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Journal of Law and Health
Note:
Liability for Post-Transfusion AIDS:
An Analysis and Proposal*

*In the time between writing and publication, specific numbers quoted in this Note may have been superceded, but the trends in the course of AIDS and blood-transfusion law have not substantially changed. The Editor

I. Introduction

The nature of the acquired immune deficiency syndrome (AIDS) epidemic and the methods used to protect the blood supply from contamination by the AIDS virus indicate that an increasing number of actions seeking recovery for post-transfusion infection may reach the courts in the next decade. The theories under which plaintiffs usually seek relief for transfusion-related infection — e.g., negligence or strict liability — lead to complex factual, procedural, and public policy problems which do not readily lend themselves to consistent, just adjudication.

The interests of fairness, judicial efficiency, and preservation of an adequate and safe blood supply may be best served by codification of certain surgical and blood-collection practices already being observed in many areas. Codification of these practices will serve to supply a uniform standard of care for both the judiciary and the medical/blood-service community. It will also put the public on notice of a risk that they may not have foreseen and serve to ensure the safety of the blood supply.

Details of blood collection and testing are key to this discussion. They are therefore described at some length in this Note. The theories under which plaintiffs may seek recovery for transfusion-related illness or death are examined in light of what is known of the AIDS virus and current medical practices. Finally, legislative proposals will be suggested which may alleviate many of the problems related to the nature and scope of the possibility of AIDS in the blood supply.

II. The Nature of AIDS

Acquired Immune Deficiency Syndrome (AIDS) is a severe suppression of the immune system, characterized by a range of opportunistic infections (*i.e.*, caused by microorganisms that rarely cause infection in healthy individuals) and uncommon cancers,¹ or disturbing nervous system disorders.² Nearly 22,000 victims of AIDS have been identified to date (mid-1986), all of whom will probably die in the next few years.³ The average life expectancy of AIDS victims is eighteen to twenty-four months, but some individuals have survived up to six years.⁴ At present, it is invariably fatal.⁵

AIDS was first recognized in the United States in 1979, but retrospective examinations of blood samples from Zaire show positive serological responses to human immunodeficiency virus as far back as 1959.⁶ *Human immunodeficiency virus* (HIV) has been isolated from blood, semen, saliva, tears, breast milk and urine.⁷ The virus has been shown to be spread by sexual intercourse with an infected male or female partner, by introduction of in-

¹Ammann, *What We Can Say About Acquired Immune Deficiency Syndrome*, CONSULTANT, Sept. 1983, at 35.

²Angerer, Angerer, Berin & Eskins, *Human T-Cell Lymphotropic Virus Type III Infections of the Central Nervous System*, 256 J.A.M.A. 2360 (1986).

³Seligmann, Hager & Springen, *Spreading Alarm About AIDS*, NEWSWEEK, June 23, 1986, at 68 [hereinafter Seligmann].

⁴McLaughlin, *AIDS Update*, CLEVELAND BAR ASSOCIATION HEALTH CARE LAW INSTITUTE, at 1 (April 15, 1986) (available in JOURNAL of LAW and HEALTH offices).

⁵Langone, *AIDS Update: Still No Reason for Hysteria*, DISCOVER, Sept. 1986, at 28.

The Centers for Disease Control (CDC) estimate that between 1.0 and 1.5 million Americans have already been infected with the virus responsible for the spread of AIDS, human immunodeficiency virus (HIV), Baum, *AIDS Researchers Make Inroads in Understanding a Complex Virus*, 64 CHEMICAL & ENGINEERING NEWS 7 (1986). (Throughout this Note, the putative agent responsible for the spread of AIDS will be referred to as human immunodeficiency virus, or HIV. In the literature, it is variously referred to as human T-cell leukemia virus-III, or HTLV-III, lymphadenopathy-associated virus, or LAV; HTLV-III/LAV or LAV/HTLV-III. These all refer to the same putative agent.) 20% to 30% of those infected will actually develop AIDS per se. Langone, at 29. Others infected may develop AIDS-related complex (ARC), characterized by swollen lymph nodes, fever, diarrhea or other symptoms, while up to 50% of those infected may show no symptoms at all. Baum, 9. Fifteen to twenty percent of individuals diagnosed with ARC convert to AIDS in a two to five year period. McLaughlin, *supra* note 4, at 2. In some cases, no symptoms are manifested for up to eight years. Office of Medical Applications of Research, National Institutes of Health, *The Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on Public Health*, 256 J.A.M.A. 1778, 1780 (1986).

⁶Quinn, Mann, Curran & Piot, *AIDS in Africa: An Epidemiologic Paradigm*, 234 SCIENCE 955, 956 (1986) [hereinafter Quinn].

⁷McLaughlin, *supra* note 4, at 3.

fecting blood or blood products into the bloodstream, or *in utero* infection of fetuses by HIV-carrying mothers.⁸

Approximately 72.5% of AIDS victims are homosexual or bisexual men, 16.8% are intravenous drug users, and 1.4% are children.⁹ Hemophiliacs and transfusion recipients make up approximately 0.8 and 1.7% respectively.¹⁰ These relative proportions have remained remarkably constant over time.¹¹ By 1991, the Department of Health and Human Services anticipates that 270,000 Americans may be diagnosed as having AIDS.¹²

Efforts to combat the spread of AIDS center primarily on educating high risk groups and the general population on how the virus is transmitted¹³ because the development of a vaccine for AIDS is unlikely for a minimum of five years.¹⁴

Once an individual has been infected with HIV the virus will persist indefinitely, and that individual will be at risk of developing AIDS, AIDS-related complex (ARC), or becoming an avenue of infection to others.¹⁵ Most of the spread of HIV to persons not already infected may be eliminated by the use of "safe sex" methods (*e.g.*, monogamy, use of condoms) or by the avoidance of shared intravenous (IV) drug needles.¹⁶ By eschewing high-risk practices, an individual can radically reduce his chance of HIV infection by the predominant characterized vectors.¹⁷

Notwithstanding the above, the HIV factor is predicted to be present in 5 to 10,000,000 Americans by 1991.¹⁸ The largest part of this continued spread will probably be due to lapses in public awareness or misunderstanding of

⁸Baum, *supra* note 5, at 8.

⁹Norman, *Sex and Needles, Not Insects and Pigs, Spread AIDS in Florida Town*, 234 SCIENCE 415, 416 (1986).

¹⁰*Id.*

¹¹OP. ATTY GEN., No. 86-19, slip op. at 1 (Ga. April 24, 1986).

¹²Seligmann, *supra* note 3.

¹³Norman, *\$2-Billion Program Urged for AIDS*, 234 SCIENCE 661 (1986).

¹⁴*War on AIDS: Panel Urges More Education, Research*, 64 CHEMICAL & ENGINEERING NEWS 4 (1986).

