Aids and the Blood Bank: The Argument for Strict Liability Exemption

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Introduction

The Australian Red Cross Society has recently been a defendant in a number of civil actions brought in negligence by plaintiffs alleging they contracted AIDS[1] as a result of the administration of contaminated blood or blood products supplied by the Society. The Society provides a full-scale Blood Transfusion Service (BTS) in all States and Territories of Australia.[2] The BTS, the only source of blood collection in Australia, operates entirely on a system of voluntary donation. The blood and blood products distributed by the BTS are provided to hospitals free of charge upon request by the hospitals or medical practitioners.

So far, the Society has not been found to be negligent. However, a recent Bill introduced into Federal Parliament threatens to make it easier for plaintiffs to bring actions against the Society based upon strict product liability legislation. This author argues that the Society, as a provider of life-giving blood and blood products, should be immune from strict liability actions on the basis of public policy. The author points to exemptions given to blood banks in the United States, and suggests similar exemptions be drafted here into the proposed legislation.

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1 AIDS is an acronym for Acquired Immunodeficiency Syndrome. The disease is associated with the breakdown of the immune defence system, leaving the way open for potentially serious invaders (viruses and other organisms) which the body would normally reject.

2 The basic functions of the Blood Transfusion Service are the recruitment of donors and the collection, testing and distribution of their blood and its derivatives. These include Factor VIII and IX concentrates, Cryoprecipitate (both used for the treatment of haemophilia), whole blood, red cells, platelet concentrate and plasma, including fresh frozen plasma. The concentrated clotting factors are produced by the Commonwealth Serum Laboratories (CSL), and returned back to the various State and Territory Blood Transfusion Services. For further details regarding the Blood Transfusion Services in Australia, see the booklet 'The Vital Factor' produced by the Australian Red Cross Society.

Current Theories Of Liability

Courts have been reluctant to hold the Society liable for the transmission of the AIDS virus in cases brought to trial to date.[3]

In *"E" v Australian Red Cross Society & Ors,*[4] the most recent case to come to trial, the applicant contracted AIDS by way of a post-operative blood transfusion. The applicant alleged breaches of the Trade Practices Act 1974 (Cth), and that the Society had been negligent in the collection, testing and administration of blood.

Trade Practices

His Honour dismissed the applicant's claims of alleged negligent misrepresentations in breach of s. 52 and s. 55A of the Act, holding that there had been no relevant representation as to the suitability of the plasma.[5]

Further, the applicant relied on sections 71 and 74 of the Act, which imply into certain types of contracts particular conditions and warranties regarding merchant ability and fitness for purpose. Alternatively, the applicant relied on s. 19 of the Sale of Goods Act 1923 (NSW). His Honour held that the applicant had no contract with the Society for the supply of the blood plasma, and therefore his claims under those sections, which presupposes a contract, failed.[6]

Negligence

The applicant's claim in negligence lay in two parts: he claimed that the procedures adopted by the Society for the exclusion from the blood donor pool of persons within the known AIDS high risk categories were inadequate. Second, conceding that no specific test for HIV infection was available, the applicant alleged that the Society ought, by the date of the donation, to have had in place a surrogate

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3 In *Dwan v Farquhar* (1988) 1 Qd R 234, the appellant contracted HIV from a blood transfusion given in May 1983 after he had knee surgery. He argued that the doctrine of res ipsa loquitur applied-that the fact that contaminated blood had been given was in itself evidence of negligence. The Court rejected this argument saying that there was no evidence that the Society had departed from acceptable standards of conduct.
In *'H' v Royal Princess Alexandra Hospital for Children* (1990) Aust Torts Reports ¶81-000, a 16 year old haemophiliac contracted HIV from infected FVIII. It was held that the Society had adopted proper practices when collecting blood from donors.
In *"PQ" v Australian Red Cross Society & Ors* (unreported), a jury found that the Society had acted according to current standards of blood collection and were not negligent.

4 (1991) ATPR ¶41-085.

5 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,359. In any event, the applicant was statute barred under s82(2) of the Act which required him to commence his action within three years after the date on which the action accrued.

