The AIDS Blood-Transfusion Cases: A Legal and Economic Analysis of Liability

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The AIDS Blood-Transfusion Cases: A Legal and Economic Analysis of Liability†

ROSS D. ECKERT*

Through 1991 over 4,000 persons contracted AIDS through transfusion. Statutes in forty-nine states exempt blood banks from strict liability, and the usual negligence rule is weak. Analyzing the medical literature, regulation, and case law, Eckert argues that blood bankers have superior information for reducing risk and that stronger liability rules should be reconsidered.

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† I am grateful to many persons and organizations for assistance. The Lowe Institute of Political Economy at Claremont McKenna College provided me with a grant and research assistants. Anthony Bonoli, Michael Chan, Lynn Marshall, and Lesley Scott helped me obtain sources, as did Cynthia Albrecht, Kathryn Golden, and the staff of the University of La Verne Law Library. Alfred Balitzer and his staff reorganized my computer system. Arthur De Vany, Harold Edgar, Richard A. Epstein, F. Carl Grumet, George W. Hilton, W. T. Jones, and Robert J. Ranucci made valuable comments on drafts. Enid F. Eckert and Rodney T. Smith made extensive comments on several drafts. The American Association of Blood Banks, American National Red Cross, Blood Center for Southeast Louisiana, Central Indiana Regional Blood Center, Irwin Memorial Blood Centers (San Francisco), Puget Sound Blood Center, Stanford University Blood Center, Taft B. Schreiber Blood Bank at Cedars-Sinai Medical Center (Los Angeles), Tulane Medical Center Blood Bank, and the United States Food and Drug Administration (FDA) provided information that I requested. I alone am responsible for the views expressed and remaining errors.

* B.A. 1963, Ph.D. 1968, University of California, Los Angeles. Boswell Professor of Economic and Legal Organization, Claremont McKenna College, and member of the Graduate Faculty in Economics of the Claremont Colleges.

In 1987 I was appointed by the Secretary of Health and Human Services to a four-year term as a member of the Blood Products Advisory Committee of the FDA. The views that I have expressed in this article are in my private capacity as a nonmedical specialist on the blood banking industry, and no official support or endorsement by the FDA is intended or should be inferred.
There are catastrophes ahead. We live in evolutionary competition with microbes—bacteria and viruses. There is no guarantee that we will be the survivors.

Joshua Lederberg

I. Introduction

Historians, writing years from now, probably will view the 1980s and 1990s as the “age of viruses.” One of the deadliest agents to appear so far in the age of viruses is the human immunodeficiency virus (HIV) that causes acquired immune deficiency syndrome (AIDS). AIDS is the failure of the body’s immune system and is a uniformly fatal disease. It caused the public health crisis of our time. Through February 1992 the Centers for Disease Control (CDC) received reports of 213,641 cases, of which 4,770 (2.2%) were caused by blood transfusion. In 1987 the CDC estimated that

3. CENTERS FOR DISEASE CONTROL, HIV/AIDS SURVEILLANCE REP., Mar. 1992,
between 1978 and 1984 blood transfusions transmitted HIV infection to 12,000 adults who were still alive—more than twice the number of cases reported to CDC through February 1992. That estimate does not take into account HIV infections spread by transfusion recipients in turn to others through sex, pregnancy, or both.

AIDS litigation has grown with diagnoses. As of 1987 about twenty percent of persons who were transfused and developed AIDS as a result sued the blood bank, hospital, physician, or some group of them. In 1991 it was estimated that three hundred lawsuits were in process against blood banks, with over twenty consolidated in San Francisco alone.

The only successful actions against blood banks have been in negligence. Blood banking, unique among industries, is immune from strict liability in all but one state owing to what are called "blood shield laws." Enacted mainly in the 1960s and 1970s when hepatitis at 9. Another 1,944 cases occurred among persons with coagulation disorders, who are transfused with blood or blood products frequently. The CDC counts AIDS cases among that group separately from cases among persons who were not at risk for AIDS except as a result of transfusion. Litigation by persons with coagulation disorders is not the subject of this Article.

HIV-related deaths for the period covered by this Article probably were understated by an estimated 10-30% owing to the CDC's restrictive surveillance definition of AIDS, under-diagnosis, and under-reporting of AIDS cases. Centers for Disease Control, First 100,000 Cases of Acquired Immunodeficiency Syndrome—United States, 38 MORBIDITY & MORTALITY WEEKLY REP. 561, 561-63 (1989) [hereinafter Centers for Disease Control, First 100,000 Cases of AIDS].


