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NOTE

BLOOD BANK AND BLOOD PRODUCTS MANUFACTURER LIABILITY IN TRANSFUSION-RELATED AIDS CASES

AIDS forces us to confront our mortality, the limits of modern medicine, and the contours of our compassion. How we respond is a measure of our society and a reflection of our values and priorities.¹

Can a blood bank or a blood products manufacturer be held liable if a patient contracts AIDS through a transfusion of blood or a blood product? And, if so, should the bank or manufacturer be held liable? As of February 1989, approximately 200 cases touching on this issue were pending in the United States.²

Since the first cases of what has become known as Acquired Immune Deficiency Syndrome (AIDS) were diagnosed in 1981,³ the disease has spread in epidemic proportions and has rapidly become the nation's "primary health concern."⁴ As recently as 1984, it was believed that AIDS victims fell into one of four "at risk" categories — homosexual males (71%), intravenous drug users (17%), Haitian immigrants (5%), and hemophiliacs (1%).⁵ Since then a fifth category of victims, comprised of

1. George J. Annas, *Faith (Healing), Hope and Charity at the FDA: The Politics of AIDS Drug Trials*, 34 VILL. L. REV. 771, 771 (1989).

2. Virginia Cope, *Trends: Blood Bank Held Negligent in AIDS Case*, TRIAL, Feb. 1989, at 96.

3. CDC Update: *Acquired Immunodeficiency Syndrome — United States*, 34 MORBIDITY & MORTALITY WEEKLY REPORT 245, 248 (1985).

4. See Robert C. Greif, Comment, *Hospital and Blood Bank Liability to Patients who Contract AIDS Through Blood Transfusions*, 23 SAN DIEGO L. REV. 875, 875-76 (1986).

5. CDC Update: *Acquired Immunodeficiency Syndrome (AIDS) — United States*, 32 MORBIDITY & MORTALITY WEEKLY REPORT 688, 689 (1984).

individuals who have contracted AIDS⁶ through transfusions of blood and blood products,⁷ has emerged.

For this last category of AIDS victims, the road to legal recovery is a difficult one. Transfusion-related AIDS victims usually advance three theories of liability: strict products liability, breach of implied warranty and negligence. Each of these theories presents substantial obstacles for plaintiffs. These obstacles often result from the public policy choices made by the state legislatures, which have decided to insulate blood banks and blood products manufacturers by statute from sales-based liability.⁸ This Note explores the three theories of liability and the public policies surrounding them that, more often than not, make these unfortunate AIDS victims two-time losers.

I. AN AIDS CHRONOLOGY

Before exploring the theories of liability, it is useful to establish a chronology of knowledge about AIDS in the medical and scientific communities and, perhaps more importantly, highlight when these discoveries were made.

In the early 1980's, the scientific community identified intravenous drug users, and to a much lesser degree hemophiliacs, as groups at risk for AIDS. This prompted researchers to suspect that AIDS might be transmitted through the blood.⁹ In December 1982, the Centers for Disease Control reported the diagnosis of an infant who had contracted AIDS after receiving a transfusion of blood platelets, and subsequently blood transfusions became the focus of the medical community's battle against AIDS.¹⁰

As of January 4, 1983, there were five reported cases of AIDS infection among hemophiliacs, one possible blood transfusion-related case, and five other cases related to blood products. This data prompted the Workgroup to Identify Opportunities for the Prevention of AIDS to agree that mem-

6. There are three stages of HIV infection: (1) seropositivity, meaning that a person tests positive for the presence of antibodies to the virus and is capable of transmitting the virus and is vulnerable to developing AIDS, but remains asymptomatic and appears totally healthy; (2) AIDS-related complex (ARC), a lesser form of AIDS which is infectious but not life threatening; and (3) AIDS, which is always fatal. *Howell v. Spokane & Inland Empire Blood Bank*, 818 P.2d 1056, 1057 n.2 (Wash. 1991) (citing Sharon L. Dieringer, Comment, *Blood Donation: A Gift of Life or a Death Sentence?* 22 AKRON L. REV. 623, 626-27 (1989)).

7. For the purposes of this Note, the term "blood products" includes platelets, whole blood, fresh frozen plasma, and blood coagulants.

8. See discussion *infra* part II.C.

9. Greif, *supra* note 4, at 877.

10. *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1051 (D.D.C. 1987) (citing 31 MORBIDITY & MORTALITY WEEKLY REPORT 652-54 (Dec. 10, 1982)), *modified*, 851 F.2d 437 (D.C. Cir. 1988).

bers of groups at high risk for contracting AIDS should be excluded from donating blood.¹¹ However, the Workgroup failed to reach a consensus as to the best method for screening donors.¹²

On March 4, 1983, the United States Public Health Service issued recommendations for blood donor screening; a few weeks later the Food and Drug Administration also issued recommendations.¹³ The primary focus of the recommendations issued by both organizations was on the distribution of informational pamphlets to potential donors in an effort to discourage high risk groups from donating blood. Significantly, no recommendations were then made about testing donated blood for contamination.¹⁴

In the Spring of 1984, it was discovered that a retrovirus, known as HTLV-III/LAV, was the probable cause of AIDS.¹⁵ This breakthrough finally created agreement among the medical and scientific communities that the disease could be spread by blood and blood products. On February 19, 1985, the Food and Drug Administration (FDA) issued a recommendation that all blood facilities voluntarily begin testing blood for AIDS as soon as testing supplies became commercially available.¹⁶ By May 1985, an "enzyme-linked immunosorbent assay (ELISA) test . . . which screens for antibodies sensitive to HTLV-III" became commercially available.¹⁷ The FDA licensed the test on March 2, 1985.¹⁸ The ELISA test has proven 98.6% effective in detecting exposure to AIDS, and when coupled with a second test, the Western Blot Analysis, the rate of detection rises to 100%.¹⁹ This medical and scientific chronology pro-

11. *Id.* at 1051-52. The Workgroup was composed of representatives from several organizations, including: the American Red Cross, the Centers for Disease Control, the National Institutes of Health, the Food and Drug Administration, the American Association of Blood Bankers, the National Gay Task Force, and other blood banking and public health organizations. *Id.* at 1051.

12. *Id.* at 1052. The report summarizing the meeting noted that the "participants had 'differing perceptions' regarding not only the risk of AIDS from blood donation but also 'the best approach for establishing altered guidelines for blood donation donor screening or testing and donor restriction.'" *Snyder v. Mekhjian*, 582 A.2d 307, 311 (N.J. Super. Ct. App. Div. 1990), *aff'd*, 593 A.2d 318 (N.J. 1991).

13. *Kozup*, 663 F. Supp. at 1052.

