

/* This case is reported in 582 A.2d. 307 (N.J. Superior 1990). In this case, the court permits the discovery of limited information concerning the donors of contaminated blood. */

William SNYDER and Roslyn Snyder, Plaintiff - Appellants,

v.

Haroutune MEKHJIAN, M.D., individually; Haroutune Mekhjian, M.D., P.C.; Youngick Lee, M.D.; Wilmo Orejola, M.D.; St. Joseph's Hospital; St. Joseph's Blood Bank; Bergen Community Blood Center; American Association of Blood Banks, Defendants-Respondents.

and

Anthony Losardo, M.D.; Leonard Savino, Thil Yoganathan, M.D.; John Klian, M.D.; Molly Zachariah, M.D.; Thomas Raymundo, M.D.; John Doe, M.D., a Fictitious Name; Richard Roe, M.D., a fictitious name; John Roe, M.D., a Fictitious Name; John Smith, M.D., a Fictitious Name; John Jones, M.D., a Fictitious Name; W Blood Bank, a Fictitious Name; Z Blood Bank, a Fictitious Name; XYZ Blood Bank, a Fictitious Name; Jane Doe, a Fictitious Name; Richard Roe, a Fictitious Name; Joseph Williams, a Fictitious Name; Joseph Rogers, a Fictitious Name; Gregory Smith, a Fictitious Name; Joseph Smith, a Fictitious Name; Jane Smith, a Fictitious Name; William Smith, a Fictitious Name; Individually and as Agents, Employees and Servants of St. Joseph's Hospital, Defendants.

Superior Court of New Jersey, Appellate Division.

Argued Oct. 2, 1990.

Decided Oct. 30, 1990.

The opinion of the court was delivered by

PRESSLER, P.J.A.D.

The fundamental issue raised by this action is whether liability attaches to anyone, and if so to whom and under what legal theory, when a surgical patient contracts Acquired Immune Deficiency Syndrome as a result of transfusion with contaminated blood supplied by a non-profit blood bank. We granted plaintiffs leave to appeal from the trial court's interlocutory order dismissing the strict liability counts against all defendants, and we now affirm that order. We also granted plaintiffs' motion for leave to appeal from the interlocutory order denying their motion for discovery from the blood bank of the infected donor's identity, medical records, and recollections of the screening process to which he was required to submit before his donation

was accepted. We reverse the order denying discovery subject to the protective conditions hereafter described.

Plaintiff William Snyder, whose wife Roslyn sues per quod, underwent elective coronary artery by-pass surgery and an aortic valve replacement at St. Joseph's Hospital in Paterson on August 23, 1984. The surgery was performed by defendants Youngick Lee and Wilmo Orejola. Some hours after the original surgery, a second surgical procedure was performed to repair a bleeding artery. During this procedure plaintiff was infused with, among other blood products, a unit of platelets, identified as serial number 29F0784, which had been supplied to St. Joseph's by defendant Bergen Community Blood Center (BCBC), a non-profit collector and distributor to hospitals of donated blood. Plaintiff's recuperation proceeded uneventfully, and he was discharged from the hospital several weeks later.

In April 1984 the HTLV-III virus (HIV) was identified as the cause of AIDS. By March, 1985, tests were available which enabled the nation's blood banks to screen all donated blood for antibodies. This screening process was attended by a nation-wide "Look Back" program by which the blood banks were able to determine whether a now-identifiable HIV-positive donor had given blood prior to March 1985 and, if so, to which hospital that donor's blood had been supplied. In October 1986, BCBC wrote to St. Joseph's to advise that unit number 29f0784, supplied by it to the hospital on August 23, 1984, had come from a donor now testing positive for HIV antibodies. The hospital, by review of its records, ascertained that plaintiff had received that unit, and in April, 1987, it so advised his physician, offering the hospital's resources should further testing of the patient and counseling services be required. According to the physician's note on the hospital's follow-up report, he determined that:

Recipient [plaintiff] now lives in Florida. Prior to my notifying him he was tested in response to the CDC [Center for Disease Control] recommendation that all recipients be tested. His tests were positive. His wife and two sons were subsequently tested and found to be negative. He is being counseled by a physician in Florida. The recipient has no risk factors.

