Health Law

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HEALTH LAW

I. BLOOD SUPPLIERS' LIABILITY FOR AIDS CONTAMINATED BLOOD

In less than a decade, the medical phenomenon of acquired immune deficiency syndrome (AIDS) has developed from an obscure disease into a national epidemic. As with most developing crises, AIDS has raised unique legal issues, especially in relation to hospital or blood bank liability for supplying AIDS infected blood. This survey analyzes the developing South Carolina law in the area of liability for AIDS contaminated blood products.

A. Background

The issue of blood bank liability for "defective" blood is not new to the legal profession. Throughout the 1960s and 1970s blood banks faced the prospect of liability for blood contaminated by the serum hepatitis virus. With AIDS infected blood, however, blood banks face a significantly greater risk of liability. Unlike the 5 to 10 percent fatal-

4. Blood products include platelets, plasma, and packed cells.
5. For a general discussion as well as a research guide to articles addressing this topic, see Comment, Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform, 24 AM. U.L. REV. 367, 368 n.7 (1975) (listing over 45 articles on the subject).
ity rate of serum hepatitis, AIDS almost certainly ends in death. Furthermore, as a result of the AIDS crisis, blood suppliers contend they can no longer obtain insurance to cover liability for contaminated blood.

Additionally, the sheer number of AIDS infected blood cases makes the potential liability overwhelming. Although most early AIDS victims were homosexual men, at least three hemophiliacs had contracted AIDS by 1982, and "[b]y late 1983 twenty-seven cases of AIDS in hemophiliacs had been reported." While the initial number of reported cases seems insignificant, the Centers for Disease Control estimate that by 1984, 12,000 individuals in the United States had been exposed to AIDS from blood transfusions, and by 1988 at least 10 percent of these had developed AIDS. Accordingly, this exponential growth of the number of AIDS infected blood cases creates a dilemma for every court facing the prospect of holding blood banks liable for contaminated transfusions.

The policy of compensating innocent victims requires that injured parties and their families receive compensation for the lethal disease contracted as a direct result of the transfusion. The need for insuring an adequate supply of blood, however, dictates that blood banks be insulated from absolute liability. As a result, courts generally have denied recovery under a no-fault theory of liability, but have allowed recovery under a negligence theory.

B. Theories of Liability

1. Liability Without Fault

Since the first infected blood case, Perlmutter v. Beth David Hos- pital, plaintiffs have attempted to recover under a no-fault theory of liability. Following Perlmutter, most courts have rejected claims of


8. Curran & Morgan, supra note 1, at XXI-II.


breach of implied warranty\textsuperscript{12} and strict liability.\textsuperscript{13} In addition to this common law tradition, almost all state legislatures have adopted "blood shield statutes" to protect blood suppliers from no-fault liability.\textsuperscript{14} Although no uniform blood shield statute exists, the statutes can be roughly divided into three categories.

First, a number of states merely codified the \textit{Perlmutter} case, which held that blood is a service rather than a sale.\textsuperscript{15} By defining the provision of blood as a service, the legislatures avoid liability for breach of implied warranty since no "sale" has occurred. Furthermore, many courts in these jurisdictions have also concluded that the sale/service distinction bars recovery under strict tort because, by definition, blood is not a product.\textsuperscript{16} A second category of statutes explicitly

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14. New Jersey and Vermont are the only two states that have not adopted some form of blood shield statute. The New Jersey Supreme Court has ruled, however, that blood suppliers cannot be liable under either strict tort or implied warranty. \textit{See Brody, 127 N.J. Super. at 331, 317 A.2d at 392}. The Vermont Supreme Court has not considered the issue. The District of Columbia has also rejected no-fault liability for blood suppliers. \textit{See Kozup}, 663 F. Supp. 1048.


16. \textit{See, e.g.}, \textit{McKee v. Miles Laboratories, Inc.}, 675 F. Supp. 1060 (E.D. Ky. 1987), \textit{aff'd sub nom. McKee v. Cutter Laboratories, Inc.}, 866 F.2d 219 (6th Cir. 1989); \textit{Cramer...
precludes liability for breach of implied warranty, but does not mention strict liability.\textsuperscript{17} Nevertheless, courts have extended such statutes to preclude strict liability in tort as well.\textsuperscript{18} The third category of statutes, to which the majority of states subscribe, declares that “no strict liability in tort, nor any implied warranty, attaches to the... distribution[on] [of blood]...”\textsuperscript{19}

The South Carolina blood shield statute fits into the second category, since the statute expressly exempts liability only for breach of warranty. The statute, South Carolina Code section 44-43-10, reads:

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.\textsuperscript{20}

\textsuperscript{17} Queen of Angels Hosp., 62 Cal. App. 3d 812, 133 Cal. Rptr. 339 (1976).