¹⁵Morganthau, Hager, Cohn, Raine, Reese, Anderson & Ernsberger, *Future Shock*, NEWSWEEK, Nov. 30, 1986, at 30, 31 [hereinafter Morganthau].

¹⁶C. KOOP, SURGEON GENERAL'S REPORT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (1986).

¹⁷Address by Dr. Mervin Silverman, Pres. of American Foundation for AIDS Research, Cleveland City Forum (Jan. 30, 1987).

¹⁸Morganthau, *supra* note 15, at 31.

the nature of the disease.¹⁹ An important part of the spread, however, which will not be restricted to high risk groups, will be through unwitting transfusion of HIV-contaminated blood.²⁰

III. Disease and the Blood Supply

AIDS is not the only disease which may be spread via blood transfusion. Hepatitis, cytomegalovirus, and malaria are other serious diseases that may be so transmitted.²¹ In the case of hepatitis, 0.02 to 25% of the patients receiving conventional homologous²² transfusions develop post-transfusion hepatitis, though the largest part is subclinical or asymptomatic.²³

Recognizing the possibility that diseases may be so transmitted, blood banks follow several standard procedures designed to minimize risk. Blood donors are usually interviewed about their general health, well-being, and medical history to prescreen inappropriate donors.²⁴ After the blood is drawn into a plastic bag, tests for ABO blood type, syphilis, hepatitis B surface antigen, and the HIV antibody are then performed on the blood.²⁵ These tests are usually performed regardless of the answers to the pre-donation interview.²⁶ The blood may then be stored until ordered for transfusion for up to 45 days in a refrigerator, depending on the anticoagulant preservative solution.²⁷ Alternatively, it may be separated into red cells, clotting concentrate, and plasma ("components"), the latter of which may be further pro-

¹⁹For example, a survey of San Francisco high school students showed that 40% were unaware that use of a condom during intercourse decreases risk of infection. Norman, *supra* note 13.

²⁰Heil & Hemley, *Taking Aim at AIDS*, HIGH TECHNOLOGY, Jan. 1987, at 44.

²¹Council on Scientific Affairs, American Medical Association, *Autologous Blood Transfusions*, 256 J.A.M.A. 2378 (1986).

²²*Homologous blood transfusions* use conventionally-collected, essentially random third-party blood donations. *Autologous blood donations* use blood previously donated by the patient for use during his operation. *Directed donations* are from specific donors — usually family or friends — for a specific patient.

²³Coffin, *Current Issues in Transfusion Therapy*, POSTGRADUATE MEDICINE, Dec. 1986, at 219, 220. Estimates vary depending on differences in definition and methods of detection.

²⁴*See, e.g.*, Hoder v. Sayet, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967).

²⁵Cooper, *Blood: Its Components and Derivatives*, LEGAL ISSUES IN TRANSFUSION MEDICINE 15, 16 (1985).

²⁶*See, e.g.*, Morse v. Riverside Hosp., 44 Ohio App. 2d 442, 339 N.E.2d 846 (1974).

²⁷Cooper, *supra* note 25, at 16.

cessed into such products as albumin or serum globulins ("derivatives").²⁸ This separation process may lead to the pooling of plasma from thousands of donors.²⁹

Pre-screening of donors and testing for antigens does not, however, eliminate the risk of infection. Blood products may have warnings to that effect.³⁰

In the case of AIDS, high risk populations have been identified, as have high risk behaviors. In addition, FDA-approved diagnostic tests are commercially available for routine screening of blood for indications of HIV presence.³¹ The human immunodeficiency virus causes the infected person's immune system to produce specific HIV antibodies which may be detected by the most commonly used test, Enzyme-Linked Immunosorbent Assay, or ELISA.³² A second, more specific type of test, the Western Blot assay, is used by the non-profit blood banking system to provide unambiguous identification of infected donors.³³

It has been suggested in the medical literature that an initial negative ELISA result being accepted as proof of absence of HIV antibodies may be a flaw in the testing protocol, allowing the use of otherwise excludable (i.e., contaminated) blood samples.³⁴ Further, because the commercial ELISA diagnostic tests detect only HIV antibodies (and not HIV itself), and the body may take from three to six months after exposure to the virus to produce sufficient antibodies to be detected, any blood donation in that interim pe-

²⁸*Id.* at 15.

²⁹*Id.* at 21.

³⁰*See, e.g.,* Fogo v. Cutter Laboratories, 68 Cal App. 3d 744, 137 Cal. Rptr. 417 (1977).

³¹Heil & Hemley, *supra* note 20, at 45.

³²Office of Medical Applications of Research, *supra* note 5, at 1779. Because of its high sensitivity, if one ELISA test indicates that HIV antibodies are present (i.e., tests positive), two more ELISA tests are performed: if both subsequent tests are negative, the blood is considered acceptable; if either test is positive, the blood is destroyed. *Id.* Each ELISA test costs approximately \$6. Morganthau, *supra* note 15, at 39. Repeat testing reduces the potential for "false positives" which would cause needless destruction of possibly safe blood and disqualification of a donor for future blood donations. *Safeguarding America's Blood Supply*, DU PONT MAZAZINE, Jan.-Feb. 1987, at 22, 23.

³³If a donor shows repeat positive ELISA reactions, and shows a positive Western Blot test, the individual is considered infected. Office of Medical Applications of Research, *supra* note 5, at 1779. If the Western Blot is negative, the individual is probably not infected, but the specific blood sample is disposed of, regardless. *Id.* The Western Blot test is considered impractical for mass screenings. *Safeguarding America's Blood Supply*, *supra* note 32, at 23. It requires special equipment, expertise, and is difficult to standardize. Office of Medical Applications of Research, *supra* note 5, at 1779. Each Western Blot test costs \$60 to \$80. McLaughlin, *supra* note 4, at 2.

³⁴Mann, *Screening Blood Donors for HTLV-III Antibody*, 256 J.A.M.A. 2344 (1986). For details of ELISA protocol, see note 32.

riod will not be rejected as tainted.³⁵ False negatives therefore cannot be eliminated from either the ELISA or Western Blot tests, because some serum samples will contain too little antibody to be detected due to too short time between exposure and donation or slow formation of antibodies.³⁶ Newly developed tests which detect the presence of the virus directly may ameliorate these problems when commercially available,³⁷ assuming they receive FDA approval and are suitable for large-scale, routine use.

Between 12 million³⁸ and 23 million³⁹ units of blood are collected each year. Approximately \$60 million was spent on blood-bank screening in the United States in 1985 alone,⁴⁰ and the market for AIDS diagnostics is expected to reach \$400 million worldwide by 1990.⁴¹ Each unit of blood or blood component carries with it a number identifying the donor.⁴² In the event a donor tests positive for HIV-antibodies, recipients may be tracked down for subsequent HIV-testing to be warned, counseled, etc. Programs of this nature are already in place in New York, San Francisco, and elsewhere.⁴³

Given the HIV-antibody test limitations, however, detection may not occur and each recipient may thereby become another vector for spreading HIV. The same holds true for donors who have had sexual relations with an HIV-carrying partner in the last six months — whether the partner was heterosexual, homosexual, bisexual, a prostitute, or in any other way non-mogamous which allowed exposure to HIV.