5. Transfusion Associated AIDS Lawsuits May Eventually Number 4000, AMERICAN ASSOCIATION OF BLOOD BANKS BLOOD BANK WEEK, June 12, 1987, at 5 [hereinafter AABB BLOOD BANK WEEK, followed by date of publication].


was the worst blood-borne disease, they also shield blood banks from strict liability for AIDS. In negligence actions, usually the courts have held that industry custom is the standard of due care that blood banks must meet. Custom often emerges from joint agreements among blood banks.

In essence, the strategy for regulating blood banks is to displace the *ex post* private damage action with *ex ante* incentive controls through a combination of industry self-regulation and direct governmental regulation by the United States Food and Drug Administration (FDA). There remains only a residual negligence liability that in the context is quite weak. As a result courts have exerted little influence over blood bank care levels. The level of risk transfusion recipients bear is determined mainly by the “experts” in the industry and the politicians in state legislatures and the FDA.

The evidence shows that the experts managed risk poorly and spread AIDS unnecessarily. Published estimates by blood bankers of the risk of transfusion AIDS in 1983-1984, which in part were the basis for the precautions they took at the peak of the danger and public concern, fell short by two or three orders of magnitude. In 1988 the Presidential Commission on the Human Immunodeficiency Virus Epidemic concluded that “[t]he initial response of the nation’s blood banking industry to the possibility of contamination of the nation’s blood by a new infectious agent was unnecessarily slow.” It criticized the FDA for “rel[y]ing heavily on that industry for advice on what standards to set—a relationship that presents a significant opportunity for conflicts of interest to arise.”

The test for antibody to HIV that blood banks introduced in March 1985 reduced the risk markedly—to perhaps 1 in 7,100 patients during 1985-1989. The test has an error rate and, as explained *infra*, the risk is still higher than necessary because blood banks do not do all they can to exclude high-risk donors. In 1988 the CDC’s “worst case” estimate was that up to 460 recipients of properly tested blood would be infected with HIV each year. Twenty such cases caused by transfusion and two caused by tissue transplantation were reported through February 1992.

What is at stake in risk management by blood bankers, and in

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their advisory relationship with regulators, is not only the spread of AIDS, but whether the AIDS calamity will reoccur if another lethal blood-borne virus arrives. Reducing risk requires changes in common and statutory law, federal and state regulation, and the role of courts and expert regulatory agencies.

My thesis is that the present system of direct governmental regulation and industry self-regulation is a poor substitute for liability. Strict liability is absent, and the weak negligence rule based on industry custom gives blood bankers fewer incentives to compare the benefits and costs to society of taking extra precautions. The weak rule is caused in part by the factual complexity of transfusion, a technical field that is little understood by outsiders. That complexity helps to explain how the court in the first AIDS case to be decided made a series of egregious factual errors, which other courts accepted uncritically. After describing the medical and regulatory background of transfusion, I argue that blood bankers have better information than anyone else in the system for reducing risk to patients. Industry-wide standards of care often emerge from agreements among the three associations of blood banks. They claim expert status and exercise joint control over transfusion risk. Accordingly, I analyze liability cases in other industries where industry custom or joint action were issues. I argue that joint liability for blood banks should be considered and discuss the probable factual focus if joint liability is litigated. I conclude that blood banks should be subject to strict liability in tort, and I discuss the effects on their operations of repealing the shield laws.

II. Blood Transfusion: Medical Risks and Background

Blood banks and the FDA make several key decisions that determine risk for patients: (i) how to screen donors; (ii) how extensively to test blood; and (iii) when to warn physicians of new disease risks. Understanding the present levels of risks and how, through these three decisions, the industry controls risk is necessary for understanding why present practices and regulations are unsatisfactory substitutes for liability.

A. The Risks

AIDS occurs when a certain group of white blood cells no longer protects the body from invading pathogens. Victims succumb to a
series of severe pneumonias or other bacterial, viral, fungal, or protozoal infections caused by germs that normally are harmless, and in some cases to a rare type of cancer. These “marker” diseases along with typical white cell abnormalities defined AIDS in the period covered by this Article.\(^\text{11}\) HIV infection in otherwise healthy persons is established by a sequence of blood tests. HIV may incubate for more than six years before symptoms develop, and it mutates faster than any known virus.\(^\text{12}\)

The laboratory test for antibody to HIV (anti-HIV) appears to have reduced the risk of infection by an order of magnitude. In Table 1 the estimated per-patient risk when blood banks began testing in March 1985 was 1 in 487; the CDC’s estimate for 1986-1987 was 1 in 7,122. Estimates vary according to the assumptions of statistical models or the region and period under study. Risk is higher in urban areas but tends to decline secularly as infectious donors are culled.\(^\text{15}\)

In Table 1 the lowest estimates appear to arise in studies produced by affiliates of blood banks.