14. *Id.*

15. *Id.* (citations omitted); Greif, *supra* note 4, at 879. This retrovirus is more commonly referred to as the Human Immunodeficiency Virus (HIV). For the purposes of this Note, it will be referred to as the HIV virus.

16. *Kirkendall v. Harbor Ins. Co.*, 887 F.2d 857, 860 (8th Cir. 1989).

17. *Kozup*, 663 F. Supp. at 1052 (citation omitted).

18. 50 Fed. Reg. 9909 (1985). The date of March 2, 1985 is very important for the purpose of the ensuing litigation involving blood banks and blood products suppliers, especially on the issue of the applicable standard of care in negligence cases. See discussion *infra* part IV.

19. 663 F. Supp. at 1052-53 (citations omitted). In fact, because of the possibility of false-positive results using the ELISA test, positive ELISA results must be confirmed by Western Blot analysis or by an immunofluorescence assay (IFA). *AIDS: The Legal Issues*, Discussion

vides the background against which the courts have examined the following theories of liability.

II. STRICT LIABILITY IN TORT UNDER SECTION 402A OF THE RESTATEMENT

A. *The Sale versus Service Analysis*

Transfusion-related AIDS victims often seek to impose liability under the theory of strict liability in tort for the sale of an unreasonably dangerous product.²⁰ Section 402A of the *Restatement (Second) of Torts* sets out the general applicability of this common law doctrine.²¹ Significantly, strict liability under Section 402A applies only where there has been a sale of a product and is specifically inapplicable to the provision of services. In cases involving infection through blood or blood products, then, the threshold issue is whether the provision of blood or blood products is considered "a sale of a product" for the purposes of the strict liability doctrine.²²

Almost unanimously, courts have held that when a *hospital* provides blood or blood products to a paying patient as an incident to hospital treatment, the provision is a service rather than a sale. *Perlmutter v. Beth David Hospital*²³ is the leading case dealing with this issue.²⁴ In *Perlmutter*, a patient brought an action against the treating hospital for injuries he sustained after receiving a blood transfusion contaminated

Draft of the American Bar Association AIDS Coordinating Committee 83 (1988). "These tests are more expensive and time-consuming than the ELISA test, but are more specific for HIV." *Id.* (citations omitted).

20. Strict products liability is not an alternative in Delaware, Massachusetts, Michigan, North Carolina, Virginia, or the District of Columbia, because the doctrine has not been adopted either judicially or by statute in those jurisdictions. See 2 AMERICAN LAW OF PRODUCTS LIABILITY §§ 16:8-16:27 (3d ed. 1987).

21. Section 402A states:

(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) The rule stated in subsection (1) 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).

22. This is also the critical analysis when seeking to impose liability under the theory of breach of implied warranty. See discussion *infra* part III.

23. 123 N.E.2d 792 (N.Y. 1954), *reh'g denied*, 125 N.E.2d 869 (N.Y. 1955).

24. See *infra* note 29 and accompanying text.

with hepatitis and jaundice.²⁵ The plaintiff alleged that a "sale" of the blood had taken place within the meaning of the New York Sales Act (as then in force).²⁶ He alleged that as a consequence an implied warranty of merchantability had attached to the sale, which was breached by the hospital when it provided him with contaminated blood.²⁷

Rejecting the plaintiff's argument, the court in *Perlmutter* reasoned that because a hospital is devoted to the care and healing of the sick, the predominant purpose of the contract between a hospital and its patients is the provision of services. The court held that this purpose predominates regardless of whether the patient is charged separately for "healing materials":

That the property or title to certain items of medical material may be transferred, so to speak, from the hospital to the patient during the course of medical treatment does not serve to make each such transaction a sale. . . . It has long been recognized that, when service predominates, and transfer of personal property is but an incidental feature of the transaction, the transaction is not deemed a sale. . . .²⁸

Nearly every state court that has confronted this issue has followed *Perlmutter*, at least with respect to actions against hospitals in blood contamination cases.²⁹

Although the blood-borne disease at issue in *Perlmutter* was hepatitis, the court's analysis should apply with equal force to AIDS cases. As one commentator has noted, significant similarities exist between AIDS and serum hepatitis: both are blood-borne, both were initially of unknown origin, and both were originally thought to be undetectable in blood.³⁰ In fact, just as "[c]ourts denying recovery for transfusion transmitted hepatitis have premised their decisions upon the fact that in each case at the time of transfusion hepatitis was undetectable," many of the courts deny-

25. *Perlmutter*, 123 N.E.2d at 793.

26. N.Y. PERS. PROP. LAW § 96 (Consol. 1941) (repealed 1962) (now codified at N.Y. U.C.C. LAW § 2-317 (Consol. 1981)).

27. *Perlmutter*, 123 N.E.2d at 793.

28. *Id.* at 794 (citations omitted). Most courts follow this "predominant purpose" test in analyzing the distinction between services and sales of goods. See generally 1 BARRY L. ZARETSKY ET AL., COMMERCIAL LAW & PRACTICE GUIDE ¶ 3.02[1][d][iii] (1991).

29. *Roberts v. Suburban Hosp. Ass'n*, 532 A.2d 1081, 1087 (Md. Ct. Spec. App. 1987). See generally, *St. Luke's Hosp. v. Schmaltz*, 534 P.2d 781 (Colo. 1975); *Fisher v. Sibley Memorial Hosp.*, 403 A.2d 1130 (D.C. 1979); *White v. Sarasota County Pub. Hosp. Bd.*, 206 So. 2d 19 (Fla. Dist. Ct. App.), cert. denied, 211 So. 2d 215 (Fla. 1968); *Holder v. Sayet*, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967); *Lovett v. Emory Univ., Inc.*, 156 S.E.2d 923 (Ga. Ct. App. 1967); *Weber v. Charity Hosp.*, 487 So. 2d 148 (La. Ct. App. 1986); *Diblee v. Dr. W.H. Groves Latter-Day Saints Hosp.*, 364 P.2d 1085 (Utah 1961); *Foster v. Memorial Hosp. Ass'n*, 219 S.E.2d 916 (W. Va. 1975); *Koenig v. Milwaukee Blood Ctr., Inc.*, 127 N.W.2d 50 (Wis. 1964).

30. Greif, *supra* note 4, at 881.

ing recovery for transfusion-related HIV have likewise done so because, at the time of the transfusion the HIV virus was similarly undetectable in blood.³¹

B. Blood Shield Statutes — An Absolute Defense to Sales-Based Liability?

Today most courts do not have to venture into the "sale versus service" analysis when confronted with blood contamination cases because the issue has been preempted in large measure by state statutes. A great majority of states have enacted "blood shield statutes" which expressly characterize blood transfusions as services³² or explicitly state that blood transfusions will not be subject to strict liability.³³ These statutes, as interpreted by the courts, effectively grant hospitals, blood banks and blood

31. *Id.* at 881 n.28 (citing *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118, 120-21 (Colo. 1983); *Fogo v. Cutter Lab., Inc.*, 137 Cal. Rptr. 417, 420 (Cal. Ct. App. 1977); *Fisher v. Sibley Memorial Hosp.*, 403 A.2d 1130, 1131 (D.C. 1979)).