Because of the sheer number and diversity of such encounters, and the potential for non-detection up to six months after exposure, it is likely that the next few years will see an increasing amount of litigation arising over the question of blood supplier liability for AIDS infection via blood transfusion.

³⁵Heil & Hemley, *supra* note 20, at 46.

³⁶Office of Medical Applications of Research, *supra* note 5, at 1779.

³⁷*Oncor to Offer Test to Detect AIDS Virus*, 64 CHEMICAL & ENGINEERING NEWS 6 (1986).

³⁸Clark, *AIDS: The Trail of Tainted Blood*, NEWSWEEK, Aug. 25, 1986, at 55.

³⁹Heil & Hemley, *supra* note 20, at 45.

⁴⁰Quinn, *supra* note 6, at 962.

⁴¹Heil & Hemley, *supra* note 20, at 44.

⁴²Clark, *supra* note 38.

⁴³*Id.* Between May, 1985, and August, 1986, the Look Back Program in San Francisco traced about 400 recipients of HIV-antibody-positive blood, seven of whom had developed AIDS.

IV. Approaches to Recovery

Blood products manifest many of the elements associated with the concept of "product" — packaging of discrete units with intrinsic economic value for introduction into commerce.⁴⁴ The transactions related to blood transfusion — a bargained-for exchange of a property (blood) for a consideration (money) — appear to have the major attributes of a sale.⁴⁵ It seems reasonable, then, that transfusion of blood or its components may, in some contexts, be considered a sale of a product for contract or tort liability purposes. If they were considered products in the usual sense, blood and blood products would be subject to such statutory provisions as the Uniform Commercial Code implied warranties of merchantability and fitness for a particular purpose.⁴⁶ If a patient could show that he had contracted an illness from a blood transfusion, then the blood transfused is certainly unfit for its obvious intended use, and the patient could pursue recovery based on breach of implied warranties. A significant part of the case law surrounding blood transfusion, in which recovery is typically sought for transmission of hepatitis, follows this thinking.⁴⁷

In *Mercy Hospital, Inc. v. Benitez*, for example, a patient recovered against a hospital-operated blood bank after contracting hepatitis.⁴⁸ The court held that the transaction regarding the blood, involving transfer of a product for a consideration, constituted a product sale (governed by contract law), and not a service (governed by the law of torts), thus allowing an action for breach of warranty.⁴⁹ *Rostocki v. Southwest Florida Blood Bank, Inc.*,⁵⁰ relying on the reasoning of *Mercy Hospital*, extended this strict liability based on contract theories to blood banks outside the hospital, which are unambiguously concerned with sales of blood rather than rendering medical services. The

⁴⁴Though many blood banks are themselves non-profit organizations, hospitals may charge patients up to \$250 per unit used. Cooper, *supra* note 25, at 18. Questions of charitable or governmental immunity will not be discussed in this Note.

⁴⁵See, e.g., *Reilly v. King County Cent. Blood Bank*, 6 Wash. App. 172, 492 P.2d 246 (1971).

⁴⁶See, e.g., U.C.C. § 2-314 (implied warranty of merchantability), § 2-315 (fitness for particular purpose), § 2-318 (extension to certain third parties). *But see* U.C.C. § 2-607 (requirement that buyer must notify seller of breach within a reasonable time or be barred from remedy).

⁴⁷See, e.g., *Belle Bonfil Mem. Blood Bank v. Hansen*, 195 Colo. 529, 579 P.2d 1158 (1978) (blood bank clearly selling blood; hospital providing services); *Mercy Hosp. v. Benitez*, 257 So. 2d 51, (Fla. Dist. Ct. App. 1972) (blood from hospital blood bank is a product to which warranties of fitness apply); *Reilly v. King County Cent. Blood Bank*, 6 Wash. App. 172, 492 P.2d 246 (1971).

⁴⁸*Mercy Hosp.*, 257 So. 2d at 51.

⁴⁹*Id.*

⁵⁰*Rostocki v. Southwest Fla. Blood Bank*, 276 So. 2d 475 (1973).

Rostocki court held that since blood is intended for human consumption, the provider thereof should be held strictly liable for harms resulting from defects therein, just as are vaccine or food product manufacturers.⁵¹

Earlier decisions held under similar circumstances that to hold manufacturers of products intended for human consumption liable for harms they cause only if the deleterious substance was capable of being detected or removed would be counter to fundamental strict liability theory: "[A] manufacturer's or seller's actual knowledge or opportunity for knowledge of a defective or unwholesome condition is wholly irrelevant to his liability on the theory of implied warranty . . ." ⁵²

However, the implied warranty theory is generally applicable only to sales, and not to services, and all but four states currently have statutes defining blood supply as a service or excluding blood from its definition of a product.⁵³ Even without statutory preclusion, however, many courts had rejected implied warranty suits for post-transfusion illness on the basis of the sales/service distinction alone. In *Perlmutter v. Beth David Hospital*,⁵⁴ the New York Court of Appeals reasoned that although certain tangible goods — medicine, blood — were provided for a patient, the contract between patient and hospital considered in its entirety was for services, and no implied warranties could attach.

⁵¹*Id.*

⁵²*Community Blood Bank v. Russell*, 196 So. 2d 115, 119 (Fla. 1967) (Roberts, J., concurring specially).