A second strain of the virus, HIV-2, also causes AIDS and is spread like HIV-1. Through June 1990 eighteen cases of HIV-2 infection were found in North America, mostly in the Northeast among heterosexual immigrants from West Africa where HIV-2 is endemic. Out of over two million donors tested, one American (who had visited West Africa) was positive. In 1990 the FDA licensed a test for anti-HIV-2 but the FDA and the blood banks agreed that they should not use it. Prevalence of HIV-2 among donors was “quite low,” the FDA said, and the test for anti-HIV-1 reacted to anti-HIV-2 60-90% of the time. The extra test would cost $60 million per year.\(^\text{14}\)

By September 1991, thirty-two cases of HIV-2 infection had been reported to the CDC. The FDA licensed a single test

\(^{11}\) In late 1991 the CDC was considering changing the definition of AIDS from the diagnosis of marker diseases to a laboratory-based measure of the number of T4 lymphocytes, the white blood cells that control the immune system and that HIV destroys. The new definition was expected to increase the number of AIDS cases by 160,000. Glenn Ruffenach, New Definition Almost Doubles U.S. AIDS Cases, WALL ST. J., Nov. 15, 1991, at B3, col. 6.

\(^{12}\) HIV mutates five times faster than the influenza virus and can mutate several times within the life of an AIDS patient, which complicates making a vaccine. Boyce Rensberger, AIDS Virus a Clever Enemy, Study Shows, WASH. POST, Sept. 6, 1987, at A1.

\(^{13}\) Annual prevalence rates of anti-HIV in the ANRC Chesapeake Region declined from 5.1 per 10,000 donations in 1985 to 1.8 in 1989. Paul M. Ness et al., Declining Prevalence of HIV-Seropositive Blood Donors, 321 NEW ENG. J. MED. 615 (1989).

to detect antibodies to both HIV-1 and HIV-2 and recommended that blood banks implement it by June 1, 1992.\textsuperscript{15}

The greatest transfusion risk is not HIV but hepatitis, an inflammation of the liver that also increases the risk of cirrhosis and cancer. Until mid-1990, probably 200,000 or more recipients each year were infected with hepatitis viruses, which eventually caused an estimated 4,000 cases of cirrhosis—more deaths \textit{per year} than \textit{all} cases from transfusion AIDS through 1990. A new test licensed in 1990 was expected to cut the risk of hepatitis infection by at least half.\textsuperscript{16}
# Table 1. Estimates of the Risk of Transmitting HIV Infection by Transfusion Study

<table>
<thead>
<tr>
<th>Type and Authors</th>
<th>Affiliation</th>
<th>Period</th>
<th>Region</th>
<th>Estimated Risk</th>
<th>Per Unit</th>
<th>Per Patient^4</th>
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</thead>
<tbody>
<tr>
<td><strong>Large Sample</strong></td>
<td></td>
<td></td>
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<tr>
<td>Schorr et al.1</td>
<td>ANRC</td>
<td>3/85^5</td>
<td>All ANRC centers^c</td>
<td>1:2,631^4</td>
<td>1:487</td>
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<td><strong>Statistical Model</strong></td>
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<tr>
<td>Ward et al.2</td>
<td>CDC et al.</td>
<td>5/86-5/87</td>
<td>Nationwide</td>
<td>1:38,461</td>
<td>1:7,122</td>
<td></td>
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<tr>
<td>Kleinman &amp; Secord3</td>
<td>ANRC</td>
<td>3/85-2/87</td>
<td>Los Angeles</td>
<td>1:68,000</td>
<td>1:12,593</td>
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<tr>
<td>Cumming et al.4</td>
<td>ANRC</td>
<td>4/85-12/87</td>
<td>51 ANRC centers^e</td>
<td>1:153,123</td>
<td>1:28,356</td>
<td></td>
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<tr>
<td><strong>Prospective</strong></td>
<td></td>
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<tr>
<td>Cohen et al.5</td>
<td>Med. schools</td>
<td>4/85-12/88</td>
<td>Baltimore/Houston</td>
<td>1:36,282^4</td>
<td>1:6,718</td>
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<tr>
<td>Donahue et al.6</td>
<td>Med. schools</td>
<td>4/85-1989</td>
<td>Baltimore/Houston</td>
<td>1:40,315^8</td>
<td>1:7,466</td>
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<tr>
<td><strong>Donor Cell Culture</strong></td>
<td></td>
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<tr>
<td>Busch et al.7</td>
<td>Blood bank,</td>
<td>11/87-12/89</td>
<td>San Francisco^b</td>
<td>1:61,171</td>
<td>1:11,328</td>
<td></td>
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<td></td>
<td>med. school,</td>
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<td></td>
<td>et al.</td>
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</tbody>
</table>

Notes:

^4Based on experience in the ANRC system, these calculations assume that each patient receives an average of 5.4 units of blood or blood components. Source 4, at 941.