6 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,362.

test[7] for hepatitis B core antibodies, which it was said would have identified many of those persons in high risk groups who gave blood despite the warning not to do so, and if applied to the donation which infected him, the donation would probably have been discarded and the infection avoided. The applicant failed at trial on both claims, and appealed on these same issues.[8]

The appeal court agreed with his Honour in holding that in October of 1984 a reasonable person in the position of the respondent would have foreseen the possibility of HIV infection from the transfusion supply to the applicant.[9] However, the appeal court found that in relation to donor screening, the Society was not negligent, and that it had adopted proper screening practices.[10] In response to the AIDS cases, amendments to blood and tissue donation legislation have been introduced requiring declarations verifying the medical suitability of donors. In jurisdictions with specific legislation,[11] limitation of civil and criminal liability is offered for the advertent transmission of AIDS through the transfusion of blood and blood products.

Of more interest was the finding in relation to surrogate testing. The Court of Appeal supported the view of the trial judge who held that the introduction of the surrogate test would have had a serious effect on the blood supply, resulting in about 5 percent of donations, many of the harmless, being discarded. His Honour said that even though the body of evidence suggested that surrogate testing was not used, he was prepared to find that the Society was negligent in not

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7 A surrogate test detects certain antibodies other than AIDS which, if identified in the donor's blood, indicate that the donor is a high risk for carrying the AIDS virus. Approximately ninety percent of those infected with AIDS also test positive for the hepatitis-B antibody.

8 *E" v Australian Red Cross Society & Ors* (1992) ATPR ¶41-156.

9 *"E" v Australian Red Cross Society & Ors* (1992) ATPR ¶41-156 at 40,125.

10 *"E" v Australian Red Cross Society & Ors* (1992) ATPR ¶41-156 at 40,128.

11 *NSW Human Tissue Act* 1983; *Vic Health (Infectious Diseases) Regulations* 1990; *WA Blood Donation (Limitation of Liability) Act* 1985; ACT Blood Donation (Acquired Immune Deficiency Syndrome) Ordinance 1985; *Tas Blood Transfusion (Limitation of Liability) Act* 1986; *NT Notifiable Diseases Act* 1981 and *SA Blood Contaminants Act* 1985.
Broadly, the legislation requires that:
*accurate declarations have been sought and obtained from donors;
*the blood or blood product has been tested in accordance with approved tests;
*the blood or blood product was accompanied by a certification verifying that approved
tests produced negative results for the presence of the AIDS virus.
The statutory defence fails if the Australian Red Cross Society, hospital or person administering the blood or blood product was negligent. Negligence is established if the society, hospital or person has reasonable grounds for believing that the blood or blood product is contaminated, or has been informed of likely contamination, and fails to take reasonable steps to prevent administration of the blood or blood product.

introducing the test before October 1984, if not for the effect on the blood supply.

> But it was clear that any serious practical effects upon the blood supply might cost lives. Upon the material before the Court, and in the absence of evidence which establishes that a 5 per cent reduction in the blood supply would not have endangered lives, I cannot be affirmatively satisfied that the [Society] breached their duty in failing to decide to adopt anti-HBc surrogate testing.[12]

This was despite the fact that, upon the probabilities, the earlier introduction of anti-HBc surrogate testing would have led to the discarding of the donation which caused the applicant to become HIV infected.[13]

Although no plaintiff has yet succeeded in establishing negligence on behalf of the Society, proposed new strict products liability legislation will make it easier for plaintiffs to bring actions.

Strict Liability

The definition of strict liability

Strict liability can most simply be defined as liability without proof of fault.[14] Under a strict product liability regime, responsibility to compensate will arise (subject to such defences as are allowable), upon proof that the loss resulted from the existence of some defect in, or some unsafe characteristic of, the product. A manufacturer would, prima facie, therefore be liable although it may have exercised all possible care in the preparation and sale of the product, and although the defect may not have been discoverable. The burden of proof would shift to the defendant who would then have to prove the availability of a defence.[15]

Strict liability in Australia

Australia is presently devoid of a cohesive body of laws relating to product liability.[16] Until now, actions in relation to product liability can be sourced in contract, negligence or breach of statutory duty under the manufacturers' implied warranties in the Trade Practices Act 1974 (Cth) and Fair Trading Acts in each State. Also, examples of strict liability in existing law in relation to products can be found in the warranties implied pursuant to Sales of Goods Acts in the States.