⁵³ALA. CODE § 2-314 (1985); ALASKA STAT. § 45.02.316 (1985); ARIZ. REV. STAT. ANN. §§ 32-1481, 36-1151 (1985); ARK. STAT. ANN. §§ 82-1608, 85-2.316(3)(d) (1985); CAL. HEALTH & SAFETY CODE § 1606 (West 1984); COLO. REV. STAT. § 41-2-11 (1985); CONN. GEN. STAT. § 139-1 (1984); FLA. STAT. § 672-316(5) (1985); GA. CODE ANN. §§ 11-2-316, 51-1-28 (1984); HAW. REV. STAT. § 327.15 (1984); IDAHO CODE §§ 6-1402(3), 39-3702 (1984); ILL. REV. STAT. ch. 111, § 5102 (1985); IND. CODE § 16-8-7.2 (1984); IOWA CODE § 142A.8 (1985); KAN. STAT. ANN. § 65-37d (1985); KY. REV. STAT. § 139.125 (Baldwin 1984); LA. CIV. CODE ANN. art. 1764 (Act No. 301 West 1968); ME. REV. STAT. ANN., tit. 11, § 2-108 (1983); MD. HEALTH-GENERAL CODE ANN. § 18-402 (1985); MASS. GEN. LAWS ANN. ch. 106, § 2-316(5) (West 1984); MICH. COMP. LAWS § 691-1511 (1985); MINN. STAT. § 525-928 (1983); MISS. CODE ANN. § 41-41-11 (1985); MO. REV. STAT. § 431.069 (1985); MONT. CODE ANN. § 50-33-102 (1985); NEB. REV. STAT. § 71-4001 (1985); NEV. REV. STAT. § 460.010 (1984); N.H. REV. STAT. ANN. § 507.8b (1985); N.M. STAT. ANN. § 24-10-5 (1985); N.Y. PUB. HEALTH LAW § 580.4 (McKinney 1985); N.C. GEN. STAT. § 90-220.10 (1984); N.D. CENT. CODE § 41.02-33(3)(d) (1985); OHIO REV. CODE ANN. § 2108.11 (Baldwin 1985); OKLA. STAT. tit. 63, § 34-2151 (1984); OR. REV. STAT. § 97.300 (1985); PA. STAT. ANN. tit. 35, § 10021 (Purden 1985); S.C. CODE ANN. § 44-43-10 (Law Co-op 1984); S.D. CODIFIED ANN. LAWS § 57A-2-315.1 (1985); TENN. CODE ANN. § 47-2-316(5) (1984); TEX. BUS. & COM. CODE ANN. § 2-316(e) (Vernon 1985); UTAH CODE ANN. § 26-31-1 (1984); VA. CODE § 32.1-297 (1984); WASH. REV. CODE ANN. § 70.54.120 (1985); W. VA. CODE § 16-23-1 (1984); WIS. STAT. § 146.31 (1984); WYO. STAT. §§ 34-21-233, 35-221-10 (1985).

⁵⁴*Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 123 N.E.2d 792 (1954).

It has been held, however, that even though the transaction could not be characterized as a sale, a patient could nonetheless recover on an implied warranty theory.⁵⁵ Further, in what has become a key case in blood transfusion law, *Brody v. Overlook Hospital*,⁵⁶ it has been held that, "If it is otherwise determined that the basic policy considerations which lead to the application of the doctrine of strict liability are here present, that doctrine will be applied regardless of whether such activity . . . be characterized as a sale or a service." In this case, plaintiff has developed serum hepatitis and died after receiving a blood transfusion.

In what has become known as the strict liability in tort doctrine, articulated in Restatement, Second, Torts, § 402A,⁶¹ the seller of a defective, unreasonably dangerous product is liable for physical harms to users or consumers if it reaches those users or consumers without substantial change in the condition in which it was sold, notwithstanding that the seller exercised all possible care in preparation and sale of that product.⁵⁷ In that no negligence needs to be proved, strict liability provides an effective incentive to offer the safest products possible for market consumption.

Imposition of strict liability on blood suppliers not immune from suit would make their business more financially risky, given that the estimated costs involved with the care of an individual contracting AIDS may be \$50,000 per patient per year.⁵⁸ This could easily lead commercial blood suppliers to choose to leave the blood supply business, perhaps further exacerbating the severe blood shortages felt in numerous metropolitan areas.⁵⁹

Notwithstanding the above, blood and blood products are typically supplied in packages which are to be used as delivered, without any modification by the physician or other party. Also, transfusion procedures other than

⁵⁵*Hoffman v. Misericordia Hosp. of Philadelphia*, 439 Pa. 501, 267 A.2d 867 (1970) (even if not technically a sale, recovery based on breach of warranty allowed).

⁵⁶*Brody v. Overlook Hosp.*, 127 N.J. Super. 331, 317 A.2d 392 (1974), *aff'd*, 66 N.J. 448, 332 A.2d 596 (1975). Uncontroverted evidence adduced at trial indicated that the overall incidence of transfusion hepatitis was "about 1.3 in a hundred cases transfused," *Brody*, 66 N.J. at 449, 332 A.2d at 597. a considerably higher incidence than the chance of contracting AIDS from blood, which is estimated to be one in 250,000. Clark, *supra* note 38. Estimates of blood contamination by HIV run as high as 1 in 500, based on a U.S. Public Health Service assessment that HIV-antibody testing is 99.8% reliable. S.F. Chronicle, Aug. 1, 1985, at 6, col. 1.

⁵⁷Restatement (Second) of Torts § 402A (1965). "The purpose of such liability is to insure that costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than the injured persons who are powerless to protect themselves." *Greenman v. Yuba Power Products*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

⁵⁸*Morganthau*, *supra* note 15, at 33. Location, type of care, and other factors result in large variations in the cost of care.

⁵⁹*Safeguarding America's Blood Supply*, *supra* note 32, at 22.

combining blood products are unlikely to produce HIV contamination in a given unit.⁶⁰ In addition, HIV- or hepatitis-contaminated blood is inarguably defective. It is thus no surprise that blood has been held to be a product within the ambit of § 402A.⁶¹ Further, relying on the language of § 402A, *Cunningham v. MacNeal Memorial Hospital*⁶² maintained that inability to detect hepatitis in blood was irrelevant to a strict liability discussion.

Like the *Brody* court, the *Cunningham* court examined the language of § 402A, focussing especially on the "unreasonably dangerous" criterion. The *Brody* court had found that as "a prerequisite to the application of the doctrine of strict liability a plaintiff must show that the product he alleges as defective was *unreasonably* dangerous for its intended use."⁶³ *Brody* went on to classify blood as an "unavoidably unsafe product" as defined by Comment k of § 402A, and thus not unreasonably dangerous.⁶⁴ Comment k provides:

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 vaccine for 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 unavoidable 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 The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning

⁶⁰If sometimes they take the unit of blood and decide, "Well, I have to give an antibiotic at the same time, I'm just going to squirt the antibiotic into the unit of blood," you can get an allergic reaction or hemolysis. We try to convince doctors to leave blood alone and not doctor it up with other stuff." Ness, *What Can Go Wrong With Transfusion*, LEGAL ISSUES IN TRANSFUSION MEDICINE 25, 30 (1985).

⁶¹*Cunningham v. MacNeal Mem. Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

⁶²*Id.* at 443, 266 N.E.2d at 903. For a detailed analysis of *Cunningham*, see 69 MICH. L. REV. 1172 (1971).

⁶³*Brody*, 332 A.2d at 394 (italics in original).