^5The test for anti-HIV was implemented at blood banks in March 1985, so this study constitutes the best estimate of risk before the test began to cull infectious donors from the pool. Subsequent studies in Sources 2-7 estimate the risk that infectious donors whose blood tested negative for anti-HIV will be missed owing to the “window” period problem and the standard blood bank donor screening practices described in Section II.C.

^6The ANRC serves regions that include Los Angeles-Orange counties and Washington, D.C. but not the cities with the highest prevalence of AIDS (New York and San Francisco).
The published estimate of risk was 38:100,000, or 1:2,631 units. The population for this study was 1,027,786 donated units. This estimate assumes a “window” period of only eight weeks. Assuming fourteen weeks would yield a per-unit risk of 1:88,267 and a per-patient risk of 1:16,346. Source 4, at 943.

Pre-surgery and post-surgery blood samples were taken and tested for anti-HIV from 4,163 adult cardiac surgery patients, 3,400 of whom received 36,282 units of blood components (an average of 10.7 units per patient). One unit had anti-HIV.

A second HIV infection in a cardiac surgery patient occurred in 1989. That made the overall risk of HIV from screened blood components at 2:80,630 units, or 1:40,315 units.

76,500 donated units that tested negative for anti-HIV were divided into 1,530 pools of cells from 50 donors each and were evaluated for HIV by viral culture and other techniques. One pool proved to contain HIV, and the probability that it contained cells from more than one donor with HIV was 0.03 percent.

Sources:
4 Paul D. Cumming et al., Exposure of Patients to Human Immunodeficiency Virus Through the Transfusion of Blood Components that Test Antibody-Negative, 321 NEW ENG. J. MED. 941 (1989).
5 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).
Cytomegalovirus (CMV) infection is found in perhaps half the population and is transmitted to 3-9% of blood recipients. CMV may cause mononucleosis in healthy persons and serious or fatal disease in premature infants and transplant or chemotherapy patients. Most blood banks supply CMV-tested units only on request. Two long-latency retroviruses, HTLV-I and HTLV-II, are linked to devastating forms of leukemia. In 1989 HTLV-I was found in blood donors at a rate similar to that for HIV. No cases of HTLV-I infection by transfusion were found in this country by 1989, but its latency period of ten to thirty years makes that fact no less troubling. Blood banks have tested for these viruses since 1988. It was estimated that HTLV-I and HTLV-II were transmitted to approximately 700 blood recipients per year before routine testing began. Blood also can transmit debilitating or fatal parasites and 

17. CMV is a member of the herpes group of viruses, so it can persist without symptoms after primary infection. Tranfusion to high-risk persons who do not have CMV antibody can produce hepatitis, pneumonias, retardation, and life-threatening blood disorders. S. Gerald Sandler & F. Carl Grumet, Posttransfusion Cytomegalovirus Infections, 69 PEDIATRICS 650 (1982); Julia S. Chan & Girish N. Vyas, What We Can Do to Prevent Viral Contamination, 27 CONSULTANT 121, 128-29 (1987); John A. Armstrong et al., Cytomegalovirus Infection in Children Undergoing Open-Heart Surgery, 49 YALE J. BIOLOGY & MED. 83, 90 (1976); United Blood Services, CMV: WHAT'S IT ALL ABOUT? In 1981 Pope John Paul II's recovery from a gunshot was complicated by post-transfusion CMV infection. Is the Blood Supply Safe?, 52 CONSUMER REP. 596 (Oct. 1987).

18. Retroviruses, of which HIV is one, are insidious and known for their long latencies. They utilize the genetic material of the host cell to replicate. The disease process advances as pathogens break out of these cells and seek new hosts. Judy Berlelein, Retrovirus: AIDS Research May Yield Cure for a Family of Related Diseases, L.A. TIMES, Sept. 18, 1989, pt. II, at 3, col. 2.