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12 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,379, 52,383.

13 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,383.

14 Ferguson, 'The Proposed Product Liability Bill' (1989) 5 (2) Insurance and Liability Law Bulletin 17.

15 Akhurst and Bodger, 'Product Liability in Australia' (1988) Law Institute Journal 725..

The Proposed Strict Liability Legislation

On 19 December 1991, the Minister for Consumer Affairs, Senator Michael Tate, introduced the Trade Practices Amendment Bill 1991.[17] The purpose of the Bill is to introduce into Australia a strict product liability regime based on the 1985 European Community Product Liability Directive[18] by way of inserting a new Part VA into the Act. Under the new laws a person who is injured or suffers property damage as a result of a defective product will have a right to compensation against the manufacturer, without the need to prove negligence on the part of the manufacturer.

Under the new Part, liability is imposed on a corporation that, in trade or commerce, supplies goods (the expression is not defined specifically for the proposed Part VA) manufactured by it.[19] There is no requirement, unlike Part V of the Act, that the goods be supplied to a "consumer" or to anyone else. Liability is based upon "putting the goods into circulation".

The second condition of liability is that the goods have a defect.[20].A product is defective when it does not provide the safety which 'persons generally are entitled to expect'.[21]

The third condition of liability under Part VA is that because of the defect, a person suffers loss arising from death or personal injury.[22] Therefore, a plaintiff seeking recovery under Part VA must prove not only that the goods were defective, but also that the injury, loss or damage occurred *because* of the defect. The new Part also provides that a court must draw an inference that a defect in the goods caused the loss where it is reasonable in all the circumstances of the case to do so.[23] This section negates the difficulties faced by

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16 Simpson, 'Product Liability Reform - Draft Legislation' (1989) 63 (7) Law Institute Journal 615.

17 This paper only addresses those parts of the Part relevant to blood bank liability. For a complete discussion of the new Part see Goldring, 'Is the New Bill the Answer?' (1992) 2 (6) Australian Products Liability Reporter 82.

18 For a discussion of the EC Directive, see Beerworth E, 'The Liability of Manufacturers After the Proposed Reforms' in BLEC (ed), Product Liability (1991) 4.

19 Proposed ss75AD(1)(a) and (2)(a).

20 Proposed ss75AD(1)(b) and (2)(b).

21 Proposed s75AC(1). Matters to be taken into account when applying this standard include: the presentation of the product (manner of presentation, existence of warnings, instructions), what might reasonably be expected to be done with or in relation to the product and the time at which the product was supplied by its producer to another person: proposed ss75AC(2)(a)-(f).

22 Proposed s75AD(1)(c).

23 Proposed s75AJ. Subsequent to the completion of this article, the Trade Practices Act Amendment Act 1992 (Cth) was passed. Following pressure from a number of sources, most notably the opposition, the government was finally forced to abandon its aim to reverse the onus

plaintiffs to gather direct evidence to prove the exact nature of the alleged defect, or the precise causal connection between the defect and the loss or injury.[24] This provision is similar to the *res ipsa loquitur* rule,[25] but, like *res ipsa loquitur*, it in itself will not be proof of liability.[26]

A manufacturer or producer will have a defence to an action where it can show that the product was not defective. It must show either that the defect did not exist when the goods were supplied; that the goods were defective only because they complied with a mandatory Commonwealth or State standard, or that the state of scientific and technical knowledge at the time the product was put into circulation was not such as to enable the existence of the defect to be discovered: the 'state of the art' defence.[27]

The new Part will not supersede or replace any existing laws: in particular, rights of action arising in the law of negligence are not affected.