32. *See, e.g.*, ALA. CODE § 7-2-314(4) (1984); ALASKA STAT. § 45.02.316(e) (1986); ARIZ. REV. STAT. ANN. § 36-1151 (1986); CAL. HEALTH & SAFETY CODE § 1606 (West 1990); COLO. REV. STAT. § 13-22-104(2) (1987); CONN. GEN. STAT. ANN. § 19a-280 (West 1958); DEL. CODE ANN. tit. 6, § 2-316(5) (1974); FLA. STAT. ANN. § 672.316(5), (6) (West Supp. 1992); GA. CODE ANN. § 51-1-28 (Michie 1982); IDAHO CODE § 39-3702 (1985 & Supp. 1991); ILL. ANN. STAT. ch. 111 ½, para. 5102 (Smith-Hurd 1988); IND. CODE ANN. § 16-8-7-2(a) (Burns 1990); KAN. STAT. ANN. § 65-3701 (1985); KY. REV. STAT. ANN. § 139.125 (Michie/Bobbs-Merrill Repl. Vol. 1991); LA. REV. STAT. ANN. § 9:2797 (West 1991), LA. CIV. CODE ANN. at 2322.1 (West Supp. 1992); ME. REV. STAT. ANN. tit. 11, § 2-108 (West Supp. 1991); MD. HEALTH-GEN. CODE ANN. § 18-402 (West Supp. 1991); MASS. GEN. LAWS ANN. ch. 106, § 2-316(5) (Law Co-op 1984 & Cum. Supp.); MICH. COMP. LAWS ANN. § 333.9121(2) (West 1980 & Supp. 1991); MISS. CODE ANN. § 41-41-1 (Law Co-op. 1972 & Cum. Supp. 1991); MO. ANN. STAT. § 431.069 (Vernon 1992); MONT. CODE ANN. § 50-33-102 (1991); NEB. REV. STAT. § 71-4001 (1990); NEV. REV. STAT. § 460.010(2) (Repl. Vol. 1991); OHIO REV. CODE ANN. § 2108.11 (Anderson Repl. Vol. 1990 & Supp. 1991); OR. REV. STAT. § 97.300(1) (Repl. Vol. 1990); S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1985); S.D. CODIFIED LAWS ANN. § 57A-2-315.1 (Rev. 1988); TENN. CODE ANN. § 47-2-316(5) (Repl. Vol. 1979); UTAH CODE ANN. § 26-31-1 (Repl. Vol. 1989); VA. CODE ANN. § 31.1-297 (Michie 1985); WASH. REV. CODE ANN. § 70.54.120 (West 1975 & Cum. Supp. 1991); WIS. STAT. ANN. § 146.31(2) (West 1989); WYO. STAT. § 34.1-2-316(c)(iv) (1991).

33. *See* ARIZ. REV. STAT. ANN. § 32-1481 (1986); ARK. CODE ANN. § 20-9-802 (Michie Repl. Vol. 1991); COLO. REV. STAT. § 13-22-104(2) (1987); GA. CODE ANN. § 51-1-28 (Michie 1982); HAW. REV. STAT. § 327-51 (Repl. Vol. 1985); IDAHO CODE § 39-3702 (1985); ILL. ANN. STAT. ch. 111 ½, para. 5102 (Smith-Hurd 1985); IND. CODE ANN. § 16-8-7-2(a) (Burns Repl. Vol. 1990); KAN. STAT. ANN. § 65-3701 (1985); LA. REV. STAT. ANN. § 9:2797 (West 1991); LA. CIV. CODE ANN. art. 2322.1 (West Supp. 1992); MD. HEALTH-GEN. CODE ANN. § 18-402(1) (Repl. Vol. 1990); MICH. COMP. LAWS ANN. § 333.9121(3) (West 1980 & Supp. 1991); MO. ANN. STAT. § 431.069 (Vernon 1992); MONT. CODE ANN. § 50-33-103 to -104 (1991); NEV. REV. STAT. § 460.010(2) (Repl. Vol. 1991); N.H. REV. STAT. ANN. § 507:8-b (Repl. Vol. 1983); N.M. STAT. ANN. § 24-10-5 (Michie Repl. Vol. 1991); N.D. CENT. CODE § 43-17-40 (Repl. Vol. 1978); PA. STAT. ANN. tit. 42, § 8333(a) (1982); TEX. CIV. PRAC. & REM. CODE ANN. § 77.003(a) (West 1986); WASH. REV. CODE ANN. § 70.54.120 (West 1975 & Cum. Supp. 1992); WIS. STAT. ANN. § 146.31(2) (West 1989).

products manufacturers absolute immunity from sales-based liability,³⁴ including strict liability.³⁵

*Samson v. Greenville Hospital System*³⁶ illustrates the effect of these statutes. Helen Samson contracted AIDS through a blood transfusion she received while a patient in a hospital operated by the Greenville Hospital System in South Carolina. She brought a strict liability action in federal district court against both the hospital and the blood supplier, the Carolina-Georgia Blood Center.³⁷ The district court certified to the Supreme Court of South Carolina the question of whether blood is a product for purposes of the strict liability doctrine in light of South Carolina's blood shield statute.³⁸ The supreme court held that the language of the blood shield statute "clearly indicates that the Legislature did not intend for blood to be classified as a product. Furthermore, this construction is consistent with the underlying purpose of the blood shield statute, namely, to facilitate a readily available supply of blood by limiting liability to defects resulting from negligence."³⁹

Despite decisions like *Samson*, it is important to examine carefully the wording of each state's blood shield statute. Some blood shield statutes were expressly enacted to address only the threat of serum hepatitis,⁴⁰ and it was not until after it was discovered that the HIV virus was transmittable through the blood that legislatures amended these statutes to deal with potential AIDS liability. Courts have held that these amendments are not to be applied retroactively.⁴¹ Consequently, plaintiffs who

34. Negligence, however, still is a viable theory of recovery for transfusion-related AIDS victims. See discussion *infra* part IV.

35. Greif, *supra* note 4, at 883.

36. 377 S.E.2d 311 (S.C. 1989).

37. *Id.* at 311.

38. *Id.* The statute provides:

The implied warranties of merchantability and fitness shall not be applicable to a contract for the sale, procurement, processing, distribution or use of human tissues such as corneas, bones or organs, *whole blood, plasma, blood products or blood derivatives*. Such human tissues, whole blood, plasma, blood products or blood derivatives *shall not be considered commodities subject to sale or barter* and the transplanting, injection, transfusion or other transfer of such substances into the human body *shall be considered a medical service*.