20. Lyme disease, a bacterial infection transmitted by tick bites, causes chronic fever and pain in muscles and joints. Cases were reported in 43 states, 94% of which were in 6 states, mainly in the Northeast. No transfusion cases were reported through 1989, but blood banks began to ask donors questions to identify those at risk. Six cases of babesiosis, a malaria-like illness producing kidney failure, were reported in the 1980s. Chagas' disease, an incurable and usually fatal heart and bowel ailment, is the most common tropical disease in Latin America. From 1986 to 1989 two transfusion cases were reported in Los Angeles and New York City and a third in a non-endemic area of
bacteria.\textsuperscript{21}

\textbf{B. Blood Bank Industry Organization}

Blood for transfusion in the United States is collected by three groups of blood banks. These organizations grew out of rivalries that began after World War II\textsuperscript{22} but ended when the threat of AIDS litigation drew them together.

About 13.4 million units of blood are collected each year.\textsuperscript{23} The American National Red Cross (ANRC), incorporated by Congress in 1900, collects somewhat over half of the total in fifty-odd regional

\begin{itemize}
\item Persian Gulf veterans are prohibited from donating until January 1993 as a precaution against leishmaniasis, which can cause skin lesions and occasionally fever, chills, diarrhea, weight loss, and anemia. It is caused by a parasite and transmitted by bites from a tiny sand fly. Twenty-two cases were found among military personnel, but no cases have yet been found in a blood recipient. \textsc{AABB, 1991 Annual Report} 8-9 (1992); \textsc{AABB, ANRC, & CCBC, Joint Statement on Donor Status of Military Personnel Returning from the Persian Gulf Area} (Apr. 3, 1991); Melissa Healy, \textit{Veterans of Gulf War Face Year's Ban on Giving Blood}, \textsc{L.A. Times}, Nov. 13, 1991, at A19, col. 1.
\item Five cases of transfusion-transmitted \textit{Yersinia enterocolitica} infection were reported in 1989-1990. All were fatal. The agent is anerobic and thrives at the normal temperature for storing blood. Half the donors gave histories of diarrhea illnesses within thirty days of donation. Blood tests are available but not yet used routinely. Centers for Disease Control, \textit{Update: Yersinia enterocolitica Bacteremia and Endotoxin Shock Associated with Red Blood Cell Transfusion—United States, 1991}, 40 \textsc{Morbidity & Mortality Weekly Rep.} 176 (1991). FDA officials met with the industry on August 16, 1990 to review the problem and held a hearing to discuss possible measures. U.S. Food and Drug Administration, \textit{Yersinia enterocolitica Problem: Summary}, statement presented by the FDA to the FDA Blood Products Advisory Committee, 31st Meeting (Jan. 17-18, 1991).
\end{itemize}
centers. The remaining collections are divided about equally between the other two groups. The Council of Community Blood Centers (CCBC) includes twenty-one large, regional centers that split from the American Association of Blood Banks (AABB) in 1962. The AABB was formed in 1947 to counter the expanding blood program of the ANRC. In 1992, 1,572 hospital transfusion services, 649 hospital blood banks, and 185 blood centers (including nearly all CCBC centers and all ANRC regional centers) belonged to the AABB.24

The AABB is the professional society for individuals and institutions engaged in transfusion medicine and blood banking. Its Committee on Standards has notice-and-comment procedures and every two years publishes Standards for Blood Banks and Transfusion Services (Standards) with minimum-performance guidelines for members.25 The Standards specify the rules for donor screening and blood testing that determine the transfusion risks patients bear. The AABB inspects and accredits member facilities, and AABB accreditation is sufficient for licensing requirements in eight states.26 It provides continuing education, publishes a professional journal, keeps a registry of donors with rare blood types, comments on legislation and regulations, assists members on litigation, and files amicus curiae briefs in their behalf.27 Apparently the majority of the AABB's 10,000 individual members view it as both a professional association and a trade association.28

Most blood banks operate not-for-profit as regional monopolies or cartels. A few large hospitals in major cities collect blood, but they rarely compete for donors openly with the blood center in their region. Blood for transfusion has been collected strictly from noncash "volunteers" since the adoption of the National Blood Policy by the

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28. In 1988 AABB's President said that the debate over which kind of association the AABB was, which had been "divisive" among the membership, had "cooled." AABB, 1988 Annual Report 5 (1989).
Department of Health, Education and Welfare in 1975. That policy—a broad statement of goals, not a law or regulation—favored switching from a mix of cash and noncash donors to strictly noncash donors. Its advocates argued that noncash blood and noncompetitive banks would reduce transfusion disease, but that is debatable. Banks claim to charge hospitals (and thus patients) for soliciting, collecting, transporting, and processing blood, but not for the blood itself. The AABB, ANRC, and CCBC have clearinghouses for barter exchange among members. Cash sales between banks are common.