Attractiveness of strict liability for plaintiffs

Strict liability would be a welcome advantage to plaintiffs attempting to hold the Society liable for transmission of infection by way of blood or blood products. The case of *"E" v Australian Red Cross Society & Ors*[28] highlights some of the difficulties facing a plaintiff attempting to establish liability by the Society.

Presently, a plaintiff, it seems, is precluded from claims based upon implied warranties under the Trade Practices Act 1974 (Cth) and other State legislation, as there is no contractual relationship between the plaintiff and the manufacturers of blood products.[29] The product liability legislation removes this problem that arises because of privity of contract, as the new laws base liability upon the

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of proof in relation to claims under Part VA, and this proposed section was not included in the final Bill passed through the Senate. However the Minister hoped that courts, when applying the legislation, would follow the EC Directive which was prepared on the understanding that member States would continue to utilise existing rules of evidence and procedure so as to allow commonsense claims to proceed: Australia, Parliamentary Debates, House of Representatives, 4 June 1992, 3665.

24 'Explanatory Memorandum' (to new Bill) (1992) 2 (6) Australian Products Liability Reporter 91. As noted above, while this section is not available under the present amendment to assist claimants to discharge their burden, this may not be the last word on the subject: the government has removed the controversial elements of the proposal for consideration by an all-party Senate committee.

25 The evidentiary principle which allows the court to draw an inference of negligence from the mere happening of an event without the benefit of direct and detailed testimony about cause and responsibility.

26 See *Dwan v Farquhar* (1988) 1 Qd R 234 above n 3.

27 Proposed ss75AH(a)-(c).

28 (1991) ATPR ¶41-085.

29 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,362.

circulating of the goods, thus allowing any user of the product who suffers damage to be able to sue.

In addition, strict liability serves as a means for a plaintiff to circumvent problems of proof of negligence inherent in products liability cases by shifting the burden of proof to the defendant to prove the availability of a defence.[30] Basically, this concerns when, where and by whom and by what product he was infected.[31]

It may be difficult for a plaintiff to trace and identify the donor who was the source of the infection.[32] Further, some plaintiffs often receive hundreds of treatments over many years from different hospitals. The plaintiff will often be unable to identify the manufacturer who provided the product, that more probably than not, was the source of the infection.[33] These problems of proof could, it is argued, be insurmountable.[34]

Likely application of the new Part to Society

It seems from the decision in *"E"v Australian Red Cross Society*[35], that the Society will come under the ambit of the new Part VA. His Honour found that the Society was a trading corporation within the meaning of the Trade Practices Act 1974 (Cth). Although the gratuitous provision by the Society of the public service of supplying blood was not a trading activity by it and that it did not constitute an act 'in trade and commerce' within the meaning of the Act, he held that since trading activities, including the sale of goods, were a major source of the income of the Society, it was a trading corporation.[36]

As well, the appeal court, as did his Honour, left open the question of whether blood plasma can answer the description of 'goods' for the purposes of the Act.[37] However, they referred to US

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30 Akhurst and Bodger, loc. cit. As noted above, the onus of proof on the issues going to liability remains firmly with the claimant: see p5. A manufacturer or importer will still be strictly liable for defects in those goods, subject however to adducing evidence as to one or more of the defences available. While it is considered appropriate that the burden of proof should lie with the claimant, proving that the loss resulted from the existence of some defect in the good is still a less onerous task than having to satisfy the more strenuous requirement of proving fault in a negligence claim.

31 Plibersek, 'Transfusion Acquired AIDS: Is Anyone Legally Liable?' (1990) 28 (4) Law Society Journal 56.

32 Even if the donor can be traced, it is likely that the donor may have already have died of AIDS.

33 This was not a problem for "E", as he received his infection from a single transfusion.

34 Plibersek, loc. cit.

35 (1991) ATPR ¶41-085.

36 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085, at 52,354.

37 *"E" v Australian Red Cross Society & Ors* (1992) ATPR ¶41-156 at 40,119.

cases, with one authority suggesting that blood supplied by a blood bank may be a sale of goods.[38]

Therefore, it is not yet clear whether the Society would come under the ambit of the new laws: consideration would need to be given by the courts to whether the Society is a 'manufacturer' under the Act.

