Notes

STRICT LIABILITY, NEGLIGENCE AND THE STANDARD OF CARE FOR TRANSFUSION-TRANSMITTED DISEASE

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I. INTRODUCTION

The first time James Fogo had a tooth pulled the socket oozed blood for months afterward.[1] His doctor told him he had hemophilia. The next time he needed a tooth pulled he was injected with factor IX before the extraction. This time there was no prolonged bleeding. But three years later James Fogo was diagnosed as having AIDS. He contracted the disease from the factor IX he was given to prevent excess bleeding.

This Note will deal with liability for the transmission of AIDS and other diseases by blood and blood products such as the one given to James. There are two major legal theories that a person who is infected through blood or blood products can use. One is negligence and the other is strict products liability. Statutes in most states shield blood banks from strict products liability. The patient is not much more likely to succeed if he brings a suit based on negligence. There are two reasons for this. First, most courts apply a professional standard of care to blood suppliers. Blood suppliers follow the standards set by their industry associations, so it is unlikely that the patient can prove that the supplier of the contaminated blood that he received failed to follow the professional standard of care. Second, it is hard to prove that blood products were the source of infection. AIDS can be transmitted by sexual contact and intravenous drug use as well as by blood products. The infected patient must therefore prove that his disease did not come from these sources. Furthermore, the records and expertise are in the hands of the blood suppliers. The patient is therefore faced with a considerable barrier to success in obtaining compensation for his injury.

This is not the only consideration, however. On the other side there is the fact that blood is essential to the preservation of life and the alleviation of suffering. The legislatures of states with blood shield statutes enacted the statutes because they believed that law suits would raise the price of blood

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1. The example is based on Fogo v. Cutter Lab., 137 Cal. Rptr. 417, 419–20 (Cal. Ct. App. 1977).

prohibitively and decrease the amount of blood available. The question is therefore how to balance the right of the patients to compensation for their injuries and the importance of cheap and abundant blood.

In order to address this question it is necessary to understand the facts. The needs of the infected patient are one factor that must be considered in determining what action is appropriate. This Note will therefore first discuss the symptoms and progress of AIDS and the other diseases that can be transmitted by blood. This Note will next discuss products liability. This discussion will include an examination of the statutes and case law that deal with the application of products liability to blood and blood products, and examine whether the law is consistent with the goals of strict liability. Finally this Note will discuss the application of negligence to blood transmitted diseases.

II. BLOOD-BORNE DISEASES

Before we can evaluate the current law dealing with diseases transmitted by blood it is first necessary to understand the diseases that can be transmitted by blood and their effects on those who contract them.

A. Hepatitis

Hepatitis is an important transfusion-transmitted disease for two reasons. First, until recently, transfusion-transmitted hepatitis killed more people than transfusion-transmitted AIDS did.[2] Second, hepatitis was the first important blood-borne disease and the early cases, which are still followed in most states, dealt with hepatitis.[3]

Hepatitis is a general term for an inflammation of the liver. Hepatitis can be caused by many viruses and chemicals.[4] However, the only significant forms of hepatitis transmitted by blood are caused by two viruses: Hepatitis B and Hepatitis C.[5] Both viruses produce similar symptoms. The viruses infect the liver cells, destroying some of them and impairing the function of others. The

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2. In the 1960's 33% of transfusion recipients got hepatitis. Lorrie A. Langdale, *Infectious Complications of Blood Transfusions*, 6 INFECTIOUS DISEASE CLINICS OF NORTH AMERICA 731, 732 (1992). The screening of blood for antibody to the hepatitis B surface antigen reduced the rate to 15% and the elimination of paid donors reduced the rate to 3 to 4 %. *Id.* Between 85 and 95% of the remaining hepatitis was non-A, non-B hepatitis. *Id.*; James G. Donahue et al., *The Declining Risk of Post-Transfusion Hepatitis C Virus Infection*, 327 NEW ENG. J. MED. 369, 372 (1992); Richard D. Aach et al., *Hepatitis C Virus Infection in Post-Transfusion Hepatitis—An Analysis with First- and Second-Generation Assays*, 325 NEW ENG. J. MED. 1325 (1991). Before the introduction in 1989 of a test to detect hepatitis C, G. Kuo et al., *An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis*, 244 SCIENCE 362 (1989), the major cause of non-A, non-B hepatitis, 98% of the risk of dying from a blood transfusion was attributable to non-A, non-B hepatitis and 1% to AIDS. Jeffrey L. Carson et al., *The Risks of Blood Transfusion: The Relative Influence of Acquired Immunodeficiency Syndrome and Non-A, Non-B Hepatitis*, 92 AM. J. MED. 45 (1992).

3. *See* Jay M. Zitter, Annotation, *Blood Transfusion Liability*, 24 A.L.R. 4th 508 (1983 & Supp. 1992). The most important blood case was *Perlmutter v. Beth David Hospital*, 123 N.E.2d 792 (N.Y. 1954), *reargument denied*, 125 N.E.2d 869 (N.Y. 1955). The majority of states have statutes which follow this case. *See infra* note 118.

4. THE MERCK MANUAL 898 (Robert Berkow ed., 16th ed. 1992). Hepatitis can be caused by viruses such as the Epstein-Barr, cytomegalovirus and yellow fever viruses, and alcohol and drugs.

5. Hepatitis C is the major cause of non-A non-B hepatitis. Kuo et al., *supra* note 2.

majority of infected people have either no symptoms[6] or mild symptoms[7] similar to the symptoms of the flu. Jaundice, in which the skin turns yellowish because of the buildup of waste products that the liver ordinarily eliminates, is a common symptom. In a small number of patients, destruction of the liver cells is so extensive that death results.[8] There is also a possibility that the infection will result in the development of liver cancer at a later time.[9]

Hepatitis is transmitted by clotting factors used by hemophiliacs as well as by transfusions, and between fifty and eighty percent of hemophiliacs show evidence of having been infected.[10]

Both Hepatitis B[11] and Hepatitis C[12] can now be detected by blood tests and the risk of infection by blood transfusion is low.

B. Acquired Immunodeficiency Syndrome (AIDS)

The majority of law suits that deal with transfusion-transmitted disease now deal with AIDS infections. The first cases of AIDS were not related to

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6. About 55% of patients with hepatitis B have no symptoms. Langdale, *supra* note 2, at 732.

7. About 45% of patients with hepatitis B have mild symptoms consisting of fatigue, anorexia, vomiting and an enlarged liver. *Id.* The majority of people infected with non-A, non-B hepatitis also have minimal symptoms. *Id.* at 733. However, 20% of patients with hepatitis C infection show necrosis and cirrhosis of the liver. *Id.* Fifty percent of patients with post–transfusion non-A, non-B hepatitis develop chronic disease. Roger Y. Dodd, *The Risk of Transfusion Transmitted Infection*, 327 NEW ENG. J. MED. 419, 420 (1992). There is no increase in mortality up to 18 years following diagnosis. *Id.* at 419.

8. About 1% of patients with hepatitis B develop fulminant disease. Langdale, *supra* note 2, at 732. Acute fulminating hepatitis is characterized by destruction of liver cells and brain inflammation. *Id.* 80% of the adults and 30% of the children with fulminant disease die. *Id.* There is a higher incidence of severe disease in patients who also are infected with the hepatitis D virus as well as with hepatitis B. *Id.* at 733. Hepatitis D is a defective virus that requires the presence of hepatitis B to infect the patient. *Id.* Hepatitis D antigen is present in the blood for a brief period and the concentration of antibodies against it is frequently too low to detect. *Id.* There is therefore no good way to screen for hepatitis D in the blood supply. *Id.* Since it requires hepatitis B to infect the liver cells, screening out hepatitis B decreases the risk of getting hepatitis D. *Id.*

9. Hepatitis C is associated with liver cancer. Rosa G. Simonetti et al., *Hepatitis C Virus Infection as a Risk Factor for Hepatocellular Carcinoma in Patients With Cirrhosis*, 116 ANNALS INTERNAL MED. 97 (1992) (the presence of antibody to hepatitis C in blood is an independent risk factor for the development of hepatocellular carcinoma).

10. Jeanne Lusher, *Anti–HCV Prevalence in Relation to Type and Amount of Clotting Factor Therapy in Congenital Clotting Disorders*, 65 THROMBOSIS & HAEMOSTASIS 1074 (1991).

11. The risk of getting hepatitis B from a blood transfusion is now 1 in 200,000 units. Dodd, *supra* note 7, at 420.

12. The risk of getting hepatitis C from a transfusion was 45 in 10,000 units for blood screened for HIV–1, syphilis and hepatitis B surface antigen. Donahue, *supra* note 2, at 371. If the blood is screened for alanine transferase and antibody to hepatitis B core antigen the risk of transmission declines to 19 in 10,000 units, or a reduction of 58%. *Id.* The risk of contracting non-A, non-B hepatitis from blood tested for hepatitis C has been reported to be 3 in 10,000 units. *Id.* The first generation test does not detect all of the hepatitis C infected blood, in part, because it can be up to a year before antibody develops in the blood. *Id.* at 372; Harvey J. Alter et al., *Detection of Antibody to Hepatitis C Virus in Prospectively Followed Transfusion Recipients with Acute and Chronic Non-A, Non-B Hepatitis*, 321 NEW ENG. J. MED. 1494 (1989). The second generation test has a rate of detection of 99.7%. Aach et al., *supra* note 2; Antonio Craxi et al., *Second Generation Tests in Diagnosis of Chronic Hepatitis C*, 337 LANCET 1354 (1991) (letter).

transfusions. They were reported in 1981,[13] although the AIDS epidemic appears to have begun in the United States in late 1978.[14] The AIDS epidemic has progressed rapidly, and by March 31, 1993, 284,840 cases of AIDS had been reported in the United States.[15] The first transmission of AIDS by transfusion was reported in July 1982;[16] three further cases were reported in December 1982.[17]

Transmission of AIDS by blood products is a relatively minor method of transmission. Of the 100,777 deaths from AIDS reported between 1981 and 1990, 2943 (2.9%) were contracted from transfusion and 1019 (1%) from the use of anti-hemophilia factors.[18] Infection by transfusion peaked in 1983 for children and in 1984 for adults.[19]

1. The Natural History of AIDS

AIDS is caused by the human immunodeficiency virus (HIV),[20] which is transmitted either by blood or sexual contact.[21] HIV infects cells by binding to a

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13. The first report of diseases now known to be associated with AIDS was published on July 4, 1981. CENTERS FOR DISEASE CONTROL, *Pneumocystis Pneumonia-Los Angeles*, 30 MORBIDITY & MORTALITY WKLY. REP. 250, 305 (1981).

14. Jean L. Marx, *New Disease Baffles Medical Community*, 217 SCIENCE 618, 619 (1982). This was determined by looking at reports of Kaposi's sarcoma and requests for the drugs used to treat *Pneumocystis carinii* pneumonia. *Id.* These two diseases are characteristic of AIDS. *See infra* notes 33–39, and accompanying text.

15. CENTERS FOR DISEASE CONTROL, *The Impact of the Expanded AIDS Surveillance Definition on AIDS Case Reporting — United States, First Quarter, 1993*, 42 MORTALITY & MORBIDITY WKLY. REP. 308 (1993).

16. CENTERS FOR DISEASE CONTROL, *Pneumocystis carinii Pneumonia in Persons with Hemophilia A*, 31 MORBIDITY & MORTALITY WKLY. REP. 365 (1982).

17. CENTERS FOR DISEASE CONTROL, *Possible Transfusion Associated Acquired Immune Deficiency Syndrome*, 31 MORBIDITY & MORTALITY WKLY. REP. 650 (1982); Arthur J. Ammann et al., *Acquired Immunodeficiency in an Infant: Possible Transmission by Means of Blood Products*, 1983(1) LANCET 956 (1983).

18. CENTERS FOR DISEASE CONTROL, *Update: Mortality Attributed to HIV Infection/AIDS–United States, 1981–90*, 40 MORBIDITY & MORTALITY WKLY. REP. 41 (1990).

19. Donna S. Jones et al., *Epidemiology of Transfusion–Associated Acquired Immunodeficiency Syndrome in Children in the United States, 1981 Through 1989*, 89 PEDIATRICS 123, 126 (1992). This is probably because transfusions were screened for CMV for children beginning in 1984 and 94.7% of HIV infected people are also infected with cytomegalovirus. *Id.* The number of cases of transfusion-transmitted AIDS peaked at 8500 in 1983 and declined to 7250 in 1984. Thomas A. Peterman et al., *Estimating the Risks of Transfusion–Associated Acquired Immune Deficiency Syndrome and Human Immunodeficiency Virus Infection*, 27 TRANSFUSION 371, 372 fig. 4 (1987).

20. Robert C. Gallo et al., *Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS*, 224 SCIENCE 500 (1984); F. Barre-Sinoussi et al., *Isolation of a T-Lymphotrophic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)*, 220 SCIENCE 868 (1983). The virus that causes AIDS is now called HIV. It was previously called Human T-Lymphotrophic Virus Type-III (HTLV-III) and Lymphadenopathy Associated Virus (LAV). THE MERCK MANUAL, *supra* note 4, at 77. There are two forms of HIV. HIV-1 is the form of the virus that is prevalent in the United States, whereas HIV-2 is the form prevalent in Africa. Thomas R. O'Brien et al., *Human Immunodeficiency Virus Type-2 Infection in the United States*, 267 JAMA 2775 (1992). Seventeen people infected with HIV-2 were detected in the United States between 1987 and 1991, only one of whom had not been to an HIV-2 endemic area. *Id.* at 2776–77. The upper limit of HIV–2 infection in blood in the United States is estimated to be 2.6 in 10,000,000 units of blood drawn. *Id.* at 2778. A test for HIV-2 was mandated beginning June 1,1992. *Id.* at 2775. Immune suppression can also occur in the absence of HIV. There have been 47 reported cases of this in the United States as of September 17, 1992. Dawn K. Smith et al., *Unexplained*

specific protein in the cell membrane called CD-4.[22] The CD-4 protein is found on white blood cells, called macrophages and T-4 lymphocytes.[23] HIV destroys the majority of cells it infects.[24] However, the virus does not kill all of the T-4 cells it infects. Rather it uses the replicative machinery of some T-4 cells to make copies of itself. These newly made HIV's are then released from the infected T-cell into the blood to infect other T-cells.[25] As the infection proceeds the number of T-4 lymphocytes decreases, and those which are still present function poorly.[26]

Because T-4 cells are critical in regulating the function of the other types of cells in the immune system, destruction of the T-4 cells impairs the function of the immune system.[27] The first symptom of infection is frequently the development of mononucleosis-like symptoms within three to six weeks after infection.[28] In the first years of infection, the body makes T-4 cells faster than the virus can destroy them.[29] During this period the patient may show no symptoms.[30] This initial latent period can last from seven to ten years.[31] As the number of T-4 cells decreases, the patient develops AIDS-related complex (ARC), which is characterized by the presence of anti-HIV antibodies in the blood along with swollen lymph glands, weight loss, intermittent fever, malaise, fatigue, chronic diarrhea, and oral infections by the yeast *Candida*.[32] As more T-4 cells are destroyed, AIDS develops. When AIDS develops, the patient develops certain characteristic diseases.[33] One group of these diseases is opportunistic infections.[34] These are severe infections caused by organisms that ordinarily live in or on the human body without causing any harmful effect,[35]

Opportunistic Infections and CD4+ T-Lymphocytopenia Without HIV Infection, 328 NEW ENG. J. MED. 373 (1993). Out of 230,179 cases of AIDS reported to the CDC, HIV has not been detected in 27. *Id.* This form of immunosuppression is not believed to be caused by a transmissible agent. *Id.* at 377.

21. THE MERCK MANUAL, *supra* note 4, at 78.

22. *Id.*; Alexandra M. Levine, *Acquired Immunodeficiency Syndrome: The Facts*, 65 S. CAL. L. REV. 423, 427 (1991).

23. THE MERCK MANUAL, *supra* note 4, at 78; Levine, *supra* note 22, at 427.

24. Levine, *supra* note 22, at 427.

25. *Id.* at 428.

26. Giuseppe Pantaleo et al., *The Immunopathogenesis of Human Immunodeficiency Virus Infection*, 328 NEW ENG. J. MED. 327, 328 (1993).

27. Levine, *supra* note 22, at 428.

28. Fifty to seventy percent of people infected by HIV develop this symptom. Pantuleo et al., *supra* note 26, at 327.

29. *Id.*

30. Levine, *supra* note 22, at 429.

31. *Id.* at 430. In hemophiliacs, AIDS develops at different rates depending on the age of the patient. James J. Goedert et al., *A Prospective Study of Human Immunodeficiency Virus Type I Infection and the Development of AIDS in Subjects with Hemophilia*, 321 NEW ENG. J. MED. 1141, 1143 (1989). Eight years after infection 13.3% of patients less then 18 years old had AIDS, 27% of those between 18 and 35 had AIDS and 44% of those older then 35 had AIDS. *Id.*

32. THE MERCK MANUAL, *supra* note 4, at 81.

33. CENTERS FOR DISEASE CONTROL, *Revision of the Case Definition of Acquired Immunodeficiency Syndrome (AIDS) for National Reporting-United States*, 34 MORBIDITY & MORTALITY WKLY. REP. 373 (1985).

34. *Id.*

35. Opportunistic infections include *Pneumocystis carinii* pneumonia, which occurs in 80% of AIDS patients and is the initial opportunistic infection in 60%. Aaron E. Glott et al., *Treatment of Infections Associated with Human Immunodeficiency Virus*, 318 NEW ENG. J. MED. 1439 (1988). Twenty-five to fifty percent of AIDS patients have widespread disseminated *Mycobacterium avium* and *Mycobacterium intracellulare*. *Id.*

but cause disease in the AIDS patient because the patient's immune system can no longer fight them off.[36] Opportunistic infections are the cause of more than 95% of the deaths among AIDS patients.[37]

The suppression of the immune system also causes an increase in the rate of certain cancers because the AIDS-impaired immune system is unable to kill cancer cells before they have a chance to replicate.[38] The most common cancers associated with AIDS are Kaposi's sarcoma[39] and non-Hodgkin's lymphoma.[40] In some patients HIV also infects certain cells in the brain, which have receptors related to the CD-4 protein, leading to AIDS dementia. AIDS dementia is characterized by an inability to concentrate and decreased short and long term memory.[41] In Africa, HIV infection frequently manifests itself as a wasting disease, with weight loss of greater than 15%.[42]

AIDS is invariably fatal. Once AIDS has developed in hemophiliacs, they survive an average of 13-14 months.[43] The available drugs do not cure the disease, although they do delay death.[44] However, treatment with these drugs is quite expensive.[45]

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36. Levine, *supra* note 22, at 424.