Plaintiff instituted this action in February 1989 against the hospital, the physicians involved in his diagnosis and treatment, BCBC, and the American Association of Blood Banks (AABB). AABB is a national non-profit association of non-profit blood banks, whose members, of which BCBC is one, collect about half of the country's donated blood. The American Red Cross collects the other half. As we understand the record, AABB collects and disseminates relevant scientific and administrative information to its thousands of members, prescribes standards for their operations, and speaks for them.

Plaintiff asserted a strict liability claim against all defendants, contending that at the time of his transfusion, laboratory tests as well as donor

screening techniques were available which, had they been employed, would have screened out HIV-positive donors and rendered the supply of donated blood safe from AIDS contamination. AABB did not, however, recommend their use to its members, and BCBC did not use them. Plaintiff claims that since the blood he received from BCBC could have been made safe, all those in the chain of collection and distribution of the infected blood he did receive should be held strictly liable for providing him with a defective product.

Plaintiff also asserted negligence claims against all defendants. His claims against the physicians are based on the assertion of professional negligence in not advising him of the risk of receiving contaminated blood and of the option either to collect his own blood for transfusion prior to the surgery (autologous transfusion) or to arrange to have blood available from family members or other known donors (direct donor transfusion). He also claimed that it was the negligence of Dr. Mekhjian and his assistants in failing to repair the bleeding artery during the original surgery which caused the necessity for the second surgery and the consequent contaminated transfusion.

Plaintiff's negligence complaint against the BCBC and AABB was based on the state of scientific knowledge respecting AIDS, its diagnosis and transmission at the time of his transfusion. He alleged that these defendants greatly enhanced his risk of receiving contaminated blood by failing to prescribe and implement available risk-reducing procedures in the blood collection process. He also asserted that BCBC negligently failed to follow such screening procedures as it did then have in place, inadequate as they may have been. He claimed that but for that negligence, BCBC would have rejected the infected donor's blood. Plaintiff also asserted consumer fraud and punitive damages claims against these defendants based on their alleged knowing and irresponsible failure to protect the blood supply from AIDS contamination.

On summary judgment motions by defendants, the following dispositions ensued: 1) the consumer fraud and strict liability claims as against all defendants were dismissed; 2) all claims against St. Joseph's Hospital were dismissed; 3) the punitive damage claims against the physicians were dismissed. The claims which survived are the negligence claims against AABB, BCBC and the surgeons and the punitive damage claims against AABB and BCBC. In addition, the court ruled that BCBC was not entitled either to charitable immunity pursuant to N.J.S.A. 2A:53A-7 or to the \$10,000 damages limitation of N.J.S.A. 2A:53A-8. Finally, by separate order, the court denied plaintiff's application for production by BCBC of its records of the anonymous donor of unit number 29F0784.

Plaintiff sought leave to appeal only from the dismissal of the strict liability'

claims and the denial of the donor discovery motion. No defendant sought leave to appeal from any ruling adverse to it. Consequently strict liability and discovery of the donor records are the only issues now before us.

[1] Consideration of the strict liability claims requires a brief foray into the relevant scientific facts as they were known in August 1984 and the manner in which they, were responded to by the nation's blood-banking organizations. As appears from the experts' materials included in the record on the summary judgment motions, the critical period of AIDS contamination of the blood supply was from mid-1981, when the first AIDS cases were diagnosed, to March 1985, when the first test for HIV virus antibodies was developed and in place. According to the scientific data in the record, both the Center for Disease Control (CDC) and the Public Health Service Committee on Opportunistic Infections had, prior to the end of 1982, reported to the blood banking community the likelihood that AIDS was transmissible through blood, products. It was also by then reported that the major risk groups for AIDS included homosexual males, intravenous drug users, recently emigrated Haitians and hemophiliacs. In early January 1983, CDC held a meeting attended by among others, representatives of the blood-banking industry, the National Gay Task Force and the National Hemophilia Foundation. Its summary report of the session noted the reluctance of "some participants ... to accept the hypothesis that AIDS has been transmitted by whole blood," but nevertheless reported a consensus "that it would be desirable to exclude high-risk donors to reduce the risk of AIDS transmission via blood and blood products."