S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1985) (emphasis added).

39. *Samson*, 377 S.E.2d at 312; see also *Rogers v. Miles Lab., Inc.*, 802 P.2d 1346 (Wash. 1991) (common law doctrine of strict liability inapplicable to blood and blood products).

40. See *infra* notes 41-48 and accompanying text.

41. See, e.g., *Doe v. Miles Lab., Inc.*, 675 F. Supp. 1466 (D. Md. 1987) (discussing Md. HEALTH-GEN. CODE ANN. § 18-402); *Hansen v. Mercy Hosp.*, 570 P.2d 1309 (Colo. 1977) (discussing COLO. REV. STAT. § 13-22-104), *aff'd-sub nom.* *Belle Bonfils Memorial Blood Bank v. Hansen*, 579 P.2d 1158 (Colo. 1978); *Roberts v. Suburban Hosp. Ass'n, Inc.*, 532 A.2d 1081 (Md. Ct. Spec. App. 1987) (discussing Md. HEALTH-GEN. CODE ANN. § 18-402); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815 (Wash. 1990) (discussing WASH. REV.

received contaminated transfusions before the amendments are not barred by the blood shield statutes from bringing strict liability actions.

For example, in *Doe v. Miles Laboratories, Inc.*,⁴² the plaintiff contracted AIDS-related complex (ARC)⁴³ from a transfusion of Konyne, a blood-coagulation-factor concentrate she received in 1983 for childbirth complications.⁴⁴ The plaintiff sued the manufacturer under the theories of strict liability in tort and breach of implied warranty; she later amended her complaint to add a negligence count.⁴⁵ The defendant argued that Maryland's blood shield statute (as then in force) exempted blood and blood products from strict products liability.⁴⁶ However, noting that the statute was not amended to deal with potential AIDS liability until 1986, the court interpreted the statute as shielding blood providers only in cases of injuries from the serum hepatitis virus.⁴⁷ Accordingly, the court found that "there was no legislative intent to shield manufacturers of blood and blood products from strict liability [for AIDS transmission cases] until the 1986 amendments."⁴⁸

C. A Matter of Public Policy — Do Blood Banks and Blood Products Manufacturers Deserve the Same Protection as Hospitals?

Even if no statutory bar to strict liability exists, the common law may nonetheless bar a plaintiff's recovery by dictating that blood banks and blood products manufacturers provide a service rather than sell a product. Some courts have followed *Perlmutter v. Beth David Hospital*,⁴⁹ holding that blood banks and blood products manufacturers, like hospi-

CODE ANN. § 70.54.120); cf. *Cutler v. Graduate Hosp.*, 717 F. Supp. 338, 340 (E.D. Pa. 1989) (discussing PA. STAT. ANN. tit. 42 § 8333).

42. 675 F. Supp. 1466 (D. Md. 1987), *aff'd*, 927 F.2d 187 (4th Cir. 1991).

43. See *supra* note 6.

44. *Doe*, 675 F. Supp. at 1468.

45. *Id.*

46. *Id.* at 1475. At the time of the suit, Maryland's blood shield statute provided:

A person who obtains, processes, stores, distributes, or uses whole blood or any substance derived from blood for injection or transfusion into an individual for any purpose may not be held liable for the virus of serum hepatitis under:

- (1) Strict liability in tort;
- (2) The implied warranty of merchantability; or
- (3) The implied warranty of fitness.

MD. HEALTH-GEN. CODE ANN. § 18-402 (Repl. Vol. 1990). Since then, the statute has been amended with few significant changes and recodified at section 5-373 in the Courts and Judicial Proceedings of the state's code. MD. CTS. & JUD. PRAC. § 5-373 (Cum. Supp. 1991).

47. *Doe*, 675 F. Supp. at 1476.

48. *Id.* at 1477.

49. See *supra* notes 23-29 and accompanying text.

tals, are service providers and that therefore no sale takes place for the purposes of the strict liability doctrine.⁵⁰

*Howell v. Spokane & Inland Empire Blood Bank*⁵¹ is an example of such a decision. The plaintiff tested positive for the HIV virus after receiving a transfusion of blood supplied by the Spokane & Inland Empire Blood Bank on October 8, 1984.⁵² Although the court determined that the 1985 amendment including AIDS within the scope of Washington's blood shield statute did not apply retroactively,⁵³ it nevertheless denied recovery. The public policy reasons advanced by the court for classifying the transaction as a service, and for refusing to extend the doctrine of strict liability to the provision of blood and blood products by entities other than hospitals, are typical. The court stated:

The purposes of strict liability are not furthered when applied to blood and blood products. . . . First, the societal need to ensure an affordable, adequate blood supply furnishes a persuasive reason for distinguishing between victims of defective blood and victims of other defective products. Second, strict liability cannot provide an incentive to promote all possible accident prevention at a time when there was no possible means of screening the blood for HIV. Third, while the producers may be in a better position to spread the costs, it is not in society's best interest to have the price of a transfusion reflect its true costs. In addition, both the blood bank and the hospital are in the distribution chain of providing blood to patients as a service. Although the blood bank does charge a fee for the blood, the blood bank is a nonprofit entity providing a service for the community.⁵⁴

It is interesting to contrast the *Howell* court's treatment of this issue with the treatment of the same issue in *Doe v. Miles Laboratories, Inc.*⁵⁵ In *Doe*, the defendant had argued that *Perlmutter* and the line of cases following it established that providing blood and blood products is a ser-

50. See, e.g., *Roberts v. Suburban Hosp. Ass'n, Inc.*, 532 A.2d 1081, 1088 (Md. Ct. Spec. App. 1987) (following the *Perlmutter* theory and declining to make a distinction between hospitals and blood suppliers); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815, 821 (Wash. 1990) (declining to draw a distinction between blood banks and hospitals). But cf., *Doe v. Miles Lab., Inc.*, 675 F. Supp. 1466, 1478 (D. Md. 1987) (common law does not create a shield for blood and blood products), *aff'd*, 927 F.2d 187 (4th Cir. 1991); *Russell v. Community Blood Bank, Inc.*, 185 So. 2d 749, 752 (Fla. Dist. Ct. App. 1966) ("We believe there is a distinction between a suit against a blood bank as opposed to a hospital. . . ."), *modified*, 196 So. 2d 115 (Fla. 1967); *Miles Lab., Inc. v. Doe*, 556 A.2d 1107, 1121-22 (Md. 1989) (holding that strict liability is not applicable in a suit against commercial supplier of blood products due to policy considerations and finding that blood has unique life-sustaining qualities).

51. 785 P.2d 815 (Wash. 1990).

52. *Id.* at 817.

