

/* This case is reported in 698 F.Supp. 768 (W.D.Ark. 1988). This case is one of the few blood liability cases to go through to trial. The fact that the case was not dismissed is significant since most other cases have been. However, the court finds after trial that the blood provider was not factually negligent. */
Ann KIRKENDALL, individually and as personal representative of the Estate of Dee Franklin Kirkendall, Deceased, Plaintiff,
v.
HARBOR INSURANCE COMPANY, Defendant.
United States District Court, W.D. Arkansas, Fort Smith Division
October 21, 1988

MEMORANDUM OPINION

H. FRANKLIN WATERS, Chief Judge.

I. Introduction

This action was initiated by plaintiffs, Dee Franklin Kirkendall and Ann Kirkendall, against Blood Systems, Inc. (BSI) on February 26, 1987. Jurisdiction is founded upon diversity of citizenship. Plaintiff alleged that BSI is a non-profit corporation engaged in the business of supplying blood to various medical and hospital entities. In Arkansas, BSI operates under the firm name and style of United Blood Services (UBS). Ark.Code Ann. 23-79-210 (1987) (formerly Ark.Stat.Ann. 663240 and 663241) authorize direct actions against the insurer of such nonprofit corporations and require those entities to disclose to injured persons the identity of the liability insurance carrier and the limits of liability. Because BSI allegedly failed and refused to disclose the identity and liability limits of its insurer, BSI was named as the party defendant.

As the basis of plaintiff's claims, plaintiffs originally contended that BSI supplied blood which was contaminated with AIDS virus to Sparks Regional Hospital (Sparks). Dee Kirkendall received the contaminated blood on March 28, 1985, in the course of a transfusion necessitated during surgery while he was hospitalized at Sparks. Plaintiffs alleged that the contaminated blood was a "product" supplied in a "defective condition" which rendered it "unreasonably dangerous" by reason of which BSI should be held strictly liable. Alternatively, plaintiff contended that BSI was negligent in the "screening" of its donors and in failing to test the blood for the presence of the AIDS virus.

Dee Kirkendall was subsequently diagnosed as suffering from AIDS for which he sought compensatory relief. Plaintiff, Ann Kirkendall, claimed damages for loss of consortium and infliction of mental distress. The apparent basis of her mental distress

claim is her fear of having contracted AIDS through sexual intercourse with her husband.

By order dated July 8, 1987, this court found that BSI is a charitable institution immune from suit under Arkansas law, and directed that Harbor Insurance Company (Harbor) be substituted as the party defendant. Harbor issued and delivered to BSI liability insurance policy number HI177397 which was in effect during the relevant time period. This policy would be implicated, subject to certain limitations, upon a finding that BSI acted negligently in this case.

Dee Kirkendall died on April 23, 1987, as a result of having contracted the AIDS virus during the blood transfusion on March 28, 1985. On July 15, 1987, Ann Kirkendall filed an amended and substituted complaint, individually and as personal representative of the Estate of Dee Kirkendall, against Harbor Insurance Company, re-stating the allegations pertaining to strict liability and negligence, and asserting that Harbor Insurance Company had issued the aforementioned liability policy to BSI with coverage up to \$10,000,000. A "self-insured retention" provision amounting to a \$250,000 "deductible" was contained in the policy.

On March 14, 1988, defendant filed a motion for partial summary judgment, arguing that the supplying of blood is a "service" to which the implied warranties of the Uniform Commercial Code do not apply and further that blood is not a "product" for purposes of imposing strict product liability in tort. See Ark.Code Ann.

4-86 102; 16-116-102(2); 4-2-316; 20-9-801, 802 (1987). By order dated April 13, 1988, this court granted defendant's motion and dismissed plaintiff's strict liability claims with prejudice.

Plaintiff subsequently withdrew her request for jury trial.

Accordingly the matter was tried to the court without a jury on August 16-18, 1988. The following shall serve as the court's findings of fact and conclusions of law required by Rule 52, of the Federal Rules of Civil Procedure.

Discussion

The court will not attempt to chronicle the history and development of the body of knowledge pertaining to the recognition of and research into the etiology of the illness commonly referred to as AIDS, except insofar as relevant to the issues in this case. An excellent synopsis of that history is contained in *Kozup v. Georgetown University*, 663 F.Supp. 1048, 1051-53 (D.D.C. 1987) aff'd in part and vacated in part, 851 F.2d 437 (D.C.Cir.1988).

Briefly stated, by mid-1982 the medical community was aware of an unusual incidence of an acquired immunodeficiency among

hemophiliacs, homosexual men, and intravenous drug users. Other than having unusual stresses to their respective immune systems, it was not known what factors were common among members of these groups. In December, 1982, an article in the Morbidity/Mortality Weekly Review suggested the possibility that AIDS was transmissible by blood. Notwithstanding this article, by January, 1983, although there was a consensus that a significant public health problem was posed by the increasing numbers of persons who had developed symptoms consistent with acquired immunodeficiency, there was no consensus as to the methods of transmission of such a disease.