The US Situation: The Blood Shield Statute And Strict Liability Exemption

Strict liability in the United States

In contrast to Australia, in the application of tort law in the United States to product liability, strict liability seems universally to have been adopted:[39] the *Restatement (Second) of Torts* section 402A subjects to strict liability those who sell 'any product in a defective condition unreasonably dangerous to the user or consumer.'[40] As well as common-law strict product liability, the Universal Commercial Code (UCC) and state legislation provides for strict liability under implied warranty laws. However, US legislatures moved early to exempt blood and blood manufacturers from strict liability, recognising the importance of maintaining an adequate blood supply.

Strict liability exemption for blood and blood products

Transfusible blood was first exempted from strict products liability in *Perlmutter v Beth David Hospital.*[41] In *Perlmutter*, the plaintiff contracted hepatitis from a contaminated blood transfusion and sought recovery for breach of implied warranties. According to the New York Court of Appeals, the furnishing of blood by the hospital was not a 'sale' because it was merely incidental to the hospital's service of care and healing, and thus was an integral and indivisible part of that service. Further, the court held that it would be unfair to hold the hospital strictly liable where there was no way to

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38 Belle Bonfils Memorial Blood Bank v Hansen 579 P 2d 1158 (1978).

39 Ferguson, loc. cit.

40 (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling such a product, and
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
(2) [This rule] applies although
(a) the seller has exercised all possible care in the preparation and sale of his product, and
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.
Restatement (Second) Of Torts § 402A (1965).

41 308 N.Y. 100, 123 N.E.2d 792 (1954).

detect hepatitis in the blood and where no negligence or fault was present.[42] Therefore, the plaintiff could not recover under the theory of implied warranty because the transaction did not fall within the provisions of the New York Sales Act, guaranteeing warranties. The court emphasised the public policy underlying its decision:

> [I]f, however, the court were to stamp as a sale the supplying of blood it would mean that the hospital, no matter how careful, no matter that the disease-producing potential in the blood could not possibly be discovered, would be held responsible, virtually as an insurer, if anything were to happen to the patient as a result of 'bad' blood.[43]

Blood Shield Statutes

Legislatures, responding to public policy considerations, enacted blood shield statutes in order to protect blood banks from liability, thus codifying the *Perlmutter* holding. Blood shield statutes reflect one main policy consideration: the promotion of public health and welfare.[44] The Washington Supreme Court has acknowledged the public policy reasoning behind the passage of that State's blood immunity statute in *Garvey v St. Elizabeth Hospital*:

> The public policy represented by these statutes is not difficult to discern: blood transfusions are essential in the medical area and there are not now, and realistically there may never be, tests which can guarantee with absolute certainty that the donated blood is uncontaminated with certain viruses.[45]

Generally, blood shield statutes protect providers of blood and blood products for transfusions from non-fault based liability by defining their blood-related activities as a medical service rather than a sale of goods.[46] A 'sale of goods' or a 'sale of a product' is prerequisite for recovery by an injured party on an implied warranty contract theory and a strict product liability tort theory in the United States. By defining these blood transactions as a service rather than a sale, actions in implied warranty and strict liability are precluded.[47] Therefore, the exposure of blood providers to liability is limited to their acts of negligence.

Although the blood shield statutes vary greatly from state to state, there are two principal types of statutes.[48] The first type is set forth in the implied warranty provisions of the states' Uniform

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42 Westfall, 'Hepatitis, AIDS and the Blood Product Exemption from Strict Products Liability in California: A Reassessment' (1986) 37 The Hastings Law Journal 1109.

43 308 N.Y. 100, 123 N.E.2d 792 (1954), at 795.

44 Bennetts, 'AIDS: Blood Bank Liability' (1991) 27 (2) Willamette Law Review 371.

45 103 Wn.2d 756, 759, 697 P.2d 248 (1985).

46 Landfield, Becker and Green, Memorandum to American Blood Resources Association re: Survey of Blood Shield Statutes (1987) 2.