37. THE MERCK MANUAL, *supra* note 4, at 83.

38. Levine, *supra* note 22, at 425.

39. Kaposi's sarcoma is a cancer of the blood vessel wall. *Id.* It produces elevated round or oval pink or red papules or plaques on the skin. THE MERCK MANUAL, *supra* note 4, at 2460. Kaposi's sarcoma occurs among AIDS patients at a rate 200-fold higher than in the general population. Charles S. Rabkin et al., *Incidence of Lymphomas and Other Cancers in HIV-Infected and HIV-Uninfected Patients With Hemophilia*, 267 JAMA 1090 (1992). However, Kaposi's sarcoma is relatively rare in those who contract AIDS from blood. It occurs in 21% of homosexuals with AIDS but in only 3% of those contracting AIDS from blood products. Thomas A. Peterman & John W. Ward, *What's Happening to the Epidemic of Transfusion-Associated AIDS?*, 29 TRANSFUSION 659 (1989).

40. Non-Hodgkin's lymphoma occurs at a rate 38-fold higher in HIV infected people than in the general population. Rabkin et al., *supra* note 39. The symptoms include swollen lymph glands, anemia and leukemia. THE MERCK MANUAL, *supra* note 4, at 1250.

41. Levine, *supra* note 22, at 426.

42. *Id.* at 426. This is because weight loss occurs primarily during opportunistic infections. Carl Grunfield & Kenneth Feingold, *Metabolic Disturbances and Wasting in the Acquired Immunodeficiency Syndrome*, 327 NEW ENG. J. MED. 329, 333 (1992). In industrialized countries patients are treated for the opportunistic infections and regain the lost weight, but in third world countries the opportunistic infections are not treated and the patient continues to lose weight. *Id.*

43. Robert Holman et al., *Survival of Hemophilic Males with Acquired Immunodeficiency Syndrome With and Without Risk Factors for AIDS Other Than Hemophilia*, 39 AM. J. HEMATOLOGY 275 (1992).

44. The primary treatment for AIDS is azidothymidine, also called AZT, or Zidovudine. AZT decreases both mortality from AIDS and the rate of occurrence of opportunistic infections. Margaret A. Fischl et al., *The Efficacy of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex: A Double-Blind, Placebo-Controlled Trial*, 317 NEW ENG. J. MED. 185 (1987); Richard D. Moore et. al., *Zidovudine and the Natural History of the Acquired Immunodeficiency Syndrome*, 324 NEW ENG. J. MED. 1412 (1991) (median survival of those receiving AZT was 770 days compared to 190 days for those who have never received AZT). Dideoxyinosine, also known as DDI or didanosine, is another treatment. Changing from AZT to DDI slows the progress of AIDS. James O. Kahn et al., *A Controlled Trial Comparing Continued Zidovudine with Didanosine in Human Immunodeficiency Virus Infection*, 327 NEW ENG. J. MED. 581 (1992). Other drugs used to treat AIDS are dideoxycytosine (DDC) and D4T.

45. The cost of lifetime treatment for an AIDS patient is now $119,000. Fred J. Hellinger, *The Lifetime Cost of Treating a Person With HIV*, 270 JAMA 474 (1993). Fifty thousand dollars is spent before AIDS develops and $69,000 is spent between the time AIDS develops and the patient's death. *Id.*

2. Screening for AIDS in the Blood Supply

Considerable progress has been made in preventing the transmission of HIV by blood products. The biggest advance occurred in late 1983 and early 1984 when the virus that causes AIDS was identified.[46] This discovery led to the development of a test for the presence of HIV in blood, which was licensed on March 2, 1985.[47] This test detects antibodies to HIV rather than HIV itself.

The test for HIV is highly accurate.[48] However, there are two factors that result in the continued spread of HIV by blood products. One is that the antibodies detected by the test are not produced by the body immediately after infection.[49] This means that the test cannot detect all HIV infected blood. The other factor is that, because of clerical errors, contaminated blood is sometimes given to patients.[50]

The chances of being infected by HIV through blood products are now about 1 in 68,000 units transfused.[51] This is equivalent to about 90 cases of

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46. Gallo et al., *supra* note 20. F. Barre-Sinoussi et al., *supra* note 20.

47. Program Announcement, 50 Fed. Reg. 9909 (1985). Testing for HIV is required by the American Association of Blood Bank accreditation standards and the United States Food and Drug Administration. AMERICAN ASSOCIATION OF BLOOD BANKS, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (18th ed. 1991) standard B5.510 and 21 C.F.R. 610 (1993).

48. The test screens out more then 99% of the blood infected by the virus. CENTERS FOR DISEASE CONTROL, *Recomendations for Prevention of HIV Transmission in Health Care Settings*, 36(2S) MORBIDITY AND MORTALITY WKLY. REP. 13S (1987).

49. *Id.* Antibody usually develops within 6–12 weeks of infection. *Id.*

50. An internal review by the Red Cross found that 2,400 units of blood out of 6 million had been released in spite of being contaminated. Philip J. Hilts, *Red Cross Orders Sweeping Changes at Blood Centers*, N.Y. TIMES, May 20, 1991 at A1. In 1988 the Red Cross in Washington D.C. gave 235 people blood that tested positive for HIV. *Id.* The Red Cross instituted a reorganization of its procedures after it was cited hundreds of times for violating federal regulations in their other blood banks. Kathleen M. Berry, *All About Blood Banks; A Multibillion-Dollar Business in a Nonprofit World*, N.Y. TIMES, July 7, 1991, at B8. Procedures at approximately 10% of independent blood banks were also found to violate federal regulations. Philip J. Hilts, *More Blood Banks to Review Procedures*, N.Y. TIMES, May 29, 1991, at C10.

51. Several studies have reported slightly different risks of contracting AIDS from blood which has passed the screening test. In one study, blood that had tested free of HIV with the screening test was retested for HIV by isolating viral DNA or by culturing the virus. Michael P. Busch et al., *Evaluation of Screened Blood Donations For Human Immunodeficiency Virus Type 1 Infection by Culture and DNA Amplification of Pooled Cells*, 325 NEW ENG. J. MED. 1 (1991). This showed that, in San Francisco, 1 in 61,171 units of blood that test negative are in fact infected with HIV. *Id.* Another study found that 2 of 4163 uninfected adult cardiac surgery patients, who received 36,282 units of blood which tested free of HIV, developed antibodies to HIV. Noah D. Cohen et al., *Transmission of Retroviruses by Transfusion of Screened Blood in Patients Undergoing Cardiac Surgery*, 320 NEW ENG. J. MED. 1172 (1989). This gives a risk of 0.003% per unit or 1 in 33,333 units. *Id.* In another study of HIV infection in previously uninfected blood recipients, 2 HIV-1 infections were found in patients who had received 120,312 units of screened blood, a risk of 0.0017% per unit or 1 in 58,824 units. Kenrad E. Nelson et al., *Transmission of Retroviruses from Seronegative Donors by Transfusion During Cardiac Surgery*, 117 ANNALS INTERNAL MED. 554 (1992). A study which followed up on recipients of blood given by donors who later become HIV positive determined that the risk of being infected with HIV from blood that tested negative was 1 in 68,000 units in Los Angeles between March 1985 and August 1987. Steven Kleinman & Karen Secord, *Risk of Human Immunodeficiency Virus (HIV) Transmission by Anti-HIV Negative Blood Estimated Using the Look Back Methodology*, 28 TRANSFUSION 499 (1988). Ninety percent of recipients of HIV positive blood are infected by HIV. Elizabeth Donegan, et al., *Infection With Human Immunodeficiency Virus Type I (HIV-1) Among Recipients of Antibody Positive Blood Donations*, 113 ANNALS INTERNAL MED. 733 (1990); Herbert A. Perkins et al., *Risk of AIDS*

transfusion transmitted AIDS a year.[52] Before the test for HIV was introduced, the risk was substantially greater. When the test was introduced in March of 1985 the rate of infection among donors in San Francisco was found to be 1 in 2632.[53] It should be noted that these numbers do not reflect the risk in other parts of the United States; the number of infected people varies considerably in different parts of the country.[54]

HIV can be transmitted by the clotting factor concentrates used by hemophiliacs as well as by transfusion; a large percentage of hemophiliacs who received clotting concentrates prior to the advent of the HIV blood test became infected with HIV.[55] AIDS is now the leading cause of mortality among hemophiliacs.[56] Testing the blood used in making clotting factor has substantially decreased the rate of HIV infection in hemophiliacs.[57] Also, there are now ways to inactivate any HIV remaining in the purified coagulation factors.[58]

Whether blood banks and clotting factor manufacturers did enough to lessen the risk of HIV transmission prior to the availability of the blood test for HIV is the primary question in determining whether they should be held liable

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for Recipients of Blood Components from Donors Who Subsequently Develop AIDS, 70 BLOOD 1604, 1604–10 (1987). It should be noted that the risk of contracting AIDS is actually lower than the rate of infection because only 40% of those who receive transfusions survive the condition they were being treated for. John W. Ward et al., *Transmission of Human Immunodeficiency Virus (HIV) by Blood Transfusion Screened as Negative for HIV Antibody*, 318 NEW ENG. J. MED. 473, 476–77 (1988).

52. In 1989, the most recent year for which statistics are available, 12,525,000 units of whole blood, 7,258,000 units of red blood cells, 2,157,000 units of plasma, and 961,000 units of cryoprecipitate were transfused. Edward L. Wallace et al., *Collection and Transfusion of Blood and Blood Components in the United States, 1989*, 33 TRANSFUSION 139, 142 tbl. 2 (1992). The average patient receiving a transfusion received 3.8 units. *Id.*

53. Julian B. Schorr et al., *Prevalence of HTLV-III Antibody in American Blood Donors*, 313 NEW ENG. J. MED. 384 (1985) (38 in 100,000 donations).

54. In 1985 the frequency of HIV infected donors was highest in Washington, D.C. and Los Angeles with 0.11% of donor units testing positive. *Id.* The frequency was 0.03% in Boston, Detroit and Philadelphia; 0.015% in Portland, Or.; 0.011% in Peoria Il.; and 0.003% in Tulsa. *Id.*

55. William Fricke et al., *Human Immunodeficiency Virus Infection Due to Clotting Factor Concentrates: Results of the Seroconversion Surveillance Project*, 32 TRANSFUSION 707 (1992) (46% of hemophiliacs were infected); James J. Goedert et al., *A Prospective Study of Human Immunodeficiency Virus Type I Infection and the Development of AIDS in Subjects with Hemophilia*, 321 NEW ENG. J. MED. 1141, 1143 tbl 1 (1989) (76% of patients with severe hemophilia A had antibodies to HIV compared to 25% of patients with mild hemophilia); Margaret V. Ragin, et al., *1986 Update on HIV Seroprevalence Seroconversion, AIDS Incidence and Immunological Correlates of HIV Infection in Patients with Hemophilia A and B*, 70 BLOOD 786 (1987) (Only 10% of hemophiliacs treated with cryoprecipitate, which is made from the blood of a single donor, developed antibodies to HIV, compared to 82% of those treated with factor VIII, which is made from an average of 5,000 donors, and 48% for factor IX); George Gjerset et al., *Treatment Type and Amount Influenced Human Immunodeficiency Virus Seroprevalence of Patients with Congenital Bleeding Disorders*, 78 BLOOD 1623 (1991) (88% of hemophiliacs who use factor VIII concentrate test positive for the AIDS virus, compared with 14% who receive only cryoprecipitate from volunteer donors and 60% with hemophilia B). The peak of seroconversion was in 1982. Ragin et al., *supra* at 786. The percentage of hemophilia A patients with antibodies to HIV leveled off at 76% in 1984, and for other clotting diseases leveled off in 1985. Goedert et al., *supra* at 1143 tbl. 1.

56. Glenn F. Pierce et al., *The Use of Purified Clotting Factor Concentrates in Hemophilia: Influence of Viral Safety, Cost, and Supply on Therapy*, 261 JAMA 3434 (1989).

57. Gjerset et al., *supra* note 55 (Of 55 hemophiliacs who were exposed to clotting factor made from the blood of a total of 71,173 screened donors, all remained free from HIV).

58. Pierce et al., *supra* note 56, at 1435–36.

in negligence for the transmission of HIV by blood. This will be discussed in section V.[59]

C. Human T-Cell Lymphotrophic Viruses I & II

The human T-lymphotrophic viruses types I & II (HTLV I & II) are also transmitted by blood. Infection with HTLV-I gives a 4% risk of developing adult T-cell leukemia.[60] Infection with HTLV-II is possibly associated with adult hairy cell leukemia.[61] However, there is a low incidence of leukemia among those infected with HTLV-II, and the cancer takes along time to develop.[62]

Six out of every 10,000 donors are infected with HTLV.[63] A screening test was implemented in 1987,[64] and the risk of receiving HTLV contaminated blood is now about 1 in 50,000 units.[65] A patient who has been transfused with HTLV-contaminated blood has a 30% to 71% chance of being infected.[66]

D. Cytomegalovirus

Cytomegalovirus (CMV) can also be transmitted by transfusion. CMV infection is quite common in the United States.[67] CMV is spread by cellular components of blood such as red blood cells or platelets, but not by acellular

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59. *See, infra* notes 230–56 and accompanying text.

60. Dodd, *supra* note 7, at 420.

61. Helen H. Lee et al., *Relative Prevalence and Risk Factors of HTLV-I and HTLV-II Infection in U.S.Blood Donors*, 337 LANCET 1435 (1991).

62. Kazuo Okuchi & Hiroyuki Sato, *Transmission of Adult T-Cell Leukemia Virus (HTLV-1) Through Blood Transfusion and Its Prevalence*, 2 (Supl. 1) AIDS RES. & HUM. RETROVIRUSES s157 (1986).

63. Jeffrey McCullough, *The Nation's Changing Blood Supply System*, 269 JAMA 2239, 2242 tbl. 1 (1993) (5 in 10,000); H.H. Lee et al., *supra* note 61 (0.013% or 1.3 in 10,000 donors); P. Devine et al., *Blood Donation And Transfusion Practices: The 1990 American Association of Blood Banks Institutional Questionnaire*, 32 TRANSFUSION 683, 686 tbl. 3 (1992) (8172 units tested positive out of 7,566,878 or 11 out of 10,000); Kenrad E. Nelson et al., *Transmission of Retroviruses from Seronegative by Transfusion Donors During Cardiac Surgery*, 117 ANNALS INTERNAL MED. 554 (1992) (risk of getting HTLV from unscreened blood was 0.0039% per unit for HTLV-I, and 0.0078% per unit for HTLV-II). Fifty-two percent of infected donors were infected with HTLV-I, 3% were infected with HTLV-II and 45% were infected with both viruses. Lee et al., *supra* note 61.

64. Testing for HTLV I & II is required by the American Association of Blood Bank accreditation standards. AMERICAN ASSOCIATION OF BLOOD BANKS, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (18th ed. 1991) standard B5.510.

65. Dodd, *supra* note 7, at 420 (1 in 50,000 units); Okuchi & Sato, *supra* note 62, at s160 (42 in 10,000); K.E. Nelson et al., *supra* note 63 (1992) (no seroconversions were detected for HTLV-I when 69,272 units were transfused, and a risk of 0.0014%, or 1 in 71,429, was found for HTLV-II).

66. Steven Kleinman et al., *Transfusion Transmission of Human T-Lymphotrophic Virus Types I and II: Serologic And Polymerase Chain Reaction Results in Recipients Identified Through Look-Back Investigation*, 33 TRANSFUSION 14 (1993) (risk is 30%); Okuchi & Sato, *supra* note 62, at s157 (risk is 71%); Angela Manns et al., *A Prospective Study of Transmission by Transfusion of HTLV-I and Risk Factors Associated With Seroconversion*, 51 INT'L J. CANCER 886 (1992) (24 of 54, or 44%, recipients of cellular blood components from HTLV-I positive donors developed antibodies to HTLV-I).

67. The frequency of CMV infection in the general population varies from 17% in those less than 23 years old to 89% in those over 65. Gary E. Tegtmeir, *Posttransfusion Cytomegalovirus Infection*, 113 ARCHIVES PATHOL. LAB. MED. 236, 237 (1989). The frequency of infection is also different in different parts of the country; it is 30% in the north and 65% in the south. *Id.*

components such as plasma or clotting factors.[68] Having antibodies to CMV does not protect the transfusion recipient from being re infected by transfusion.[69] However, most infections are asymptomatic, although some manifest as mononucleosis.[70] Some studies have shown that CMV infection can cause death in 40% of newborns infected.[71] Transfusion transmitted CMV can also be fatal to bone marrow transplant recipients and AIDS patients.[72] There is no significant risk for other groups.[73] Screening for CMV is therefore done only before transfusion to patients in the high risk groups.[74] Between 1% and 3% of the CMV positive donors may not be detected by the screening test, so some mortality due to transfusion transmitted CMV can be expected to continue.[75]

III. SHOULD STRICT LIABILITY BE APPLIED TO BLOOD PRODUCT SUPPLIERS?

Before turning to an analysis of the whether strict liability should be applied to blood suppliers, it is useful to survey the case law and statutes dealing with the question, and the reasons given by courts and legislatures for prohibiting strict liability.

