers to the Civil Liability Act NSW 2002.

of allergy, illness, immunosuppression or age. Nondefective vaccines properly administered can nevertheless produce idiosyncratic allergic reactions in individual cases³.

2 Legal Options

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

For a legal claim to succeed, firstly 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.

Secondly and most importantly there must be evidence of a link between the negligence and the damage alleged – causation.

And thirdly there must of course be some measurable damage, otherwise there will be no entitlement to financial compensation. Quite recently⁴ 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.

³ Compensation programs for vaccine related injury abroad – A comparative analysis. W K Mariner, 31 St Louis University Law Journal 599 (1986-1987)

⁴ 21 October 2005

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[57]. 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 incurred⁵.

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

3 Negligence - Breach of duty

The customary first port of call for a lawyer seeking to assess whether a vaccine injury could give rise to a compensable claim is 'negligence'. The multiple elements of the test for professional negligence are now contained in Section 5 O of the Civil Liability Act NSW 2002⁶. For most purposes, claims for breach of contract are not distinguishably different⁷. The section provides:

50 *Standard of care for professionals*

⁵ CSR v Eddy [2005] HCA 64 at [28]-[31]

⁶ Slightly but not materially different definitions apply elsewhere in Australia.

⁷ See for example the discussion in "Professional Liability and Property Transactions" by S Christensen & W Duncan, Federation Press at page 39.

- (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.*

The elements are:

- Practising a profession
- Widely accepted (can be more than one and need not be universally accepted)
- In Australia
- Peer professional opinion
- Competent professional practice
- Unless irrational

Amongst those elements, the key word is, arguably, “competent”. For practical purposes⁸ there may be little difference between the Section 5 O definition and the common law test for professional negligence previously applied by the Courts and those which apply in most other Australian jurisdictions.

In passing it is interesting to note the recent reference of Hoeben J to an earlier decision of the NSW Court of Appeal⁹:

⁸ In the sense of deciding whether a claim is viable to pursue through the Courts.

⁹ At paragraph 230 of *Richards & Ors v Rahilly & Anor* [2005] NSWSC 352 (29 June 2005)

The Court of Appeal in Eagle v Prosser¹⁰ seems to endorse the proposition that the decision as to treatment is that of the doctor provided that there is a legitimate and recognised school of thought in medical circles which supported that treatment. Eagle v Prosser recognises that different doctors of different schools of thought will have different attitudes to particular treatment options. So long as those attitudes are not inconsistent with a reasonable standard of care, it is not negligent to adopt or propound or offer one to the exclusion of the other.

A claim framed as a claim in negligence for a vaccination injury is 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.

Examples of past claims framed in such a way are considered below. A decision unrelated to vaccine injury is worth reviewing, for the potential application of section 5 O and as an example of issues which arise from what might be called ‘fringe’ practice.

Hall v Petros¹¹ was a first instance decision of Judge Macknay of the District Court of Western Australia. The claim arose before the recent Western Australian Civil Liability Act 2002. The plaintiff, Margaret Hall, sued the defendant, Dr Peter Petros, in negligence. The claim was not for a breach of duty of care in the provision of treatment, but rather for a breach of duty of care in the provision of adequate information.

The widely accepted test could never have been directly applied in any event even under the broader NSW Act. Section 5P (consistently with the Ipp report recommendations) provides that the relevant division does not apply to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information. However, the issue of wide acceptance or otherwise of the

¹⁰ [1999] NSWCA 166

¹¹ [2004] WADC 87; 27 May 2004

surgical procedure performed by the defendant, nevertheless became a focus of consideration in the case.

In June 1997 the plaintiff had consulted the defendant with a complaint of incontinence and in August 1997 the defendant carried out a surgical procedure on the plaintiff which included repair of an enterocele and intra vaginal sling plasty (IVS). The IVS was carried out with nylon tape and involved the use of a technique pioneered in Australia and in Sweden by the defendant and by a Professor Ulmsten. The use of tape, and the risks of infection and/or rejection of the tape, was an important aspect of the case.

The defendant gave evidence that the surgery was based on the 'integral theory' which had as its premise, that female incontinence was chiefly due to laxity in the vagina or supporting ligaments as a result of altered connective tissue. It included the proposition that a ligament from the pubic bone to the mid-urethra, on becoming lax, was such a cause.