53. *Id.* at 820.

54. *Id.* at 822.

55. 675 F. Supp. 1466 (D. Md. 1987), *aff'd*, 927 F.2d 187 (4th Cir. 1991); see *supra* notes 42-48 and accompanying text.

vice rather than the sale of a product,⁵⁶ therefore exempting it from strict liability. The *Doe* court disagreed, holding that *Perlmutter* and its progeny were distinguishable because in the instant case "the defendant . . . is a producer of blood or blood products and *not* a hospital."⁵⁷ The court explained:

A transaction whereby a blood bank, which is engaged in the business of collecting and distributing blood, transfers the title to the commodity to a patient for a consideration, is unquestionably a "sale." . . . Nor can it be questioned that the commodity in question — blood supplied for the purpose of a blood transfusion — is a product "intended for human consumption" quite as much as is a vaccine . . . or a food product. . . .⁵⁸

The defendant in *Doe* had also argued that comment *k* to section 402A of the *Restatement (Second) of Torts*, the "unavoidably unsafe products exemption," should apply to the sale of blood and blood products.⁵⁹ Rejecting this argument, the court stated that it was "not prepared to find that HTLV-III carrying blood presents a 'reasonable danger' as Comment *k* requires The best view is to consider blood containing undetectable [sic] diseases to be a defective product and therefore that strict liability is applicable."⁶⁰

56. *Doe*, 675 F. Supp. at 1477.

57. *Id.* at 1478 (emphasis added). The court denied the defendant's motion for summary judgment on the plaintiff's strict products liability claim because the court viewed the transaction as the sale of a product under the common law of Maryland. However, the court granted the defendant's motion for summary judgment on the plaintiff's claims for breach of warranty and failure to warn. *Id.* at 1482.

58. *Id.* at 1478 (quoting *Community Blood Bank, Inc. v. Russell*, 196 So. 2d 115, 118-19 (Fla. 1967) (Roberts, J., concurring)); see also *Hansen v. Mercy Hosp.*, 570 P.2d 1309, 1310 (Colo. Ct. App. 1977) ("The sales aspect of hospital care is only incidental to the predominating service function . . . but in the case of a blood bank the converse is true."), *aff'd sub nom. Belle Bonfils Memorial Blood Bank v. Hansen*, 579 P.2d 1158 (Colo. 1978). It should be pointed out, however, that the *Hansen* court applied the pre-AIDS amendment version of Colorado's blood shield statute, COLO. REV. STAT. § 13-22-104 (1987). See *supra* notes 31-47 and accompanying text.

59. *Doe*, 675 F. Supp. at 1479. Comment *k* to § 402A excludes from strict liability:

[P]roducts, drugs in particular, which in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. *k* (1965); see also *Miles Lab., Inc. v. Doe*, 556 A.2d 1107, 1116-20 (Md. 1989).

60. *Doe*, 675 F. Supp. at 1479. Shortly after rendering this decision, the district judge reconsidered and certified the strict liability question to the Court of Appeals of Maryland. See *Miles Lab.*, 556 A.2d at 1109. The Court of Appeals also concluded that the "preparation and supplying of Konyne . . . constituted a sale," thereby invoking the strict liability doctrine of § 402A. *Id.* at 1117; see also *Doe v. Miles Lab., Inc.*, 927 F.2d 187, 190 (4th Cir. 1991).

The *Doe* court then examined the same public policy issues the *Howell* court addressed, but with strikingly opposite results:

Those who choose to operate in the economic marketplace play by the rules applicable to all.

The arguments in favor of strict products liability apply as persuasively to blood and blood products as they do to any other product. First, there is no reason why victims of defective blood should bear the costs where victims of other defective products do not. Second, strict liability would provide the incentive to promote all possible accident prevention, for it is a rational business decision to keep costs down. Third, the producers are in a better position to spread the costs than are individual consumers. Finally, it makes for a more efficient allocation of social resources when the price of a transfusion of blood or blood products reflects its true costs.⁶¹

Examined in light of the goals of the strict liability doctrine, the *Doe* court's decision is more persuasive. The fundamental goal of strict liability is "to insure that the costs of injuries . . . are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves."⁶² The doctrine is tempered by the fact that "[s]trict tort liability principles are not applicable under comment k [to section 402A] when, at the time of distribution of such products, they contain a *then* unknown and unknowable infectious agent undetectable by any available scientific test."⁶³

Blood shield statutes were enacted to grant hospitals, blood banks and blood products manufacturers absolute immunity from sales-based liability in order to "maintain the public health and welfare, to ensure sufficient blood supplies, and to enable medical treatment and discovery to advance."⁶⁴ These statutes served a logical and necessary purpose when the HIV virus was indeed undiscoverable in blood, because "[w]ithout statutory immunity, hospitals and blood banks would face enormous expense if held liable for the costs of transfusion-related AIDS contagion, especially since detection and elimination were not medically possible. . . ."⁶⁵ However, to continue to rely on this argument to reject strict products liability claims which are based on transfusions received after

61. *Doe*, 675 F. Supp. at 1480.

62. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963).

63. *Miles Lab., Inc.*, 556 A.2d at 1121 (emphasis added). The Court of Appeals of Maryland recognized four factors that are usually considered in cases which hold that blood and blood products are not unreasonably dangerous under comment k: 1) the nonexistence of any scientific test capable of detecting the viral agent which contaminated the blood at the time of the injury; 2) the great utility of the product; 3) the lack of any substitute for the product; and 4) the relatively small risk of the disease being transmitted by the product. *Id.* at 1118.

64. Greif, *supra* note 4, at 885, (footnote omitted).

65. *Id.*

March 1985 is to ignore current scientific and medical reality.⁶⁶ Given the fact that it is now possible to detect the HIV virus in the blood with almost 100% accuracy,⁶⁷ blood and blood products cannot be considered "unavoidably unsafe products" under comment *k* to section 402A. Accordingly, an absolute statutory shield to liability is no longer appropriate.

Moreover it seems equally disingenuous to label blood products manufacturers, and to a lesser extent blood banks, "service providers" when they are undoubtedly "in the business of collecting and distributing blood"⁶⁸ for compensation. As one court commented in 1966 when deciding a transfusion-related hepatitis case, "[i]t seems to us a distortion to take what is, at least arguably, a sale, twist it into the shape of a service, and then employ this transformed material in erecting the framework of a major policy decision."⁶⁹ Continuing to provide absolute sales-based immunity for such entities runs contrary to the goals of the strict liability doctrine.

III. BREACH OF IMPLIED WARRANTY

Section 2-314 of the Uniform Commercial Code imposes liability on a seller in cases in which goods sold do not conform to certain minimum standards, provided that the seller is "a merchant with respect to goods of that kind."⁷⁰ Section 2-315 imposes liability when the goods sold are

66. See *supra* notes 15-19 and accompanying text.

67. See *supra* note 19 and accompanying text.

68. *Community Blood Bank, Inc. v. Russell*, 196 So. 2d 115, 118 (Fla. 1967) (Roberts, J., concurring).