Dr. Ernest R. Simon, M.D., Executive Vice President for Medical Affairs of United Blood Services, Inc., testified that it was recognized early in 1983 that homosexual men were at "high risk" for AIDS. Nonetheless, direct questioning of prospective blood donors as to their sexual preference was not utilized by UBS, BSI or other members of the blood banking community. In the March/April, 1983, issue of Transfusion Magazine, a joint statement on Acquired Immune Deficiency Syndrome related to transfusion appeared. 23 Transfusion, March-April 1983, at 87-88. The "joint statement" dated January 13, 1983, was developed by the American Association of Blood Banks (AABB), the Council of Community Blood Centers (CCBC), and the American Red Cross (ARC) with assistance from the American Blood Commission, National Gay Task Force, the National Hemophilia Foundation, and representatives from the American Blood Resources Association, the Center for Disease Control, and the Food and Drug Administration. The "joint statement" suggested that donor screening should include specific questions to detect possible AIDS or exposure to patients with AIDS and that all donors should be asked questions designed to elicit a history of night sweating, unexplained fevers, unexpected weight loss, lymphadenopathy or Kaposi's sarcoma. However, the "joint statement" unambiguously stated, "Direct or indirect questions about a donor's sexual preference are inappropriate." The "joint statement" did not advise routine implementation of any laboratory screening program or surrogate testing for AIDS by blood banks at this time. Transfusion at 87-88.

Immediately after the MMWR article appeared, Kenneth R. Woods, Ph.D., President of the Council of Community Blood Centers, issued a newsletter noting the possibility that AIDS may be transmissible by transfusion but that:

[T]here have been no initiatives among blood center physicians to amend pre-donation interviews of males to include specific inquiries about sexual habits. Experienced physicians believe that the small number of prospective blood donors to whom such

questions would apply frequently do not respond in sufficient candor to expect that these persons could thereby be disqualified as blood donors.

An HHS News release issued by the Department of Health and Human Service, dated March 4, 1983, recognized that blood or blood products "appear to be the vehicles responsible for the increased incidence of AIDS among hemophilia patients." HHS News at 1. The following groups were considered to be at "high risk" for AIDS: patients diagnosed with AIDS, sexual partners of AIDS patients, persons with symptoms and signs suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, Haitian entrants to the United States, present or past abusers of intravenous drugs, and sexual partners of individuals at high risk for AIDS. The HHS document recommended that studies be conducted to evaluate screening procedures, including specific laboratory tests, careful medical histories, and physical examinations. HHS News at 2-3.

A March 24, 1983, memorandum from the Director of the Office of Biologics of the National Center for Drugs and Biologics recommended that the donor medical histories should include specific questions designed to detect possible AIDS symptoms or exposure to patients with AIDS, such as questions which elicit a history of night sweats, unexplained fevers, unexpected weight loss, or signs of lymphadenopathy or Kaposi's sarcoma.

In response to the research information and recommendations of public health agencies, BSI instituted various revisions in its donor screening process. On January 31, 1983, BSI issued a memorandum to its executive, technical and medical directors directing that AIDS placards be placed in obvious locations in its blood centers. AIDS handouts were to be given to each donor to read before the donor interview. Two distinct changes in the questioning were implemented: (1) donors were to be asked, "Do you understand the information we have provided you about AIDS?", and (2) donors were to be asked, "Are you in good health today?"

The placards referred to in the memorandum stated in bold print: The risk of exposure to AIDS is greater among persons who:

- * Have recently resided or traveled in Haiti.
- * Are homosexually active males with numerous contacts.
- * Are intravenous drug users.
- * Have (or may have had) hepatitis.

If you have been associated with any of these groups or if you have recently experienced:

- * Prolonged fevers.
- * Unexplained weight loss.
- * Swelling of lymph glands.
- * Unexplained skin eruptions.

PLEASE DISQUALIFY YOURSELF FROM DONATING PLASMA. You may also disqualify yourself by answering "No" when the interviewer asks you the question: 'Are you in good health today?' You do not need to state a reason. Your voluntary deferral will be kept in the strictest confidence.

On April 15, 1983, the interview process was updated so as to specifically require the interviewer to ask the following questions: "Have you been exposed to a patient with AIDS or to individuals who are at increased risk of contracting AIDS?" and "Have you had night sweating, unexplained skin eruptions or fevers, weight loss or swollen lymph glands?" Blood Service, Inc. Medical Technical Procedures Manual Memo (April 15, 1983). These questions were designed to follow FDA interim recommendations. On May 18, 1983, Dr. John C. Petricciani, M.D., Director of the Office of Biologics, wrote to Dr. Simon noting that the "Important Notice" placards submitted in April of 1983 did "not include sexual partners of individuals who may be at increased risk or bisexual men with multiple partners." The "Important Notice" placard was immediately revised to include these increased risk groups.