In Australia, surgeons who accepted the integral theory formed a body known as the Australasian Association of Vaginal and Incontinence Surgeons (AAVIS). That body was said to have been formed in 1997 (the same year as the defendant's surgery upon the plaintiff) at a meeting held at the Royal Perth Hospital, although there had been an informal group after 1995 when over 40 surgeons attended a course in the procedure conducted at the same hospital. The defendant asserted that the AAVIS was essentially a craft group.

Dr Andrew Korda gave evidence on behalf of the plaintiff. He said there were no independent studies on the IVS technique to support it. It had not been extensively reported on and was not used by the majority of gynaecologists in Australia. The 'gold standard' procedure at the time, according to Dr Korda, was the colpo-suspension. At the relevant time, the IVS procedure did not form part of the Royal Australian College of Gynaecologists examinations.

Dr Peter Dwyer, called by the defendant, agreed that the IVS procedure was not the main incontinence procedure then being carried out in Australia but said there were about 50 gynaecologists of the AAVIS group who then utilised the procedure. He agreed that the Burch colpo-suspension was the 'gold standard' for Australia at that time.

During cross examination of Dr Dwyer by Counsel for Ms Hall, the term 'widely accepted' crept in. There were in effect two central issues; a broad failure to advise that there was a lack of wide acceptance of the IVS procedure, and more specifically the failure on the part of the doctor to adequately warn the patient of the risks of tape rejection or infection inherent in the procedure.

The doctor's pro forma consent and information pamphlet for patients undergoing surgery did not include reference to other alternatives available to a patient. In effect, the patient was not told she was to undergo a procedure performed only recently in Australia and only by a small minority of surgeons.

On behalf of the plaintiff, it was submitted that there was a substantially lower risk of major complications with the colpo-suspension procedure, in that for that procedure the risk was of the order of about 4 per cent compared with a risk with the IVS procedure that, at the time, was of unknown magnitude.

The Court found that, on the expert medical evidence put forward, including that of Dr Petros' own experts, and indeed the evidence of Dr Petros himself, there was undoubtedly a failure on the part of Dr Petros to adequately warn Ms Hall as to the risks of tape rejection or infection.

There appears to have been no specific finding on the lack of wide acceptance of the IVS procedure. Even though such a finding was open, the Court by reason of the failure referred to above found it unnecessary to address all the pleaded

particulars of negligence given that the finding above was sufficient for the Plaintiff to succeed.

Hall v Petros highlights the inter-relationship between the degree of acceptance of a technique and informed decision making. It highlights the likelihood that treatment scenarios of borderline wide acceptance may well be pleaded so as to require consideration of adequate informed consent. In other words, if there is only minority support for a particular procedure that may well need to form part of the warning process¹².

As for the “irrational exclusion”, it would be a very courageous lawyer indeed who chose to pursue a claim on that basis in the current climate, particularly when faced with the prospect of a personal costs order or misconduct finding under the *Legal Profession Act NSW 1987* or more recently the *Legal Profession Act NSW 2004*.

4 Failure to Warn

The *Civil Liability Act NSW 2002* expressly disavowed application of the Section 5 O test (explained above) to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information in respect of the risk of death of or injury to a person associated with the provision by a professional of a professional service¹³. However the Act did make certain evidence of a plaintiff inadmissible, by Section 5D(3)¹⁴:

- (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:*

¹² A more detailed report appears under the title “Widely accepted medical practice”; Australian Health Law Bulletin, Volume 12 Number 10 July 2004.

¹³ Civil Liability Act NSW 2002 Section 5P

¹⁴ Civil Liability Act NSW 2002 Section 5D(3)(b).

- (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.*

It is not hard to see how a “fail to warn” claim could well be one made following a vaccination injury. But Section 5D(3) does not make such claims impossible.

The correct approach is with respect that of Kirby J in the High Court decision of *Hoyts v Burns*¹⁵, which had nothing to do with medical negligence. The case involved 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 in attempting to sit down again fell to the ground, injuring herself on the underlying seat structure.

The case was originally also presented on the basis of inappropriate design of the seat but ultimately proceeded based on a failure to warn of the risk of the injury occurring in such circumstances. 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.