Until *Samson v. Greenville Hospital System (Samson I)*,\(^{21}\) neither the constitutionality nor the scope of the statute had been challenged.

In *Samson I* Mrs. Samson received an AIDS contaminated blood transfusion in a hospital operated by the Greenville Hospital System. The hospital had received the blood from the Carolina-Georgia Blood Center, a nonprofit organization, which had drawn the blood from a volunteer. Unaware of any possible complications from the 1984 transfusion, Mrs. Samson became pregnant in the summer of 1985. In September of that year, the blood center discovered the donor was an AIDS carrier and, through a "look back" program, tracked the donor's previous donations and notified the hospital. The hospital contacted Mrs. Samson and, after testing, concluded she had been exposed to the AIDS virus. In March 1986 Mrs. Samson gave birth to a son who subsequently developed AIDS; experts predict Mrs. Samson also will develop AIDS in the future.\(^{22}\)

Consequently, Mrs. Samson, her husband, and her son sued the hospital and the blood center in the Federal District Court of South Carolina, asserting four causes of action: strict liability; breach of an implied warranty of merchantability; breach of warranty of fitness for a particular purpose; and negligence.\(^{23}\) The defendants moved for summary judgment on the warranty claims, asserting the South Carolina blood shield statute precludes such claims. In response, the Samsons argued the statute violated the equal protection clause of the South Carolina Constitution by discriminating against victims of transfusion-related diseases as distinguished from victims of defective products.\(^{24}\) Since the statute had never been challenged, the district court certified the question to the South Carolina Supreme Court.

In analyzing the equal protection claim, the supreme court relied on the established principle that a "classification will be sustained if it is not plainly arbitrary and there is 'any reasonable hypothesis' to support it."\(^{25}\) Accordingly, the court's inquiry focused on whether the classification was reasonably related to the legislative purpose. The court concluded that the purpose of the statute was to encourage a readily available supply of blood and blood products\(^{26}\) and that the classification furthered that goal.\(^{27}\)

The court rejected the Samsons' claim that the statute irrationally


\(^{22}\) Id. at 361-62, 368 S.E.2d at 666.

\(^{23}\) See Brief of Plaintiffs at 1.

\(^{24}\) *Samson I*, 295 S.C. at 366, 368 S.E.2d at 668.

\(^{25}\) Id. at 363, 368 S.E.2d at 667 (quoting Smith v. Smith, 291 S.C. 420, 424, 354 S.E.2d 36, 39 (1987)).

\(^{26}\) Id. at 364, 368 S.E.2d at 668.

\(^{27}\) Id. at 365, 368 S.E.2d at 668.
discriminated against class members. The court stated:

[W]e find nothing irrational in the legislature's decision to distinguish between individuals injured as a result of blood transfusions and individuals injured by improperly designed or manufactured man-made goods. Equally rational was the creation of a class of distributors exempt from implied warranties. We agree with the many courts and legislatures which recognize that blood and its derivatives are rendered unique and medically vital by man's inability to produce a synthetic substitute.  

Thus, the court concluded the blood shield statute was constitutional.

The district court granted the defendants' motion for summary judgment on the warranty claims, since the statute specifically precludes liability for breach of warranty. The defendants also moved for summary judgment on the strict liability cause of action, claiming that since the statute defined the supplying of blood as a service rather than a sale, the statute also precluded liability for strict tort. Once again facing a novel issue of state law, the district court certified the question to the South Carolina Supreme Court.

This second certified question led to Samson II, in which the supreme court determined that in light of the South Carolina blood shield statute, "blood is not a product for the purposes of strict liability in tort." The court reasoned that the legislature clearly intended

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28. Id. at 366, 368 S.E.2d at 668-69.

Courts also have rejected consistently other constitutional challenges to blood shield statutes. See, e.g., Heirs of Fruge, 506 F.2d at 848 (statute not violative of due process or prohibition against exclusive rights or immunities); McAllister v. American Nat'l Red Cross, 240 Ga. 246, 249, 240 S.E.2d 247, 250 (1977) (reasoning of statute free from arbitrariness which would render exemption of blood suppliers violative of Georgia Constitution); Glass v. Ingalls Memorial Hosp., 32 Ill. App. 3d 237, 241, 336 N.E.2d 495, 499 (1975) (legislation not violative of constitutional prohibition against special legislation).