C. Collection, Donor Screening, and Transfusion

About four million Americans receive transfusions each year. The average recipient gets 5.4 units of components or in some cases whole blood. Transfusions of whole blood or red cells, the most common therapy, peaked at 12.2 million units in 1986. These transfusions fell to 11.6 million units in 1987—the first decline in a decade—presumably in response to fears of AIDS. Donors are interviewed and their blood is drawn, tested, and processed at a regional center (often called a blood bank). Then it is shipped to the hospital transfusion service (sometimes also called a blood bank). In the hospital laboratory it is checked for dangerous reactions against the recipient’s blood. Figure 1 shows the route blood takes from donor to hospital to patient.

30. Eckert, supra note 22, at ch.2.
32. Paul D. Cumming et al., Exposure of Patients to Human Immunodeficiency Virus Through the Transfusion of Blood Components That Test Antibody-Negative, 321 NEW ENG. J. MED. 941 (1989). Components are separated by centrifuging whole blood. One or more units of a particular component may be given to patients, depending upon their condition. Red cells transport oxygen and replace blood lost during hemorrhage or surgery. White cells fight infection. Platelets control bleeding and replace those destroyed by disease or chemotherapy. Plasma, the amber, watery fluid through which blood cells travel, also contains vital immune and coagulation proteins. Blood banks sell some of their donated plasma to firms that manufacture blood derivative products. In 1987 in the ANRC system a donated unit of whole blood was converted into 1.54 component units, on average. Id.
33. The decline continued in 1988. Surgenor et al., supra note 23, at 1648.
34. This subsection and the next discuss industry practices and FDA regulations as
FIGURE 1
THE BLOOD DELIVERY SYSTEM

Donation begins at the blood center with an interview and a mini-physical examination by a qualified physician or by persons trained by and under the supervision of a physician. Since the early 1970s the FDA has required that donors be screened for "[f]reedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations." Donors are excluded if they give a history of malaria, travel within six months to endemic areas, or having emigrated within three years from endemic countries. They are also excluded if they give a history of any of the following: viral hepatitis; within twelve months had close contact with a person having viral hepatitis, had a tattoo (increasing the risk of hepatitis), or had received a transfusion of blood or components capable of transmitting viral hepatitis; or present or past clinical or laboratory evidence of infection with viral hepatitis, HTLV-I/II, or HIV. They are also excluded if they previously donated the only unit of blood or components to a patient who developed any of those viral infections. Donors are asked if they are feeling well, have acute respiratory infections, have had serious illnesses, or are taking prescription drugs (to which the transfusion recipient could be allergic). The examination takes pulse, weight, blood pressure, and temperature, tests the blood hemoglobin level to make sure the donor is not anemic, and checks arms for evidence of infectious skin diseases and self-injected drugs. Donors may not give more than once every eight weeks.35

HIV is transmitted mainly through sex, transfusion, and sharing intravenous needles among drug addicts. In February 1990 the FDA listed the following high-risk groups:

- Persons with clinical or laboratory evidence of HIV (AIDS virus) infection;
- Men who have had sex with another man even one time since 1977;
- Past or present intravenous drug users;
pools of plasma of thousands of donors];
- Persons born in or emigrating from countries where heterosexual activity is thought to play a major role in transmission of HIV-1 or HIV-2 infection (i.e., Haiti, sub-Saharan Africa, and islands located near these areas of Africa);
- Persons who have had sex with any person meeting the above descriptions;
- Men and women who have engaged in sex for money or drugs since 1977 and persons who have engaged in sex with such people during the preceding six months.38

From early 1983 to December 1990, the period of most of the litigation covered in this Article, individual donors were never asked directly about their sexual preference or promiscuity. Such questions, FDA and industry experts believed, could offend some low-risk donors, lead some high-risk donors to lie, and alienate others into donating regardless of their health.37 In March 1983 the FDA recommended, and blood banks adopted, the "voluntary self-exclusion" process. Donors were given a pamphlet stating the signs and symptoms of AIDS, how it is spread, the list of high-risk groups, and warning those who had contact with persons at risk not to donate. Donors signed a consent that they had read and understood the pamphlet, and that they agreed not to donate if they considered themselves at risk. They could ask clarifying questions of blood bank personnel, but they were not questioned directly. They alone decided whether to donate.