⁶⁴*Brody*, 332 A.2d at 394.

is given, where the situation calls for it, is not to be held to strict liability for the unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.⁶⁵

Cunningham, narrowly construing Comment k as applying only to "products which are not impure,"⁶⁶ imposed strict liability against the defendant hospital because hepatitis-infected blood is obviously impure. The *Cunningham* holding has been criticized for its narrow construction,⁶⁷ and its reasoning was explicitly rejected by the *Brody* court.⁶⁸

As previously discussed, the current state-of-the-art large-scale HIV testing is the ELISA HIV-antibody detection method. This method cannot detect contamination of a blood sample unless enough time has passed since infection for sufficient antibodies to have been produced to be detected. Developmental tests which detect the HIV itself are not commercially available or FDA approved at this writing and may not be suitable for large-scale testing. Moreover, 3% of known AIDS victims have no known risk factors,⁶⁹ and therefore could not have been discovered by any pre-screening interview or examination. Heterosexual transmission is predicted to account for 9% of AIDS cases in the U.S. by 1991.⁷⁰ The incubation period between infection by the virus and the onset of AIDS or ARC symptoms may be as long as eight years. The identifiable high-risk behaviors pre-screening interviews are intended to discover, therefore, will become more and more commonplace, because the chances that a given potential donor has unwittingly contacted HIV in the previous few weeks from an asymptomatic (though possibly clinically detectable) individual will have become much higher.

According to the Red Cross, the list of individuals who should refrain from donating blood or plasma already include any man who has had sex with a man since 1977; persons of either sex who have taken illegal drugs intravenously; natives of Burundi, Kenya, Rwanda, Tanzania, Uganda, or Zaire who entered the U.S. after 1977; hemophiliacs that have received clotting factor concentrates; persons who have tested positive for the HIV anti-

⁶⁵Restatement (Second) of Torts § 402A (1965), Comment k.

⁶⁶*Cunningham*, 47 Ill. 2d at 444, 266 N.E.2d at 904.

⁶⁷See 69 MICH. L. REV. 1172 (1971); 24 VAND. L. REV. 645 (1971); 16 VILL. L. REV. 983 (1971); 66 NW. U.L. REV. 80 (1971); 32 OHIO ST. L.J. 585 (1971).

⁶⁸*Brody*, 332 A.2d at 395.

⁶⁹Norman, *supra* note 9, at 416.

⁷⁰Morganthau, *supra* note 15, at 31.

body; persons with AIDS or its symptoms; male or female prostitutes; the sex partners of any of the above-described individuals since 1977.⁷¹ Realistically, then, blood products cannot be supplied without a finite chance that they are HIV-infected, and therefore cannot be supplied entirely "safe for their intended and ordinary use." This chance is estimated by the Surgeon General to be less than one in 100,000⁷² which translates into between 120 and 230 contaminated units annually in the U.S.⁷³

According to Comment k, the justification for the use of blood products that are accompanied by a risk of carrying HIV must be a function of their "useful and desirable product nature." The risk of deleterious effects must therefore be weighed against the therapeutic value of blood products and the availability of alternative, lower-risk treatments. In treatment of trauma cases involving substantial loss of blood, for example, the risk of AIDS may be clearly outweighed by the risk of imminent death.

In other cases, for example hemophilia, the balance is not between one present risk and another, but between the risk of HIV exposure and the value of a more normal lifestyle, aided by blood coagulants isolated from many separate donors. The plasma of 1,000 to 20,000 donors is pooled to produce a given lot of factor concentrate, and the approximate factor usage in a year by a hemophiliac may range from less than 15,000 to more than 60,000 units.⁷⁴ The risk is therefore very high for hemophiliacs, and in fact the prevalence of HIV antibody in hemophiliacs exceeds 90%.⁷⁵ Techniques have been developed to heat-treat coagulation concentrates that eliminate most of the risk of transmission.⁷⁶ This advance in the Comment k "proper preparation" requirement for these particular products may be relevant to hemophiliac treatment begun since the development of this procedure, since the average adult with hemophilia receives 40 to 60 transfusions per year.⁷⁷

⁷¹Gabe, *Keeping the "Gift of Life" Ever-flowing*, *The Plain Dealer* (Cleveland), Feb. 24, 1987, at 7-B, col. 6.

⁷²KOOP, *supra* note 16, at 22. *But see supra* note 56 and accompanying text.

⁷³This is determined by multiplying the total units of blood collected by the fraction of blood contaminated. Based on twelve to twenty-three million units (*see supra* notes 38 and 39 and accompanying text) and 1/500 contamination rate (*see supra* note 56), HIV contamination could run as high as twenty-four to forty-six thousand units.

⁷⁴The Hemophilia/AIDS Collaborative Study Group, *Effect of Exposure to Factor Concentrates Containing Donations from Identified AIDS Patients*, 256 *J.A.M.A.* 1758, 1759 (1986).

⁷⁵Bennett, *AIDS Epidemiology Update*, 85 *AM. J. NURSING* 968, 970 (1985).

⁷⁶Cooper, *supra* note 25, at 22.

⁷⁷Bennett, *supra* note 75, at 970.

In the case of major surgical operations, often several units of blood are transfused to maintain homeostasis, each unit attended by its own risk. The possibility of contracting AIDS must then be weighed against the utility of the surgery. In the case of necessary surgery, the case is not fundamentally different from an emergency situation, other than that the consent of the patient may be sought. In the case of elective surgery, however, it is again a balancing of the risk of HIV exposure against the quality of life without the procedure.

To summarize briefly, the plaintiff seeking to recover under a strict liability theory may find that a breach of warranty approach can fail because blood supply can be characterized, often by statute, as a service to which UCC theories are inapplicable. Pursuing a strict liability in tort approach, he may find that approach blocked by characterization of blood and blood products as "unavoidably unsafe." Further, there is a reasonable chance that a national Product Liability Act may pass into law in the relatively near future, precluding state statutes and case law in that area.⁷⁸ These proposed laws, as well as the proposed Model Uniform Product Liability Act, uniformly exclude blood and its constituents from their coverage,⁷⁹ and, thereby, exclude blood from most applications of the strict liability doctrine.

A *res ipsa loquitor* theory may likewise prove unsuccessful, given the epidemiology of AIDS. Unlike unexplained injuries to an unconscious patient,⁸⁰ it is statistically unlikely that transfusion, rather than one of the other epidemiologically identified vectors, caused a given case of AIDS.⁸¹

There are more conventional negligence theories, however, which do not have the statutory, doctrinal, or demographic roadblocks to which the theories discussed so far are prone. However, conventional negligence theories require proof of the elements of the tort (duty of care, breach of that duty, harm, proximate cause) that the other theories dispense with. These problems of proof can be particularly difficult to overcome.

One avenue of negligence liability would be the physician's failure to warn the patient of the risk of HIV infection through transfusion. This informed consent action, a subclass of medical malpractice, may lie if:

⁷⁸U.S. CONST. art. VI, § 2.

⁷⁹See, e.g., MODEL UNIFORM PRODUCT LIABILITY ACT § 102(c); S.100, 99th Cong., 1st Sess. § 2(11).

⁸⁰*Ybarra v. Spangard*, 93 Cal. App. 2d 43, 208 P.2d 445 (1949).

⁸¹See *supra* notes 9 and 10 and accompanying text.