In December, 1984, Dr. Elaine C. Esber, M.D., then Acting Director of the Office of Biologics Research and Review, issued a memorandum to all blood centers advising that the HTLV-III virus had been reported as the etiological agent of AIDS. Department of Health and Human Service (Dec. 14, 1984). A revised set of recommendations to blood centers was issued. These recommendations included a recommendation that educational materials be provided to donors informing them that the following persons should refrain from donating blood: (1) persons with AIDS or one of the following symptoms-weight loss, night sweats, blue or purple spots on or under the skin or on mucous membranes, swollen lymph nodes lasting more than one month, persistent white spots or unusual blemishes in the mouth, fever in excess of 99 degrees Fahrenheit for more than ten days, persistent cough and shortness of breath, persistent diarrhea; (2) past or present abusers of intravenous drugs; (3) males who have had sex with more than one male since 1979, and males whose male partner has had sex with more than one male since 1979; (4) Haitians who have entered the United States after 1977; (5) patients with hemophilia; and (6) sexual partners of individuals in any of the above categories. It was not recommended that specific questions be asked regarding intravenous drug use, homosexuality, bisexuality, Haitian residence, or hemophilia, although specific questions were to be asked regarding physical symptoms. These recommendations also suggested that a confidential means be provided whereby the donor could prevent his or her blood from

being transfused.

In January, 1985, a document entitled, "Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome" was published. This document noted that the newly discovered retrovirus "human T-lymphotropic virus type III" (HTLV-III) is the cause of AIDS, and that tests to detect antibody to HTLV-III would be licensed in the near future. The antibody tests are modifications of the enzyme-linked immunosorbent assay (ELISA), which uses antigens derived from whole disrupted HTLV-III. These recommendations stated that persons accepted as donors should be informed that their blood will be tested for HTLV-III antibody and that they will be notified if their test is positive. This document clearly indicates that all blood or plasma should be tested for HTLV-III antibody by ELISA as soon as such testing became commercially available. If the ELISA test was found to be positive, another test, such as the Western blot technique was to be utilized. In the Western blot test, antibodies can be detected to HTLV-III proteins of specific molecular weights. According to the January, 1985, document, the Western blot test should be considered positive if band p24 or gp41 is present alone or in combination with other bands.

A February 19, 1985, memorandum from the Director of the Office of Biologics Research and Review to all registered blood establishments informed blood centers that the FDA would soon license the HTLV-III virus antibody test. Department of Health and Human Services (Feb. 19, 1985). Collection facilities were encouraged to voluntarily begin performing the test as soon as supplies were "commercially available". Prior to mandatory testing, a voluntary phase-in period would exist during the period of time before final regulations could be put into effect. Because of the potentially serious impact that a positive test result could have on individual donors, it was recognized that it was "very important" that staff be adequately trained. On March 2, 1985, the FDA licensed the ELISA test manufactured by Abbott Laboratories. In October of 1984, BSI had issued a letter-commitment to Abbott for the purchase of kits for 60,000 tests, when licensed. March 2, 1985, was a Saturday. The following Monday, March 4, 1985, UBS ordered 400 kits for use in the Fort Smith center. The kits were shipped on March 12, 1985, and received in the Fort Smith center on March 13, 1985. On March 22, 1985, 400 more kits were received. The kits which had been received on March 13, 1985, were stored and refrigerated until Abbott representatives arrived in Fort Smith on March 18, 1985, to train the UBS employees. Training was conducted on

March 18-19, 1985. Routine testing of newly donated blood began in Fort Smith on March 23, 1985.

On March 6, 1985, an unidentified individual donated a unit of blood, referred to as unit number 26013-6582, during a blood drive at an industrial plant in Rogers, Arkansas. On March 7, 1985, this unit of blood was shipped to Boone County Hospital in Harrison, Arkansas. On March 19, 1985, the unit of blood was returned to UBS in Fort Smith. Because blood has a "shelf life" of only 35 days, this unit was shipped to Sparks Regional Medical Center in Fort Smith on March 20, 1985. Sparks is UBS' largest single user of blood. It was common practice for blood which was unused by hospitals in outlying counties to be routinely returned and routed to Sparks in order that it may be used prior to its expiration date.

On March 25, 1985, Dee Kirkendall was admitted to Sparks Hospital for heart surgery. The surgery was performed on March 28, 1985. During surgery, Dee Kirkendall received blood unit 26013-6582. That unit of blood was not tested for the presence of HTLV-III antibodies by any test at any time.