A. Case Law Dealing With Blood Supplier Liability

Several courts have addressed the question of whether liability should be applied to blood suppliers in the absence of fault.[76] There are two kinds of liability without fault: products liability and implied warranty. Implied warranty is based on contract law and is defined in article 2 of the Uniform Commercial Code.[77] Strict product liability, on the other hand, is a tort theory. Strict product liability was first enunciated in *Greenman v. Yuba Power Products, Inc.*,[78] and is codified in §402A of the Restatement (Second) of Torts,[79] which provides that, if a party is in the business of selling a product,

68. This is because the DNA of the cytomegalovirus incorporates itself into the DNA of cells. *Id.* at 236.
69. *Id.* at 237–38.
70. *Id.* at 236.
71. *Id.* at 239–40.
72. *Id.* at 241.
73. *Id.* at 241.
74. *Id.* at 242 (1989); Donna S. Jones et al., *Epidemiology of Transfusion-Associated Acquired Immunodeficiency Syndrome in Children in the United States, 1981 through 1989*, 89 PEDIATRICS 123 (1992).
75. Langdale, *supra* note 2, at 736.
76. As is discussed below, most states have statutes that prohibit the application of strict liability or implied warranty to blood products. *See, infra* notes 116–148 and accompanying text. The present section deals solely with cases that were decided when no statute applied.
77. § 2–314 deals with the warranty of merchantability and §2–315 deals with the warranty of fitness or a particular purpose.
78. 377 P.2d 897 (Cal. 1963).
79. Section 402A of the Restatement (Second) of Torts reads:
§ 402A Special Liability of Seller of Product for Physical Harm to User or Consumer
(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
(a) the seller is engaged in the business of selling the product, and

and if the product reaches the consumer without substantial changes in its condition, the seller is liable for any injuries that result from the unreasonably dangerous condition of the product even if the seller took all possible precautions in making the product. Most courts dealing with blood products hold products liability and implied warranty to be identical,[80] but most plaintiffs still plead both theories.[81]

Courts analyze the question of whether blood suppliers should be held liable without fault in two ways. Some courts approach the question by determining whether blood is a service or a product. Implied warranty and product liability apply to products but not services. Other courts determine whether blood is unreasonably unsafe under §402A.

1. The Sales/Service Distinction

Many courts do not apply strict liability because they find that blood products are part of a medical service rather than a product.[82] The first case to use this distinction was *Perlmutter v. Beth David Hospital.*[83] This case arose before strict products liability in tort existed and was based on an implied warranty claim. In *Perlmutter*, the New York Court of Appeals held that providing blood is a service rather than a sale and, therefore, that a suit based on a warranty theory could not be brought for hepatitis caused by a transfusion.[84] The court reasoned that a patient goes to a hospital to receive treatment, not to buy drugs, blood or bandages. The drugs, blood, bandages and other things provided by a hospital are part of the treatment the patient is seeking. Blood transfusion is therefore a service and not a sale. Many courts have followed this reasoning.[85] One of these courts went further in explaining

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(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of the product, and

(b) the user has not bought the product or entered into any contractual relation with the seller.

80. McMichael v. American Red Cross, 532 S.W.2d 7, 11 (Ky. 1975); Fischer v. Sibley Memorial Hosp., 403 A.2d 1130, 1133 (D.C. Ct. App. 1979); Moore v. Underwood Memorial Hosp., 371 A.2d 105, 106 (N.J. Super. Ct. App. Div. 1977). In fact the two theories are not identical. Strict liability only applies when there is injury, whereas implied warranty applies whenever the product is different from what it should be. This difference is not important in blood cases which always involve injury. A second difference may be important. Strict liability requires that adequate warning be given, but it is not clear whether implied warranty of merchantability does, although it may require labeling. U.C.C. § 2–314(2)(e).

81. Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978); Russell v. Community Blood Bank, Inc., 185 So. 2d 749 (Fla. Dist. Ct. App. 1966); Hoder v. Sayet, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967).

82. Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 822 (Wash. 1990); Roberts v. Suburban Hosp. Ass'n, Inc., 532 A.2d 1081, 1088 (Md. Ct. Spec. App. 1986). One court found that the sales/service distinction does not protect blood suppliers from implied warranty because implied warranty can apply to services as well as sales. Hoffman v. Misericordia Hosp. of Philadelphia, 267 A.2d 867, 870 (Pa. 1970).

83. 123 N.E.2d 792 (N.Y. 1954), *reargument denied,* 125 N.E.2d 869 (N.Y. 1955).

84. *Id.*

85. A Maryland Court has refused to make a distinction when a patient goes to the hospital solely for a transfusion. *Roberts,* 532 A.2d at 1088. The court went on to explain that it applied the sales/service distinction for two reasons: one was that it was the majority view; the other was the statute passed by the legislature after the events leading to the case also followed the distinction. *Id.*

the sales/service distinction by explaining that blood is inherently dangerous and that the important factor is the physician's judgment about whether the risks of the patient's condition outweigh the risks of the blood.[86] The service aspect therefore outweighs the product aspect of blood.

The only Arizona case to deal with contaminated blood, *Whitehurst v. American National Red Cross*,[87] also follows the sales/service distinction. Following abdominal surgery, Mrs. Whitehurst was given a series of transfusions of whole blood from which she contracted hepatitis. She brought suit on an implied warranty theory, and the trial court granted summary judgment for the Red Cross. The Arizona Court of Appeals upheld the summary judgment. The court held that a blood transfusion was a service rather than a sale, and therefore an implied warranty of merchantability did not attach.[88] The court's reasoned that the Red Cross was not paid the entire cost of the blood, and "[p]eople who receive blood from the Red Cross know that there is a 'gift' involved—not a 'sale.'"[89] This statement implies that the court did not adopt the full sales/service distinction since it implies that, had the patient paid the entire cost of the blood, it would be classified as a sale.

If blood is a service when provided by a hospital, the question then arises whether blood is a service when provided by a blood bank. Several courts have held that it is a product.[90] The reasoning is that a blood bank does not provide a service.[91] Supplying blood may be an incidental function of a hospital but it is the predominant function of a blood bank.[92] A Maryland court, however, has held that the blood supplied by a blood bank, even if it is run for profit, is a service.[93]

Another question that arises is whether clotting factor for hemophiliacs supplied by commercial producers is a product or a service. In another Maryland case, the transaction was held to be a sale because the sole purpose of the supplier is to sell its products for a profit[94] and because the sale is the predominant factor in the transaction.[95] However, the court found that blood products were protected from product liability by comment k of §402A.[96]

There are two problems with the sales/service analysis of blood liability cases. One is that the idea that the sale of blood by a blood bank is a service rather than a sale is inconsistent with other areas of the law. If blood is considered a service, drugs would appear to be too. Drugs such as anesthetics and intravenous contrast agents used in taking X-rays, are as much a part of the service provided by a hospital as blood is. Yet courts have not held that drugs

86. Foster v. Memorial Hosp. Assoc. of Charleston, 219 S.E. 2d 916 (W. Va. 1975).
87. 1 Ariz. App. 326, 402 P.2d 584 (1965).
88. *Id.* at 586.
89. *Id.*
90. Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978); Russell v. Community Blood Bank, Inc., 185 So. 2d 749 (Fla. Dist. Ct. App. 1966); Hoder v. Sayet, 196 So. 2d 205 (Fla. Ct. App. 1967).
91. *Russell*, 185 So. 2d at 752.
92. *Belle Bonfils*, 579 P.2d at 1159.
93. Roberts v. Suburban Hosp. Ass'n, 532 A.2d 1081, 1088 (Md. Ct. Spec. App. 1986).
94. The "gravamen test." Miles Lab. v. Doe, 556 A.2d 1107, 1115 (Md. 1989).
95. The "predominant purpose test." *Id.* at 1117 n. 10.
96. *Id.* at 1121. Comment k is quoted, *infra*, in note 104.

in either of these classes are services rather than sales.[97] The second problem with the sales/service analysis is that it is artificial. A person has a right to expect the same standards of manufacture whether a product is used by a doctor or the patient buys and uses the product himself. Just because a doctor uses a product on the patient should not mean that it does not have to be generally fit for its ordinary purpose as the implied warranty of merchantability requires or reasonably safe as products liability requires.

2. Is Blood Unreasonably Unsafe?

Other courts determine whether strict liability should apply to blood by determining whether blood is unreasonably unsafe under §402A.[98] Courts rely on the comments that follow §402A to determine whether blood products are unreasonably dangerous and strict liability should apply.

The only court to find blood suppliers strictly liable for injuries caused by contaminated blood relied on the definition of unreasonably dangerous found in comment i.[99] Comment i says that a product is unreasonably dangerous if it is more dangerous than the average person would expect. The Louisiana Supreme Court held that the blood was more dangerous than the average patient would expect and that the supplier was therefore liable under strict product liability.[100]

Consumer expectation is an important policy consideration underlying product liability,[101] but it is not the only consideration. Encouraging blood suppliers to produce safer products and spreading the cost of the harm caused by their products are other important considerations.[102] Comment i does not appear to be the best way to determine whether strict liability should be applied to blood products because it ignores these other considerations. Comment i implies that once the fact that blood is dangerous is widely known suppliers are no longer strictly liable for injuries that blood causes. This may be appropriate for most products since the user can weigh the risks and benefits before deciding whether to use the product. But the user of blood products is usually in dire need of blood and is therefore in no position evaluate the risks and make a choice.

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97. Savina v. Sterling Drug, Inc., 795 P.2d 915, 927 (Kan. 1990) (metrizamide used as a contrast agent in myelogram to diagnose back pain led to paralysis); Stewart v. Janssen Pharmaceutica, Inc., 780 S.W.2d 910, 912 (Tex. Ct. App. 1989) (anesthetic); Holley v. Burroughs Wellcome Co., 330 S.E.2d 228, 235 (N.C. Ct. App. 1985), *aff'd*, 348 S.E.2d 772 (N.C. 1986) (malignant hyperthermia resulting from anaesthetic caused severe brain damage).

98. The text of § 402A can be found, *supra*, note 79.

99. DeBattista v. Argonaut-Southwest Ins. Co., 403 So. 2d 26, 30–31 (La. 1981). The Louisiana Supreme Court first held that the statute that prevented actions against blood suppliers based on implied warranty did not effect action based on products liability. *Id.* The court then relied on comment i, even though section 402A had not been adopted in Louisiana. *Id.* The court found that section 402A had been the inspiration of Louisiana law and that the comments attached to section 402A could therefore be used to interpret the Louisiana law. *Id.* The court reaffirmed *DeBattista* in Faucheaux v. Alton Ochsner Medical Found. Hosp. & Clinic, 470 So. 2d 878 (La. 1985) *reconsideration denied* 474 So. 2d 944 (La. 1985), and held that the statute passed in response to it did not apply retroactively. In Shortess v. Touro Infirmary, 520 So.2d 389, 391 (La. 1988) the court extended strict liability to hospitals that used the blood.

100. *DeBattista*, 403 So. 2d at 31. There was no discussion of why it was decided that the patient did not expect the danger. *Id.*

101. *See infra* notes 152–157 and accompanying text.

102. *See infra* notes 185–207 and accompanying text.

Other courts rely on the definition of unreasonable risk in comment k.[103] Comment k[104] states that a seller is not liable for the unfortunate consequences of the use of an apparently useful product attended by apparently reasonable risks, provided that the product is properly prepared and adequate warnings are given.[105] The policy behind comment k is to encourage the manufacture and distribution of new medical products because they are important in saving lives and alleviating suffering.[106] Comment k specifically applies only to "products

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103. The Maryland Supreme Court gives four criteria for the application of comment k. These are: 1) nonexistence of test for contaminant; 2) great utility of product; 3) lack of a substitute; 4) relatively small risk that disease will be transmitted. Miles Lab. v. Doe, 556 A.2d 1107, 1118 (Md. 1989). The Fourth Circuit found that factor IX concentrate met all of these criteria. Doe v. Miles Lab., 927 F.2d 187, 192 (4th Cir. 1991). The Colorado Supreme Court dealt with the question of whether comment k should apply in two cases. In Belle Bonfils Memorial Blood Bank v. Hansen, 579 P.2d 1158, 1159 (Colo. 1978), the court held that strict liability applied to blood products. In Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 121 (Colo. 1983), the court held that comment k applied. The Court said that four elements must be proved by the manufacturer in order for comment k to apply. These are: 1) the benefit must be unique or profound, and must extend to the vast majority of users; 2) the risk must be known; 3) there must be a warning about the risk; and 4) the risk must be unavoidable. *Id.* at 123. Courts have held that, whether donor questioning, Doe v. University Hosp., 561 N.Y.S.2d 326, 328 (N.Y. Sup. Ct. 1990), or testing the blood for characteristics which are frequently associated with AIDS, such as antibody to hepatitis B core, Snyder v. Mekhjian, 582 A.2d 307, 13 (N.J. Super. Ct. App. Div. 1991), could prevent transmission is a negligence question. Other cases that have applied comment k are: Rogers v. Miles Lab., 802 P.2d 1346, 1351 (Wash. 1991); Miles Lab., v. Doe, 556 A.2d 1107, 1121 (Md. 1989).

104. Comment k to Section 402A of the Restatement (Second) of Torts (1965) reads:

> k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even purity of the ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended by a known but apparently reasonable risk.

105. Comment k requires that a product be pure, *see, e.g.*, Rostocki v. Southwest Florida Blood Bank, Inc., 276 So. 2d 475, 477 (Fla. 1973), but the Colorado Supreme Court, Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 124 (Colo. 1983), the Washington Supreme Court, Rogers v. Miles Lab., 802 P.2d 1346, 1350–51 (Wash. 1991), and the New Mexico Court of Appeals, Hines v. Saint. Joseph's Hosp., 527 P.2d 1075, 1076 (N.M. Ct. App. 1974), have said that comment k applies even though the blood contains contaminating virus particles. The Washington court supported its reasoning by referring to testimony by a physician that rabies vaccine, which is the example given in comment k, is dangerous because it is contaminated with brain tissue. Since the example given in the Restatement is attributable to impurity, the court reasoned that impurity of the blood should not prevent application of comment k.

which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."[107] This means that once a method for making a product safe, such as the test for HIV antibodies in blood, is available, comment k no longer applies, and the manufacturer is strictly liable for injuries caused by the product.

One requirement for comment k to apply is that the benefits of the product must outweigh the risks. Courts have uniformly found that the usefulness of blood outweighs its risks. This balancing of risks and benefits is implicit in the statement made by many courts that products liability should not be applied because it would decrease the availability of blood.[108] However comment k requires that the product be properly prepared before the court can balance the risks and benefits of the product. All courts dealing with blood supplier liability equate proper manufacture with whether the supplier has taken reasonable precautions to ensure that blood is safe.[109]

A blood supplier can take various precautions to ensure that blood is safe. One is to use tests that directly detect the infectious agents.[110] Another is to screen out donors who are at risk of having the disease. This can be done by asking whether the donor engages in risky activities, such as intravenous drug use, or by screening the blood for factors that are correlated with exposure to the infectious agent.[111] In the past, some courts have found that blood products are not properly manufactured when the blood bank did not adequately question the donors to detect and exclude those at high risk of transmitting the disease.[112] Recently, however, the majority of courts have found that the failure to screen out high risk donors by questioning or by surrogate testing does not mean that the blood was not properly manufactured.[113] It is unclear why these courts have

106. Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifyng the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1141 (1985).

107. *See supra* note 104.

108. Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 821 (Wash. 1990); Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 123–124 (Colo. 1983); Russell v. Community Blood Bank, Inc., 185 So. 2d 749, 755 (Fla. Dist. Ct. App. 1966); Snyder v. Mekhjian, 582 A.2d 307, 312–13 (N.J. Super. Ct. App. Div. 1991); Miles Lab., v. Doe, 556 A.2d 1107, 1118, 1121 (Md. 1989). This rationale was earlier applied to contamination by hepatitis before there was a test for the presence of the hepatitis virus in blood. Fogo v. Cutter Lab., 137 Cal. Rptr. 417, 422 (Cal. Ct. App. 1977): McMichael v. Am. Red Cross, 532 S.W.2d 7, 9 (Ky. 1975); Brody v. Overlook Hosp., 317 A.2d 392, 395 (N.J. Super. Ct. App. Div. 1974), *aff'd*, 332 A.2d 596 (N.J. 1975); Hines v. Saint. Joseph's Hosp., 527 P.2d 1075, 1076 (N.M. Ct. App. 1974); Fischer v. Sibley Memorial Hosp., 403 A.2d 1130, 1133 (D.C. 1979); Rogers v. Miles Lab., 802 P.2d 1346, 1351 (Wash. 1991); Coffee v. Cutter Biological, 809 F.2d 191, 193–4 (2nd Cir. 1987).

109. This is not the only logical interpretation of the phrase 'properly manufactured.' It could also mean that the supplier has followed his own procedures rather than accidentally omitting a step.

110. Blood tests are now available for many infectious organisms. *See supra* section II. Many of these tests have only been invented in the past ten years.

111. The current questioning scheme reduces the number of infected donors by 40-to 80-fold. Roger Y. Dodd, *The Risk of Transfusion Transmitted Infection*, 327 NEW ENG. J. MED. 419 (1992). This calculation is based on the observed rate of HIV infected donors compared to the estimated frequency of infection in the general population.

112. *Russell*, 185 So. 2d at 755; Hoder v. Sayet, 196 So. 2d 205, 208 (Fla. Dist. Ct. App. 1967).

113. Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 821 (Wash. 1990); Snyder v. Mekhjian, 582 A.2d 307, 312 (N.J. Super. Ct. App. Div. 1991); Miles Lab., v. Doe, 556 A.2d 1107, 1118, 1121 (Md. 1989); Fogo v. Cutter Lab., 137 Cal. Rptr. 417, 422 (Cal. Ct. App. 1977); McMichael v. Am. Red Cross, 532 S.W.2d 7, 9 (Ky. 1975); Hines v. Saint.

ignored the fact that disease can be prevented by screening out donors who are likely to transmit the disease.[114]

One court has recognized that there are alternative ways to decrease risk but held that failure to use a test that would screen out 88% of contaminated blood does not constitute improper manufacturing.[115] This decision is clearly wrong. A manufacturer who has not used a known procedure that reduces deaths among users by 88%, or even by 10%, has not properly manufactured its product.