‘...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 one¹⁶. 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.’

¹⁵ [2003] HCA 61

¹⁶ As is made clear now in CLA s5D(3)(a)

Helpfully, Justice Kirby goes on to foreshadow how the Court might proceed in circumstances where such evidence is excluded.

'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 CLA section 5D(3)(b) – the establishment of an 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 & Ors v Rahilly & Anor*¹⁷, when he said¹⁸:

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 Vigabatin.

*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* (p 443, para 25). The reliability of such evidence needs to be assessed by reference to other evidence¹⁹."*

Finally under this heading, there is some recent authority concerning the width of the duty to warn, also from Hoeben J in *Richards v Rahilly*²⁰. Essentially Hoeben

¹⁷ [2005] NSWSC 352

¹⁸ Paragraph 256-257

¹⁹ Author's emphasis

²⁰ [2005] NSWSC 352

J appears to confirm that a medical practitioner need not identify each and every possible treatment option²¹:

In such circumstances it seems to me that a doctor is not only entitled but bound to recommend to patients (in this case the parents) that treatment which the doctor considers most appropriate in the circumstances. It is not a question of that choice involving the personal preference of the doctor but rather the doctor performing the fundamental duty for which he or she has been retained, ie to diagnose and treat. Once the doctor has recommended a treatment then it is incumbent upon him or her to explain fully to the patient the risks involved in that treatment.

The submission is put in such broad terms as to make its implementation unworkable as a matter of practicality. In essence it is submitted that Vigabatrin should have been discussed because it was a “legitimate” treatment that “could have worked”. It would impose an impossible burden on the medical profession if a doctor was bound to offer a patient every “legitimate” treatment option that “could work” and discuss the advantages and disadvantages of each option with the patient and then allow the patient to choose his or her option.

On the facts of this case, the Hospital would have been obliged before deciding upon any treatment for Rhiannon, to have discussed all of the medications which were legitimate treatment options which could have worked (Dr Manson says at least five) and then request the parents to choose the treatment option which they preferred. Such an approach is unrealistic, involves enormous practical difficulties and unfairly imposes on patients/parents a decision which they are unqualified to make. It is quite different to the situation where a certain form of treatment has been recommended, but before undergoing the treatment the patient has the advantages and disadvantages of the treatment fully explained. Finally, the submission not only is not authorised by Rogers v Whitaker but runs contrary to that decision. An obligation to warn of a “material” risk inherent in a proposed treatment is a significantly different obligation to one requiring the provision of full information concerning a number of treatment options preparatory to the patient choosing his or her treatment.

In my opinion there was no obligation on the part of the Hospital to explain the various treatment options to Rhiannon’s parents, or either of them, including the option of being

²¹ Paragraph 234-237.

treated with Vigabatrin so as to enable them to choose which treatment option they preferred.

5 Loss of a chance²²

Quite recently we obtained the benefit of a unanimous decision of the NSW Court of Appeal, *Rufo v Hosking*²³, a case which thus far seems to have produced little fanfare²⁴.

Michelle Rufo was born in 1977 and was diagnosed in early January 1992 to be suffering from systemic lupus erythematosus (lupus or SLE), a very serious inflammatory condition. In due course she came under the care of Dr Hosking, a paediatric immunologist. Only eight months later in August 1992, Ms Rufo was admitted to the John Hunter Hospital at Newcastle suffering from vertebral microfractures.

It became common ground at the trial that the microfractures arose from osteoporosis caused by the corticosteroid dosages (dexamethasone) that Ms Rufo had been having over that short eight month period.

It was further held by Studdert J at trial that in not introducing a “steroid sparer” Imuran to the treatment regime on or about 10 June 1992 the doctor was in breach of his duty of care to the patient .

Relevantly for the loss of a chance issue, the possibility of Ms Rufo developing osteoporosis and vertebral compression fractures from the administration of corticosteroids for less than eight months was not considered to have been high

²² For a more comprehensive review of this decision, see the paper of Julia Lonergan Barrister, presented at the Lawyers Alliance Professional Negligence Conference 14-15 July 2005 Melbourne.