On July 22, 1986, Dr. O.L. Davenport, M.D., Medical Director of UBS, wrote a letter to the unidentified donor informing him that a unit of blood he had donated on April 23, 1986, had been confirmed positive for AIDS. Dee Kirkendall's physician was notified of this fact in October, 1986. When Dee Kirkendall's blood was subsequently tested, it too was confirmed positive for AIDS. It is not seriously disputed that he was infected with the AIDS virus via the transfusion with blood unit number 26013-6582 on March 28, 1985. Nor is there any doubt that Dee Kirkendall died of AIDS on April 23, 1987, as a result of the March 28, 1985, transfusion.

Plaintiff's proof is directed toward two principal contentions: (1) that UBS was negligent in its "screening" procedures, and (2) that UBS was negligent in failing to provide Dee Kirkendall with blood which had been tested in some manner for the presence of antibodies to the HTLV-III (HIV) virus at the time of the March 28, 1985, transfusion.

With respect to the former contention, plaintiff attempted to prove at trial through the testimony of Dr. Melvin Kramer, Ph.D. and other witnesses that the donor interview process observed by UBS was flawed and that the staff was inadequately trained to detect possible AIDS-infected donors prior to the implementation of routine ELISA testing. As discussed previously, it is clear that UBS revised its donor information placards and interview questionnaire as expeditiously as possible in order to correlate its "screening" with the latest research information available to the scientific community. Additionally,

a confidential unit exclusion procedure was available whereby a donor could notify the blood bank within hours that his blood should not be used for transfusion purposes. The question, "Are you in good health today?" further provided a donor with an opportunity to self-defer without embarrassment.

Plaintiff essentially maintains that donors should have been directly asked explicit questions, such as "Are you a homosexual or a bi-sexual?" and "Have you visited male or female prostitutes?" UBS' position, as well as that of the entire blood banking industry, is that this would offend potential donors and would ultimately cause a significant reduction in the blood supply. This position of the industry was repeatedly referred to during trial as "cooperation, not confrontation."

The court considers it fairly obvious that very little insight or imagination is required to understand that such questions would be offensive to a significant segment of the population. However, this alone is not a sufficient reason to prohibit such questions. If such questioning of potential donors would measurably reduce the risk of transmission of the AIDS virus without jeopardizing the supply of blood available to the public, then the standard of care required of blood centers would seem to dictate such questioning. Nonetheless, not only is there absolutely no proof in the record that such questions would in general reduce the risk of transmission by blood of the AIDS virus, there is no proof whatsoever that such questioning would have had any effect on Dee Kirkendall's receipt of untested blood unit 26013-6582.

Neither the Food and Drug Administration, the Centers for Disease Control, the Council of Community Blood Centers, the American Association of Blood Banks, nor the American Red Cross has ever recommended the use of direct "confrontational" questioning of potential donors regarding their sexual habits. See Joint Statement on Acquired Immune Deficiency Syndrome Related to Transfusion, *supra*. However, even assuming that the unidentified donor of blood unit 26013-6582 would respond candidly to such questions, there is not one iota of proof that the donor had any symptoms or signs suggestive of AIDS at the time of the donation, nor that he was a sexually active homosexual or bisexual man with multiple partners, that he was a recent Haitian entrant to the United States, that he was a present or past user of intravenous drugs, that he was a sexual partner of an individual at increased risk of AIDS, nor that he visited prostitutes. Thus, even had the donor been confronted with specified questions about his sex habits and the like while being interviewed in the manner suggested by the plaintiff, there is not the slightest proof or indication that this would have had any effect whatsoever on the donor's

blood having been collected by UBS. Therefore, not only is there a complete lack of "proximate causation" between the failure of UBS personnel to ask these questions (or use a different "screening" process altogether) and the collection of blood unit 26013-6582, there is not even a "but for" causation relationship between the two events. Had the absent proof been forthcoming, the court would have been squarely presented with the issue regarding "confrontation" of donors. However, in the complete lack of such evidence a discussion regarding the theoretical effectiveness of screening procedures, as observed or in the abstract, becomes academic and irrelevant to the issue of liability. Suffice it to say that there is no evidence to suggest that the notification/interviewing/screening procedure utilized by UBS has anything to do with this case.

Plaintiff also contends that, in addition to proper donor "screening", UBS should have utilized "surrogate testing", i.e. testing for something other than AIDS in an attempt to screen out AIDS-infected blood. Prior to the development of ELISA testing, there were 15 to 20 possible "surrogate tests" which had been considered by researchers. Dr. Simon testified that as of 1983 no test for AIDS was available at all, surrogate or otherwise. After a joint study involving its medical director in 1983, UBS concluded that surrogate testing would not be useful because there was no statistical difference between different risk groups and there appeared to be no correlation between the various surrogate tests which measured different things. At trial, Mr. Jack Smythe of the Western Tennessee Regional Blood Center confirmed this view. It is not disputed that the FDA has never licensed surrogate testing for AIDS. Neither the AABB nor the CCBB ever recommended the use of any surrogate tests. One such surrogate test was known as the Hepatitis B core antibody test, which plaintiff contends would have screened out a significant percentage of AIDS infected donors. With regard to the Hepatitis B core antibody test the evidence reflects the existence of no organization, governmental or medical, which advocated the use of such a test as a screen against AIDS. Unless the entire blood banking industry was negligent the failure of UBS to utilize this test cannot give rise to liability.