47 ibid.

48 ibid.

Commercial Code (UCC)[49]. This provision typically states that the implied warranties of merchant ability and fitness for a particular purpose do not attach to certain blood-related activities and that, for purposes of the UCC, these activities are construed to be the provision of a service rather than a sale. But, in limiting the scope of the definition of a transfusion as a service to transactions otherwise covered by the UCC the statute fails to provide blood manufacturers with insulation from strict liability in tort claims.

The second prototype blood shield statute is one usually contained within the health section of the particular state code.[50] The provisions based in the health code are generally more favourable than a UCC-based provision in that the definition of blood-related activities as a service is given a broader scope, thus precluding strict liability claims against providers of blood products. The health code statutes also tend to give broader scope to definitions of blood-related activities, blood products and sources of blood products.[51] Furthermore, it is more likely that this kind of statute contains a pronouncement of legislative policy on the importance of maintaining an adequate supply of blood, blood products and transfusion services.[52]

A blood shield statute bars strict liability in one of three ways.[53] First, the statute may provide that the distribution of blood is a service and not the sale of a good. This variation effectively eliminates both warranty and strict liability claims because it

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49 The equivalent in the United States to the Sale of Goods Acts in each State.

50 An example of this is the California Health & Safety Code §1606 (West 1979) which provides in full: 'The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, plasma, blood products, or blood derivatives, for any purpose whatsoever.'

51 Landfield, Becker and Green, op. cit., p. 3.

52 The Illinios blood shield statute is preceded by a declaration of public policy:
§ 1. Declaration of public policy. The availability of scientific knowledge, skills and materials for the purpose of injecting, transfusing or transplanting human whole blood...is important to the health and welfare of the people of this State. The imposition of legal liability without fault upon the persons engaged in such scientific procedures inhibits the exercise of sound medical judgment and restricts the availability of important scientific knowledge, skills and materials. It is therefore the public policy of this State to promote the health and welfare of the people by limiting the legal liability arising out of such scientific procedures to instances of negligence or wilful misconduct.

53 Bennetts, op. cit., pp. 367-8.

characterises transactions in blood as services. In the US, this variation also prevents the operation of the *Restatement (Second) of Torts* section 402A, which subjects to strict liability those who sell 'any *product* in a defective condition unreasonably dangerous to the user or consumer.'

Second, the statute may expressly bar claims arising from breach of implied warranties, but remain silent as to strict liability claims. Courts interpreting this type of blood shield statute have nonetheless denied recovery to plaintiffs asserting strict liability claims.[54] Finally, the third type of statute plainly states that the distribution of blood is protected from both warranty and strict liability claims.

Currently, forty-eight states have passed blood shield legislation which insulate, to some degree, blood practitioners from legal liability. The degree to which a certain practitioner is protected is determined by (a) the scope of legal limitations in the statute and (b) the type of blood-related activity conducted by the practitioner and whether the activity and the practitioner or source are included within the statutory language.[55]

Application to blood, blood products and AIDS

The immunity given to hospitals in *Perlmutter* was later extended to blood banks and finally to blood product manufacturers. In *Klaus v Alameda-Contra Costa County Medical Association Blood Bank,*[56] the court held that immunity from strict liability must be extended to blood banks for the same policy reasons that apply to hospitals: the need to promote an adequate blood supply.[57] In *Fogo v Cutter Laboratories*[58], a wrongful death action was brought by the wife of a haemophiliac who died after using a blood clotting product which was contaminated with hepatitis. The court held that the distribution of blood products was also a service and not a 'sale', thus

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54 ibid., p. 368.

55 Landfield, Becker and Green, op. cit., p. 4. But the coverage afforded upon the states may be distinguished by five elements or characteristics:
1.The exemption provided by a statute does not apply to transactions where the donor receives compensation;
2. The statutory definition of a blood-related activity as a "service" is limited to implied warranties under the Uniform Commercial Code and thus do not preclude strict liability in tort;
3. The exemption provided by a statute does not apply to blood derivative products;
4. The exemption provided by a statute may not apply to blood fractionators;
5. The exemption provided by a statute is restricted to certain enumerated diseases.