(1) defendant physician failed to inform him (the patient) adequately of a material risk before securing his consent to the proposed treatment;

(2) if he (the patient) had been informed of the risks he would not have consented to the treatment;

(3) the adverse consequences that were not made known did in fact occur and he (the patient) was injured as a result of submitting to the treatment.⁸²

Courts have been particularly emphatic about this aspect of physician duty:

A medical doctor, being the expert, appreciates the risks inherent in the procedure he is prescribing, the risks of a decision not to undergo the treatment, and the probability of a successful outcome of the treatment. But once this information has been disclosed, that aspect of the doctor's expert function has been performed. The weighing of these risks against the individual subjective fears and hopes of the patient is not an expert skill A patient should be denied the opportunity to weigh the risks only where it is evident he cannot evaluate the data, as for example, where there is an emergency or the patient is a child or incompetent.⁸³

Given the inevitably fatal nature of AIDS and its 20% to 30% probability of development from exposure to HIV,⁸⁴ the exposure risk via transfusion could reasonably be found material even though its statistical probability is quite small. And, as the above quote unequivocally indicates, this is a decision for the patient. Nor is it likely that the transfusion risk could be found to be generally known, obviating a duty to disclose, given, for example, New York Times headlines which read "Blood Supply Called Free of AIDS."⁸⁵

In both informed consent and conventional malpractice considerations, the availability of alternative, significantly safer procedures would weigh heavily in considerations of liability. Malpractice is usually determined to be a failure of a professional to exercise the degree of care and skill ordinarily possessed and employed by members of the profession in good standing. If schools of thought differ, the doctor is generally entitled to be judged accor-

⁸²Scott v. Bradford, 606 P.2d 544 (Sup. Ct. Okla. 1979).

⁸³Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

⁸⁴See *supra* notes 1-5 and accompanying text.

⁸⁵Altman, *Blood Supply Called "Free of AIDS"*, N.Y. Times, Aug. 1, 1985, at 1, col. 1.

ding to the standards of the school of thought to which he belongs, assuming it is shared by some respectable minority of the profession.⁸⁶

It must be emphasized, however, that the general standards of a profession or school of thought may be rejected by the court as insufficient: "[I]n most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It may never set its own tests, however persuasive be its usage. *Courts must in the end say what is required.*"⁸⁷

This caveat is key to many blood transfusion situations because of the availability of other, safer methods of supplying blood for any non-emergency surgery. Autologous blood transfusions, wherein blood is collected from a patient for retransfusion at a later time, is one such method. Autologous transfusions eliminate the risk of infection entirely, are endorsed by the American Association of Blood Banks as the safest type of transfusion, and in some cases may be less expensive than homologous (*i.e.*, conventional, third-party donor) transfusions.⁸⁸ In addition, any patient whose status is stable enough to allow elective surgery can generally donate several units of blood for autologous transfusions in the weeks leading up to surgery, including, if necessary, pregnant women or people with cardiovascular disease.⁸⁹ A consortium of blood supply organizations have strongly endorsed more frequent use of autologous blood transfusions, especially in elective surgery situations, in light of the AIDS epidemic.⁹⁰ This is recommended notwithstanding the fact that "local blood center protocols for autologous donation may be unwieldy and inconvenient for surgeons, patients, the transfusion service, and the blood center."⁹¹

Surgeons underutilizing autologous transfusions, though following accepted surgical practices, may nevertheless be exposing themselves to liability unnecessarily. (It should be emphasized that directed donations — in which family or friends donate blood for use during an operation on a partic-

⁸⁶See, *e.g.*, *Creasy v. Hogan*, 292 Or. 154, 637 P.2d 114 (1981); *Hersh v. Hendley*, 626 S.W.2d 151 (Tex. Ct. App. 1981); *Roberts v. Tardif*, 417 A.2d 444 (Me. 1980); *Joy v. Chau*, 177 Ind. App. 29, 377 N.E.2d 670 (1978); *Chumbler v. McClure*, 505 F.2d 489 (6th Cir. 1974).

⁸⁷*Helling v. Carey*, 83 Wn. 2d 514, 519 P.2d 981 (1974) (quoting *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932) (*italics in original*)).

⁸⁸Council on Scientific Affairs, *supra* note 21.

⁸⁹*Id.*

⁹⁰*Joint Statement on Acquired Immune Deficiency Syndrome Related to Transfusion*, 23 TRANSFUSION 87, 88 (1983) [hereinafter *Joint Statement*].

⁹¹*Underutilization of Autologous Blood Donation Among Eligible Elective Surgical Patients*, 152 AM. J. OF SURGERY 483, 485 (1986).

ular individual — are almost uniformly condemned as being no safer than blood collected routinely from volunteer donors.⁹² Failure to suggest directed donations would therefore not be equivalent to failure to describe autologous procedures.)

The informed consent doctrine duty to warn is separate from the Comment k requirement that products are "accompanied by proper directions and warning." It is rare that the seller of a unit of blood interacts with the patient in any way, or that the patient has effective access to the warnings of the blood product itself. Blood products may have warnings affixed to them regarding the risk of hepatitis,⁹³ but do not yet have warnings regarding the possibility of contracting AIDS.

Some pharmaceutical cases have held that even where a warning is made to the physician, such as might be written on a blood bag, if the manufacturer had reason to know that the drug will reach the recipient without an explanation of the risks attending the use of the drug, the manufacturer must take reasonable steps to warn the recipient directly.⁹⁴ Some of the factual questions related to the manufacturers' duty to warn and the adequacy of those warnings have been examined, indicating that both actual and constructive knowledge of the manufacturer may be weighed.⁹⁵

These issues are made somewhat more murky by the possibility of six months passing before it becomes technologically feasible in a clinical environment to detect whether or not exposure to HIV has caused an infection. Outside the clinical environment, it may take eight years for symptoms to manifest themselves, if they are going to at all.⁹⁶ Because of these time lags, any casual affair — homosexual, bisexual, or heterosexual — could be an avenue of HIV exposure even if it took place several years before,⁹⁷ as could any experimentation with intravenous drug use involving shared needles.

In that intravenous drug use, homosexuality promiscuity, and use of prostitutes are frequently viewed as morally questionable — and are in

⁹²Meritove & Bove, *Potential Liability for Transfusion-Associated AIDS*, 255 J.A.M.A. 195, 197 (1986).

⁹³See, e.g., *Whitehurst v. American Nat'l. Red. Cross*, 1 Ariz. App. 326, 402 P.2d 584 (1965).

⁹⁴See, e.g., *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974).

⁹⁵See, e.g., *Dalke v. Upjohn Co.*, 555 F.2d 245 (9th Cir. 1977); *McEwen v. Ortho Pharmaceutical*, 270 Or. 375, 528 P.2d 522 (1974) (generally maintaining that actual knowledge may be measured by adverse reaction reports, research results, etc., and that constructive knowledge may be inferred from scientific literature and other technical and non-technical sources).