²³ [2004] NSWCA 391

²⁴ It is interesting to contrast the approach of the NSW Court of Appeal with that of the majority in the House of Lords in a similar recent decision *Gregg v Scott* [2005] UKHL 2

and indeed less than 50/50. However the treatment did result in a material increase in that risk.

Nevertheless it was a risk which, if it did transpire, would be likely to have very serious consequences for her, as it did.

In *Chappel v Hart*²⁵, Mrs Hart succeeded in proving that if “warned” she would simply have refused the surgery. In an ordinary elective surgery failure to warn case that would have been the end of the matter - the patient would simply never have the surgery so the adverse outcome would never arise.

However Mrs Hart’s surgery was not truly elective in the sense that she would have needed it sooner or later. Nevertheless, the Court accepted that if she had refused the surgery on the relevant occasion, then on the balance of probabilities the adverse outcome would not later have arisen. There was no true loss of a chance of a better result.

However in *Rufo*, the treatment which ought to have been offered to the patient may or may not have resulted in the relevant adverse outcome. Even with the correct treatment regime, there was a significant chance that the fractures would have occurred.

Per Santow JA:

.....the present claim can be framed in terms of losing the benefit, not of a superior surgeon with better chance of circumventing the operation’s risks, but of a superior treatment regime with better chance of circumventing the risks of bone microfractures, while still curing the Lupus. In each case that better chance was less than even, but still material. There could be no question but that the better chance was a thing of value, even if its quantification posed considerable difficulty.

²⁵ (1988) 195 CLR 232

Ms Rufo ultimately succeeded in her claim, with the primary judgment coming from Campbell AJA and Santow JA & Hodgson JA expressing agreement. However, in my view the clearest summary of the reasoning comes from Santow JA and I can do no better than to quote from his judgment:

It is concededly the case that an unqualified all or nothing approach in allowing damages for the actual harm suffered affords, in the words of Gaudron J in Naxakis at [30], “at best, rough justice”.

However, it would be productive of injustice if the plaintiff were to receive 100% of the loss where a chance or prospect exceeds 50% (say 51%) yet receive nothing at all if such loss were, say, 49%. The fairest solution is to base compensation on whatever be the percentage, whether above or below 50%, wherever one is dealing with future events or hypothetical ones.....

What Callinan J describes in Naxakis at [129] as a possible approach may therefore be thought too generous to plaintiffs, if understood as allowing 100% recovery where the chance lost is merely 51% but if 50% or below allowing the full percentage. However, if Callinan J is understood as simply illustrating the outcome of the traditional approach compared to the loss of a chance approach in a medical negligence context, that example brings out the difference with clarity.

In Naxakis when Gaudron J explained why she rejected loss of chance as a basis for recovery in medical negligence cases, she observed that the doctrine of loss of chance would not necessarily benefit individual plaintiffs. “If damages were to be awarded for the chance lost, rather than the actual injuries or disabilities suffered, consistency would require the damages be assessed according to the value of the chance, not the injury or disability. Thus a chance which is 51% or greater but less than 100% must result in an award of damages less than would be the case if damages were awarded for the injury or disability which eventuates” at [33].

While that observation is undoubtedly correct where the chance is above 50% but below 100%, several points can be made. First, the plaintiff who suffers an injury which on the balance of probabilities would have occurred anyway but nonetheless is deprived of a chance of averting that outcome as a result of the defendant’s negligence, on the all or

nothing rule that plaintiff would receive nothing. The plaintiff is then indubitably worse off²⁶.

The Court of Appeal took some care to confirm that the outcome in Rufo does not alter the law in respect of causation in fail to warn cases. It does not allow a patient to argue that he or she lost the chance of accepting or refusing a particular course of treatment, based on what decision might of might not have been made in response to a suggested warning.

Causation is still a real hurdle, as noted in the judgment of Santow JA:

Moreover, in medical negligence cases causation must still be demonstrated at greater than 50% probability in two respects. First, the chance must be proven to exist on balance of probabilities. Second, the plaintiff must prove on balance of probabilities that if offered the chance lost, in terms of treatment, the plaintiff would have elected to have that chance. Thus “where the chance lost was a chance that the plaintiff may have acted in such a way as to receive a benefit or avert a detriment, the plaintiff must prove on the balance of probabilities that there was such a chance and that the plaintiff would have so acted” (per Badgery-Parker J in Tran v Lam NSWSC, 9 February 1995, unreported BC 9504451). That is an important control mechanism. It means that loss of a chance cannot be invoked where there is not a greater than 50% chance that the patient, properly advised, would have undertaken the particular course of treatment or operation²⁷.