56 62 Cal. App. 3d 417, 133 Cal. Rptr. 92 (1976).

57 Westfall, op. cit., p. 1112.

58 68 Cal. App. 3d 744, 137 Cal. Rptr. 417 (1977).

extending the exemption from strict liability to manufacturers of blood products.

In California, courts followed the hepatitis cases in rendering their decisions in AIDS cases, citing the similarities in the diseases. The plaintiffs in *Burg v Cedars-Sinai Hospital*[59] and *Kushnick v Cedars-Sinai Hospital*[60] received blood transfusions during hospitalisation and contracted AIDS. Both plaintiffs filed suit against the hospital on a strict products liability theory. In both cases, the trial court dismissed the actions.

Blood shield statutes also have uniformly been interpreted to apply to blood factor concentrates.[61] The legislatures which have enacted blood shield statutes have recognised that blood and blood components are frequently the only therapies which can save a patient's life, that the provision of blood and blood components has little in common with the manufacture and sale of ordinary consumer products, and that, therefore, blood and blood components must be treated differently from consumer goods. The California Supreme Court recently held, in barring the application of strict liability to prescription drugs generally:

> [T]here is an important distinction between prescription drugs and other products such as construction machinery a lawn mower or perfume...In the latter cases the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life.[62]

In the recent case of *Rogers v Miles Laboratories and Baxter Healthcare Corporation*,[63] the court left no doubt as to the importance it placed upon relieving blood product manufacturers from strict liability. In granting a motion brought by the defendants to dismiss the plaintiff's strict liability claims, Judge Dimmick stated:

It is apparent to this Court that, in the absence of clear legislative direction, a Washington court would have to weigh the medical and social value of producing and supplying medication such as Factor IX against the principle of common-law strict liability which favours the innocent consumer. In doing so, the Washington court would likely come down on the side of immunising vital blood components such as Factor IX.[64]

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59 No. WEC 84010 (Santa Monica Super. Ct. filed Nov. 3, 1983).
60 No. WEC 82861 (Santa Monica Super. Ct. filed Jan. 7, 1984).
61 68 Cal. App. 3d 744, 137 Cal. Rptr. 417 (1977), at 422.
62 *Brown v Superior Court* 245 Cal. Rptr. 412, 44 Cal. 3d 1049, 1063, 751 P.2d 470, 478 (1988).
63 No. C88-1441D Filed January 4 1990.
64 Order, 4 January 4 1990.

The Arguments For Strict Liability

A number of authors have suggested that strict liability exemptions in relation to blood and blood product supplies in the US should be removed, or at least modified in certain circumstances.[65] However, the Australian situation is unique, with the BTS the sole provider of blood and blood products.

Four primary public policy rationales support strict liability.[66] Firstly, as mentioned before, it relieves the plaintiff from the burden of proving a negligence claim. However, the difficulties in tracing suspected infected donations is made easier by the fact that the Society keeps records of all blood distributed to the hospitals.[67] This difficulty in proving negligence is not as prevalent in cases involving contamination from blood transfusions supplied by the blood bank. It is easier for the victim of a contaminated blood transfusion to pinpoint the source of the blood and to identify the standard of care.[68]

A related policy consideration is that of confidentiality of the donor: the concern that the chance that an infected donor's identity may be revealed in a negligence claim may dissuade donors from giving blood, thus penalising voluntary donations.[69] The opposite argument is that fear of disclosure would result in a safer blood supply by discouraging high-risk donors from donating blood.[70] Strict liability, it is argued, would eliminate the need to obtain the donor's identity by only requiring that the plaintiff show that the blood was unreasonably defective when it left the supplier.[71]

Another argument in favour of strict liability is that it provides an incentive to improve safety. It is argued that blood manufacturers

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65 Strict liability should apply only in situations where tests for detecting infectious diseases are available for use by the blood industry. Absent an available detection test, blood banks would be immune from strict liability: Bennetts, op. cit., p. 379. Suppliers of transfusible blood, such as hospitals and blood banks, should continue to be exempt from strict products liability. But immunity should not extend to manufacturers of blood products: Westfall, op. cit., pp. 1101-1102.