31. Id. (plaintiffs relying on Deloach v. Whitney, 275 S.C. 543, 273 S.E.2d 768 (1981) (strict liability statute applies only to products and not to services)).
33. Id. at 411, 377 S.E.2d at 312.
to define the provision of blood as a service rather than a product. Therefore, since services are not subject to strict liability, the provision of blood cannot be subject to strict liability. Furthermore, the court noted that strict liability would defeat the underlying purpose of the act by allowing a party to circumvent the statutory bar against no-fault liability. Finally, the court noted that the majority of other jurisdictions with blood shield statutes similar to South Carolina’s statute have determined that blood was not a product subject to strict tort liability. Thus, Samson I and Samson II conclusively establish that a party will not be able to recover for infected blood under a no-fault theory of liability.

In both Samson cases, the court’s holdings were based on the apparent legislative intent of the blood shield statute to avoid no-fault liability for blood suppliers. Arguably, these decisions undercut the policies supporting strict liability for defective products: relieving plaintiffs of the difficult burden of proving negligence; “encouraging” defendants to improve product safety; and equitably spreading the economic risk involved in transfusions. The legislature determined, however, that other policy considerations justify the exemption for blood suppliers.

Even if blood is to be considered a product, its uniqueness justifies special treatment. Unlike many of our modern day conveniences, an ample blood supply is essential to life. Nevertheless, present day technology cannot always detect contaminated blood, and, unlike penicillin, it cannot be replaced with a safer synthetic substitute. Thus, to insure an adequate blood supply and avoid crippling the industry, the legislature has exempted blood suppliers from strict liability, especially since all volunteer blood for transfusions comes from charitable organizations. Although the causal link between the imposition of strict liability and the resulting “crippling liability” may be questioned, legislatures have almost unanimously concluded that any attempt “to require providers to serve as insurers of the safety of these materials might

34. Id.
35. Id. at 411 n.2, 377 S.E.2d at 312 n.2.
36. See generally Comment, Hepatitis, AIDS & Blood Products Exemption, supra note 3, at 1124-29 (arguing that policies supporting strict liability justify holding blood suppliers liable in strict tort). But see Comment, Hospital and Blood Bank Liability, supra note 3, at 886-88 (concluding that policies of strict liability support exempting blood suppliers from no-fault liability).
37. See infra notes 58-61 and accompanying text (discussing procedures for discovering contaminated blood).
38. The American Red Cross collects 50% of this blood and hospitals and community blood banks each collect 25%. See Brief of Appellee at 1, Doe v. American Red Cross Blood Services, 297 S.C. 430, 377 S.E.2d 323 (1989).
impose such an overwhelming burden as to discourage the gathering and distribution of blood."}

2. Negligence

While courts seem willing to hold blood banks liable for negligently supplying AIDS contaminated blood, plaintiffs rarely will succeed in asserting such claims. First, to be liable for negligence, a blood supplier must have acted unreasonably in light of risks which he knew or should have known. Accordingly, since there were no confirmed cases of individuals developing AIDS from transfusions until 1983, there can be no liability for pre-1983 transfusions contaminated with AIDS.

Proving negligence for post-1983 transfusions also will be difficult, because most courts only hold blood banks to a "professional" rather than a "reasonable man" standard of care. In Doe v. American Red Cross Blood Services the South Carolina Supreme Court adopted this rule by holding that a blood supplier will be liable for negligence only if it fails to follow the generally recognized practices in the profession.

In Doe the plaintiff received a unit of AIDS contaminated blood during surgery at Lexington County Hospital on January 9, 1985. The blood had been collected by the Red Cross on the fourth of January.


41. See Lipton, supra note 3, at 144.

42. For a comprehensive discussion of the exact time the first AIDS transfusion cases were reported and confirmed, see id. at 140-44.

43. See Jones, 700 F. Supp. at 1130 (plasma center could not be negligent for failure to screen donors before 1983 when medical community discovered AIDS in blood transfusions and FDA released proposed screening recommendations).