CDC also reported the then availability of several surrogate laboratory tests for AIDS, including the Hepatitis B Core Antibody Test and the T4, T8 Ratio Test. As we understand the record, a surrogate test in this context is one which does not reveal the presence of HIV virus antibody itself but rather is based on the high statistical correlation between infection with the HIV virus and the presence of other physical manifestations for which there are tests. The theory is that laboratory verification of these other manifestations is a reliable indicator of AIDS infection. According to the CDC data assembled in December 1982, the various surrogate tests would correctly identify between 66% and 88% of AIDS-infected donors, the degree of correlation depending on the risk category to which they belonged. The tests, however, had about a 5% false positive rate, which would result in rejection of "safe" blood and hence in a diminution of the nation's blood supply. Moreover, the cost of the tests would add to the price of collection and distribution of blood products.

The report summarizing the January 1983 meeting observed that the various 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." But as information continued to be collected, the CDC became increasingly concerned about AIDS contamination of the blood supply. In

March 1983, a recommendation was issued designed to keep members of high risk groups from donating blood, urging donor Screening procedures which would include "specific laboratory tests as well as careful histories and physical examinations," and advising use of autologous transfusions where indicated. By January 12, 1984, according to one of plaintiff's experts who cited the issue of the New England Journal of Medicine of that date, "the national medical community officially recognized that which was generally known for well over a year," namely, that "AIDS was transmissible through blood and blood products." The virus was isolated several months later, testing began in March 1985, and it is apparently now believed in the scientific community that as a result of later test refinement, blood can now be made virtually 100% safe from AIDS contamination.

The controversy centers on the period from early 1983 to the inception of specific HIV antibody testing in March 1985. According to the record, the nation's commercial blood bankers had initiated surrogate testing and aggressive donor screening of high-risk groups starting in late 1982 when the hepatitis core antibody test was initially licensed by the FDA. The medical director of the Stanford University Blood Bank started surrogate test screening there in July 1983, and by June 1, 1984 such testing was routinely done by other non-profit blood banks throughout northern California. The American Red Cross and the AABB however, apparently because of their concern over maintaining the adequacy of the blood supply and containing the cost of its collection, continued to take the publicly expressed view, despite privately expressed reservations by some of its officials, that the risk of AIDS infection from blood transfusion was minimal (less than one in a million), that routine surrogate testing of blood was not advisable, and that aggressive interviewing to determine a donor's membership in a high-risk group was inappropriate. Instead, the AABB recommended - educational campaigns for self screening by high-risk donors, donor inter-viewing to elicit physical symptoms associated with AIDS, non-targeting of high-risk groups for donor recruitment, and use of autologous transfusion when appropriate. Consequently, most of AABB's members, including BCBC, did not perform any laboratory testing until the spring of 1985 and did not aggressively seek to exclude male homosexuals or members of other high-risk categories.
[footnote 1]

We address the strict liability claims against this factual background. The critical point which emerges from the foregoing recitation is that however safe from AIDS contamination donated blood may now be, the best that can be said for the blood supply in August 1984 is that the risk of contamination, while then subject to significant reduction, nevertheless remained appreciable. That is to say, if a blood bank had then employed all the laboratory testing and donor screening techniques available to it, it would nevertheless have missed, statistically, at least 12%, and perhaps as much as 33%, of all AIDS-infected blood. We are satisfied that aside from any

other consideration, this margin of error rendered the blood supply unavoidably unsafe, precluding the application of strict liability principles to all of those in the chain of collection and distribution.

In *Brody v. Overlook Hospital*, 127 NJ Super. 331, 317 A.2d 392 (App.Div.1974), *affd*, 66 NJ. 448, 332 A.2d 596 (1975), we reviewed the policy considerations which impelled our conclusion that strict liability cannot be imposed on a non-profit blood bank and its non-profit distributees in the case of hepatitis - contaminated blood. To be sure, at the time of the blood transfusion in *Brody*, there was apparently no available test at all for the serum hepatitis virus with which that plaintiff was infected. It was thus manifest that we were dealing with an unavoidably unsafe product having a high degree of public utility and social benefit which was therefore exempt from strict liability doctrines. See generally *Shackil v. Lederle Laboratories*, 116 NJ 155, 561 A.2d 511(1989); Restatement (Second) Torts 402A comment k, (1965). And see N.J.S.A. 2A:58C-3(a)(3); see also Senate Judiciary Committee Statement accompanying L. 1987, c. 197, codified as N.J.S.A. 2A:58C-1 to -7.