69. *Russell v. Community Blood Bank, Inc.*, 185 So. 2d 749, 752 (Fla. Dist. Ct. App. 1966) (distinguishing between blood banks and hospitals despite authority to the contrary), *aff'd as modified*, 196 So. 2d 115 (Fla. 1967).

70. Section 2-314 states:

(1) Unless excluded or modified (Section 2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.

(2) Goods to be merchantable must be at least such as

(a) pass without objection in the trade under the contract description; and

(b) in the case of fungible goods, are of fair average quality within the description; and

(c) are fit for the ordinary purposes for which such goods are used; and

(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and

(e) are adequately contained, packaged, and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any.

(3) Unless excluded or modified (Section 2-316) other implied warranties may arise from course of dealing or usage of trade.

not fit for the particular purpose for which they are sold.⁷¹ Because sections 2-314 and 2-315 apply only to the sale of goods, it must be determined whether blood and blood products can be considered goods, subjecting the "seller" of such goods to liability under the Uniform Commercial Code in transfusion-related AIDS cases.⁷²

In drawing a distinction between services and sales of goods to determine the applicability of Article 2 of the Uniform Commercial Code, most courts apply the predominant purpose test.⁷³ "If the primary function of the contract is the rendition of services for a price, the contract is a common law contract for services. If the focus of the contract is on the end product, the contract is an Article 2 contract."⁷⁴

As previously discussed, most states have enacted blood shield statutes which specifically provide that the supply or transfusion of blood and blood products is a service and not a sale.⁷⁵ While most of these statutes effectively create an absolute bar to sales-based liability for blood banks and blood products manufacturers,⁷⁶ some states' statutes (including Virginia's) may allow recovery under the theory of breach of implied warranty when defects in the blood are detectable by established medical procedures.⁷⁷ Yet, as one commentator has pointed out, "a focus upon medical standards looks to a negligence cause of action, rather than one of implied warranty which looks to liability without fault."⁷⁸ To make matters worse, many courts have treated actions for breach of implied

U.C.C. § 2-314 (1991).

71. Section 2-315 states:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

Id. § 2-315.

72. See *supra* notes 20-31 and accompanying text.

73. See generally 1 ZARETSKY, *supra* note 27, at ¶ 3.02[1][d][ii].

74. Michael J. Herbert, *Commercial Law*, 25 U. RICH. L. REV. 681, 682 (1991).

75. See *supra* note 32.

76. See *supra* notes 32-48 and accompanying text.

77. Virginia's blood shield statute provides:

No action for implied warranty shall lie for the procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives . . . for the purpose of injecting, transfusing or transplanting any of them into the human body *except where any defects or impurities in the said whole blood, plasma, blood products, blood derivatives . . . are detectable by the use of established medical and technological procedures employed pursuant to the standards of local medical practice.*

VA. CODE ANN. § 32.1-297 (Michie 1985) (emphasis added).

78. Greif, *supra* note 4, at 888 n.62. Because no showing of fault is required, a cause of action for breach of warranty is the "next best thing" to a cause of action for strict liability in those states which have not adopted § 402A. See *infra* note 85 and accompanying text.

warranty and strict liability as one and the same,⁷⁹ and have further clouded the issue by inserting what amounts to a negligence analysis into the equation.⁸⁰

The decision in *Miles Laboratories, Inc. v. Doe*⁸¹ illustrates this confusion. The case involved actions brought on behalf of patients who contracted AIDS through blood transfusions against the suppliers of blood and blood products.⁸² Although the court held that the provision of blood and blood products constituted sales under the Uniform Commercial Code, it nonetheless held that a breach of warranty action could not be sustained:

where the claim for strict tort liability under § 402A fails under comment *k* — that when, because of an unknown and unknowable virus contained in the blood product which is undetectable [sic] by any available scientific test, the product is incapable of being made entirely safe, yet must be marketed due to the profound and essential public need for it.

. . . To otherwise hold is to fasten upon the blameless seller of a vitally essential lifesaving product a wholly unreasonable liability certain to prove antithetical to the general public interest.⁸³

The reasoning of the court in *Miles Laboratories* is flawed for one simple reason. Under the theory of breach of implied warranty, the blood supplier's negligence or fault should not enter into the liability calculus. As the Supreme Court of Florida held in *Green v. American Tobacco Co.*,⁸⁴ "a manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition is wholly irrelevant to his liability on the theory of implied warranty."⁸⁵ Under the implied war-

79. See, e.g., *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048, 1058 (D.D.C. 1987) ("[T]he current doctrines of implied warranty and strict liability in tort are but two labels for the same legal right and remedy."), *modified*, 851 F.2d 437 (D.C. Cir. 1988); *Miles Lab., Inc. v. Doe*, 556 A.2d 1107, 1123 (Md. 1989) (implied warranty claims cannot be sustained where the claim for strict tort liability fails).

80. One court wrote:

[A] plaintiff can state a cause of action against a blood bank for breach of implied warranty, but can only recover for injuries if they were caused by the failure to detect or remove a deleterious substance capable of detection or removal. Admittedly, this language goes right to the threshold of a suit for negligence, and this apparent anomaly in legal theory has been recognized before. . . . However, the practical effect of the difference between an action in negligence and one in implied warranty when dealing with a product "unavoidably unsafe" is to shift the burden of proof.

Russell v. Community Blood Bank, Inc., 185 So. 2d 749, 755 (Fla. Dist. Ct. App. 1966) (citations omitted) (hepatitis contamination case) (superseded by statute as stated in *Sicuranza v. Northwest Florida Blood Ctr., Inc.*, 582 So. 2d 54 (Fla. Dist. Ct. App. 1991)).

81. 556 A.2d 1107 (Md. 1989).

82. *Id.*

83. *Id.* at 1123-25.

84. 154 So. 2d 169 (Fla. 1963), *cert. denied*, 377 U.S. 943 (1964).

85. *Id.* at 170-71.

ranty provisions of the Uniform Commercial Code the critical inquiry is whether a sale of goods has occurred by a merchant who deals in goods of that kind.⁸⁶ Once this threshold requirement has been met, proof of a defect in the product should suffice to impose liability upon the seller.