In spite of the fact that courts have not always applied comment k correctly, it still represents the best balancing of the interests of the patient in obtaining compensation for injury and societies need for an adequate blood supply. Under comment k the blood supplier would not be liable for disease transmission that could not be prevented. This would protect the blood supplier and ensure an adequate blood supply. Once there are procedures to improve the safety of the blood, the supplier would be liable to the patient for the injury that is done by not using those procedures. This protects the patient's right to redress.

However, this summary of recent cases demonstrates that, although courts apply different theories to justify their decisions, there is wide agreement that liability without fault should not be applied to blood products in any situation.

B. Statutes Dealing with Blood and Blood Products

In 48 states the common law of liability for diseases transmitted by blood no longer applies because the legislatures have passed statutes to protect hospitals and blood banks from strict liability.[116] The exceptions are New

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Joseph's Hosp., 527 P.2d 1075, 1076 (N.M. Ct. App. 1974); Fischer v. Sibley Memorial Hosp., 403 A.2d 1130, 1133 (D.C. 1979); *Belle Bonfils*, 579 P.2d at 1159.

114. This can be done by questioning donors about behavior that puts them at risk of contracting the disease, and by surrogate tests which rely on the fact that people with one symptom are likely to have the disease. *See infra* notes 233–240 and accompanying text.

115. *Snyder*, 582 A.2d at 312.

116. ALA. CODE § 7–2–314(4) (1993); ALASKA STAT. § 45.02.316(e) (1993); ARIZ. REV. STAT. ANN. §§ 12–561 and 12–563 (1991); ARIZ. REV. STAT. ANN. § 32–1481 (1991); ARIZ. REV. STAT. ANN. § 36–1151 (1991); ARK. CODE ANN. §§ 4–2–316(3)(d)(i), 20–9–801, and 20–9–802 (Michie 1987); CAL. HEALTH & SAFETY CODE § 1606 (West 1989); COLO. REV. STAT. § 13–22–104 (1988); CONN. GEN. STAT. § 19a–280 (1986); DEL. CODE ANN. tit. 6, § 2–316(5) (1982); FLA. STAT. § 672.316(5) (1992); GA. CODE ANN. §§ 11–2–316(5) and 51–1–28(a) (1984); HAW. REV. STAT. §§ 325–91 and 327–51 (1989); IDAHO CODE § 39–3702 (Supp.1992); ILL. ANN. STAT. ch. 745 para. 40/1–2 (Smith-Hurd 1988); IND. CODE § 16–41–12–11(a) (1992); IOWA CODE § 142A.8 (1989); KAN. STAT. ANN. § 65–3701 (1985); KY. REV. STAT. ANN. § 39.125 (Michie/Bobbs-Merrill 1989); LA. REV. STAT. ANN. § 9:2797 and LA. CIV. CODE ANN. art. 2322.1 (West Supp. 1992); ME. REV. STAT. ANN. tit. 11 § 2–108 (West Supp. 1992); MD. CODE ANN., CTS. & JUD. PROC. § 5–373 (1989); MASS. GEN. L. ch. 106, § 2–316(5) (1988); MICH. COMP. LAWS. § 333.9121 (1989); MINN. STAT. § 529.221(e) (1987); MISS. CODE ANN. § 41–41–1 (Supp. 1992); MO. ANN. STAT. § 431.069 (Vernon 1989); MONT. CODE ANN. § 50–33–102 to 104 (1989); NEB. REV. STAT. §§ 71–4001, 71–4809 and 71–4810 (1986); NEV. REV. STAT. § 460.010 (Supp. 1992); N.H. REV. STAT. ANN. § 507:8–b (1988); N.M. STAT. ANN. § 24–10–5 (Michie Supp. 1992); N.Y. PUB. HEALTH LAW § 580(4) (McKinney Supp.1992); N.C. GEN. STAT. § 130A–410 (1986); N.D. CENT. CODE §§ 41–02–33(3)(d) and 43–17–40 (1989); OHIO REV. CODE ANN. § 2108.11 (Anderson 1988); OKLA. STAT. tit. 63, § 2151 (1987); OR. REV. STAT. § 97.300 (1990); 42 PA. CONS. STAT. ANN. § 8333 (1988); R.I. GEN. LAWS § 23–17–30 (Supp. 1992); S.C. CODE ANN. § 44–43–10 (Law. Co-op. 1985); S.D. CODIFIED

Jersey,[117] and Vermont.[118] The majority of these statutes follow *Perlmutter v. Beth David Hospital.*[119] and specify that blood is a sale and not a service.[120] The majority of the statutes also either specify that negligence is the only theory available,[121] or specifically exclude both strict products liability and implied warranty theories.[122] Other statutes are not as clear in the protection they

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LAWS ANN. § 57A–2–315.1 (1988); TENN. CODE ANN. § 47–2–316(5) (1990); TEX. CIV. PRAC. & REM. CODE ANN. § 77.001–.004 and TEX. BUS. & COM. CODE ANN. § 2.316(e) (West 1986 & Supp. 1992); UTAH CODE ANN. § 26–31–1 (1989); VA. CODE ANN. § 32.1–297 (Michie 1985); WASH. REV. CODE § 70.54.120 (Supp. 1992); W. VA. CODE § 16–23–1 (1985); WIS. STAT. § 146.31 (1989); WYO. STAT. §§ 34.1– 2–316 (c)(iv) and 35–5–110 (1988).

117. The New Jersey Supreme Court has held that blood suppliers are not subject to strict liability. Brody v. Overlook Hosp., 317 A.2d 392 (N.J. Super. Ct. App. Div. 1974), *aff'd,* 332 A.2d 596 (N.J. 1975).

118. The Supreme Court of Vermont has not addressed blood bank liability.

119. 123 N.E.2d 792 (N.Y. 1954), *reargument denied,* 125 N.E.2d 869 (N.Y. 1955).

120. ALA. CODE § 7–2–314(4) (1993); ALASKA STAT. § 45.02.316(e) (1993); ARIZ. REV. STAT. ANN. § 36–1151 (1991); ARK. STAT. ANN. § 4–2–3163(d)(i) (Michie 1987); CAL. HEALTH & SAFETY CODE § 1606 (West 1989); COLO. REV. STAT. § 13–22–104(2) (1988); CONN. GEN. STAT. § 19a–280 (1986); DEL. CODE ANN. tit. 6, § 2–316(5) (1982); FLA. STAT. § 672.316(5) (1992); GA. CODE ANN. §§ 11–2–316(5) and 51–1–28(a) (1984); IDAHO CODE § 39–3702 (Supp.1992) (does not apply if donor is paid or if blood bank operates for profit); ILL. ANN. STAT. ch. 745 para. 40/2 (Smith-Hurd 1988); IND. CODE § 16–41–12–11(a) (1992); IOWA CODE § 142A.8 (1989); KAN. STAT. ANN. § 65–3701 (1985); KY. REV. STAT. ANN. § 139.125 (Michie/Bobbs-Merrill 1989); LA. CIV. CODE ANN. art. 2322.1 and LA. REV. STAT. ANN. § 9:2792 (West Supp. 1992); ME. REV. STAT. ANN. tit. 11 § 2–108 (West Supp. 1992); MASS. GEN. L. ch. 106, § 2–316(5) (1988); MICH. COMP. LAWS § 333.9121(2) (1989); MISS. CODE ANN. § 41–41–1 (Supp. 1992); MO. ANN. STAT. § 431.069 (Vernon 1989); MONT. CODE ANN. § 50–33–102 (1989) (applies to physician or hospital that does not have a financial interest in blood bank); NEB. REV. STAT. § 71–4001 (1986); NEV. REV. STAT. § 460.010 (Supp. 1992) (applies only to transmission of disease); N.Y. PUB. HEALTH LAW § 580(4) (McKinney Supp.1992); N.C. GEN. STAT. § 130A–410 (1986); N.D. CENT. CODE § 41–02–33(3)(d) (1989); OHIO REV. CODE ANN. § 2108.11 (Anderson 1988); OKLA. STAT. tit. 63, § 2151 (1987) (uses the word "transaction" rather than service); OR. REV. STAT. § 97.300 (1990); R.I. GEN. LAWS § 23–17–30 (Supp. 1992); S.C. CODE ANN. § 44–43–10 (Law. Co-op 1985); S.D. CODIFIED LAWS ANN. § 57A–2–315.1 (1988); TENN. CODE ANN. § 47–2–316(5) (1990); UTAH CODE ANN. § 26–31–1 (1989); WASH. REV. CODE § 70.54.120 (Supp. 1992); W.VA. CODE § 16–23–1 (1985); WIS. STAT. § 146.31 (1989); WYO. STAT. § 34.1–2–316(c)(ii) (1988) (service rather than "commodity").

121. ARK. CODE ANN. § 20–9–802(c) (Michie 1987); COLO. REV. STAT. § 13–22–104(2) (1988); GA. CODE ANN. § 51–1–28(a) (1984); HAW. REV. STAT. § 327–51 (1989); IDAHO CODE § 39–3702 (Supp. 1992) (negligence is still available); ILL. ANN. STAT. ch.745 para. 40/2 (Smith-Hurd 1988); KAN. STAT. ANN. § 65–3701 (1985); LA. REV. STAT. ANN. § 9:2797 & LA. CIV. CODE ANN. art. 2322.1 (West Supp. 1992); MICH. COMP. LAWS § 333.9121 (1989); MONT. CODE ANN. §§ 50–33–102 to 104 (1989); NEB. REV. STAT. § 71–4810 (1986); NEV. REV. STAT. § 460.010 (Supp. 1992); N.M. STAT. ANN. § 24–10–5 (Supp. 1992); N.D. CENT. CODE § 43–17–40 (1989); OKLA. STAT. tit. 63, § 2151 (1987); 42 PA. CONS. STAT. ANN. § 8333 (1988); R.I. GEN. LAWS § 23–17–30 (Supp. 1992); TEX. CIV. PRAC. & REM. CODE ANN. § 77.003(a) (1986 & Supp. 1992); WASH. REV. CODE § 70.54.120 (Supp. 1992) (if donor not paid); WIS. STAT. § 146.31 (1989); WYO. STAT. § 35–51–110 (1988).

122. COLO. REV. STAT. § 13–22–104 (1988); GA. CODE ANN. § 51–1–228(a) (1984); IDAHO CODE § 39–3702 (Supp.1992); ILL. ANN. STAT. ch. 745 para. 40/2 (Smith-Hurd 1988); IND. CODE § 16–41–12–11(a) (1992); IOWA CODE § 142A.8 (1989); LA. REV. STAT. ANN. § 9:2797 (Supp. 1992); MD. CODE ANN., HEALTH–GEN. § 18–402 (1989); NEV. REV. STAT. § 460.010 (Supp. 1992) (no liability under implied warranty "or other theory"); N.H. REV. STAT. ANN. § 507:8–b (1988); N.D. CENT. CODE § 41–02–33(3)(d) (1989); N.M. STAT. ANN. § 24–10–5 (Michie Supp. 1992); 42 PA. CONS. STAT. ANN. § 8333 (1988); TEX. CIV. PRAC. & REM. CODE ANN. §§ 77.001–.004 (West 1986 & Supp. 1992); WASH. REV. CODE § 70.54.120 (Supp. 1992).

provide. Eight statutes do not mention any theory specifically, but rather rely exclusively on the sales/service distinction.[123] These statutes exclude strict product liability as well as warranty since both apply to sales, but not to services. Twelve statutes only specifically mention implied warranty.[124] Of these statutes, all but Virginia's also define blood as a service rather than a product. Since strict products liability only applies to products this means that strict liability is prohibited by these statutes, too. Virginia does not recognize strict products liability,[125] so the question of whether strict products liability would be permitted under the Virginia statute does not arise.

The legislatures of six states stated the policy reasons behind the "blood shield" statutes.[126] These states did not want to inhibit the exercise of sound medical judgment and restrict the availability of knowledge, skill and material by allowing recovery based on liability without fault.

Several states exempt the supplier of blood products from strict products liability only when there is no way to make the blood safer.[127] This makes the protection provided by these statutes similar to that provided by comment k. However, the protection is not identical because these statutes do not require the court to balance the usefulness of the product and the product's risks. Under these statutes, if there is a test that can eliminate the risk, blood suppliers are subject to product liability whether or not the importance of their products in saving lives outweighs the risk of contracting disease.

Several states have multiple statutes dealing with liability for injuries caused by blood.[128] The three Arizona statutes that address the question of liability resulting from injury caused by blood products are unique because each of them limits liability in a different way. These statutes must be analyzed in detail to determine how Arizona law limits liability for blood transfusions.

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123. ALA. CODE § 7-2-314(4) (1984); CAL. HEALTH & SAFETY CODE § 1606 (West 1989); KY. REV. STAT. ANN. § 139.125 (Michie/Bobbs Merrill 1988); ME. REV. STAT. ANN. tit. 11 § 2-108 (West Supp. 1992); MISS. CODE ANN. § 41-41-1 (Supp. 1992); N.Y. PUB. HEALTH LAW § 580(4) (McKinney Supp.1992); OR. REV. STAT. § 97.300 (1990); UTAH CODE ANN. § 26-31-1 (1989).

124. ALASKA STAT. § 45.02.316(e) (1993); CONN. GEN. STAT. § 19a-280 (1986); DEL. CODE ANN. tit. 6, § 2-316(5) (1982); FLA. STAT. § 672.316(5) (1992); MASS. GEN. L. ch. 106, § 2-316(5) (1988); MO. ANN. STAT. § 431.069 (Vernon 1989); N.C. GEN. STAT. § 130A-410 (1986); OHIO REV. CODE ANN. § 2108.11 (Anderson 1988); S.C. CODE ANN. § 44-43-10 (Law. Co-op 1985); S.D. CODIFIED LAWS ANN. § 57A-2-315.1 (1988); TENN. CODE ANN. § 47-2-316(5) (1990); VA. CODE ANN. § 32.1-297 (Michie 1985); W.VA. CODE § 16-23-1 (1985).

125. Sensenbrenner v. Rust, Orling & Neal, Architects, Inc., 374 S.E.2d 55, 57 n. 4 (Va. 1988).

126. ARK. CODE ANN. § 20-9-802 (Michie 1987); COLO. REV. STAT. § 13-22-104(2) (1988); ILL. ANN. STAT. ch. 745 para. 40/1 (Smith-Hurd 1988); NEB. REV. STAT. § 71-4810 (1986); N.D. CENT. CODE § 43-17-40 (1989); TEX. CIV. PRAC. & REM. CODE ANN. § 77.002 (West 1986 & Supp. 1992).

127. FLA. STAT. § 672.316.5 (1992); HAW. REV. STAT. § 325-91 (1989) (only hepatitis is mentioned); IDAHO CODE § 39-3702 (Supp. 1992); LA. REV. STAT. ANN. § 9:2797 and LA. CIV. CODE ANN. art. 2322.1 (West Supp. 1992); MO. ANN. STAT. § 431.069 (Vernon 1989); S.D. CODIFIED LAWS ANN. § 57A-2-315.1 (1988); VA. CODE ANN. § 32.1-297 (Michie 1985) (procedure for detection must be used locally).

128. Arizona, Arkansas, Georgia, Hawaii, Louisiana, Nebraska, North Dakota, Texas and Wyoming have multiple statutes.

The first statute to deal with blood bank liability was Ariz. Rev. Stat. Ann. §36-1151.[129] This statute provides that, when hepatitis is contracted, procurement, processing, distribution, and use of blood or blood products is to be considered a service rather than a product. This means that strict liability and warranty theories are not available to the plaintiff. As discussed above, this is typical of statutes in most states.[130]

Because the Arizona statute only mentions hepatitis, the question arises whether this statute should be applied to the transmission of AIDS, and other transfusion-transmitted diseases, as well.[131] The fact that only hepatitis is mentioned indicates that only hepatitis was meant.[132] Moreover, the Arizona Senate specifically amended the initial bill, which applied to all diseases transmitted by blood, to refer only to hepatitis.[133] The legislature clearly intended the statute to apply only to hepatitis. The validity of this interpretation is supported by the fact that Maryland courts gave a similar interpretation to the former Maryland statute covering liability for blood borne disease. The original bill that became the former Maryland statute applied to all diseases, just as the Arizona bill did. The Maryland courts interpreted an amendment to the bill specifying hepatitis to mean that the statute applied only to hepatitis.[134] The same reasoning has been followed by the Washington Supreme Court.[135]

The most convincing evidence that the Arizona legislature meant the first statute to apply only to hepatitis is that the legislature passed another statute dealing with blood bank liability. In 1972 the legislature passed Ariz. Rev. Stat. Ann. §32-1481.[136] This statute did not replace Ariz. Rev. Stat. Ann. §36-1151,

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129. ARIZ. REV. STAT. ANN § 36–1151 (1993), which was enacted in 1964, reads:

> The procurement, processing, distribution, or use of whole human blood, plasma, blood products and blood derivatives for the purpose of injecting or transfusing them into the human body shall be construed as to the transmission of serum hepatitis to be the rendition of a service by every person participating therein and shall not be construed to be a sale.

130. *See supra* note 119 and accompanying text.

131. Other states also have statutes that specify that they apply only to certain diseases. HAW. REV. STAT. § 325–91 (1993) (limited to hepatitis) but § 327–51 is not limited to any disease; N.M. STAT. ANN. § 24–10–5 (Michie 1993) (hepatitis and HIV); WASH. REV. CODE ANN. § 70.54.120 (Supp. 1992) (hepatitis and AIDS).

132. This is the principle of *inclusio unius est exclusio alterius*, the inclusion of one thing is the exclusion of another. Burgin v. Forbes, 169 S.W.2d 321, 325 (Ky. 1943).

133. J. SENATE 175 (Feb. 11, 1964) shows that Senate Bill No. 166, which created the statute, was amended by adding the phrase "as to the transmission of serum hepatitis" after the word "construed."