We appreciate the difference between having no test at all and having a test with a significant, if not perfect, degree of reliability. But even an 88% reliability factor is, in our view, insufficient to overcome the other policy reasons on which we relied in *Brody* in rejecting strict liability. In sum, considering the public health implications of blood collection and distribution and the non-profit status of that segment of the industry involved in *Brody*, we were there convinced that it would be inimical to the public interest to call upon the non-profit blood bank and those in its distributive chain to warrant a blood product whose safety was beyond their power to ensure. In 1984, no matter how diligent and aggressive BCBC might have been in donor screening and laboratory testing, it would nevertheless necessarily have supplied some AIDS-contaminated blood. The unfortunate recipient of that blood would be in no different legal or equitable position than the plaintiff in *Brody*, nor would the blood bank. In short, product protection for the patient and legal protection for the blood bank remains the same - that is, that the blood bank is obliged to do everything it reasonably can do to ensure safety, but it cannot be responsible for what is not within its capacity to control. This rationale of *Brody* was forcefully reiterated by the Supreme Court in *Feldman v. Lederle Laboratories*, 97 NJ: 429, 442, 479 A.2d 374 (1984), the Court there holding that:

When the essential nature of the transaction involves a service rather than a product, public policy may dictate, in view of the status of the provider, that the general welfare is served better by inapplicability of the strict liability doctrine. Further, when the provider is a nonprofit institution that supplies a product and that product is vital to the public health, the doctrine may similarly be inapplicable. The common thread that runs through these cases is that in each of those situations there is a strong public policy rooted in the

general welfare that justifies imposing responsibility only on the basis of a want of due care (negligence) rather than on the basis of a defective product (strict liability).

We need not consider the question of whether strict liability principles could apply, at least to the blood bank, upon a showing, as we now understand could be made, that with proper testing techniques, blood can be made completely safe from AIDS contamination. We note only that New Jersey does not have any statutory inhibition to such a result [footnote 2] and that it might be cogently argued that the blood-banking industry's scientific capacity to warrant the freedom of blood from AIDS Contamination should result in its legal obligation to so warrant.

[2] Little need be said respecting the inapplicability of strict liability to defendants St. Joseph's, AABB, and the physicians. The physicians are clearly exempt under the holding and rationale of *Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 258 A.2d 697 (1969). AABB is not itself a supplier or tester of blood. It itself does not deal in producing or distributing a product whether or not the blood bank itself does. As to St. Joseph's, we concur with the holding of *Johnson v. Mountainside Hosp.*, 239 N.J. Super. 312, 571 A.2d 318 (App.Div.1990), that for purposes of product liability law, a hospital cannot be held strictly liable for a latently defective product supplied to it by another for its use in rendering treatment.

[3, 4] What we have said respecting strict liability does not, of course, affect plaintiffs' remaining negligence causes of action against the remaining defendants. There is certainly enough in this record to raise a factual question as to the reasonableness of AABB's conduct in opting to forego guidelines which would have required its members to perform surrogate laboratory testing or more vigorous donor screening. There is also a factual question as to BCBC's conduct in collecting blood without these techniques, irrespective of AABB's guidelines. [footnote 3] If it were determined that the conduct of either BCBC or AABB, or both, unreasonably created an appreciable enhancement of plaintiff's risk and that the enhanced risk was a substantial factor in producing his injury, they would be liable to him in negligence even though he might have contracted AIDS even if they had taken every available precaution. See *Evers v. Dollinger*, 95 N.J. 399, 417, 471 A.2d 405 (1984). See also *Ayers v. Jackson Tp.*, 106 N.J. 557, 591-599, 525 A.2d 287 (1987). In addition, there is a more direct negligence claim against BCBC, namely the allegation that but for its unreasonable conduct in screening the donor of the contaminated blood, that infected unit would have been initially rejected.

[5] Finally we have no doubt that the viability of the negligence cause of action against the physicians has been adequately demonstrated. Aside from the issue of the unrepaired bleeder, there is record support for the proposition that a jury could find that in the case of elective surgery in Au-

gust 1984, the physician's duty to inform the patient included advice as to the possibility of AIDS contamination and the availability of autologous and direct donor transfusion.