Plaintiff's argument that the entire industry was, in fact, negligent will be discussed infra. More immediately dispositive of plaintiff's "surrogate-test argument" is that plaintiff can point to no test which would have screened out the donor whose contaminated blood Dee Kirkendall received. In fact, there is no proof that even had the ELISA test itself been performed the donor would have been deferred.

In any event, plaintiff must show that UBS' failure to implement

the hepatitis-B core antibody test or some other surrogate test caused Dee Kirkendall to become infected. As the proof stands, it is a matter of the purest speculation what any surrogate test would have disclosed that the blood was infected. Because plaintiff has failed to demonstrate what surrogate test, if any, would have prevented Dee Kirkendall's receipt of blood unit 26013-6582, the critical element of causation is lacking. The court recognizes that once the blood contained in unit 26013-6582 was disposed of, no further tests could later be made.

Nonetheless, in the absence of any showing as to how UBS' failure to perform any particular surrogate test proximately caused blood unit 26013-6582 to be transfused into Dee Kirkendall, i.e. that had UBS performed any particular surrogate test that blood unit would not have been transfused into Dee Kirkendall, the court cannot impose liability upon UBS on the basis that surrogate testing was not performed. Even if the failure to perform surrogate testing was "negligent" in the abstract, there can be no liability unless that failure proximately caused Dee Kirkendall to become infected with AIDS and unless Dee Kirkendall would not otherwise have become so infected. The required showing of proximate causation is lacking and plaintiff's argument with respect to surrogate testing must fail on that basis. However, as discussed infra, even if there could be found a causal relationship between UBS' failure to utilize surrogate testing for AIDS and Dee Kirkendall's receipt of blood unit 26013-6582, the failure to utilize surrogate testing cannot be considered negligent conduct.

Finally, plaintiff contends that under the circumstances of this case UBS was negligent in its failure to test blood unit 26013-6582 for the presence of HTLV-III (HIV) antibodies prior to the transfusion of March 28, 1985. As indicated earlier, the ELISA test first became commercially available and licensed on March 2, 1985. UBS received its first test kits on March 13, 1985, sufficient to perform 400 tests. On March 22, 1985, UBS received testing kits sufficient in number to perform 400 additional tests.

Training of UBS employees on the use of the test kits was conducted on March 18-19, 1985. The testimony indicated that training as to the use of the kits was absolutely essential in order for test results to have any meaning. Patricia Jones testified that 375 to 500 tests were made in the training. On March 13, 1985, the day the first 400 kits arrived, the Fort Smith center had 1513 units of blood components in its "inventory", including units "in process" and on consignment in other locations. On March 23, 1985, the inventory of blood and blood products consisted of 1753 units. Approximately 300 to 425

kits remained after training.

Obviously it would not have been possible to test all of the blood components in inventory as of March 23, 1985. However, only red blood cells and whole blood would "expire" in a short period of time as the "shelf life" of these products is 35 days compared to a year for cryoprecipitate and frozen plasma. On March 23, 1985, there were 193 units of red blood cells in inventory. The question naturally arises at this point why the red blood cells could not have been tested, deferring testing of other blood components until latter. Because 169 ELISA-tested units of red blood cells were available on March 28, 1985, plaintiff contends that the tested blood should have been substituted for untested blood as it became available. The answer is that it is not that simple. According to the uncontradicted testimony of UBS employees, as a matter of logistics alone it would have required two days to have all of the blood units located in hospitals in outlying areas collected and brought back to Fort Smith. If all 1753 units of blood components available on March 23, 1985, were "recalled" for testing, it would have taken approximately 90 consecutive hours of testing to have performed the ELISA test on each unit, even if sufficient kits were available, which they were not. In the three day period subsequent to March 23, 1985, approximately 349 units of blood and blood products were used for transfusion purposes by area hospitals serviced by the Fort Smith UBS facility.

The testimony indicated that UBS could not cease using untested blood because the 169 units of tested red blood cells would not supply UBS' customers with a minimum supply. To further complicate the problem, at Sparks Hospital 35 to 55 "cross-matches" of donor serum with recipient cells are performed each day for prospective blood transfusions. This is required to assure recipient compatibility with the donor's blood. After a cross-match is completed, the donor's blood is held for 48 hours, earmarked for use by one particular donor. Approximately 25 patients per day actually used or received blood cross-matched and "tagged" for their use. On any given day, Sparks hospital had "on hold" 150 to 200 units of cross-matched blood.