As seen in the strict liability analysis, discussed above in Section II, absent a statutory shield expressly stating that providing blood and blood products is a service some courts have been willing to hold that blood banks and blood products manufacturers do indeed sell a product.⁸⁷ Moreover, blood banks and blood products manufacturers are unquestionably merchants dealing in "goods of the kind" (in these cases, blood and blood products).⁸⁸ With this point established, proof of a defect in the goods should be sufficient to establish liability.⁸⁹ Clearly, under any test for defectiveness, blood or blood products contaminated with the HIV virus must constitute defective products. As the court in *Roberts v. Suburban Hospital Ass'n*⁹⁰ stated, "[i]f the blood is contaminated with an infectious virus, it is just as unmerchantable and unfit and unreasonably dangerous whether the virus produces hepatitis or AIDS."⁹¹ Consequently, blood banks and blood product manufacturers who distribute goods contaminated with the HIV virus should be held liable under the theory of breach of implied warranty.

IV. NEGLIGENCE

As a result of the courts' and legislatures' reluctance to expose blood banks and blood products manufacturers to sales-based liability, a cause of action for negligence is often a plaintiff's best hope for recovery. To recover under a negligence cause of action a transfusion-related AIDS victim must prove that a standard of care existed, that the defendant's conduct fell below that standard, and that this conduct was the proximate cause of the plaintiff's injury.⁹² Plaintiffs who have contracted AIDS through transfusions of blood and blood products have alleged negligence in both blood testing and donor screening.⁹³

86. U.C.C. § 2-314 (1991).

87. See, e.g., *Doe v. Miles Lab., Inc.*, 675 F. Supp. 1466 (D. Md. 1987).

88. *Id.* at 1478 (citing *Russell v. Community Blood Bank, Inc.*, 185 So. 2d 749 (Fla. Dist. Ct. App. 1966), *aff'd as modified*, 196 So. 2d 115 (Fla. 1967)).

89. PAUL SHERMAN, *PRODUCTS LIABILITY FOR THE GENERAL PRACTITIONER* § 3.15 (McGraw-Hill 1981).

90. 532 A.2d 1081 (Md. 1987).

91. *Id.* at 1089.

92. Greif, *supra* note 4, at 889.

93. *Id.* An interesting by-product of this litigation has been a controversy over whether plaintiffs can discover information about blood donors. See, e.g., *Borzillieri v. American Nat'l Red Cross*, 139 F.R.D. 284 (W.D.N.Y. 1991); *Sampson v. American Nat'l Red Cross*, 139 F.R.D. 95 (N.D. Tex. 1991); *Stenger v. Lehigh Valley Hosp. Ctr.*, 563 A.2d 531 (Pa. Super. Ct. 1989); *Doe v. Puget Sound Blood Ctr.*, 819 P.2d 370 (Wash. 1991); Peter B.

Blood banks and blood products manufacturers are usually held to a professional standard of care, "established by looking to the conduct of the industry or profession in similar circumstances as of [the date of the injury]." ⁹⁴ In *Doe v. American Red Cross Blood Services*, ⁹⁵ the Supreme Court of South Carolina held that the transfusion of blood was a medical service and that the Red Cross, as a blood collector, should be treated as a professional. ⁹⁶ The court then applied this professional standard of care to the Red Cross, stating, "[i]n a professional negligence cause of action, the standard of care that the plaintiff must prove is that the professional failed to conform to the generally recognized and accepted practices in his profession." ⁹⁷

The cornerstone to recovery for negligence in transfusion-related AIDS cases lies in establishing what the medical and scientific communities knew about AIDS, and more importantly, when they knew it. ⁹⁸ This knowledge, or the lack thereof, determines the applicable standard of care. To quote the Court of Appeals for the Sixth Circuit, "the crucial date is not when plaintiff's decedent was diagnosed as having AIDS, but when he actually contracted the disease. . . ." ⁹⁹ In most of the reported cases the plaintiffs received their transfusions *before* the medical and scientific communities had developed a reliable method for diagnosing the HIV virus in blood and, primarily for this reason, recovery was denied. ¹⁰⁰

Kunin, Note, *Transfusion-Related AIDS Litigation: Permitting Limited Discovery from Blood Donors in Single Donor Cases*, 76 CORNELL L. REV. 927 (1991).

94. *McKee v. Miles Lab., Inc.*, 675 F. Supp. 1060, 1064 (E.D. Ky. 1987), *aff'd*, 866 F.2d 219 (6th Cir. 1989); *cf.* *Quintana v. United Blood Servs.*, 811 P.2d 424 (Colo. Ct. App.), *cert. granted*, 1991 Colo. LEXIS 350 (Colo. 1991). In *Quintana*, the court held that Colorado's blood shield statute, COLO. REV. STAT. § 13-22-104 (Repl. Vol. 1987), "affirms that general negligence standards, not product liability standards, shall apply in determining the liability of a blood bank supplying tainted blood." *Id.* at 429. The court, against the great weight of authority, was "not persuaded that the blood banking industry possesses the professional characteristics which justify this preferred position." *Id.* at 431 (emphasis in original).

95. 377 S.E.2d 323 (S.C. 1989).

96. *Id.* at 326.

97. *Id.*

98. See discussion *supra* part I.

99. *McKee v. Cutter Lab., Inc.*, 866 F.2d 219, 224 n.3 (6th Cir. 1989). Another view would be to look at the date of the blood donation as the crucial date for determining the standard of care.

100. See, e.g., *Doe v. Miles Lab., Inc.*, 927 F.2d 187 (4th Cir. 1991) (1983 transfusion); *Hoemke v. New York Blood Ctr.*, 912 F.2d 550 (2d Cir. 1990) (1981 transfusion); *McKee v. Cutter Lab., Inc.*, 866 F.2d 219 (6th Cir. 1989) (pre-1983 transfusion); *Jones v. Miles Lab., Inc.*, 887 F.2d 1576 (11th Cir. 1989) (contaminated donations made in January and February 1983); *McKee v. Miles Lab., Inc.*, 675 F. Supp. 1060 (E.D. Ky. 1987), *aff'd*, 866 F.2d 219 (6th Cir. 1989) (Fall 1983 transfusion); *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048 (D.D.C. 1987) (January 1983 transfusion), *modified*, 851 F.2d 437 (D.C. Cir. 1988).