⁹⁶Heil & Hemley, *supra* note 20.

⁹⁷"When a person has sex, they're not just having it with that partner. They're having it with everybody that partner has had it with for the past 10 years." Health and Human Services Secretary Otis Bowen, quoted in *Overhead*, NEWSWEEK, Feb. 9, 1987, at 21.

many cases illegal — questions of character, reputation, and conduct could play a large role in the litigation of AIDS/blood transfusion cases, but for their civil (rather than criminal) nature.

Just as a woman alleging rape by a given defendant may be met by that defendant's attempts to introduce evidence of her character to support a defense of consent,⁹⁸ a plaintiff alleging that he had contracted AIDS through transfusion of tainted blood could expect to be met by allegations of prior practices known to be high risk behaviors if any such evidence were available. Although evidence of a pertinent trait of character may be admissible in the form of a criminally accused or a victim "for the purpose of proving he acted in conformity therewith on a particular occasion,"⁹⁹ it has been held that such evidence may not be introduced in civil cases.¹⁰⁰ The effect of these rules is somewhat tempered by allowing the credibility or character for truthfulness of witnesses to be attacked.¹⁰¹

In civil cases, however, the physical condition of a party may be examined if there is "good cause" shown, and his condition is "in controversy."¹⁰² Presumably, all blood tested positively for HIV antibodies is disposed of. Donor(s) alleged to be the source of contaminated transfusion would require additional testing to determine whether or not HIV presence has been manifested subsequent to donation to establish a *prima facie* case. (Clearly, HIV presence in a donor would be by no means conclusive, but it would be a *sine qua non* of the actual cause element of a tort claim.) Such presence is the essence of the plaintiff's claim and would probably pass both the "good cause" and "in controversy" tests, and such tests would probably be allowed in the event the donor was made a party.¹⁰³

The records of blood testing are often kept confidential, however, because of a physician/patient privilege, or to maintain donor anonymity and minimize the risk of employer or insurance discrimination.¹⁰⁴ Under certain circumstances, there may be modifications to discovery orders which can provide the factual information sought without violating privacy of parties

⁹⁸FED. R. EVID. 404(a)(1), 405.

⁹⁹Statutes which disallow evidence of prior sexual history may conceivably be distinguished by legislative intent.

¹⁰⁰See, e.g., *Nakasian v. Incontrade, Inc.*, 78 F.R.D. 229 (S.D.N.Y. 1978).

¹⁰¹FED. R. EVID. 607, 608.

¹⁰²FED. R. EVID. 35(a).

¹⁰³See generally *Schlagenhauf v. Holder*, 379 U.S. 104 (1964).

¹⁰⁴*Morganthau*, *supra* note 15, at 39.

wishing to remain anonymous.¹⁰⁵ Where this question has been explicitly raised, however, the court has chosen to forego allowing discovery of donor names in deference to the privacy interests involved and the public interest in maintaining the voluntary blood donor system.¹⁰⁶

In *Rasmussen v. South Florida Blood Services*,¹⁰⁷ the plaintiff sought damages for aggravation of injuries received in an automobile accident. In the course of treatment, the plaintiff was transfused with 51 units of blood collected from volunteer donors.¹⁰⁸ The District Court of Appeals of Florida held that for purposes of assessing a discovery request for those donors' names and addresses, many factors had to be balanced.¹⁰⁹ In assessing the relative interests of the parties, the court seemed to find the defendant's checking its list of donors against the county health service list of AIDS victims sufficient to make "the probative value of the evidence which might be discovered . . . questionable."¹¹⁰

In that nearly a decade could pass before an HIV-infected donor might manifest symptoms, this view may unfairly favor the blood supplier and unduly prejudice the plaintiff's case. This fact was characterized by the dissent as "overkill of the worst kind."¹¹¹

Notwithstanding the dissent, the District Court of Appeals certified the following question:

Do the privacy interests of volunteer blood donors and a blood service's and society's interest in maintaining a strong volunteer blood donation system outweigh a plaintiff's interest in discovering the names and addresses of the blood donors in the hope that further discovery will provide some evidence that he contracted AIDS from transfusions necessitated by injuries which are the subject of his suit?¹¹²

The Supreme Court of Florida has answered this question in the affirmative.¹¹³

¹⁰⁵See, e.g., FED. R. CIV. P. 26(c)(2).

¹⁰⁶*South Fla. Blood Serv., Inc., v. Rasmussen*, 467 So. 2d 798 (Fla. Dist. Ct. App. 1985).

¹⁰⁷*Rasmussen*, 467 So. 2d at 798.

¹⁰⁸*Id.* at 798.

¹⁰⁹*Id.* at 798.

¹¹⁰*Id.* at 801.

¹¹¹*Id.* at 805.

¹¹²*Id.* at 805, n.13.

¹¹³*Rasmussen v. South Fla. Blood Serv., Inc.*, No. 67081 (Sup. Ct. Fla. Jan. 5, 1987).

Rasmussen not only prevents the discovery of information which could help establish cause-in-fact in possibly showing that one or more donors was an HIV carrier (which is, again, inconclusive, in that the donor could have been exposed to HIV subsequent to donation), it also prevents a patient from constructing other aspects of a negligence claim.

For example, it has been held that although statutorily immune from strict liability, blood suppliers must nonetheless exercise the standard of care expected of them.¹¹⁴ Those making tort claims against them for alleged blood-product defects bear the burden of showing that the manufacturer was either negligently or intentionally at fault.¹¹⁵ Blood suppliers have been found negligent for laxness in donor screening. In *Hoder v. Sayet*,¹¹⁶ for example, potential donors were not asked pertinent questions about their medical history which would have excluded them from donating. It has also been suggested that collecting blood from high risk areas (such as poor neighborhoods) may be negligent.¹¹⁷ In the case of AIDS, it could be found to be negligence to collect blood from prison inmates, given that 50% of inmate deaths are from AIDS.¹¹⁸

Even the exercise of careful testing might not ameliorate collection from such a population, given the exposure/detection gap in current tests. Without access to the donors via discovery (which may certainly be controlled to prevent disclosure in any public forum or record¹¹⁹), no opportunity arises to question them on the blood donation routine they were actually exposed to, effectively cutting off much of the development of evidence necessary to a negligence claim.

V. Proposed Legislative Measures

The alarming growth of AIDS and its crossover from high risk groups into the general population promise to multiply the cases alleging transfusion-

¹¹⁴*Hoder v. Sayet*, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967).

¹¹⁵*Hyland Therapeutics v. Superior Court*, 175 Cal. App. 3d 509, 220 Cal. Rptr. 590 (1985), *rev'g Gallagher v. Cutter Laboratories*, No. 548947 (Santa Clara Super Ct. filed May 11, 198), *aff'g Fogo v. Cutter Laboratories*, 68 Cal. App. 3d 744, 137 Cal. Rptr. 417 (1977) (barring strict liability claims against blood products manufacturers).