134. Miles Lab., v. Doe, 556 A.2d 1107, 1112 (Md. 1989). *See also* Roberts v. Suburban Hosp. Ass'n, Inc., 532 A.2d 1081, 1085 (Md. Ct. Spec. App. 1987). It should be noted that the *Roberts* court found that the common law of Maryland recognized that blood was a service not a sale in part to be consistent with the statute. *Id.* at 1088.

135. Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 819–20 (Wash. 1990)

136. ARIZ. REV. STAT. ANN. § 32–1481 (1992) reads:

> A. No physician, surgeon, hospital or person who assists a physician, surgeon or hospital in obtaining, preparing, injecting or transfusing blood or its components from one or more human beings to another human being shall be liable on the basis of implied warranty or strict tort liability for any such activity but such person or entity shall be liable for his or its negligent or wilful misconduct.
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> B. No nonprofit blood bank, tissue bank, donor or entity who donates, obtains, processes or preserves blood or its components from one or more human beings for the purpose of transfusing or transferring blood or its components to

but instead protected blood banks from strict liability for diseases other than hepatitis. The 1972 statute provides that strict liability and implied warranty theories are not available when the blood or blood product is obtained from a non-profit blood bank. Actions under a negligence theory are still permitted.

Since the legislature specified non-profit blood banks, it is clear that for-profit blood banks are not protected by this statute. This interpretation is supported by the fact that when the bill was first proposed the word "non-profit" was absent.[137] The Arizona House amended the bill by including the word non-profit,[138] and the Arizona Senate concurred.[139] That the legislature did not alter or remove Ariz. Rev. Stat. Ann. §36-1151 indicates that it intended to protect commercial providers of blood products from strict liability only when hepatitis was involved.

The most recent Arizona legislation dealing with blood bank liability modified the Arizona medical malpractice statutes, Ariz. Rev. Stat. Ann. §§ 12-561[140] and 12-563, to cover blood banks, blood centers and plasma centers.[141] Unlike §36-1151, §12-561 makes no distinction between for-profit and non-profit suppliers of blood and blood products.[142]

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another human being shall be liable on the basis of implied warranty or strict tort liability for any such activity but such person or entity shall be liable for his or its negligent or wilful misconduct.

137. The entire wording of the statute, with the exception of the word "non-profit" was proposed by Senator Alexander in a floor amendment to Senate Bill 1171 on March 30, 1972. The amendment was adopted by the Committee of the whole on the same day. J. SENATE 334 (Mar. 30, 1972).

138. J. HOUSE 1276 (May 13, 1972) shows that the bill was amended by the Committee of the whole on May 13, 1972.

139. The Arizona Senate concurred in the amendment on May 14, 1972. J. SENATE 557 (May 14, 1972).

140. ARIZ. REV. STAT. ANN. § 12–561 (1992) reads:

In this chapter, unless the context otherwise requires:

1. "Licensed health care provider" means both:

(a) A person, corporation or institution licensed or certified by the state to provide health care, medical services, nursing services or other health-related services and includes the officers, employees and agents thereof working under the supervision of such person, corporation or institution in providing such health care, medical services, nursing services or other health-related services.

(b) A federally licensed, regulated or registered blood bank, blood center or plasma center collecting, processing or distributing whole human blood, blood components, plasma, blood fractions or blood derivatives for use by a licensed health care provider and includes the officers, employees and agents working under the supervision of the blood bank, blood center or plasma center.

2. "Medical malpractice action" or "cause of action for medical malpractice" means an action for injury or death against a licensed health care provider based upon such provider's alleged negligence, misconduct, errors or omissions, or breach of contract in the rendering of health care, medical services, nursing services or other health-related services or for the rendering of such health care, medical services, nursing services or other health-related services, without express or implied consent, including an action based upon the alleged negligence, misconduct, errors or omissions or breach of contract in collecting, processing or distributing whole human blood, blood components, plasma, blood fractions or blood derivatives.

141. The change was made in 1991.

142. ARIZ. REV. STAT. ANN. § 12–562 was not modified by the Arizona legislature. ARIZ. REV. STAT. ANN. § 12–562 (1992) reads:

A. No medical malpractice action shall be brought against a licensed health care provider except upon the grounds set forth in § 12–561.

Ariz. Rev. Stat. Ann. § 12-563[143] restricts malpractice actions to negligence by specifying the elements that the plaintiff must prove in a malpractice suit. The plaintiff must prove that the health care provider failed to exercise that degree of care which would be exercised by a reasonably prudent provider in the same profession or class within the state under the same circumstances. The plaintiff must also prove proximate cause. However, subsection B of §12-563 says that the inclusion of blood suppliers in the list of those covered by the medical malpractice act is not meant to restrict or enlarge the elements of proof required in a malpractice action against a blood bank.[144] This means that the professional standard of care does not have to be used in cases against blood suppliers based on negligence, although the courts are still free to adopt a professional standard of care. Subsection B means that theories that were available in Arizona before the malpractice statutes were altered are still available. As the analysis above shows,[145] these theories include strict liability for commercial blood suppliers. The earlier statutes clearly preclude liability without fault for non-commercial suppliers, so negligence is the only theory available against them.[146]

This leaves the question of what the legislature intended to accomplish by making these statutory changes. The answer may be that the legislature wanted to make the periodic payment section of the malpractice statutes apply to blood

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B. No medical malpractice action brought against a licensed health care provider shall be based upon assault and battery.

C. No medical malpractice action based upon breach of contract for professional services shall be brought unless such contract is in writing.

143. ARIZ. REV. STAT. ANN. § 12–563. Necessary elements of proof

A. The following shall be necessary elements of proof that injury resulted from the failure of a health care provider to follow the accepted standard of care:

1. The health care provider failed to exercise that degree of care, skill and learning expected of a reasonable, prudent health care provider in the profession or class to which he belongs within the state acting in the same or similar circumstances; and

2. Such failure was a proximate cause of the injury.

B. Notwithstanding § 12–561, nothing in this chapter shall restrict or enlarge the necessary elements of proof in a medical malpractice claim against a federally licensed, regulated or registered blood bank, blood center or plasma center operating in this state.

Laws 1991, Ch. 260, § 3 provides:

Sec. 3. Neutrality of the act on standard of care

The provisions of § 2 of this act shall not be interpreted to evidence a legislative intent that court should or should not apply the elements of proof set forth in § 12–563, subsection A, Arizona Revised Statutes, in an action against a federally licensed, regulated or registered blood bank or plasma center operating in this state.

144. The legislature felt that it was necessary to reiterate this in the law that enacted the changes in § 12–561 and § 12–563. Laws 1991, ch. 260 § 3 says that the provisions of the act are not intended to be interpreted as evidence that the elements of proof should or should not be applied to blood banks or plasma centers. At writing the Arizona House of Representatives has passed a bill repealing this section. The Arizona Senate has not yet acted. This change may violate article 18, section 6 of the Arizona Constitution since it makes it harder for the plaintiff to prove her case. In Hazine v. Montgomery Elevator Co., 176 Ariz. 340, 342–43, 861 P.2d 625, 627–28 (1993), the Arizona Supreme Court struck down limits on strict liability because negligence may be harder to prove.

145. *See supra* notes 127–138 and accompanying text and Whitehurst v. Am. Nat'l Red Cross, 1 Ariz. App. 326, 402 P.2d 584 (1965).

146. *Whitehurst* would also appear to rule out liability for non-profit suppliers since the court bases the decision on the fact that everyone knows that blood from the Red Cross is a gift. *Id.* at 328, 402 P.2d at 586.

product suppliers. Indeed, in some committee hearings, representatives of the blood industry testified that their support for the bill was based on the fact that it made periodic payments available.[147]

Analysis of the Arizona statutes therefore leads to the conclusion that blood suppliers, with the exception of commercial suppliers whose blood products are contaminated by disease organisms other than hepatitis, are protected from suits based on strict liability or implied warranty.[148]

C. Conclusions

It can be seen from this survey that the majority of state legislatures, as well as the majority of courts, have found that public policy requires the protection of blood products suppliers from strict liability and implied warranty. The next question is whether the courts and legislature are correct.

IV. SHOULD STRICT PRODUCTS LIABILITY BE APPLIED TO BLOOD PRODUCTS?

The preceding review of the case law and statutes shows a broad consensus that strict products liability should not be applied to suppliers of blood products. In order to determine whether the protection of blood suppliers from products liability is consistent with the policies underlying strict product liability, it is necessary to review these policies and investigate how they apply to the particular circumstances of the use of blood products.

The courts deciding blood liability cases provide some indication of the policies that are important to them. However it is helpful to put the blood cases in the context of product liability in general. Professor James Henderson recently published a statistical analysis of the policy reasons considered by courts deciding products liability cases.[149] His study identifies three classes of policy reasons: fairness, efficiency, and procedure. Fairness and economic efficiency are the two most important considerations in determining who should bear the costs of harm caused by products.

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147. Minutes of the Committee on Health of the Arizona House of Representatives, Feb. 18, 1991. The same people testified before the Senate committee that the blood industry was interested in the bill because it would affect the collateral source rule and impose a professional standard of care. Minutes of the Committee on Health, Welfare and Aging of the Arizona Sentate, Apr. 2, 1991. The foregoing analysis and the plain words of the statute show that it does not change the standard of care.

148. The Arizona Supreme Court has held that article 18 section 6 of the Arizona Constitution protects the right to sue in strict liability for product defects. Hazine v. Montgomery Elevator Co., 176 Ariz. 340, 345, 861 P.2d 625, 630 (1993). This raises the question of whether the Arizona blood shield statutes are unconstitutional. The statutes clearly prevent suits in strict liability for injuries by blood products. In *Hazine* the court said that the fact that injured parties can still bring suit under a negligence theory is not enough to overcome the protection that the Arizona Constitution provides for actions for injuries. *Id.* at 342, 861 P.2d at 627. However if *Whitehurst* is seen as demonstrating that the Arizona courts do not recognize actions in products liability for injuries caused by contaminated blood, the blood shield statutes have not abrogated any right, and are therefore constitutional. *Whitehurst*, however, appears to apply only to non-profit blood suppliers. *See supra* note 145.

149. James A. Henderson, *Judicial Reliance on Public Policy: An Empirical Analysis of Products Liability Decisions*, 59 GEO. WASH. L. REV. 1570 (1991). The study involved 2517 opinions published between 1983 and 1989.

A. Rationales Related to Fairness

In justifying the imposition of products liability, courts cite general fairness, the idea that those who benefited from the product should pay for the injuries that it causes, and the idea that the consumer should be compensated for the disappointment of his expectations by the product.[150] All of these rationales concern the proper relationship between the manufacturer and the consumer. Strict products liability can be seen as a way of holding manufacturers responsible for failing to live up to the duties society imposes upon them.

It is noteworthy that courts tend to find these fairness arguments more compelling than the economic arguments discussed below; when economic and fairness arguments lead to different conclusions, the majority of courts favor the fairness arguments.[151]

1. Disappointment of Patient Expectation

One reason cited by courts for imposing products liability is that the product does not live up to the consumer's expectation.[152] This would appear to apply to transmission of AIDS and other diseases by blood. The patient expects the treatment to help him get well but instead the treatment causes serious harm.

However, it has been argued that the patient does not rely on the safety of the blood but on the skill of the physician in weighing the risks and benefits of the treatment.[153] Blood requires a high degree of training to properly appreciate the risks and benefits. It is therefore similar to prescription drugs. In the case of drugs, the reliance of the patient on the doctor's judgment has led to the "learned intermediary" doctrine, which says that the drug manufacturer owes the patient a duty to warn the physician of all risks associated with the drug.[154] The statement that the patient relies on the physician's judgment rather than the safety of the blood is essentially a restatement of the learned intermediate doctrine. This same idea no doubt underlies the statements of some

150. *Id.* at 1576. Seventy-three percent of courts cite general fairness, 27% cite the idea that those who benefit should pay and 15% cite the idea that the consumer should be compensated for disappointment of expectations. *Id.* at 1591. The idea that a person should get what he expected is also the basis of implied warranty. W. PAGE KEETON, ET AL., PROSSER & KEETON ON THE LAW OF TORTS §98 at 692 (5th ed. 1984) (hereinafter PROSSER AND KEETON).

151. Henderson, *supra* note 149, at 1596.

152. *Id.* at 1576.

153. Heirs of Fruge v. Blood Servs., 506 F.2d 841, 847 (5th Cir. 1975).

154. Some recent cases where the learned intermediary doctrine has been applied are: Fane v. Zimmer, Inc., 927 F.2d 124, 129 (2nd Cir. 1991); Hill v. Searle Lab., 884 F.2d 1064, 1070 (8th Cir. 1989); Abbot by Abbot v. American Cyanamid Co., 844 F.2d 1108, 1115 (4th Cir. 1988); Swayze v. McNeil Lab., Inc., 807 F.2d 464, 470 (5th Cir. 1987); Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989); Kirk v. Michael Reese Hosp. & Medical Ctr., 513 N.E.2d 387, 393 (Ill. 1987), *cert. denied,* 485 U.S. 905 (1988); Savina v. Sterling Drug, Inc., 795 P.2d 915, 929 (Kan. 1990); Niemiera by Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989); Bacardi v. Holzman, 442 A.2d 617, 619 (N.J. Super. Ct. App. Div. 1981); Glucksman v. Halsey Drug Co., Inc., 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990); Bikowicz v. Nedco Pharmacy, Inc., 517 N.Y.S.2d 829, 831 (N.Y. App. Div. 1987); Makripodus by Makripodus v. Merrell-Dow Pharmaceuticals, Inc., 523 A.2d 374, 377, 378 (Pa. Super. Ct. 1987).

courts that blood is a service and not a sale.[155] Blood is a service because the patient relies on the doctor's judgment.

It is no doubt true that the patient relies on the doctor's judgment in evaluating risks and benefits of the use of blood and prescription drugs. This is not the same as saying that the patient does not expect blood or drugs to be as safe as possible. In fact it is safe to say that patients expect that modern medicine provides the best treatment possible in the current state of knowledge. As discussed above, §402A of the Restatement (Second) of Torts only imposes liability for blood products if they are not made as safe as possible.[156] Applying products liability to blood products therefore vindicates the patient's expectation and satisfies this rationale for products liability.[157]

2. Those Who Profit from a Sale Should Pay for the Harm that the Product Causes.

Strict products liability has also been justified on the grounds that those who benefit from the use of a product should pay for the harm the product causes.[158] The cost of injury by products must be borne by someone, whether it is the injured party, private insurance or government insurance programs, or those who benefit from the product. It is fairest if those who benefit pay. Two groups of people benefit from the use of the product. One is the manufacturer who can be said to deliberately appropriate, for profit, the physical well being of those who are injured, and who should therefore pay for the injuries.[159] This reasoning would appear to apply to for-profit blood banks and to drug companies that supply clotting factors but not to non-profit blood banks.[160] Although non-profit companies do not appropriate the well being of those they serve in order to make profits, they do appropriate it to further the purpose of the organization. In the case of non-profit blood banks the purpose is to supply blood to those who require it. It is therefore the ultimate user of the blood who is appropriating the health of those who contract diseases from blood, not the organization that supplies the blood.

The second group of people who benefit are those who use the product. Those who benefit from the use of a risky product should pay for the harm that others sustain in using the same product.[161] This is a moral aspect of the loss spreading policy discussed below under economic rationales.[162] The idea is that if one derives a benefit from something which harms others, one has a moral

155. The sales/service distinction is discussed *supra* notes 82–97 & 118–119 and accompanying text.

156. *See supra* notes 103–114 and accompanying text.

157. A brief note is required here to say that when the court evaluates whether the product is made as safe as possible it is not using a negligence based analysis. Products liability differs from negligence in that the safety of the product is evaluated in the light of all that is known after the injury has occurred whereas negligence is evaluated on the basis of what the blood supplier knows at the time of manufacture. PROSSER & KEETON *supra* note 150, §99.

158. Henderson, *supra* note 149, at 1576.

159. *Id.*

160. Brody v. Overlook Hosp., 317 A.2d 392, 395 (N.J. Super. Ct. App. Div. 1974), *aff'd*, 332 A.2d 96 (N.J. 1975) (the relationship is the antithesis of a commercial relationship).

161. Henderson, *supra* note 149, at 1576–77.

162. *See infra* notes 164–183 and accompanying text.

responsibility to pay for the harm. For example, those who benefit from tires should pay for the injuries suffered by some users of tires.[163]

In the case of diseases caused by blood, those who benefit from the availability of blood products in either of these two ways should pay for the harm blood products cause to others by paying a higher price for blood. Product liability will do this by causing the supplier to pay directly when the plaintiff wins, and making the users pay indirectly by raising the price of the product. This rationale would not be served as well by negligence because all of those who benefit are not negligent. This is one reason why the question of whether the product is safe as possible is made based on hindsight. Otherwise this policy would not be fully accomplished.

B. Economic Rationales for Strict Liability.

The next group of policy rationales falls under the general classification of economic efficiency.[164] Economic efficiency means that resources are put to their best use. Particular examples of this are given below.

1. Loss Spreading

The most popular economic policy cited by courts is that strict liability serves to spread losses.[165] The idea behind loss spreading is that a large group

163. Schump v. Firestone Tire and Rubber Co., 541 N.E.2d 1040, 1044 (Ohio 1989).

164. The distinction between economic and fairness policies is not absolute. It has been argued that cost spreading, deterrence, and cost internalization accomplish important moral goals, too. The argument is that the ability of a person to direct his life as he pleases is of intrinsic value, because otherwise human dignity would be compromised and the person would be the plaything of external forces. John B. Attanasio, *The Principle of Aggregate Autonomy and the Calabresian Approach to Products Liability*, 74 VA. L. REV. 677, 679–80 (1988). Cost spreading increases autonomy because the victim is not incapacitated by the cost of the injury. *Id.* at 712–13. Requiring the one who can most cheaply avoid the problem to pay the cost means that the minimum possible cost is paid and therefore the overall autonomy is maximized. *Id.* at 707. Cost internalization promotes autonomy because it permits the person to make decisions based on the true cost of the product. *Id.* at 709. These arguments apply with special strength to AIDS since it is hard to imagine anything that would impair a person's ability to shape her own life more than a disease that results in debilitation and premature death.