46. Id. at 436, 377 S.E.2d at 326.
three months before the HIV antibody test to screen blood for the AIDS virus was developed.\footnote{47} Several surrogate tests\footnote{48} were available, but were not used by the Red Cross. Doe sued the Red Cross for negligence, alleging that it acted unreasonably in not using the substitute tests. Even though the blood bank profession had rejected the use of surrogate tests, Doe argued that industry custom did not establish the standard of care, especially since the Red Cross, as the dominant supplier, dictated the custom of the industry.\footnote{49}

The supreme court rejected Doe's arguments, holding that blood suppliers only had to conform to the custom of the profession in order to avoid liability. Although the court admitted there were no explicit precedents for applying a professional standard of care, it discussed several cases that implicitly applied a professional standard.\footnote{50} The court then fashioned a test for professional negligence cases: "the plaintiff must prove . . . that the professional failed to conform to the generally recognized and accepted practices in his profession. If the plaintiff is unable to demonstrate [this failure], then the professional cannot be found liable as a matter of law."\footnote{51} The court then applied the standard to the Red Cross. Relying on its ruling in \textit{Samson I}, that the blood shield statute reflected a legislative intent to characterize the transfusion of blood as a medical service, the court held that "the Red Cross, as a blood collector and processor, should be treated as a

\footnote{47} See \textit{infra} notes 62-64 and accompanying text (discussion of test and development).

\footnote{48} A surrogate test tries to identify characteristics in blood which often accompany the AIDS virus. Accordingly, even though the target condition (in this case AIDS) cannot be directly identified, the presence of other serological or metabolic products tends to prove that the "target condition" is nevertheless present. For example, since the hepatitis B core antibody was often present in AIDS contaminated blood, some researchers attempted to screen blood with the hepatitis B core antibody test to avoid the AIDS virus. These surrogate tests, however, never have been implemented by the blood industry, because results of the screening were far from conclusive: blood may be contaminated with the AIDS virus yet not contain the hepatitis antibody; or, blood may contain the hepatitis antibody yet not be contaminated with the AIDS virus. See generally, \textit{generally}, Lipton, \textit{supra} note 3, at 147-48 (explaining the various surrogate tests and the reasons the Red Cross chose not to implement them).

\footnote{49} See Brief of Plaintiff at 10, Doe v. American Red Cross Blood Servs., 297 S.C. 430, 377 S.E.2d 323 (1989). Doe's argument was primarily based on the principle laid down by Judge Hand in \textit{T.J. Hooper} that the custom of the industry cannot set the standard of care because the whole industry "may have unduly lagged in the adoption of new and available devices." The T.J. Hooper, 60 F.2d 737, 740 (2d Cir.), cert. denied sub nom. Eastern Transp. Co. v. Northern Barge Corp., 287 U.S. 682 (1932).


\footnote{51} Doe, 297 S.C. at 435, 377 S.E.2d at 326.
professional.\textsuperscript{52}

In Doe the supreme court faced a troubling issue. Unlike the unregulated shipping industry in The T.J. Hooper,\textsuperscript{53} blood suppliers set strict safety standards and "adhere rigidly to the regulatory procedures in order to protect the integrity of their business and their licensure status."\textsuperscript{54} In fact, the FDA explicitly approves standards set by the American Association of Blood Banks and the American Red Cross in its "good manufacturing practices" recommendations.\textsuperscript{55} On the other hand, the FDA is subject to regulatory capture, and the Red Cross, whose reasonableness is not subject to jury review, is setting its own standard of care. Nevertheless, the court determined that the blood profession's standards reflect the composite judgment of a highly regulated and complex industry and guarantee, to the greatest extent possible, a safe blood supply.

Furthermore, the supreme court recognized that resolving complicated issues on the standard of care in a technical profession is beyond the purview of an ordinary lay juror and should be left to the "collective wisdom of a profession."\textsuperscript{56} This rationale clearly applies to contaminated blood cases. Faced with the sympathetic facts that most AIDS transfusion cases present, few juries would hesitate to award damages, even if the blood bank had done everything possible to insure pure blood.\textsuperscript{57}

Although the professional standard established in Doe places a greater burden on plaintiffs, parties who prove a blood bank has failed to follow industry custom will be able to recover for damages resulting from infected blood. Generally, the blood supplier will commit one of two errors: failure to screen donors adequately or failure to test adequately the blood itself.