[6] We now address the question of donor records. To begin with, we note that BCBC has already supplied plaintiffs with the registration form of the donor of unit number 29F0784 with his name and any other identifying information redacted. This form consists of a series of questions relating to medical history, previous blood donation and vital signs at the time of the donation. BCBC asserts that this information is adequate for plaintiff's purposes. It also asserts that any further information either identifying the donor or in any other way permitting plaintiff to penetrate the donor's anonymity or privacy would breach BCBC's obligation of confidentiality imposed both by considerations of public policy and by the dictates of NJSA. 26:5~5 to -14 (confidentiality of records of AIDS patients).

We consider first plaintiff's need for further information. He claims that he requires it for several reasons. First, none of the defendants is now willing to admit that unit number 29F0784 was contaminated. While there is no question that the donor of that unit tested positive for HIV antibodies in 1986, defendants apparently insist on putting plaintiff to his proof that the donor had been infected as far back as August 1984. It is certainly inferential from the circumstances that he was then infected, particularly in view of the medical assurance referred to supra that plaintiff had no other risk factor. But defendants refusal to concede the point entitles plaintiff to seek direct proof that the donor was HIV-positive in 1984. [footnote 4]

Beyond that causation issue, plaintiff cogently asserts a need in respect of the question of BCBC's negligence. Illustratively, it was known before August 1984 that early symptoms of AIDS - infection include particular lymph-node swelling and skin disorders, and, in fact, by 1983 the commercial blood bankers were conducting routine physical examinations of donors to determine the presence of these symptoms. Did the donor here have those symptoms then? Was he asked about them? Was he physically examined in this respect? Was he given the appropriate high-risk group self-screening information? Was a reasonable effort made to determine if he was in a high-risk category? Were his responses to the medical history questions accurately recorded? Were the questions adequately explained to him? Would present screening requirements, short of laboratory testing, have revealed his AIDS infection? [footnote 5] Undoubtedly other relevant lines of interrogation would suggest themselves. All of this information is, in our view, highly pertinent to the issue of BCBC and AABB negligence and is, moreover, to a large extent not available from any source other than the donor himself.

The question then is how to balance plaintiff's need to gain relevant information against the donor's right to privacy and the public's need to maintain

confidentiality, which is said to be a cornerstone of the nation's blood donation program. We start with N.J.S.A. 26:5C-5 to -14, which is intended to protect the confidentiality of individual AIDS records while assuring their limited availability for essential health, scientific and other legitimate purposes. [footnote 6] The statute stipulates that unless disclosure is expressly provided for by N.J.S.A. 26:5C-8, it may be obtained only by court order for good cause shown. N.J.S.A. 26:5C-9(a). In assessing good cause, moreover, the court is required to "weigh the public interest and need for disclosure against the injury to the person who is the subject of the record, to the physician-patient relationship, and to the services offered by the program [of diagnosis and treatment of AIDS and conditions related to HIV infection]." Moreover, if good cause is found, the court is required to determine the extent to which disclosure is necessary and to impose appropriate safeguards.

We are convinced that confidentiality of blood bank AIDS records rests upon significant public and private considerations and is ordinarily essential to assure the continued effectiveness of the screening process, the willingness of donors to continue to participate in blood collection efforts, and the general integrity of the nation's blood programs. Nevertheless where, as here, a litigant's discovery need cannot otherwise be met and it is possible to accommodate that need with limited and controlled intrusive access under careful court supervision is appropriate and justifiable. See *Belle Bonfils Mem. Blood Center v. District Court*, 763 P.2d 1003 (Sup.Ct.Colo. 1988); *Tarrant County Hosp. Dist. v. Hughes*, 734 S.W.2d 675 (Ct.App.Tex.1987); *Stenger v. Lehigh Valley Hosp. Center*, 386 Pa.Super. 574, 563 A.2d 531 (1989); *Boutte v. Blood Systems, Inc.*, 127 F.R.D. (W.D.La.1989); *Mason v. Regional Medical Center of Hopkins County*, 121 F.R.D.. 300 (W.D.Ky.1988); But see contra *South Florida Blood Service v. Rasmussen*; 467 So. 2d 798 (Fla.App.1985); *Krygier v. Airweld, Inc.*, 520 NYS2d 475, 137 Misc.2d 306 (Sup.Ct.1987); *Doe v. American Red Cross Blood Services*, 125 F.R.D. 646 (D.S.C. 1989)