165. Henderson, *supra* note 149, at 1591. Sixty-two percent of the courts cite this policy. *Id.* Also note that this reason is reported to be convincing to courts. *See* PROSSER AND KEETON, *supra* note 150, at 692-693. *See also* George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L.J. 1521, 1534 (1987). Loss spreading has been called the most important function of strict liability. Alinka Baker, *Liability Without Fault and the AIDS Plague Compel a New Approach to Cases of Transfusion-Transmitted Disease*, 61 U. COLO. L. REV. 81, 97 (1990). However at least one court has referred to it as a make-weight argument. Brody v. Overlook Hosp., 317 A.2d 392, 398 (N.J. Super. Ct. App. Div. 1974), *aff'd*, 332 A.2d 96 (N.J. 1975) (policy reasons considered in determining whether to apply strict liability to blood bank). There is debate about what losses should be spread. It is clear that pecuniary damages such as medical expenses and lost wages should be covered, but there is debate about whether pain and suffering should also be included. The idea of compensating people for pain and suffering has been criticized on the basis that people would not buy insurance against such things if given a choice. Alan Schwartz, *Proposals for Products Liability Reform*, 97 YALE L.J. 353, 363 (1988). For example, parents do not buy insurance that will pay them if their child dies when he is four. Priest at 1546-47. In fact it has been argued that if people knew that they were going to be in great pain after some point in time, they would want more money to use before that time, not after it. *Id.* at 1547. Therefore it seems likely that pain and suffering damages are not really an economic replacement but relate to fairness and come from the idea that people should compensate those they harm. This means that the award of pain and suffering damages under strict liability cannot be justified exclusively as loss spreading; only compensation for actual expenditures and monetary losses is justified under a policy of cost spreading.

of people can sustain a loss that would wipe out an individual.[166] This is considered to be an important effect of products liability because the injured person would become a burden on society if his resources were wiped out.[167] Although AIDS can not be cured, treatment can significantly increase the life span of AIDS patients.[168] The cost of lifetime treatment for AIDS is now over $100,000.[169] If the AIDS patient cannot afford medical treatment, disability will occur sooner. Society will therefore lose the benefits of that patient's productivity sooner than is necessary. The loss spreading policy would therefore be served by applying products liability to blood products.

However, tort law is not the only means of spreading the cost of injuries caused by products. Insurance is one alternative. The question is whether tort law or insurance is the better way to spread costs? There are several reasons to believe that tort law is not the best method.

One problem is that tort remedies are slow. Although many people infected with HIV live for more than 10 years without symptoms, many develop symptoms, and many die within the first few years following infection.[170] Therefore, some patients will die before their case is resolved. Cost spreading will be of no benefit to them. In addition, those who develop symptoms but who do not die before receiving compensation will have to survive for a considerable period of time without the benefits of cost spreading.

Another argument against using tort law to spread the costs of injuries pertains mainly to people with hemophilia. Only 2000 people use clotting factor IX in the United States.[171] One court has said that this group is too small to bear the cost of the injuries caused by the clotting factor IX.[172] Many of the people who use factor IX are infected with HIV and will eventually contract AIDS.[173] These people will need the benefits of cost spreading and therefore will not be available to share the burden. This argument applies to people who use factor VIII as well. Although there are many more people who use factor VIII, a large percentage of them are also infected with HIV.[174] Once again the number of healthy users available to bear the burden of the costs of the injuries will be substantially decreased.

This argument ignores several possibilities. First, insurance will pay part of the cost of the medications used by many hemophiliacs. Thus part of the cost will actually be spread over a large portion of society through the insurance system. Also, the clotting factor manufacturer may spread costs to all of its cus-

166. Henderson, *supra* note 149, at 1579.
167. *Id.* at 1579.
168. Richard D. Moore et. al., *Zidovudine and the Natural History of the Acquired Immunodeficiency Syndrome*, 324 NEW ENG. J. MED. 1412 (1991) (median survival of those receiving AZT was 770 days compared to 190 days for those who have never received AZT).
169. Hellinger, *supra* note 45.
170. *See supra* note 43.
171. Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 822 (Wash. 1990); Rogers v. Miles Lab., 802 P.2d 1346, 1351 (Wash. 1991).
172. 802 P.2d at 1351.
173. M.V. Ragni, et al., *1986 Update on HIV Seroprevalence Seroconversion, AIDS Incidence, and Immunologic Correlates of HIV Infection in Patients with Hemophilia A and B*, 70 BLOOD 786 (1987) (48% are infected).
174. In one study 76% of patients with severe hemophilia A and 25% of patients with mild hemophilia A had antibodies to HIV. James J. Goedert et al., *A Prospective Study of Human Immunodeficiency Virus Type I Infection and the Development of AIDS in Subjects with Hemophilia*, 321 NEW ENG. J. MED. 1141, 1143 tbl. 1 (1989).

tomers by increasing the prices of all of its products.[175] It is difficult to say *a priori* how much of the cost will be spread solely to the hemophiliacs, but it is clear that the analysis is not as simple as the courts have assumed.

Another argument against the tort system as a means to spread losses is that too little of the award goes to the victim. According to one estimate, only 18-54% of the damages awards in a tort case go to the victim.[176] In contrast, the administrative costs of insurance are between 8% and 21% of the benefits paid out.[177] Insurance[178] is therefore much more efficient than the tort system at distributing money to the injured. Since insurance would probably pay only lost wages and medical expenses, the injured person would get less money than from the tort system, which includes compensation for pain and suffering and possibly punitive damages. However, if the purpose is only to prevent the patient from becoming a burden on society, this compensation is adequate. As discussed below, there are legitimate concerns about whether products liability would raise the price of blood to a prohibitive extent.[179] The lower amount of the award and the greater efficiency of the insurance system would mean that the price of blood would be raised less than it would be by the tort system.

There are problems with insurance, too. These problems differ depending on what kind of insurance is involved: Medical and disability insurance purchased by the consumer or patient, or liability insurance purchased by the manufacturer. Medical insurance as it stands now would not be adequate, since not all people are covered.[180] Another problem with medical insurance is that it spreads the costs to all those who have insurance, rather than just to those who profit from the product. This would not serve the fairness purpose that those who profit from the use of a product should pay for the injuries it causes.[181] Spreading the cost over all those who have insurance would also fail to serve as an incentive for the suppliers to decrease the risk of harm from their products.[182] These problems could be overcome if the manufacturers were required to buy liability insurance to cover those injured by their products. The insuring agency would determine if the patient should be reimbursed and pay the pecuniary losses of those who were injured by the product. Since the suppliers would pay for the insurance, they would have an incentive to improve the product to keep down the cost of insurance. This type of insurance has been introduced in the vaccine industry by the federal government in order to stem the withdrawal of vaccine manufacturers from the market.[183]

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175. This will not serve the fairness rationale that those who benefit should pay for the harm. *See supra* notes 158–163 and accompanying text.

176. Priest, *supra* note 165, at 1560 (estimating that 53% of the total goes to legal and administrative costs).

177. *Id.*

178. Insurance could either be medical and disability insurance purchased by the individual or liability insurance purchased by the manufacturer.

179. *See infra* note 219 and accompanying text.

180. In 1991, 33.5 million people or 13.5% of the U.S. population did not have medical insurance. U.S. BUREAU OF THE CENSUS, UNITED STATES STATISTICAL MANUAL 115 TBL. 165 (1993).

181. *See supra* notes 158–163 and accompanying text.

182. Incentives for product improvement will be discussed below. *See infra* notes 185–207 and accompanying text. For a discussion of the idea that first party insurance would allow too many bad products on the market, see Schwartz, *supra* note 165, at 406.

183. 42 U.S.C.A. §§ 300aa–10 to 300aa–34 (West 1991 & Supp. 1994).

Insurance bought by individuals is arguably more efficient than liability insurance bought by the suppliers. First party insurance can be tailored more closely to the needs of the particular person and there are means available in first party insurance to discourage abuse of the system.[184] However, efficient cost spreading is not the only policy that is served by product liability. Less efficient cost spreading is offset by better deterrence by industry purchased insurance.

2. Deterrence

The next major economic policy that products liability serves is to encourage improvement in product safety. This policy is based on the belief that the manufacturer will take steps to decrease the amount that it must pay out for injuries caused by its products.[185] There are two types of deterrence: The cost of liability may be high enough to drive the product off the market, or it may be high enough to lead the producer to make the product safer. Either way, the amount of harm caused by the product is reduced. Clearly, blood products are too important to be driven off the market. Therefore encouraging the manufacturer to produce safer products is the important part of deterrence when blood is involved.

a. Objections to the Deterrent Effect of Product Liability on the Blood Industry

The deterrence aspect of product liability has been argued to be insignificant because the manufacturer can get insurance and insurance is only crudely proportioned to individual behavior.[186] If the insurer rather than the manufacturer pays for the damage that the manufacturer's products cause, and if the insurance payments do not decrease substantially when the manufacturer improves the safety of its products, the manufacturer has little incentive to improve the safety of its products.[187] Insurance companies group manufacturers according to their likely liability and set rates primarily according to the overall risk of the group.[188] Safety improvements made by one member of the group will not affect the group's overall risk and, therefore, will have a small effect on the rates. This argument does not apply to the blood industry. The blood industry as a whole sets standards for the safety of blood products.[189] Since all blood banks follow the same standards, improvements in safety afforded by the standards will decrease lawsuits for all members and the insurance costs for the industry as a whole will be kept down.

Another criticism of products liability is that it will result in an increase in accidents because the plaintiffs will have less incentive to take care.[190] It is argued that this will partially offset the decrease in injuries due to the

184. Priest, *supra* note 165, at 1539–48.

185. Deterrence is cited by fifty-three percent of the courts citing policy reasons. Henderson, *supra* note 149, at 1591. It is also cited as a justification for strict products liability in PROSSER AND KEETON, *supra* note 150, at 692–693 and in Priest, *supra* note 164, at 1534.

186. Glen O. Robinson, *Rethinking the Allocation of Medical Malpractice Risks Between Patients and Providers*, 49 LAW & CONTEMP. PROB., 173, 176 (1986).

187. *Id.*

188. *Id.*

189. The standards are published in AMERICAN ASSOCIATION OF BLOOD BANKS, STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES (18th ed. 1991).

190. Schwartz, *supra* note 165, at 370.

precautions taken by the manufacturer.[191] This argument would not appear to apply to physical injuries. It seems unlikely that a person would expose himself to the physical pain and inconvenience of an injury because he knows that someone else will reimburse him for it. Even if it did apply to physical injuries it would only apply to those that result from the voluntary actions of the injured person. Patients do not choose to use blood; they need blood because of some injury or illness. Furthermore, once the disease or injury has occurred it is not the patient but the physician who controls the use of blood. Since the physician is still liable under malpractice for bad decisions, she will have an adequate incentive to use care.

Some courts have said that the rationale of encouraging product improvement should not apply to AIDS cases that arose before there was an AIDS test[192] because the blood banks could not have done anything to make the blood safer.[193] This argument ignores the fact that other measures could have been taken to significantly improve the safety of the blood supply before screening for HIV was developed. One method was to screen out high risk donors before they donated blood by asking them questions. This is a highly effective method; the current donor screening methods decrease the number of HIV infected donors by between 40 and 80 fold.[194]

Another technique that could have been implemented in 1983 to decrease the risk of AIDS transmission by blood was testing for antibody to the hepatitis B core antigen. This antibody is not directly related to HIV infection, but the CDC reported in January 1983 that 90% of AIDS patients had this antibody in their blood. The combination of donor interviews and blood testing could therefore have significantly reduced the risks of AIDS transmission long before the development of the blood test for HIV.[195]

Even if no test for HIV was available before the blood test was developed, it can be argued that liability should have been imposed because liability not only encourages manufacturers to use existing techniques to improve safety, it encourages them to seek new methods. However, liability may also lead the suppliers to stop producing the product. How a manufacturer responds depends on how much liability the product is causing, and how much the price of the product can be raised. If the liability does not consume the profits that a product earns for the manufacturer, the manufacturer is likely to seek ways to improve the safety of the product rather than discontinue it. Damages for injuries which cannot be prevented should therefore be adjusted to a level that will encourage research to improve the product.

In the case of non-profit blood banks there is a similar argument that liability must be tailored so that it is large enough to encourage product

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191. *Id.*

192. The test for HIV was licensed by the FDA on March 5, 1985. Program Announcement, 50 Fed. Reg. 9909 (1985).

193. Miles Lab. v. Doe, 556 A.2d 1107, 1121 (Md. 1989) (the seller was not in a better position to make the product safe); Rogers v. Miles Lab., 802 P.2d 1346, 1351 (Wash. 1991); Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 822 (Wash. 1990); Coffee v. Cutter Biological, 809 F.2d 191, 194 (2d Cir. 1991).

194. Jeffrey McCullough, *The Nation's Changing Blood Supply System*, 269 JAMA 2239, 2240 (1993).

195. *Id.*; Jean L. Marx, *Health Officials Seek Ways to Halt AIDS*, 219 SCIENCE 271 (1983).

improvement, but not so large that the blood bank goes out of business or raises the price of blood to prohibitive levels. Limitation by courts of the amount of damages recoverable from blood suppliers would be preferable to excluding recovery altogether.

There are other reasons to question whether tort liability is the best way to deter blood suppliers from releasing hazardous blood products. First, blood banks are regulated by the Food and Drug Administration (FDA).[196] The FDA has the responsibility of ensuring that the blood supply is safe: if the FDA does not set standards high enough or police the blood suppliers adequately, blood suppliers may not produce safe blood. There is in fact evidence that the FDA did not adequately regulate the blood industry.[197] Political pressure on the FDA corrected this problem.[198] However, this is an inefficient way to ensure safe blood since political pressure only comes about when the problem becomes widespread enough to cause public outcry, which could be a considerable time after patients have begun to suffer.[199] In contrast, tort liability has the advantage of making the manufacturer the watch dog. If the manufacturer is aware that it may have to pay large amounts in damages it will have an incentive to take early action to correct problems.

A second factor affecting the deterrent aspect of products liability is the fact that the federal government does research on blood safety. If the government, rather than the blood suppliers, is doing the majority of the research to improve the safety of blood, applying incentives to the blood suppliers will have little effect on safety. The importance of government research on blood is shown by the fact that government scientists isolated the organism that causes AIDS and developed and patented the test now used to detect the presence of the AIDS virus in blood.[200] The federal government also funds much of the research on blood. If the government does the majority of work toward improving blood safety, political pressure on the federal government would be a more effective means of improving safety than imposing products liability on the blood suppliers. However, the argument that political pressure on the government to increase research is the best way to improve the safety of blood is only valid if an increase in research is needed to make the blood supply safer. Research was not required to substantially increase the safety of blood. As discussed above, techniques were available in 1983 that would have made blood products much safer had they been implemented.[201]

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196. *See* 21 C.F.R. §§ 606.3–607.65 (1993).

197. McCullough, *supra* note 194, at 2242 (reporting that blood banks have traditionally had a collegial rather than a "law enforcement" relationship with the FDA). In addition it is remarkable that there was no requirement in the Code of Federal Regulations that blood products be tested for HIV until 1988, three years after the test was approved. General Biological Products Standards, Additional Standards for Human Blood and Blood Products, 53 Fed. Reg. 111 (1988).

198. Congressional and public pressure led the FDA to tighten its regulation of the blood industry. McCullough, *supra* note 194, at 2242.

199. It was not until 1988 that the FDA began to tighten regulation of the blood industry in response to congressional pressure. *Id.*

200. Robert C. Gallo et al., *Frequent Detection and Isolation of Cytopathic Retrovirus (HTLV-III) from Patients with AIDS or at Risk for AIDS*, 224 SCIENCE 500 (1984).

201. *See supra* notes 194–195 and accompanying text.

b. The Effect of Deterrence on the Blood Industry

The importance of products liability to increased blood safety can best be seen by considering the response of the blood products industry to the possibility that AIDS could be transmitted by blood. During 1983 there was no agreement among experts on whether AIDS could be transmitted by blood transfusion. Some researchers believed that blood products could not transmit AIDS.[202] Many others believed that AIDS was transmitted by blood transfusion.[203] Blood product suppliers therefore faced conflicting opinions about whether blood transfusions could cause AIDS. They decided to act on the

202. Marx, *supra* note 195 (Medical Director of The National Hemophilia Foundation said that he believed that AIDS was due to over stimulation of the immune system caused by the large number of foreign proteins hemophiliacs are exposed to through clotting factor concentrates; James Curran, head of the CDC AIDS task force, said "[t]he sense of urgency is greatest for hemophiliacs. The risk for others [who receive blood products] now appears small, but is unknown."); *Plasma Products Withdrawn After Donor Dies of AIDS*, AM. FAM. PHYSICIAN, Dec. 1983, at 18 (the FDA believed there was little chance that AIDS was transmitted by transfusion); Charles Marwick, *'Contaminated' Plasma: No Automatic Recall*, 250 JAMA 1126 (1983)(the Blood Products Advisory Committee of the National Center for Drugs and Biologicals of the FDA, composed of university researchers, involved in blood banking, said that recalling blood products when the donor later developed AIDS, was not necessary); *AIDS Transmission Through Transfusion 'Infinitesimal,'* MODERN HEALTHCARE, July 1983, at 20 (Gary Gitnick of UCLA School of Medicine said that AIDS cannot be transmitted by blood); Thomas F. Zuck, *Editorial — Greetings with a Brief Look Back*, 23 TRANSFUSION 459 (1983) (journal published by the American Association of Blood Banks, whose members collect approximately half of the blood collected in the United States each year, published an editorial saying that the risk of contracting AIDS was one in a million if it existed at all and the press had overblown the issue); *The Mysterious Plague of Acquired Immunodeficiency*, HOSP. PRAC., May 1983, at 72, 261.