As soon as the link between AIDS and blood transfusions was established in 1983, blood banks adopted procedures for screening high risk donors.\textsuperscript{58} Accordingly, a blood bank may be negligent if it fails to follow one or more of the following accepted procedures: educating

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\textsuperscript{52} Id. at 436, 377 S.E.2d at 326.
\textsuperscript{54} Comment, Transfusion-Associated AIDS, supra note 3, at 98.
\textsuperscript{55} See 21 C.F.R. §606.100(d)(1)-(2)(1988).
\textsuperscript{57} See, e.g., Jones v. Miles Laboratories, Inc., 700 F. Supp. 1127 (N.D. Ga. 1988) (JNOV on basis that jury relied more on emotions than facts of the case).
\textsuperscript{58} See Lipton, supra note 3, at 144-45. But see generally R. Shilts, AND THE BAND PLAYED ON (1987) (criticizing the blood profession for reacting too slowly to the AIDS crisis).
possible AIDS carriers of the dangers of donating blood; questioning donors on diseases, symptoms of the AIDS virus, or even on sexual practices; providing a call-back mechanism whereby a donor who suspects he may have AIDS can anonymously have his blood removed from the pool; avoiding high risk AIDS areas when choosing donation centers; refusing to accept blood from donors who have tested positive for AIDS in the past and disposing of any blood previously given by these donors; educating blood bank personnel to recognize symptoms of AIDS which would place a donor in a high risk category.

A blood bank also may be liable for failing to test blood collected after 1985. By late 1984 scientists finally had identified the source of the AIDS virus as HTLV III/LAV (HIV) virus and were able to develop a test to detect HIV antibodies in blood. The test was licensed by the FDA in March of 1985. Although the test cannot actually detect the AIDS virus, it has been accepted and implemented by the blood profession. Consequently, if a supplier fails to test blood collected after 1985 for HIV antibodies, the supplier probably will be liable for negligence.

59. See Lipton, supra note 3, at 146. In March of 1983, the FDA listed donor education as one of the most important screening procedures, since any effective screening procedure depended upon the cooperation of the infected donors. Id.

60. In the hepatitis context, courts have held blood suppliers liable for failing to question a donor. See, e.g., Morse v. Riverside Hosp., 44 Ohio App. 2d 422, 339 N.E.2d 846 (1974); Hoder v. Sayet, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967). Subsequent studies by the Red Cross, however, indicate that questioning will rarely identify an AIDS carrier, since “high-risk donors who refuse to refrain from donating blood after being requested to do so can also be expected to provide untruthful answers to 'direct' questions about sexual practices...” Lipton, supra note 3, at 147. See also Jones 700 F. Supp. at 1132 (homosexual lied to plasma center more than 25 times when asked about sexual practices).

61. See generally COMMITTEE ON STANDARDS OF THE AMERICAN ASSOCIATION BLOOD BANKS, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (12th ed. 1987) (discussing the various screening procedures available to blood banks).

62. Before 1985 a few blood banks experimented with surrogate tests in high risk areas such as San Francisco. After the studies were completed, however, the Red Cross decided not to implement the surrogate tests. See Lipton, supra note 3, at 148 (listing the five reasons on which the Red Cross based its decision). Therefore, following the standard of the profession, a blood bank should not be held liable for failing to test blood until the HIV antibody test was developed in 1985 and adopted by the blood profession. This is essentially the conclusion of the court in Doe, since Red Cross’s motion for summary judgment was based on the fact that the practice among blood banks in January of 1985 was not to use surrogate tests. See Doe v. American Red Cross Blood Servs., 297 S.C. 430, 433-35, 377 S.E.2d 323, 325-26 (1989).


64. See Lipton, supra note 3, at 151 ("All evidence, thus, suggests that, nationwide, the tests were implemented as soon as they became available.").
C. Conclusion

In the Samson and Doe cases the South Carolina Supreme Court delineated the applicability and scope of the blood shield statute in cases against a blood supplier for defective blood: a party cannot recover for breach of implied warranty or strict tort, and can only recover in negligence when the blood supplier has failed to comply with the custom of the profession.

Furthermore, even though the defendants in the cases were non-profit organizations, the supreme court probably would apply the same standard to commercial blood derivative manufacturers and suppliers. In Samson I the supreme court rejected the plaintiff's argument that the blood shield statute discriminated against commercial blood suppliers by noting that “the statute does not distinguish paid donors from voluntary donors or commercial distributors from charitable distributors.” Moreover, courts construing statutes similar to South Carolina’s have held that they apply with equal force to commercial blood suppliers. Commercial suppliers, then, should have to meet the standard of care established for nonprofit suppliers. Accordingly, the Samson and Doe cases have laid the framework for future “defective” blood cases, giving the bar a solid basis on which to evaluate and predict such claims.

James K. Lehman