¹¹⁶*Hoder*, 196 So. 2d at 205.

¹¹⁷*See, e.g., Hutchins v. Blood Serv. of Montana*, 161 Mont. 359, 506 P.2d 449 (1973).

¹¹⁸*Doe v. Coughlin*, 125 A.D.2d 783, 509 N.Y.S.2d 209, 212 (1986).

¹¹⁹*See generally, South Fla. Blood Serv., Inc. v. Rasmussen*, 467 So.2d 798 (Fla. Dist. Ct. App. 1985).

contracted AIDS. While some of these cases may be motivated by a desire to demonstrate that a particular case of AIDS was not a product of activities some find normatively questionable, hundreds of cases per year will be fully justified based on current estimates of HIV contamination in the blood supply.¹²⁰ Because of the potential for very long incubation periods, the problem may persist for decades. Already AIDS/transfusion actions have been dismissed as time-barred by the relevant statute of limitations.¹²¹ The interests of fairness, judicial expediency, and safety of the blood supply suggest that legislative measures are in order to minimize or ameliorate problems associated with current practices.

Codification of more highly discriminating donor screening procedures may go far toward standardizing criteria for both collecting agencies and the courts. Blood clotting factor manufacturers have added cervical lymph node palpation for lymphadenopathy, a potential precursor to AIDS, to their donor screening routine.¹²² FDA donor-deferral recommendations have been reworded to screen out any man that has had sex even once with another man since 1977.¹²³ Case law has upheld one state's requirement that interviewers be "ingenious" in their prescreening questions, to most effectively minimize high risk donors.¹²⁴ However, joint statements from The American Association of Blood Banks and Council of Community Blood Centers have indicated that "[d]irect or indirect questions regarding a donor's sexual preference are inappropriate."¹²⁵

It is possible to provide privacy of interviews and examinations, as it is possible to ensure confidentiality of results. The American Red Cross already has an operational "confidential unit exclusion" system which allows donors to confidentially self-defer their blood if they have somehow been pressured to donate, though there is some reason their blood ought not be transfused.¹²⁶ Voluntary self-deferral alone, it must be emphasized, is inadequate to protect the blood supply. One study showed that a request for voluntary self-exclusion decreased at-risk group donations by no more than

¹²⁰See *supra* notes 38, 39, 56, 73, and accompanying text.

¹²¹*Savino v. Nassau Hosp.*, No. 2600E (N.Y.App. Div. Feb. 2, 1987).

¹²²*Guidelines for Recall of Blood from AIDS Donors? FDA Says No*, MEDICAL WORLD NEWS, Aug. 22, 1983, at 24.

¹²³Center for Drugs and Biologics, FDA & AIDS Bureau, CDC, *Revised Definition of Persons Who Should Refrain from Donating Blood and Plasma* 254 J.A.M.A. 1886 (1985).

¹²⁴*Joint Statement*, *supra* note 90.

¹²⁵*Hoder v. Sayet*, 196 So. 2d 205 (Fla. Dist. Ct. App. 1967).

¹²⁶*Gabe*, *supra* note 71, at 7-B, col. 5.

50%.¹²⁷ Donations were even received from homosexual men diagnosed with ARC, all of whom had read a request for voluntary self-exclusion.¹²⁸

To ensure greater safety of the blood supply, then, detailed questioning to determine whether or not an individual may be in a high-risk group and at least a cursory physical examination should be performed. Each of these may already be the routine practice at blood banks, but codification of these procedures would convert a cause of action for post-transfusion AIDS to one of negligence *per se*, which is free of many of the problems to which other theories are prone. Some certification by the blood collecting entity that the appropriate questions were asked and the examination performed, initialed by the donor, could attend these more involved screening procedures to facilitate judicial scrutiny. With these codified, standardized procedures, judicial scrutiny would be consistent from case to case, a comparison of actions to statutory requirements rather than against conflicting testimony of expert witnesses.

Autologous blood transfusions should be encouraged wherever possible — perhaps statutorily required for all elective surgery. This would ensure that patients are not exposed to any diseases they do not already have, and would effectively eliminate the possibility of such suits as have been discussed in this Note. While establishing protocols for autologous blood supply may involve an initial capital outlay, reduced testing and typing requirements and presumably lower liability insurance may serve to offset some of these costs.

Where homologous blood is used, the ordering physician or surgeon should be required to warn the patient of the HIV-contamination risk. This warning should be accompanied by a written consent form, similar to, but separate from the consent form originally required for surgery. This would ensure that patients are not exposed to any diseases they do not already have, and would effectively eliminate the possibility of such suits as have been discussed in this Note. While establishing protocols for autologous blood supply may involve an initial capital outlay, reduced testing and typing requirements and presumably lower liability insurance may serve to offset some of these costs.

This would also serve to meet the requirements of the informed consent doctrine, and give the patient explicit warning of the remote possibility of

¹²⁷Wykoff & Halsey, *The Effectiveness of Voluntary Self-Exclusion on Blood Donation Practices of Individuals at High Risk for AIDS*, 256 J.A.M.A. 1293 (1986).

¹²⁸*Id.*

HIV infection. Blood and blood products themselves should be accompanied by warnings of the risk of HIV presence, both to meet the Comment k warning requirement and to remind physicians of their own duty to warn.

In order to counter the possible reduction in volunteer blood donations because of misunderstanding of some aspect of these decisions (e.g., that donation rather than transfusion may be an AIDS vector), an incentive to donate in the form of a tax deduction or credit is also recommended. This could be so structured to encourage donations from population segments that do not share the possible health problems often associated with paid blood donors.¹²⁹ In that each AIDS victim requires approximately \$140,000 for his care,¹³⁰ the encouragement of donations from non-high-risk populations serves a serious, legitimate state health interest.

VI. Conclusion

The details of blood collection and current methods of ensuring the safety of the blood supply have been described. The common causes of action for post-transfusion illness were examined, with an emphasis on how AIDS has been or might be treated by the courts. These common theories of recovery — breach of warranty, strict liability in tort, *res ipsa loquitur*, negligence — present procedural, proof, or policy complexities that do not lend themselves to consistent, just adjudication. To ameliorate problems associated with these theories, legislation is suggested to set uniform, high standards for blood donor screening, to promote safer alternatives to homologous transfusions and provide adequate warnings where alternatives are unavailable, and to provide tax incentives to promote volunteer blood donations. These measures collectively serve the interests of fairness, judicial efficiency, and the preservation of an adequate and safe blood supply.

Lawrence K. English

¹²⁹Gabe, *supra* note 71.

¹³⁰51 Fed. Reg. 20,553 (1986). Costs vary greatly from city to city, with the type of care, and with the longevity of the victim.