203. William A. Chech, *Preventing AIDS Transmission: Should Blood Donors be Screened?*, 249 JAMA 567 (1983); *Hospital Staff Warned About AIDS Syndrome*, HOSPITALS February 16, 1983 at 57 (CDC recomended that clinical and laboratory staffs take the precautions against transmission that are used in working with hepatitus B); Jane F. Desfarges, *AIDS and Preventative Treatments in Hemophilia*, 308 NEW ENG. J. MED. 94 (1983) (editorial saying that the treatment for hemophilia may be more dangerous than hemophilia itself); Anthony S. Fauci, *The Acquired Immune Deficiency Syndrome; The Ever Broadening Clinical Spectrum*, 249 JAMA 2375 (1983) (AIDS could be transmitted by sexual contact among homosexuals and by blood); *AIDS Figures Mount as Researchers Seek Answers to Puzzle*, AM. FAM. PHYSICIAN, September 1983 at 331 (Stanford University blood bank began screening blood for helper suppressor T-cell ratios; it believed the extra blood discarded was worth it); Jean L. Marx, *Minimizing the Risk of Contracting AIDS*, 219 SCIENCE 1301 (1983) (Companies that made clotting factor concentrates for hemophiliacs reported that they were going to institute direct questioning of donors about high risk behaviors at the request of the National Hemophilia Foundation); Chech at 569 (Companies that made clotting factor concentrates for hemophiliacs reported that they were instituting direct questioning of donors about high risk behaviors at the request of the National Hemophilia Foundation). Representatives of the homosexual community strongly opposed questioning about sexual preference. *Id.* Many health care workers appear to have believed that AIDS was transmitted by blood because there were reports that health care workers were unwilling to be vaccinated with the new hepatitis B vaccine because it was made from the blood of hepatitis B patients, many of whom were at risk for AIDS. Catherine Macek, *AIDS Transmission: What About Hepatitis B Vaccine?*, 249 JAMA 685 (report of health care workers refusing hepatitis B vaccine because it is made from human blood of people who may have AIDS); *Hepatitis B Vaccine tie to AIDS Dismissed*, HOSPITALS, Sept. 1, 1983, at 59 (CDC and Merck say disinfection procedures during manufacture of the vaccine are sufficient to kill any organism that might cause AIDS); *Health Workers Get AIDS; Fear Slows Immunization*, MODERN HEALTHCARE, Aug. 1983, at 10 (280 of 1200 employees of the University of Illinois hospital in Chicago have refused to take Hepatitis B vaccine); Jeffrey A. Goldin, Letter, 308 NEW ENG. J. MED. 1163 (1983); David Dickson, *AIDS Fears Spark Row Over Vaccine*, 221 SCIENCE 437 (1983) (controversy over French hepatitis B vaccine made in part from American blood).

opinions that the threat of AIDS transmission by transfusion was minimal, and that minimal safeguards were required. If they had been subject to products liability, they may well have decided to err on the side of caution and act on the information that transfusions may cause AIDS, in order to minimize the chance that they would be found liable for the injuries caused by their product. This is the effect strict liability is supposed to have.

The importance of the deterrent aspect of products liability is also shown by the complacent attitude of the blood bankers. In 1983, they rejected surrogate testing of blood because they thought it would decrease the amount of blood available. However, the test for antibody to the hepatitis B core antigen was introduced by the blood industry as a surrogate test in 1987[204] to lessen the chance of infection from non-A non-B hepatitis, which had been around long before the AIDS crisis began.[205] This shows that the AIDS crisis raised the level of concern about blood safety in the blood industry. If the blood industry had been subject to strict liability, it is likely that it would have been concerned about the deaths due to hepatitis long before 1987. Tests would have been implemented as soon as they became available, and many fewer people would have died of hepatitis and AIDS. Another example of the complacency of the blood industry is the fact that even today the industry resists the implementation of standardized techniques which would ensure that the public is not exposed to risky blood.[206]

3. Cost Internalization

Another economic policy underlying products liability is that use of a product is decreased when the user must pay a higher price because the cost of product-caused injuries is added to the price of the product.[207] This optimizes the use of the product because the user can determine if the cost of injuries is worth paying.[208] This policy is not widely cited by courts.[209] Those courts that have cited it in blood cases have misinterpreted it. They have said that product liability is intended to drive hazardous products off the market.[210] The real purpose is to optimize use, not eliminate use.

Although blood products are essential to the preservation of life, research has actually shown that blood is overused.[211] Since even tested blood presents

204. The introduction of surrogate screening increased the amount of discarded blood from an average of 10% between 1982 and 1986 to 17.5% in 1987. D.M. Surgenor et al., *Collection and Transfusion of Blood in the United States, 1982–1988*, 322 NEW ENG. J. MED 1646, 1648 tbl. 3, 1649 (1990).

205. There is no regulation in the Code of Federal Regulations requiring either the test for elevated alanine transferase or the test for the antibody to the hepatitis B core antigen.

206. Jay E. Monitove, *Controversies in Transfusion Medicine*, 33 TRANSFUSION 439 (1993). The blood bankers object to the FDA requirement that they follow the good manufacturing practices that have long been required of drug manufacturers. *Id.* The objection is based in part on the fact that the regulations would limit professional judgment. *Id.*

207. Henderson, *supra* note 149, at 1579; Priest, *supra* note 168, at 1534. This is also cited as an important policy objective in PROSSER AND KEETON, *supra* note 150, at 692–693.

208. Henderson, *supra* note 149, at 1579.

209. Only 7% of courts that cite policy reasons cite this one. Henderson, *supra* note 149, at 1591.

210. Doe v. Miles Lab., 927 F.2d 187, 192 (4th Cir. 1988); Miles Lab. v. Doe, 556 A.2d 1107, 1121 (Md. 1989).

211. Niles R. Rose et al., *Transfusion Therapy: Improved Patient Care And Resource Utilization*, 33 TRANSFUSION 341, 342 tbl. 2 (1993) (physician education reduced blood usage

some risk, blood should only be used when necessary to preserve life. The question is, therefore, whether raising the price of blood will decrease the unnecessary usage of blood. This is probably not the case. A decrease in usage due to an increase in price may not apply to medical products since costs can be passed on even if they are excessive.[212] People are willing to pay high prices in order to improve their health.[213] Furthermore, the decision of how much blood to use is made by the physician. The physician is unlikely to consider the cost of the blood since few physicians know the cost of medical products or services.[214]

Another reason that cost internalization is not an important consideration with blood products is that an increase in product cost is needed to optimize consumption only if the user does not understand the risks involved in the use of the product.[215] If the user understands the risk of harm that can arise from the use of the product, he will weigh the risk in determining whether to use the product. It is not necessary to use high price as a way of bringing the risk of the product to the attention of the user who understands the risk. Since blood products are used by physicians, who will evaluate the risks and benefits before prescribing the therapy, this argument does not apply to blood products with the same strength that it does to consumer products. Physician education is a better way to optimize use than increased price.[216]

The increase in cost that would result from strict liability is the primary argument used against its application in blood cases. Blood is essential for many procedures. The argument in favor of blood shield statutes is that they promote public health and welfare by ensuring an adequate supply of inexpensive blood. Strict liability would increase the price of blood, thus making it less available to low income patients, and decrease the supply, because some suppliers would go out of business if products liability suits were permitted.[217] Courts adopting this reasoning have been criticized for not presenting any evidence that strict

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in one hospital by 19.4% in three years in spite of an increase in procedures requiring blood); L.T. Goodnough et al., *Identifying Elective Orthopedic Surgical Patients Transfused with Amounts of Blood in Excess of Need: The Transfusion Trigger Revisited*, 32 TRANSFUSION 648 (1992) (between 25 and 60 % of orthopedic surgery patients receive more blood than necessary); Richard K. Spence et al., *Transfusion Guidelines for Cardiovascular Surgery: Lessons Learned from Operations on Jehovah's Witnesses*, 16 J. VASCULAR SURGERY 825 (1992) (blood use can be reduced to nearly zero in cardiovascular surgery by the use of intra-operative autotransfusion and by acceptance of a postoperative hemoglobin minimum of 7.0 grams per deciliter).

212. Glen O. Robinson, *Rethinking the Allocation of Medical Malpractice Risks Between Patient and Provider*, 49 LAW & CONTEMP. PROB., 173, 178 (1986). Judge Learned Hand's Formula is not used in medical cases. *Id.* at 179.

213. *Id.*

214. Harry Greene et al., *Physician Attitudes Toward Cost Containment*, 149 ARCH. INTERN. MED. 1966 (1988).

215. Schwartz, *supra* note 165, at 374-75; Alan Schwartz, *The Case Against Strict Liability*, 60 FORDHAM L. REV. 819, 821–22, 828 (1992).

216. In one study, physician education reduced blood usage in one hospital by 19.4% in three years in spite of an increase in procedures requiring blood. Rose et al., *supra* note 211.

217. Jan M. Bennetts, Note, *AIDS: Blood Bank Liability*, 27 WILLIAMETTE L. REV. 355, 371 (1991). Brody v. Overlook Hosp., 317 A.2d 392 (N.J. Super. Ct. App. Div. 1974), *aff'd*, 332 A.2d 596 (N.J. 1975); Rogers v. Miles Lab., 802 P.2d 1346, 1351 (Wash. 1991); Howell v. Spokane & Inland Empire Blood Bank, 785 P.2d 815, 822 (Wash. 1990). It has been said that the legislature's intent in enacting the blood shield statutes was to ensure an adequate blood supply, and that this is the same purpose comment k is meant to serve. Miles Lab. v. Doe, 556 A.2d 1107, 1121 (Md. 1989).

liability would endanger the blood supply.[218] However, liability can lead to decreases in the availability of health services. For example, half of the manufacturers of the diphtheria-pertussis-tetanus vaccine in the United States ceased making vaccines because of the cost of lawsuits.[219] It therefore appears that the benefits of cost internalization do not occur when blood products are involved.

4. Strict Liability is Less Expensive to Administer

Another argument for strict liability is that it requires the plaintiff to prove fewer elements than negligence does.[220] Reducing what the plaintiff must prove decreases administrative costs.[221] Another argument based on administrative concerns is that, in the case of blood and other products, negligence is hard to prove. The supplier has control of the information about the production processes.[222] Furthermore, these things are complex and therefore difficult for outsiders to understand.[223] This argument has been adopted by some courts that have accepted strict liability for blood.[224] In negligence cases involving the transmission of disease by blood plaintiffs commonly seek to prove that the blood products supplier failed to ask the donor the correct questions to eliminate possible disease carriers.[225] In the case of AIDS, the questions include whether the donor is homosexual, uses intravenous drugs or has been to Haiti.[226] The only relatively independent witness to the organization asked these questions is often the donor. But, in AIDS cases, the donor may be dead and therefore unable to testify.[227] Even if the donor is alive, he may be unwilling to testify, and restrictions may be placed on his giving evidence in order to protect his privacy.[228] The plaintiff in a negligence action may also need to prove that the blood test was not done correctly or that contaminated and safe blood were confused.[229] Information about how the blood test was done and how the records were kept is clearly in the hands of the blood products manufacturer.

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218. *See, e.g.*, Baker, *supra* note 165.

219. Nina H. Compton & J. Douglas Compton, *DPT Vaccine Manufacturer Liability: Chipping Away at Strict Liability to Save the Product*, 20 N.M. L. REV. 531, 534 (1990); Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149, 151–52 (1988). The cost of insurance for blood banks has risen from $0.65 to $3.00 per unit. David Stevens, *Negligence Liability for Transfusion-Associated AIDS Transmission: An Update and Proposal*, 12 J. LEGAL MED. 221, 239 (1988).

220. Henderson, *supra* note 149, at 1579. This reasoning is cited by 9% of the courts that cite policy reasons. *Id.* at 1591.

221. Stephen G. Gilles, *Negligence, Strict Liability and the Cheapest Cost Avoider*, 78 VA. L. REV. 1291, 1304–5 (1992).

222. Pamela T. Westfall, Note, *Hepatitis, AIDS and the Blood Product Exemption from Strict Products Liability In California: A Reassessment*, 37 HASTINGS L. REV. 1101, 1106 (1985); Baker, *supra* note 165, at 84 ("Negligence is an inadequate theory. The victim...has neither the financial nor the physical resources [required] to bear the heavy burden of proof required for a negligence cause of action.").

223. Westfall, *supra* note 222, at 1106.

224. *DeBattista*, 403 So.2d 26, 31.

225. *See supra* notes 236–240 and accompanying text.

226. *See supra* notes 236-240 and accompanying text.

227. Bennetts, *supra* note 217, at 373.

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

229. There have been reports of this occurring. *See supra* note 50.

However, the argument that negligence is harder to prove is not convincing by itself. This argument is based on the assumption that the plaintiff should have an advantage in the trial. This advantage must be justified by other policies.

C. Conclusions

Strict products liability for blood products is most strongly supported by the deterrent effect of strict liability. The remarkable inaction of the blood banks before and at the advent of the AIDS crisis shows that strict liability is necessary to ensure the safety of the blood supply. The fairness policy that those who benefit should pay for injuries is also furthered. The majority of the other policies are not furthered by applying strict liability to blood, but neither are they threatened: cost internalization will not limit the use of blood; easing the plaintiff's proof can only be justified by other policies; and patient expectations probably do not include absolutely safe blood. The only policy that may be accomplished better by means other than strict liability is loss spreading. Losses might be spread faster and more efficiently by insurance than by the tort system. This is a disadvantage to patients because they are not compensated fast enough by the tort system, and it is a disadvantage to society because it raises the cost of blood unnecessarily.

V. NEGLIGENCE

As discussed above, in Arizona and the majority of other states, blood suppliers are not subject to products liability or implied warranty theories.[230] Although strict products liability would be the best theory to apply to the transmission of disease by blood products, it is unlikely to be adopted in most states. This means that negligence is the only theory available to those who have been infected with AIDS or other diseases by blood products. Some courts have held that blood suppliers cannot even be found negligent because the risk of transmission of AIDS by blood was not known at the time of the transfusion.[231] However, most courts have accepted the possibility of negligence.[232] In order to apply negligence, the appropriate standard of care must be chosen.

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230. *See supra* notes 116–148 and accompanying text.

231. Hoemke v. New York Blood Ctr., 912 F.2d 550 (2nd Cir. 1990); Kozup v. Georgetown Univ. Hosp., 663 F. Supp. 1048, 1057 (D.D.C. 1987), *aff'd in pertinent part,* 851 F.2d 437 (D.C. Cir. 1988) (the court concludes that AIDS was not known to be transmitted by blood until 1984 and that the blood bank is not held to a super-standard of knowing about disease before others did because it was a leader in the field).

232. Since the FDA regulates blood banks, the question arises of whether federal regulation preempts state tort law. This would mean that tort law could not impose higher standards than federal regulations, but that state tort lawsuits could be brought if the blood supplier failed to follow federal regulations. No court has addressed this question in the context of liability for contaminated blood. However in the context of drugs courts have held that federal regulations only provide a minimum standard, and state tort law can require a higher standard. Hill v. Searle Lab., 884 F.2d 1064, 1068 (8th Cir. 1989); McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522, 534 (Or. 1974); Savina v. Sterling Drug, Inc., 795 P.2d 915, 931 (Kan. 1990); MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 70 (Mass. 1985), *cert. denied,* 474 U.S. 920 (1985); Miller v. Upjohn Co., 465 So. 2d 42, 45 (La. App. 1985), *writ denied,* 467 So. 2d 533 (La. 1985). Two federal courts have examined the question in more depth and held that neither the Food, Drug and Cosmetic Act nor the Public Health Service Act explicitly preempt state tort law, nor is their regulation so comprehensive that they implicitly preempt state law. Hurley v. Lederle Lab. Div. of Am. Cyanamid Co., 863 F.2d 1173, 1176,

The standard of care is of great importance for cases arising before there was an effective test for HIV. Before the blood test was introduced the only method available for decreasing the risk of transmitting AIDS by blood was to exclude donors who were at high risk for AIDS. One way to do this is to use a surrogate test which detects something which is present in a high number of people with AIDS. In January 1983, the CDC reported that excluding blood that tested positive for antibody to the hepatitis B core antigen would exclude 90% of donors at high risk of having AIDS.[233] Plaintiffs in several cases have contended that blood banks were negligent in failing to institute surrogate testing for the AIDS.[234] Surrogate tests were never done by the majority of blood banks,[235] so, if the professional standard of care is used, blood banks that did not implement the test would not be found negligent.

The other way to screen out blood from high risk donors is to determine whether the donors were members of a high risk group before their blood is drawn. Initially, high risk donors were detected by asking questions about symptoms of AIDS.[236] This was later augmented by telling potential donors what behavior put them at high risk for AIDS and asking then to exclude themselves if they had engaged in the risky behavior.[237] Many plaintiffs claim that the blood banks were negligent in failing to screen donors more thoroughly.[238] In particular they claim that donors should have been asked

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1177 (5th Cir. 1988); Abbot by Abbot v. Am. Cyanamid Co., 844 F.2d 1108, 1111 (4th Cir. 1988), *cert. denied*, 488 U.S. 908 (1988). The *Abbot* court has said that implicit preemption does not occur for several reasons. These are: 1) that the state law that would be preempted deals with health and safety, 2) that the regulations do not say they preempt state law, 3) that these are regulations rather than statutes, and 4) that preemption would leave no remedy at all. *Abbot*, 844 F.2d at 1112.