In December 1990, however, to end a political brouhaha, the FDA reversed course and recommended direct questioning of donors. Since 1984 the FDA had excluded Haitians who had emigrated since 1977, but in early 1990 it excluded them regardless of when they emigrated. Haitian-Americans claimed discrimination and held demonstrations in several cities. Based on data presented by the CDC in a public hearing, the FDA estimated that abandoning the Haitian exclusion, without adding any other precaution, could spread HIV infection to between 15 and 36 additional transfusion recipients each year.38 The FDA resolved the controversy by recommending

36. Memorandum from Paul D. Parkman, Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products, to all registered blood establishments (Feb. 5, 1990). These risk categories were adopted in a series of FDA memoranda since March 1983, discussed infra at notes 82-83.
38. See Blood Stigma, Blood Risk, N.Y. TIMES, Apr. 29, 1990, at 20; Around the Nation: 50,000 Protest Ban on Blood Donors by Haitians, Africans, WASH. POST, Apr. 21, 1990, at A7; U.S. Food and Drug Administration, FDA Position Statement, presented to the FDA Blood Products Advisory Committee, 29th Meeting (Apr. 20,
that, instead of excluding Haitian-Americans, blood banks should question every donor about all risk factors including sexual behavior. At the same time it excluded anyone treated for syphilis or gonorrhea in the preceding twelve months and extended the exclusion for anyone who had been transfused or had exchanged money or drugs for sex from six to twelve months. \(^{39}\)

Some high-risk persons may be under pressure from colleagues or friends to donate. Therefore, the FDA recommended blood banks also use "confidential unit exclusion," a procedure to give donors a second opportunity to decide whether their blood should be transfused. At many blood banks donors choose in privacy between one bar-coded label indicating that it should be used and another indicating it should not. \(^{40}\)

Nevertheless, some high-risk people donated even though they were given the pamphlet and an opportunity to ask questions. To avoid offense, the pamphlet was not sexually explicit, so some probably missed the point. Many did not read it. Others found it difficult to understand. Self-exclusion also required some donors to make sophisticated medical judgments beyond their capabilities, e.g., about half of bisexual men do not consider themselves high risk. In 1988 the Public Health Service found “recognized deficiencies in the systems used by blood and plasma establishments to educate donors about risk behaviors.” \(^{41}\) A CDC study of HIV-infected donors in

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40. The bar codes are so similar that not even the screening interviewer can tell the difference. Donations designated “Do Not Use” are quarantined and destroyed. The donor’s choice is kept confidential. In either case the blood is tested for anti-HIV, and the donor is notified of a positive result. Some blood banks instead use a secret or sealed ballot containing only the donation’s number or code. Others provide a phone number for donors who change their mind. B.R. Loiacono et al., Efficacy of Various Methods of Confidential Unit Exclusion in Identifying Potentially Infectious Blood Donations, 29 TRANSFUSION 823 (1989).

41. Report of the Workgroup on Blood and Blood Products, Second Public
1988-1989 revealed that almost two-thirds donated even though they knew that they had engaged in high-risk conduct. Of these only five percent used the confidential exclusion. In 1988-1989 only one of five ANRC donors who tested positive for anti-HIV excluded voluntarily. A 1990 study found that over 40% of blood donors who were at risk were not effectively screened by the procedures in place.

After donation, each unit is given an identification number, and a preservative is added to extend shelf life. The FDA requires that blood centers test for ABO blood groups, Rh type, and antibody markers indicating exposure to syphilis, hepatitis B, and HIV. The AABB requires testing for antibody to the viruses that cause leukemia (HTLV-I and -II) and hepatitis C, and for two liver abnormalities that are "surrogate" markers for exposure to hepatitis.

The test for anti-HIV has an error rate even if done properly, which is why careful donor screening is so important. Antibody tests inherently have "window" periods in which asymptomatic persons harboring a virus will not react to the test. Anti-HIV is measured by color; a positive test is recorded when the observed intensity of color exceeds the cutoff value. Individuals differ in the time after infection needed to produce enough antibody for the test to register positive. Initially HIV's window was thought to be three months, but in

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46. AABB STANDARDS § B5.500; AABB, ANRC, & CCBC, JOINT STATEMENT ON THE INTRODUCTION OF TESTING VOLUNTEER BLOOD DONORS FOR HEPATITIS C VIRUS INFECTION, with Attachment (Apr. 30, 1990).

rare cases it may be up to forty-two months for some high-risk persons. In 1989 the CDC estimated that ninety-five percent develop detectable antibody within six months. The window period also presents risks for recipients of organ and tissue transplants.