The judgment of Hodgson JA is similarly clear on this point; he also makes some helpful observations on the nature of the evidence which will be required for such cases to succeed.

It seems clear that, if avoidance of the loss in question would have depended upon the plaintiff taking a particular course of action, the plaintiff must prove on the balance of probabilities that, but for the negligence, the plaintiff would have taken that course of action. The plaintiff cannot be compensated for the loss of a chance that the plaintiff might have done so: Sellars at 353. However, otherwise I think it is consistent with the

²⁶ At paragraphs 44-48

²⁷ At paragraph 40

principles established in Malec and Sellars to say that it is enough if the plaintiff proves, on the balance of probabilities, that he or she has been deprived of a valuable chance.

That chance must be inherent in the circumstances, not merely an artefact of the way evidence is presented in the case. Thus, if it appears to be a plain fact as to whether treatment would or would not have been successful, and the element of uncertainty arises merely from different expert views, then the plaintiff will not be compensated for the chance that one expert might be correct. On the other hand, if it appears that the very best medical science can do is to say that the treatment had a quantifiable chance of success, then in my opinion that can be treated as a valuable chance for the loss of which a plaintiff can be compensated. As with other questions concerning causation, a common sense approach should be taken to the question of whether a valuable chance has been lost, or whether the situation is rather one where one or other alternative would definitely have occurred, and the only uncertainty is due to imperfections in the evidence²⁸.

This decision will have potential application in both informed consent and negligent treatment cases.

Informed consent arguments will still no doubt falter most often at the primary causation hurdle, would the patient have undergone the treatment²⁹ if warned.

The real value of *Rufo* for a patient may come where the good outcome, arising from either a failure to warn or simple negligent treatment, is less than 50%. It represents a movement away from what has been described as a “rough justice” all or nothing approach.

It is interesting to speculate whether that same move away from the all or nothing approach may see damages reduced to below full value in cases where treatment options have a greater than 50% but less than 100% chance of succeeding. If indeed any medical treatment can be said to have a 100% chance of succeeding.

²⁸ At paragraphs 9-10.

²⁹ Or in this context, vaccination.

6 Product Liability

Most commentators agree³⁰ that professionals in the practice of their profession whether as corporations (hence under the *Trade Practices Act (Commonwealth) 1974* or as individuals (hence in NSW under the *Fair Trading Act NSW 1987* or similar in other States) 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 litigation³¹, but for the purposes of this paper it is sufficient to note some aspects briefly.

An individual idiosyncratic reaction to an otherwise 'safe' vaccine will not if itself make a doctor or manufacturer liable. Some parallels may perhaps be drawn from litigation concerning a mitral valve implant, *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd*³². In that matter, the applicant suffered from a heart condition since childhood. He underwent surgery for repair of his mitral valve however during surgery the repair of valve was unsuccessful and so a mechanical mitral valve implanted. The Applicant suffered infarcts to spleen and kidney and a stroke. The mechanical valve was later removed and a porcine tissue valve implanted. The initial valve was returned to 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 product defective under s 75AD

³⁰ "Professional Liability and Property Transactions" by S Christensen & W Duncan, Federation Press at page 52.

³¹ "Professional Liability in Australia", Walmsley Abadee & Zipser, Thomson LawBookCo at page 174.

³² [2004] FCA 853 per Kieffel J

and the Applicant could not establish that chip caused thromboembolic events suffered. And so the second and central issue of causation remains a hurdle.

Evidence established that risks were advised to the applicant.

Importantly for the purposes of this paper, it was not reasonable for applicant to expect no prospect that valve would cause development of thrombi. Hence his claim under s 74B of the *Trade Practices Act 1974* was not established.

7 Case law

There are in any event 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 in the context of the legal framework outlined above.

Denis Stepanovic v ACT

*Denis Stepanovic v ACT*³³ though successful was a relatively small claim arising from development of keloid scarring after immunisation against diphtheria and tetanus.