If cross-matched blood were returned by Sparks Hospital for AIDS testing by UBS, all of the replacement blood would have to be re-cross-matched. Only five cross-matches can be performed in 45 minutes. It follows that the blood units could not be returned to UBS for testing without jeopardizing the supply of blood available for use by emergency or surgery patients of Sparks Hospital. UBS also serviced fifteen other hospitals in several counties.

In light of this, plaintiff contends that "segments" of blood on

hand at the various hospitals could be tested for HIV antibodies without disturbing the actual units of blood or the blood supply. It appears to be true that this could theoretically have been done. However, as indicated above, this assumes that UBS had unlimited testing capability, equipment, personnel, and time in which to do so. Had UBS the testing capability, it could have tested all of the blood and blood products in inventory on March 23, 1985, by some time on March 26, 1985, if it tested none of the units collected in that period of time. This ignores, too, that 349 units of blood and blood products were actually used in that period for transfusion by the hospitals serviced by the Fort Smith UBS facility. Because it is unknown at any given time what particular blood product or blood type will actually be needed by area hospitals, or the exact number of units that will be needed, only by testing all of the inventory without significantly disrupting the blood supply could the risk of transmission of AIDS be practically eliminated. Any significant disruption of the blood supply would have caused a greater risk to blood recipients than was present in the supplying of untested blood. Therefore, only by first testing whole blood and red blood cells, which are time-dated, and by testing only segments of red blood cells or whole blood contained in the entire UBS Fort Smith inventory, and only by delaying testing of newly donated blood, could UBS have possibly tested unit number 26013-6582 without impairing the blood supply. Again, this is only a possibility because it may be that some of the 349 units of blood used in the three days after March 23, 1985, would not have been tested by the time it was needed after being cross-matched for use by a particular patient. There was just as much likelihood that one of the 349 units actually used was contaminated with HTLV-III (HIV) as was unit 26013-6582. Thus, the likelihood is that some untested blood would have had to have been used in the interim period, unless, as plaintiff urges, UBS advised all sixteen of its serviced hospitals to delay all elective and non-emergency surgery until all blood could be tested. Only by taking all of the above steps could the risk of transmission of HTLV-III be significantly reduced without endangering the supply of blood. Thus, it comes down to this: was the risk of AIDS contaminated blood such as to require that these measures be taken? At this juncture plaintiff would urge that the risk of AIDS is the risk of death and all possible measures must be taken to protect human life. Patricia Jones testified that since HIV testing began in March of 1985, over 66,000 units of blood have been tested by UBS of Fort Smith for the presence of HIV antibodies. Only ten confirmed cases have been detected. Therefore, since testing began by the Fort Smith center, one in

every 6,600 units of donated blood have tested positive for AIDS antibodies. This is approximately .0151%. This percentage is comparable to the results of testing by the Western Tennessee Regional Blood Center, according to the testimony of Mr. Jack Smythe, President and Chief Executive Officer of that institution.

In retrospect it can be seen that in the years since AIDS testing began, only one of every 6,600 units of donated blood were infected with the AIDS virus, although this was not known in 1985. However, even had UBS been aware of this fact, it could not have predicted that any of the 1753 units of blood products in its inventory on March 23, 1985, would have tested positive for AIDS antibodies. The overwhelming statistical probability was that not one unit of the 1753 units in inventory would test positive. Dr. Simon testified that a higher percentage of positive test results occurs as time goes by, partially because the antibody tests will not reflect a reactive result until two to six months after actual infection. Therefore it can be inferred that a test of a given population in 1985 would reflect fewer positive results than a test of the same population in 1988, even if no "spreading" of the virus or new infection occurred in that population.

Thus, even had UBS in 1985 the benefit of the years of research and study which have occurred in the interim, it could not have foreseen that any of its inventory during the relevant time period would, upon testing, reflect the presence of AIDS antibodies. UBS could not have known that its failure to test its inventory would result in harm to any of the recipients of its blood, even if it had been possible and feasible to test all of the inventory. The collective knowledge of the blood industry in 1985 was far less than it is today. Even today, it would not be possible to accurately assume that any harm would have resulted to anyone as a result of UBS' failure to test its inventory between March 23, 1985, and March 28, 1985.

Finally, it was essentially undisputed at trial, that even had blood unit 26013-682 been tested, it may not have tested positive for the presence of HTLV-III (HIV) antibodies. After infection with the virus, a "window" of two to six months exists during which antibodies to the virus cannot be detected in the blood. For purposes of trial it was assumed that the HIV virus was present in blood unit 26013-6582 because the donor later tested positive for the presence of HIV antibodies and no other cause of Dee Kirkendall's having contracted AIDS can be located. It cannot be assumed, however, that blood unit 26013-6582 contained antibodies to the HIV virus; thus it cannot be said with any degree of certainty that had an ELISA test been made of that

unit, the results would have caused its exclusion from the blood supply.