66 Westfall, op. cit., p. 1124.

67 Each State and Territory Blood Transfusion Division has a 'Look-back' program designed to discover recipients who may have been transfused with infected blood, and to trace donors who may have unwittingly donated infected blood. In relation to blood products such as clotting factors, each is contained in small bottles which records the batch number from which it was manufactured. The Society keeps records of the batch numbers dispensed to the hospitals. CSL have records of the donation numbers of the plasma which went into each batch. When the hospitals dispense the product to a patient they record the batch number, units given, date and treatment.

68 Westfall, op. cit., p. 1125.

69 Bennetts, op. cit., p. 374.

70 ibid.

71 Bennetts, op. cit., p. 371.

need policing so that they utilise available detection tests and continue to improve the production of blood products so as to ensure their safety.[72] But this argument must be seen from the context in which it is made: in the United States, the majority of blood banks are for-profit organisations, who collect their blood from paid donors. In Australia, the Society is the sole collector of blood from only voluntary donations. Further, it is a non-profit organisation. Also, the Society is bound to use available testing procedure, at least in respect of AIDS, if it wants to limit it's civil and criminal liability. Therefore, this safety incentive policy is less relevant to the Society in Australia.

Another policy underlying strict products liability, risk-spreading, is based on the premise that it is fairer to place the cost of injury with the product manufacturer, than on the victim, who can absorb and spread the cost by increasing the price of the product.[73] But this is not a relevant consideration in Australia where blood is provided at no charge by the Society to hospitals.

Those in support of strict liability also argue that the price of a product should reflect its cost to society: under resource allocation, if two products can substitute for one another to some significant extent, and the price of the more dangerous product reflects its attendant risk factor, consumers will have a more accurate comparison when choosing which product to buy.[74] This is relevant in the context of blood products, where cryoprecipitate and freeze-dried concentrate are significant substitutes for one another in treating haemophilia. But a decision on which product to use is not made just upon cost: convenience of use is also a major consideration.[75] However, this theory is not applicable to transfusions, because there is no substitute for blood.[76]

Conclusion

Australia should follow the example of the US in exempting blood and blood product manufacturers from strict liability product claims. This can be done by either an express exclusion of blood products in a definition of 'goods', or by legislatures enacting blood statutes similar to those in the US defining the provision of these products as a service and not trade. This is the only logical: the Society does not place it's products into the general stream of commerce. They supply it directly to hospitals for use in the professional service of treating patients.

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72 ibid., p. 372.
73 Westfall, op. cit., p. 1127.
74 ibid., p. 1126.
75 Concentrate can be administered at home; cryoprecipitate requires a visit to hospital.
76 Westfall, op. cit., p. 1127.

In *Hyland Therapeutics v Superior Court,*[77] another case involving factor concentrates, the California Court of Appeals concluded:

> there is a legitimate state interest in manufactured blood products 'legislatures have determined that the production and use of human blood and its derivatives for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability' [t]o require that those who make tort claims on the basis of alleged blood-product defects bear the burden of showing that the blood-product manufacturer was either negligently or intentionally at fault [is a] relatively modest restriction upon the theories available to the plaintiffs such as these [and] is rationally related to a legitimate state purpose.

Wilcox J also recognised the wider policy considerations that needed to be considered when deciding the liability of the Society:

> to take into account the effect upon the blood supply is to say that a person in the position of the first and second respondents was entitled to give priority to the interests of all blood users - and everyone in the community is a potential blood user - over the interests of the relatively small number of individuals who might receive infected blood. To say so is to make the present applicant bear the burden of protecting the wider public interest.[78]

Exempting the Society from strict product liability under the proposed new Part will foster the whole country's interest in ensuring an adequate blood supply.

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77 220 Cal. Rptr. 590, 175 Cal. App. 3d 509 (1985).

78 *"E" v Australian Red Cross Society & Ors* (1991) ATPR ¶41-085 at 52,383.