Miles CJ noted 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?³⁴

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".

³³ [1995] ACTSC 115; 13 November 1995.

³⁴ At [2]

The Health Centre recommended to its nursing staff certain immunisation procedures in a document³⁵. 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.³⁶

Denis' 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 straight away 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 later 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

³⁵ At [6]

³⁶ At [7]

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.³⁷

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".³⁸

Of course in the adversarial system, a Court is usually presented with conflicting medical evidence. And so here, where the defendant called evidence from Dr Weedon. In material collected for his recent textbook entitled *The Skin*, Dr Weedon was able to find no reference to keloid scarring occurring as a result of CDT immunisation. He made a further search on computer line, including the main worldwide data base 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 (and only very rarely) to a lump in the nature of aluminium granulomas, which can be removed surgically. Dr Weedon said that the injection of live vaccine such as smallpox or BCG (tuberculosis) vaccine can also produce scarring, but that CDT is not a live vaccine. In cross-examination Dr Weedon accepted, as he had to, that the plaintiff's shoulder bore a large and obvious keloid scar. He said that the

³⁷ At [18] – [20]

³⁸ At [23]

factors which go to producing such a scar following injection include individual and racial disposition and wound tension. In his pathology practice over half a million patients have been injected by means of a 26 gauge needle and not one has developed a keloid complication. Dr Weedon considered that the most likely cause of such scarring as suffered by the plaintiff was wound tension and that such scarring is the more likely the closer the injection site is to the acromion process.³⁹

As Judges often do, Miles CJ stated that choosing between two bodies of medical opinion is an extremely difficult task, but 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 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.⁴⁰

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.⁴¹ Damages were assessed at a total of \$42,000.⁴²

Bonello v Lotzof

³⁹ At [26] – [27]

⁴⁰ At [29] – [30]

⁴¹ At [30]

⁴² 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 is 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; \$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. \$1,000 for the cost of the possible future operation.

In a 1997 NSW case, David Bonello brought an unsuccessful action against a general practitioner, Dr Lotzof⁴³.

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 immunizations 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 immunization in the circumstances alleged to have been current, a reasonably skilful general medical practitioner would not have then administered DTP or, 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 contra indicate⁴⁴ immunization nor were there any matters of history which the

⁴³ Bonello v Lotzof Matter No 11530/93 (23 September 1997) Grove J

⁴⁴ There was considerable exploration of available advice (in 1978) concerning contraindications and precautions when contemplating immunization. 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 vaccine. (By way of example):

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 material in the records of Blacktown Hospital later that day.

Bryden v Health Department

In *Bryden v Health Department*⁴⁵ 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 cortico steroid 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

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."

⁴⁵ (1987) Aust Torts Reports 80-075; a 1986 decision of Vincent J of the Victorian Supreme Court

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 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 entitlements⁴⁶. The fact that such cases exist even under schemes is noteworthy and will be returned to later.

*Graham v Wyeth Laboratories*⁴⁷ was a pharmaceutical products liability case involving the whole-cell pertussis DPT vaccine. As a result of the toxins in the pertussis vaccine, the plaintiffs' infant-child suffered severe brain damage. A jury returned a \$15 million verdict for plaintiff that was reversed on appeal. The case settled during the second trial.

⁴⁶ A website at <http://www.whale.to/vaccine/law7.html> provides links to a number of such cases; the primary website appears to be one which opposes vaccination.

⁴⁷ 666 F. Supp. 1483 (D. Kan. 1987)

In England, there was an extensive albeit older history of claims concerning pertussis vaccination⁴⁸. A key claim in 1985-1986 was brought on behalf of Johnnie *Kinnear*, a 15 year old with cognitive deficits said to arise from 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 & the Wellcome Foundation*⁴⁹ has been described as the final test case concerning pertussis vaccine, again concerned causation. There were in fact some nine cases, however Stuart Smith J on March 1988 found the cases unconvincing as none had symptoms in the first forty eight hours and there appeared to be convincing alternate diagnoses such as viral encephalitis:

*"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*⁵⁰. ..."

*Thompson v Bradford*⁵¹ was a quite recent October 2004 decision of Wilkie J. Similar to the above decision of *Bonello v Lotzof*, it focused on whether a 1997 immunization (polio) ought to have been given when the health of the child was said to be uncertain. It appears 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*⁵².