Against this remote degree of risk is to be balanced the feasibility of testing inventory in the manner suggested by the plaintiff. At the risk of oversimplifying the matter, resort to basic principles of negligence law instructs us that "if one's conduct was reasonable in the light of what one could anticipate, there would be no negligence, and no liability." W. Keeton, Prosser and Keeton on Torts, 43, p. 280 (5th Ed.1984). Stated another way, "those (injuries) which, although foreseeable, were foreseeable only as remote possibility, those only slightly probable, are beyond and not within the circle (of liability) W. Keeton, Prosser and Keeton on Torts, supra, p. 281, n. 7, quoting *Mauney v. Gulf Refining Co.*, 193 Miss. 421, 9 So.2d 780 (1942).

The issue with which the court is confronted is whether the failure to test inventory between March 23, 1985, and March 28, 1985 (assuming it to have been possible), constitutes negligence in light of the probable consequences. We are not confronted with a failure to test at all. The evidence indicates that a failure to ever test for HIV antibodies would naturally and probably result in harm at some point, even if the chances of receiving AIDS contaminated blood from any particular unit is one in 6,600. Further, we are not dealing with a failure to test the 1753 units at a time when to do so would be more feasible and less threatening to the quantity of blood available. We are presented with the question of whether the failure to test the inventory between March 23, 1985, when testing began, and March 28, 1985, when Dee Kirkendall received blood unit 26013-6582, was unreasonable in light of the risk of harm known at the time and the feasibility of doing so.

Resort to general principles of negligence law indicate that it was not unreasonable for UBS to decide not to test inventory and to test only new donations after March 23, 1985. This conclusion is buttressed somewhat by the conduct of other hospitals, blood banks, and organizations across the country. In *Kozup*, supra, the district court for the District of Columbia held that the standard of care for a hospital is established by looking to the conduct of the medical profession in similar circumstances as of that date. The court wrote:

Yet, plaintiffs cannot point to a single hospital that was taking the measures which plaintiffs contend it was negligent for Georgetown not to take. All they offer is the testimony of two physicians who contend in hindsight that all hospitals should have been doing more to screen blood and donors than they were doing in late 1982 and early 1983. These opinions cannot be

permitted to supplant the standard of care as established by the conduct of the medical community which plaintiffs' experts criticize.

Kozup, *supra*, at 1055. On July 15, 1988, Kozup was affirmed by the Court of Appeals for the District of Columbia Circuit with regard to the negligence claims. See *Kozup v. Georgetown University*, 851 F.2d 437 (D.C.Cir.1988).

McKee v. Miles Laboratories, Inc., 675 F.Supp. 1060 (E.D.Ky.1987) expressly followed the Kozup standard. In *McKee*, a pharmaceutical company had pooled the plasma of thousands of individuals in manufacturing Factor VIII Concentrate for use by hemophilia patients. Plaintiff contended that the company was negligent in failing to use alternative testing methods to protect recipients from AIDS. In granting defendant's motion for summary judgment on negligence the court noted:

[P]laintiff can point to no organization, government entity or medical association within the United States which advocated the use of plaintiff's alternative testing as a means of screening defendant's product for AIDS.

McKee, at 1064. The applicable standard of care was to be established by "looking to the conduct of the industry or profession in similar circumstances... ." *Id.*

Prior to the current advent of AIDS cases, a wealth of hepatitis transfusion-related cases indicated that the applicable standard of care was that of a reasonably prudent blood bank in the same or similar situation. *Juneau v. Interstate Blood Bank, Inc.*, 333 So.2d 354 (La.App.1976) cert. denied, 337 So.2d 220 (1976); *Hines v. St. Joseph's Hospitals*, 86 N.M. 763, 527 P.2d 1075 (1974); See *Hutchins v. Blood Services of Montana*, 161 Mont. 359, 506 P.2d 449 (1973). An interesting malaria transfusion case in accord is *Tufaro v. Methodist Hospital, Inc.*, 368 So.2d 1219 (La.App.1979). See also Annotation: Liability of Blood Supplier or Donor For Injury or Death Resulting From Blood Transfusion, 24 A.L.R. 4th 508 (1987). These cases establish that compliance with existing federal regulations, guidelines of blood banking organizations, and conduct in accordance with the conduct of other blood banks similarly situated satisfies the duty of care owed to potential recipients.

This being the case, it is noted that UBS complied with all FDA regulations during the relevant time period, as well as the recommendations of the American Red Cross, Council of Community Blood Centers, and the American Association of Blood Banks, particularly with regard to its screening interview process and its decision not to utilize surrogate testing for AIDS. Dr. Simon testified that UBS' testing of all new donors after March 23, 1985, exceeded the standard of care in the industry, as did Mr.