Plaintiff has not yet been able to determine if the donor is still alive. That is the first order of business for BCBC's disclosure. If he is not alive, the trial judge shall explore with counsel the possibility of obtaining information respecting the stage of his disease in 1984, his membership in a high risk category, and any other relevant information from other sources. The donor's personal representative will, moreover, have to be noticed of these proceedings. If the donor is alive, the court shall determine procedures best calculated to provide plaintiff with the information he requires while giving maximum protection to the donor. For example, the donor's name need not be supplied if his "veiled" deposition is permitted. If such a deposition were to be permitted, the court could appropriately limit in advance the areas of questioning and impose such other conditions as would insure the donor's anonymity. If, on the other hand, only a deposition on written questions

pursuant to R. 4:15 were permitted, the court could rule on the list of questions prior to their submission and permit an alias identification and oath. It may also be that the donor would have no objection to providing, openly and frankly, the information plaintiff requires or he may authorize his physician to do so. Thus it may also be prudent for the court itself initially to communicate with the donor. In addition, it is likely that the parties themselves will be able to suggest to the court further limitations on the substance of the inquiry and the technique by which it is to be pursued that will afford plaintiff a reasonable discovery opportunity at the least possible cost to the confidentiality interests here implicated.

The ultimate point of course is that plaintiff has suffered a most grievous harm which was apparently inflicted upon him by this donor, whether unwittingly or not. He does not seek redress from the donor but rather from those defendants whose responsibility it was to stand protectively between them. The degree of plaintiff's injury, his right to redress from those who may have negligently failed to protect him, and his need for information which only the donor can provide if redress is to be obtained, all justify the limited disclosure we here sanction without unduly prejudicing the interests of the public and the donor's privacy rights.

The order appealed from is affirmed insofar as it dismissed all strict liability claims. It is reversed insofar as it denied all discovery of donor information, and we remand for further discovery proceedings consistent with this opinion and for trial of the negligence causes of action.

FOOTNOTES:

1. factual recitation is culled from documents in the record before us. The same chronology but without reference to such matters as surrogate testing and the response of the commercial blood banks and the northern California non-profit blood banks' activity is reviewed in *Kozup v. Georgetown University* 663 F.Supp. 1048, 1051-1053, (D.D.C.1987), affirmed in part and vacated in part 851 F.2d 437 (D.C. Cir.1988). For recent discussion and analysis of the position of the American Red Cross and AABB from January 1983 to March 1985 on such matters as surrogate testing and aggressive donor interviewing. See *Feldschuh and Weber, Safe Blood* (Free Press, 1990); *Rock, Inside the Billion-Dollar Business of Blood*, "Monty Magazine (March 1986). Note further that on July 13, 1990, the Subcommittee on Oversight and Investigations of the U.S. House of Representatives Committee on Energy and Commerce conducted public hearings on the safety of the nation's blood supply. The opening statement of the Chairman, Congressman John D. Dingell, noted that the inquiry has its roots in the early to mid 1980's, when the blood industry and the Government failed to prevent the transfusion of thousands of units of blood and blood products infected with

the AIDS virus.

2. Forty-eight states have statutory provisions exempting suppliers of contaminated blood from liability on various alternative bases. See *Roberts v. Suburban Hospital*, 73 Md.App. 1, 532 A2d 1081, 1086, n. 3 (1987).

3. We point out that the northern California blood banks using surrogate testing in 1983 and 1984 were AABB members.

4. More direct proof may be available by way of discovery, permitted by court order, of the medical records of other donees of components of the 29F0784 donation.

5. See N.J.A.C. 8:8-6.5, adopted February 1987, amended May 1989, prescribing detailed AIDS screening requirements. At the time of the August 1984 donation, N.J.A.C. 8:8-5.2 provided only that medical history and physical examinations be consistent with the Code of Federal Regulations and AABB guidelines. See also 21 CFR. 640.3 (1990).

6. The confidentiality requirement attaches to blood banks by express provision of N.J.S.A. 26:5C-7f.