⁴⁸ The cases referred to below are drawn from "The pertussis vaccine controversy in Great Britain 1974 – 1986", by JP Baker published in *Vaccine* 21 (2003) at p 4003. Available online at www.sciencedirect.com

⁴⁹ [1990] Med LR 117

⁵⁰ At page 125.

⁵¹ [2004] EWHC 2424

⁵² The Act provides for a one off payment of £100,000; however recipients remain entitled to social security benefits and the like.

The mother, a nurse, gave evidence that she voiced her concern to the doctor as to whether the vaccination at age 8 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, described 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 concluded that the general practitioner's conclusion that there was no underlying systemic illness was a reasonable one. However he found the doctor breached his duty to properly inform the parents, and also concluded that if properly informed the parents would have postponed the immunization. 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 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 system⁵³.

⁵³ Some commentators have queried whether the Court's conclusion 'stretched the boundaries' of the evidence, given the heart rending condition of the child. "Polio vaccines" SJ 22 April 2005 at p 463, R Barr

8 Concluding remarks

From this admittedly cursory review, some conclusions can be drawn.

There is no doubt a sound policy argument for establishment of a vaccine injury compensation scheme in Australia. The difficulty of bringing a successful claim is 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.

The situation is perhaps analogous with proposed⁵⁴ amendments to the 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.

However even under a scheme, there may remain the challenge of discerning which are ‘valid’ vaccine adverse events, as opposed to disabilities arising from other causes or for no ascertainable reason. Hence the various US cases referred to above.⁵⁵

Such a scheme need not deprive victims of medical negligence of their current legal rights; indeed the preservation of that alternative avenue of compensation would assuage concerns about what might be lesser levels of compensation available under a scheme compared to the modified common law.

⁵⁴ Announced by the NSW Roads Minister following a car accident where the driver suffered an unexpected epileptic seizure, lost control and injured two children in a child care centre. Referred to also by Mr D Bowen in GPSC #1 Enquiry into Personal Injury Compensation 14 October 2005.

⁵⁵ See footnote 46

Should this conclusion extend to a broader ‘no fault’ compensation scheme for adverse medical outcomes? The answer becomes more complex, if only because of funding issues, and perhaps too great a hurdle at the present time⁵⁶.

Proponents of no fault compensation often point to the New Zealand scheme⁵⁷ (NZ ACC). But for medical misadventure, the New Zealand scheme is not “no fault”. 1992 changes saw the introduction of a negligence test⁵⁸, for benefits to be payable. Those changes persisted through the later amendments in 1998 & 2001, in what has been described as an “oddity in a scheme essentially based on no fault cover⁵⁹”.

On one view, Australia already has a no fault system. It is called the Department of Social Security or Centrelink, and 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. The scheme is there – but it is not very generous.

Given the case examples outlined above, it seems likely that a vaccine injury compensation scheme in Australia, at least in relation to neurological claims, would face as its principal hurdle the issue of causation – demonstrating the relationship between the vaccination and the injury. And of course, locating political enthusiasm and funding to establish such a scheme.

⁵⁶ The Australian, 2 November 2005 - National accident scheme crashes, by Sean Parnell

“ Plans for a national scheme to care for people with catastrophic injuries have been abandoned after governments balked at the cost...”

⁵⁷ The New Zealand scheme grew from the Compensation for Royal Commission for Personal Injury in New Zealand, Report of the Royal Commission of Inquiry (Woodhouse Report) 1967, implemented by the Accident Compensation Amendment Act 1974 which incorporated reference to medical, surgical, dental or first aid misadventure in section 2.

⁵⁸ Accident Rehabilitation and Compensation Insurance Act 1992, section 29 provided a definition of medical error as the failure of a medical health professional to observe a standard of care and skill reasonably to be expected in the circumstances.

⁵⁹ At page 816, Petra Butler, “Brief introduction to Medical Misadventure”; Victoria University of Wellington Law Review, Volume 35 Number 4 December 2004

Finally, such a scheme may provide some support for victims should vaccine manufacturers be granted legal immunity in certain circumstances, such as has been mentioned in the context of rapid avian influenza vaccine production.

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