Jack Smythe, Dr. Robert Randell, and Mr. Michael Couch. The AABB mandated testing as of July 1, 1985. The FDA did not require it until January 5, 1988. Michael C. Couch, Chief Executive Officer of the Louisiana Blood Center, testified that that organization began HIV antibody testing on March 25, 1985, through March 27, 1985, in various parts of Louisiana. That organization did not test its inventory, but only new donors as did UBS. Patricia Jones testified that the American Red Cross did not begin HIV testing until late March or early April of 1985, and that organization did not test its inventory. Dr. Robert Randell of the Sacramento Blood Center indicated that testing at that center did not begin until April 15, 1985. Not until May 22, 1985, were all units of blood and blood products in that center tested for HIV antibodies. Dr. Jack Smythe related that routine testing did not begin at the Western Tennessee Regional Blood Center until April 22, 1985, and that no inventory was tested there. All of these persons testified that the standard of care observed by blood banks across the country did not require the testing of inventory for the presence of HIV antibodies.

All of these individuals testified that UBS met or exceeded the standard of care observed by reasonably prudent blood banks in their screening procedures, decision not to implement surrogate testing for HIV antibodies, the beginning of routine testing for HIV antibodies on March 23, 1985, and the decision not to test inventory. Additionally, as noted earlier, plaintiff has failed to demonstrate any dispositive nexus between any of UBS' screening procedures or its failure to utilize surrogate testing and the injuries received by Dee Kirkendall. Thus, even had UBS fallen short of industry standards with regard to these practices, no liability could attach as a result.

Plaintiff was unable to point to any organization that began routine HIV testing earlier than did UBS. Plaintiff demonstrated the existence of no blood bank which tested inventory after testing was implemented. Had Sparks Hospital been located within the area serviced by the Sacramento Blood Center, Dee Kirkendall would have received blood unit 26013-6582 approximately two and one half weeks before any HIV testing began. If the Western Tennessee Regional Blood Center had been the blood bank involved, Dee Kirkendall would have received the tainted blood some three and one-half weeks before any testing began. UBS began testing two to four days prior to the institution of routine testing by the Louisiana Blood Center and more than three months before it was required by the AABB.

Only if the entire blood banking industry was negligent in the manner in which HIV testing was implemented and carried out, as

Dr. Melvin Kramer suggested, could the court conclude that UBS acted negligently in this case. A similar argument was advanced in Kozup. Of this contention that court stated:

This is not, as plaintiffs contend, an instance where 'what ought to be done is fixed by a standard of reasonable prudence' but is simply not complied with by an entire community. (citation omitted) In that situation, courts have not hesitated to compel an entire community to upgrade its standard of care.

Kozup, supra, at 1057-1058.

As an example, the court in Kozup referred to the T.J. Hooper, 60 F.2d 737 (2d Cir.1932), wherein Judge Learned Hand required all tugboats to be equipped with radios although none were so equipped at the time. Courts are naturally reluctant to allow an industry to set its own standards. Even compliance with statutory or regulatory standards is not conclusive on the issue of due care. See W. Keeton, Prosser and Keeton on Torts, supra, 36, p. 233. Such a statutory or regulatory standard is no more than a minimum and it does not necessarily preclude a finding that the actor was negligent in failing to take additional precautions. See Restatement (Second) of Torts, 288C. Neither does compliance with a de facto industry standard necessarily insulate an actor from liability.

However, whether UBS' conduct in this case is judged by a general standard of reasonable prudence or by looking to the actual conduct of reasonably prudent members of the blood banking industry as of the date in question, plaintiff has failed to meet her burden of proving that UBS acted negligently by failing to test its inventory of blood and blood products between March 23,1985, and March 28,1985. As UBS did not cause injury to Dee Kirkendall through any negligence on its part, Harbor Insurance Company is not liable to the plaintiff on its policy of insurance under Arkansas' "direct action" statute, Ark.Code Ann. 23-79-210.

A separate judgment in accordance herewith will be concurrently entered.

JUDGMENT

On August 16, 1988, through August 18, 1988, the above entitled matter was tried to the court sitting without a jury, pursuant to agreement by and between the parties. Plaintiff appeared in person and through her counsel, Sam Sexton, Jr., and the defendant appeared by and through designated corporate representatives and its counsel, Robert L. Henry, III and G. Spence Fricke. From the testimony of the witnesses for the respective parties, exhibits introduced and received in evidence, and the statements and arguments of counsel the court finds and

concludes that this court has jurisdiction of the subject matter hereof and the parties hereto; and that defendant is entitled to judgment on the merits with regard to all issues raised in plaintiff's complaint, as amended;
IT IS, THEREFORE, CONSIDERED, ORDERED, AND ADJUDGED that plaintiff's complaint, as amended, be dismissed with prejudice for the reasons set forth in the court's memorandum opinion filed concurrently herewith.
IT IS SO ORDERED.