A leading case is *Kozup v. Georgetown University*.¹⁰¹ Susan Kozup was admitted to the High Risk Obstetrical Unit of Georgetown University Hospital on December 26, 1982, when it became apparent that she would experience childbirth complications. She gave birth to a son, Matthew, on January 10, 1983. During the three days following his birth, Matthew received three blood transfusions that were later discovered to be contaminated with the HIV virus. Matthew died on July 10, 1986, from AIDS-related complications, and his parents and sister brought suit against the hospital and the American Red Cross.¹⁰²

The *Kozup* court began its analysis with a chronology of medical knowledge about AIDS, from before Matthew's birth until the discovery and marketing of the ELISA test in 1985.¹⁰³ The court then addressed plaintiffs' allegations that the American Red Cross negligently failed to: (1) screen donors who belonged to high-risk groups; (2) implement tests that would eliminate blood contaminated with AIDS; and (3) warn plaintiffs of the dangerous condition of the transfused blood.¹⁰⁴ The Kozups' primary allegation was that as of October of 1982, when the American Red Cross collected the blood that Matthew received, the organization knew or should have known that AIDS could be transmitted through blood.¹⁰⁵

The court flatly rejected this theory, noting that the earliest diagnosis of a possible transfusion-related case of AIDS occurred in December 1982, two months *after* the American Red Cross collected the contaminated blood that Matthew received.¹⁰⁶ In order for donor screening and blood testing to have prevented Matthew's infection, these measures would have had to have been implemented by October 1982. However, at that early date no organization in the country, "including blood banks, hospitals, or federal health care regulators," recommended donor screening or blood testing.¹⁰⁷ In light of this evidence, the court held that the Red Cross had not fallen below the then-applicable standard of care.¹⁰⁸

101. *Kozup*, 663 F. Supp. 1048.

102. *Id.* at 1050.

103. *Id.* at 1051-53.

104. *Id.* at 1055-56.

105. *Id.* at 1056.

106. *Id.* (emphasis added).

107. *Id.*

108. *Id.*; accord *Doe v. Miles Lab., Inc.*, 927 F.2d 187, 195 (4th Cir. 1991) (defendants complied with the standard of care as it existed in September 1983); *Valdiviez v. United States*, 884 F.2d 196, 199 (5th Cir. 1989) (self-screening of donors not negligent in 1984, as this was the method then recommended by the Centers for Disease Control); *Knight v. Department of the Army*, 757 F. Supp. 790, 794 (W.D. Tex. 1991) (expert's testimony that transmission of AIDS through blood a "theoretic problem" in 1984, therefore no duty to warn).

One recent case has hinted at what might be an appropriate standard of care after 1985, at least with regard to self-screening methods for donors. In *Crandall v. Southwest Florida Blood Bank, Inc.*,¹⁰⁹ the plaintiff's husband allegedly received a contaminated transfusion in April 1987, and died of AIDS-related complications in January 1988.¹¹⁰ Reversing the circuit court's grant of summary judgment in favor of the blood bank on the issue of negligent donor screening, the district court of appeals held that a genuine issue of material fact existed as to whether the donor questionnaire should have inquired of the donors whether they had a recent medical history of the following symptoms: "fever, skin eruption, aching joints and muscles, weakness, lymph gland enlargement, sore throat, gastrointestinal symptoms, headache, or sensitivity to light."¹¹¹

The HIV virus was identified as the cause of AIDS in the spring of 1984,¹¹² and the Food and Drug Administration licensed the ELISA test to diagnose the virus in blood on March 2, 1985.¹¹³ Because of the lack of medical and scientific knowledge about AIDS and the absence of an accurate diagnostic test prior to 1985, it remains practically impossible for plaintiffs who received contaminated transfusions before 1985 to establish that the then-applicable standard of care was breached by a failure to test donated blood. However, the licensing and commercial availability of the ELISA test in early 1985, in conjunction with the FDA's recommendation that same year that donated blood be screened for the HIV virus, should establish a medical standard of care on which to base negligence actions for subsequent transfusions.¹¹⁴ As the Eighth Circuit Court of Appeals has stated, "we believe that the FDA's recommendation of February 19, 1985, that blood facilities begin testing all donated blood as soon as testing supplies became commercially available imposed a duty on [the blood bank] to test all its blood supplies for antibodies to the AIDS virus."¹¹⁵ Interestingly, in the unreported case *Osborn v. Irwin Memorial Blood Bank*,¹¹⁶ a jury found a blood bank negligent for not screening a blood transfusion given to a patient in February, 1983.¹¹⁷ Nevertheless,

109. 581 So. 2d 593 (Fla. Dist. Ct. App. 1991).

110. *Id.* at 594.

111. *Id.* at 595. It should be noted that an expert witness for the plaintiff suggested that these procedures be used in conjunction with the testing of the donated blood, a procedure which was already conducted by the blood bank. *Id.*

112. See *supra* note 15 and accompanying text.

113. 50 Fed. Reg. 9909 (1985).

114. Greif, *supra* note 4, at 891.

115. *Kirkendall v. Harbor Ins. Co.*, 887 F.2d 857, 861 (8th Cir. 1989).

116. No. 88-891642 (San Francisco Super. Ct. Dec. 1, 1988) (discussed in Cope, *supra* note 2).

117. *Id.* Another court held that the fact that a screening test for AIDS was not available until 1985 did not foreclose a claim of negligence for a 1984 transfusion and that plaintiff was entitled to discovery on the issue of screening procedures. *Doe v. University Hosp.*, 561 N.Y.S.2d 326, 328 (1990).

because of the state of medical and scientific knowledge in 1983, it seems far more likely that the Spring of 1985 will prove to be the crucial date for plaintiffs seeking to recover in negligence for AIDS-contaminated transfusions.¹¹⁸ Only after that date can it conclusively be established that a failure to test donated blood for the HIV virus constitutes negligence.

V. CONCLUSION

Transfusion-related AIDS victims usually assert three theories for recovery against blood banks and blood products manufacturers — strict liability in tort for the sale of an unreasonably dangerous product, breach of implied warranty, and negligence. However, the blood shield statutes enacted by most states make it difficult, if not impossible, for plaintiffs to recover under the strict liability and breach of warranty theories. These statutes, passed or amended to deal with AIDS liability at a time when the HIV virus was undetectable in blood, continue to insulate blood banks and blood products manufacturers from sales-based liability. This protection persists in spite of the fact that since at least 1985 the HIV virus has been nearly 100% detectable in blood.

Although absolute protection for these entities may have been logical or desirable when the HIV virus was undetectable in the blood, the better view based on current medical and scientific knowledge would be to allow post-1985 recipients of contaminated transfusions to recover under the theories of strict liability and breach of implied warranty. This would place the burden on the blood banks and blood products manufacturers to ensure the safety of the products they distribute. Moreover, courts and legislatures should distinguish between hospitals, blood banks, and blood products manufacturers. Blood banks, and especially blood products manufacturers, are active players in the economic marketplace, selling goods rather than providing services.

Unless this change of attitude takes place, the only cause of action that is not effectively preempted for transfusion-related AIDS victims is one sounding in negligence. For pre-1985 transfusion recipients, it has proved difficult to establish a breach of the then-applicable standard of care. But, for those plaintiffs who received transfusions after 1985, recovery should be facilitated by the imposition of stricter standards for donor screening and blood testing.

Dana J. Finberg

118. One court found May 1985 to be the crucial date. *Valdiviez v. United States*, 884 F.2d 196, 198 (5th Cir. 1989).