233. Chech, *supra* note 203, at 569–70; Marx, *supra* note 195.

234. The plaintiffs in the following cases contended that surrogate testing should have been done but the court rejected the contention: Doe v. Miles Lab., 927 F.2d 187 (4th Cir. 1991); Osborn v. Irwin Memorial Blood Bank, 7 Cal. Rptr. 2d 101, 115 (Cal. Ct. App. 1992); Kaiser v. Memorial Blood Ctr., 486 N.W.2d 762 (Minn. 1992); Hoemke v. New York Blood Ctr., 912 F.2d 550 (2nd Cir. 1990) (in this case the proposed surrogate test was for aminotransferase); Snyder v. Mekhjian, 582 A.2d 307 (N.J. Super. Ct. App. Div. 1990) (the surrogate test proposed was a ratio of T-4 to T-8 lymphocytes). The court in Doe v. Cutter Biologicals, Inc., 971 F.2d 375, 382–84 (9th Cir. 1992) accepted that surrogate screening could have been an appropriate measure. It has also been claimed that surrogate tests should have been used in hepatitis cases, but these claims have also been rejected. Hutchins v. Blood Servs. of Montana, 506 P.2d 449 (Mont. 1973); Hernandez v. Nueces County Medical Soc., 779 S.W.2d 867, 871 (Tex. Ct. App. 1989).

235. *Special Report—Joint Statement on Acquired Immune Deficiency Syndrome (AIDS) Related to Transfusion*, 23 TRANSFUSION 87 (1983) (hereinafter *Special Report*); Marx, *supra* note 195.

236. *Special Report*, *supra* note 235.

237. H.A. Perkins et al., *How Well Has Self Exclusion Worked?*, 28 TRANSFUSION 601 tbl. 1 (1988).

238. Failure to implement adequate donor screening has been claimed and rejected in Doe v. Miles Lab., 927 F.2d 187 (4th Cir. 1991); Hoemke v. New York Blood Ctr., 912 F.2d 550 (2nd Cir. 1990); Osborn v. Irwin Memorial Blood Bank, 7 Cal. Rptr. 2d 101, 115 (Cal. Ct. App. 1992); Kaiser v. Memorial Blood Ctr., 486 N.W.2d 762 (Minn. 1992); Hernandez v. Nueces County Medical Soc'y, 779 S.W.2d 867 (Tex. Ct. App. 1989). The possibility that screening was inadequate has been accepted by two courts dealing with AIDS. Doe v. Univ. Hosp., 561 N.Y.S.2d 326, 328 (N.Y. Sup. 1990) (unavailability of test does not preclude the possibility that screening was inappropriately done); Kaiser v. Memorial Blood Ctr., 486 N.W. 2d 762 (Minn. 1992). This same claim was made with more success in early hepatitis litigation. Fruge's Heirs v. Blood Servs., 506 F.2d 841 (5th Cir. 1975); Hoder v. Sayet, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967).

directly about their sexual preferences. Studies have shown that such questioning would have excluded significantly more high risk donors.[239] Direct questioning about sexual preference and other high risk behavior was not practiced by the majority of blood banks in the early years of the epidemic.[240] The fact that the majority of blood banks have not engaged in more thorough questioning in 1983 means that, if the professional standard of care applies to blood banks, they cannot be found negligent.

Courts have expressed different views on the proper standard of care for blood banks and blood product suppliers. Some courts have held that the professional standard of care applies to blood banks and the fact that a blood bank conformed its actions to the industry standard shows that it was not negligent.[241] In some cases, courts have held that the professional standard is

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239. Studies have shown that asking male blood donors directly if they have had sex with another man or if they have used intravenous drugs significantly increases the number who report such activity compared to those who voluntarily exclude themselves when told that they should if they have engaged in these risk behaviors. D.J. Mayo et al., *Screening Potential Blood Donors at Risk for Human Immunodeficiency Virus*, 31 TRANSFUSION 466, 470 (1991); A.J. Silvergleid et al., *Impact of Explicit Questions About High Risk Activities on Donor Attitudes and Donor Deferral Patterns*, 29 TRANSFUSION 362,363 (1989). A study done immediately after the HIV test became available on March 2, 1985 showed that 36 of 41 HIV positive donors were in high risk categories but had not excluded themselves because they did not believe they fit in the high risk category. Julian B. Schorr et al., *Prevalence of HTLV-III antibody in American Blood Donors*, 313 NEW ENG. J. MED. 384 (1985). Donors are not offended by explicit screening questions. Mayo et al., *supra* at 472; Silvergleid et al., *supra* at 363.

Two studies have been done to determine why donors who admit risk behavior on questioning do not exclude themselves when told that those at risk should do so. One study found that 26% believed that their behavior did not put them at risk, 26% wanted to have their blood tested for HIV, 15% felt pressure to donate and 14% knew that blood would be excluded if it tested positive. Susan F. Leitman et al., *Clinical Implications of Positive Tests For Antibodies to Human Immunodeficiency Virus Type-1 in Asymptomatic Blood Donors*, 321 NEW ENG. J. MED. 917, 920 tbl. 2 (1989). In another study, 46% donated because they did not read the material carefully, 15% did not comprehend the material, 27% were under pressure to donate, 15% desired an AIDS test, and 10% relied on screening to detect contaminated blood. L.S. Doll et al., *Human Immunodeficiency Virus Type-1 Infected Blood Donors: Behavioral Characteristics and Reinforced Donation*, 31 TRANSFUSION 704 (1991). Of those who did not believe they were at risk, the leading reasons were that they had no recent risk behavior, infrequent risk behavior, that they had modified their risk behavior, or they had no symptoms. *Id.* at 707 tbl. 1. The authors refer to this as denial. *Id.* at 708.

240. It was done by commercial plasma suppliers. Chech, *supra* note 203, at 569–70 (1983); Marx, *supra* note 195.

241. Sanders v. Colquitt County Hosp. Auth., 348 S.E.2d 490 (Ga. Ct. App. 1986); Doe v. Miles Lab., 927 F.2d 187, 193 n.23 (4th Cir. 1991) (fact that FDA and medical associations did not recommend screening or surrogate testing, and that no other blood bank followed these procedures leads to the conclusion that these procedures were not part of the standard of care); Kirkendall v. Harbor Ins. Co., 887 F.2d 857, 860–61 (8th Cir. 1989) (FDA regulations, not practice of blood banks creates standard of care); McKee v. Miles Lab., 675 F. Supp. 1060, 1064 (E.D. Ky. 1987), *aff'd*, 666 F.2d 219 (6th Cir. 1989) (expert testimony that other procedures should have been used to prepare Factor VIII that was free from HIV cannot create a standard of care contrary to the practice of the industry); Tufaro v. Methodist Hosp., Inc., 368 So. 2d 1219 (La. Ct. App. 1979) (in case where malaria was transmitted by transfusion, the standard of care was held to be the same as that of physicians and surgeons since a transfusion is a medical procedure); Hernandez v. Nueces County Medical Soc'y, 779 S.W.2d 867, 872 (Tex. Ct. App. 1989) (evidence of compliance with federal and private licensing standards is not conclusive evidence that standard of care was met); Osborn v. Irwin Memorial Blood Bank, 7 Cal. Rptr. 2d 101, 128 (Cal. Ct. App. 1992) (blood bank can not be found negligent for failing to perform a test that no other blood bank performed); Doe v. American Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989) (if defendant has conformed his activity to generally recognized professional standard of care, it can not be found negligent as a matter of law; blood banks are evaluated by a professional standard of care because the statute defines blood products

implied by a blood shield statute which defines blood as a medical service.[242] The reasoning is that a medical service should be judged by a professional standard of care. This reasoning has also been used in the absence of a statute.[243] The main concern expressed by courts that impose a professional standard is that lay jurors and judges are unable to evaluate medical information and therefore cannot evaluate medical treatment on their own.[244]

Other courts have held that blood banks should be evaluated by an ordinary standard of care.[245] The courts that apply the ordinary standard of care do so because they believe absolute adherence to a professional standard of care would allow blood banks to determine their own legal duty, which is the proper function of the courts.[246] This argument is especially strong when there are only a few entities making up the profession.[247]

Some courts have applied the ordinary standard of care to blood suppliers in an indirect way. These courts have held that the professional standard does apply to blood banks, but that it can be refuted by evidence that

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as a medical service); Osborn v. Irwin Memorial Blood Bank, 7 Cal. Rptr. 2d 101, 120, 128 (Cal. Ct. App. 1992); Valdiviez v. United States, 884 F.2d 196, 199 (5th Cir. 1989) (it is not negligent to use self screening of donors since self screening was recommended by the CDC at the time); Brown v. United Blood Servs., 858 P.2d 391, 395–96 (Nev. 1993); Wilson v. Irwin Memorial Blood Bank, 18 Cal. Rptr. 517, 523 (Cal. Ct. App. 1993).

242. United Blood Servs. v. Quintana, 827 P.2d 509, 521, 523 (Colo. 1992) (Since statute says that blood transfusions are a medical service, blood banks are held to a professional standard of care. This can be rebutted by expert testimony that the standard is unreasonably deficient in light of readily available procedures); Doe v. American Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989) (S.C. CODE ANN. § 44–43–19 characterizes a transfusion as a medical service so a blood collector or processor should be treated as a professional).

243. Tufaro v. Methodist Hosp., Inc., 368 So. 2d 1219, 1221 (La. Ct. App. 1979) (since transfusions are a medical procedure, the standard of care is logically the same as that applied to physicians and surgeons).

244. *Doe*, 377 S.E.2d at 326. The court defers to the collective wisdom of a profession because of a "'healthy respect...for the learning of a fellow profession and [our] reluctance to overburden it with liability based on uneducated judgment.'" *Id.* (quoting W. PAGE KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS § 32, at 189 (5th ed. 1984)); *See also* United Blood Servs. v. Quintana 827 P.2d 509, 520 (Colo. 1992) ("'Without expert opinion testimony in such cases, the trier of fact would be left with no standard at all against which to evaluate the defendant's conduct.'" (quoting Melville v. Southward, 791 P.2d 383, 387 (Colo. 1990)); Osborn v. Irwin Memorial Blood Bank, 7 Cal. Rptr 2d 101, 125 (Cal. Ct. App. 1991) (the collective wisdom of the profession should be followed by the court; lay jurors aided by hindsight should not evaluate the actions of a doctor which are outside common knowledge).

245. Doe v. Cutter Biological, Inc., 971 F.2d 375, 382–83 (9th Cir. 1992) (the fact that the blood products company adhered to the industry standard did not make the company non-negligent as a matter of law since the entire industry could fall short of reasonable care); Kirkendall v. Harbor Ins. Co., 887 F.2d 857, 859 (8th Cir. 1989) (although this court holds that a professional standard applies to blood banks, it uses an ordinary standard of care to determine whether the blood bank was correct in not testing all of the blood it had on hand when it obtained a limited number of AIDS tests immediately after the test was licensed); Hines v. Saint Joseph's Hosp., 527 P.2d 1075, 1979 (N.M. Ct. App. 1974) (the company acted with due care under the circumstance since it complied with all federal regulations and standards of accrediting agencies).

246. United Blood Servs. v. Quintana, 827 P.2d 509, 520 (Colo. 1992) (if the standard of practice of a profession were conclusive, the profession itself would be permitted to set the measure of its own legal liability, even though the level might be far below what could be obtained).

247. *Doe*, 971 F.2d at 382–83 (the fact that there are only four producers of factor IX means that they set the standard of care themselves).

the whole industry failed to adopt the best procedure.[248] This position is inconsistent. The most common reason given for applying the professional standard of care is that lay judges and juries are unable to evaluate technical information. However, the information the court must evaluate is the same whether the whole industry is using bad techniques or the defendant is alone in his error. It is not clear why courts are better able to evaluate this information in one case than in the another. There are more cogent reasons than this to apply the ordinary standard of care to blood banks.

The goal of malpractice law is to differentiate cases where the injury is caused by negligence from cases where the injury is caused by a lack of knowledge or technology in the medical profession as a whole, and to impose liability only for those acts which are negligent.[249] Only by doing this can malpractice law accomplish its objectives of deterring negligent conduct, insuring that the best medical care is available,[250] and educating the public and the medical profession about what can be expected from medical care.[251] If the tort system is perceived to be a game of chance, it will not raise professional standards.[252] Furthermore, if the law accurately distinguishes between harm caused by incompetence and injury due to the current state of knowledge, there will be less incentive to file malpractice suits that are not based on real incompetence. The important question is therefore whether either the ordinary standard of care or the professional standard of care produce the most accurate decisions in cases dealing with blood borne diseases.

This question is not unique to medical malpractice law. It applies equally to all areas of law. In other areas of law, the accuracy of the decision is ensured by the rules of evidence. The professional standard of care contains two evidentiary rules. First, there must be expert testimony by a physician. This is a reasonable rule; the material is technical and a jury will need the aid of expert testimony to evaluate it. Second, the testimony must deal with what the customary practice is among the physicians in the community, or nation,

248. Vuono v. New York Blood Ctr., Inc., 696 F. Supp. 743, 746 (D. Mass. 1988) (in case where an albumin prepared from blood was non-sterile, court held that custom is evidence of standard of care but the custom can be shown to be inadequate); United Blood Servs. v. Quintana, 827 P.2d at 521, 523 (since statute says that blood transfusions are a medical service blood banks are held to a professional standard of care, but the standard of care can be rebutted by expert testimony that it is unreasonably deficient in light of readily available procedures); Hutchins v. Blood Servs. of Montana, 506 P.2d 449, 452-53 (Mont. 1973) (the plaintiff failed to establish either that the blood bank did not follow the industry standard or that the standard itself was negligent); Smythe v. American Red Cross Blood Servs., 797 F. Supp. 147, 152 (N.D.N.Y. 1992) (the standard of care is that of the profession, but a court can require a higher standard if the whole profession lags: no evidence supporting either a violation of the professional standard or the lagging of the profession was given so summary judgment granted); Doe v. Miles Lab., 927 F.2d 187, 193 (4th Cir. 1991) (standards of government agency or medical society are not conclusive, but hindsight opinions of experts are not enough to determine the standard of care).

249. Richard L. Wiener, *A Psychological and Empirical Approach to the Medical Standard of Care*, 69 NEB. L. REV. 112, 139 (1990). Good practice is not encouraged by holding the individual doctor liable for the ignorance of the profession. *Id.*

250. *See* Page Keeton, *Medical Negligence—The Standard of Care*, 10 TEX. TECH. L. REV. 351, 355 (1978).

251. Wiener, *supra* note 249, at 114–15 (it is argued that educating the public about what can be expected from medical care is a way to decrease malpractice suits).

252. Jeffrey O'Connell, *Neo-No-Fault Remedies for Medical Injuries: Coordinated Statutory and Contractual Alternatives*, 49 LAW & CONTEMP. PROB. 125, 126-27 (1986).

depending on which rule the court accepts.[253] This rule is essentially identical to the rule in *Frye v. United States*,[254] which states that scientific evidence must be accepted by the relevant scientific community before it can be used as evidence in court. Both the *Frye* rule and the professional standard of care serve to remove the evaluation of technical information from the jury. Presumably this is based on the belief that lay people are incompetent to evaluate scientific information. The *Frye* rule has recently been rejected by the United States Supreme Court as superseded by rule 702 of the *Federal Rules of Evidence*.[255] Although decisions of the United States Supreme Court on evidentiary matters do not bind the state courts, this decision raises the question why medical malpractice should be judged by a different standard of evidence than other scientific questions. If the ability of juries to evaluate technical information is the only consideration, it is unclear why doctors should be treated differently from other defendants whose cases depend on the evaluation a jury's evaluation of scientific information.

There is another possible argument in favor of applying the professional standard of care to doctors. However, it does not apply to blood suppliers. Traditionally the professional standard of care applies to professionals dealing with individual cases. The doctor dealing with an individual patient is faced with decisions that must be made quickly, without time to collect every piece of relevant information. Even when a patient is only seen in the office, the pressure created by other sick people waiting to be seen limits the amount of time the doctor can devote to a particular patient's needs. The physician should therefore only be evaluated in the light of these circumstances. Lay people cannot evaluate this because they do not know the pressures that a doctor faces. A lay jury may expect perfection from the doctor, whereas the doctor's peers realize that perfection is impossible in the day-to-day practice of medicine. Therefore the court must rely on the opinions of other physicians.

An organization preparing a standard product such as blood or blood products does not face the same problems that a physician does in treating a patient. It has a large amount of time to consider the problems of its small number of products. The manufacturer may be unable to correct certain problems, but it is easy to determine what those problems are at any given time. For example, it is easy to prove when tests to detect AIDS in blood became available. There is therefore no reason to apply the professional standard of care to blood suppliers.

If courts are unwilling to remove blood suppliers from the professional standard of care, they should at least inquire into the decision making processes of the blood suppliers. The courts should determine whether the blood suppliers adequately considered all available information. The courts should also determine whether the decisions of the blood suppliers were based entirely on medical considerations. For example, if the blood suppliers made their

253. Some courts use a local standard of care whereas others use a national standard of care. PROSSER & KEETON, *supra* note 150, at 187–188. In Arizona a state wide standard is used. ARIZ. REV. STAT. ANN. §12–563(A)(1) (1992).

254. 293 F. 1013, 1014 (D.C. Cir. 1923).

255. Daubert v. Merrill Dow Pharmaceuticals, 113 S. Ct. 2786 (1993).

decisions based on business considerations rather than medical considerations, they should not be protected by the professional standard of care.[256]

VI. CONCLUSION

The transmission of hepatitis and AIDS by blood has led to the suffering and death of many people. The blood industry failed to use readily available techniques to stop the spread of disease by blood. The professional concern of the doctors who run blood banks for their patients' health, the regulation of blood banks by the FDA and the possibility of being sued for negligence failed to provide safe blood products in the 1970s and early 1980s. Strict products liability would have provided the incentive to implement adequate safety measures.

If courts are unwilling to extend products liability to blood suppliers, or if they are unable to do so because of blood shield statutes, they should at least judge the blood suppliers' actions under the ordinary standard of care. The supplying of blood does not share the characteristics of professional services and therefore courts should not defer to the judgment of the suppliers.

256. Some have suggested that blood suppliers did not implement testing because they were concerned about costs. *See generally* Jessamine R. Talavera, Note, *Quintana v. United Blood Services: Examining Industry Practice in Transfusion- Related AIDS Cases*, 2 CORNELL J.L. & PUB. POL'Y 475 (1993).