50. In 1985 a Virginia man transmitted HIV-1 to seven recipients of his organs and tissues although his blood tested negative twice before the transplants were performed. Three recipients of fresh organs died from AIDS-related conditions by 1991. All told, he provided four fresh organs and fifty-four tissue grafts. R.J. Simonds et al., *Transmission of Human Immunodeficiency Virus Type I from a Seronegative Organ and Tissue Donor*, 326 NEW ENG. J. MED. 726 (1992).
Risk also arises from blood bank clerical errors. In 1988 an investigation by the ANRC revealed that it mistakenly released 2,420 units (out of more than 6 million checked) as a result of "serious deviations" from its standard operating procedures. Thirty ANRC centers were involved; errors were concentrated at four. The FDA revoked the license of one center, and the ANRC voluntarily asked that the license of another be revoked. Several employees were demoted or fired. Errors included mislabeling, accepting high-risk donors, failing to quarantine or destroy reactive units, and releasing units to hospitals before checking records.\(^{51}\)

Physicians notify their hospital transfusion service of how many units they expect to use for each procedure, and units are ordered from the regional blood center.\(^{52}\) Figure 1 shows that the hospital process begins with taking the patient's history, noting pregnancy or prior transfusions which could predispose the patient to dangerous antibody reactions. A sample of the patient's blood is tested in the laboratory for its ABO-Rh group and then "crossmatched" to a compatible unit to check for reactivity. The identification number for each unit must be documented on the medical chart so that later a disease in the patient can be traced to the right donor, or a disease in the donor can be traced to the right patient. Risks in the hospital arise from inaccurate patient histories, mislabeling, improper refrigeration that allows bacteria to grow, transfusing the wrong unit(s) or product(s), or transfusing them too rapidly.\(^{53}\) Informed consent for transfusion is relatively new and not universal,\(^{54}\) so patients transfused while unconscious may not realize that they have been exposed to risk.

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51. Gilbert M. Gaul, Red Cross: Tainted Blood Released to Public, PHILA. INQUIRER, Sept. 15, 1988, at 1A, col. 1; Tainted Blood Recalled After Screening Lapses at Centers, L.A. TIMES, Mar. 19, 1988, pt. 1, at 27, col. 4; D.C. Red Cross Closes Laboratory Due to Errors, AABB BLOOD BANK WEEK, supra note 5, July 8, 1988, at 1; Telephone Interview with Mr. Steve Macielo, Director of Case Management, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Rockville, Md. (Nov. 13, 1991) (notes of interview in author's possession); Letter from Gerald V. Quinnan, Jr., Acting Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration, Bethesda, Md. (Dec. 2, 1991).

52. The materials in this paragraph are based on Paul Ness, What Can Go Wrong with Transfusion, in LEGAL ISSUES IN TRANSFUSION MEDICINE: MANAGING RISK IN A CHANGING ENVIRONMENT 29-30 (AABB ed. 1986) [hereinafter LEGAL ISSUES IN TRANSFUSION MEDICINE].

53. Of the roughly 4 million persons transfused each year, about 1,200 serious and unpredictable reactions occur within a few hours or days. Crossmatch errors cause about 500 more. About 80 are catastrophic. Improper administration of blood to the patient causes complications in another 1,200. Blood and Safety, 15 HARV. MED. SCH. HEALTH LETTER, Nov. 1989, at 1.

D. Regulation by the FDA

The FDA is authorized by the Public Health Service Act to regulate the 2,400 establishments that collect, process, store, test, or distribute blood or components in interstate commerce. Licensed establishments are inspected annually. Centers that distribute blood and components for sale, barter, or exchange must simultaneously obtain an establishment license to operate the facility and a product license for each component they prepare. The FDA may revoke or suspend licenses; penalties include fines and imprisonment. It also may seek an injunction to recall products. Blood banks must adopt good manufacturing practices that they may not change without approval. These cover personnel, facilities, equipment, supplies, standard operating procedures, uniform content-of-container labels for finished products, laboratory controls, records, and reporting. Banks may utilize the current standard operating procedures in the manuals of the AABB, ANRC, or other organizations or individual bank procedures approved by the FDA, as long as they are “consistent with, and at least as stringent as” FDA regulations. Banks must promptly notify the FDA of errors or accidents in the manufacture of products that could affect their safety, purity, or potency.

The FDA requires that each unit of blood and components carry a container label warning that “[t]his product may transmit infectious agents.” Blood collectors must provide hospitals and physicians with an instruction circular that describes each product, its source and preparation, the laboratory tests performed, directions for storage and administration, indications for proper use and side effects, and warnings. The circular is referred to on the container label and is considered to be an extension of the label, much like a package insert. The Circular of Information for the Use of Human Blood and Blood Components is produced for the industry and revised from time to time by an AABB committee that “coordinate[s]” with the ANRC, CCBC, and FDA. It has the approval of the FDA.

The 1991 Circular declared “WARNING: The risk of transmitting infectious agents is present. Careful donor selection and available laboratory tests do not eliminate the hazard.” It acknowledged that donor screening and testing “do not totally eliminate” the risk of transmitting HIV and other retroviruses. It also stated that “as a whole or in part [it] cannot be considered or interpreted as an expressed or implied warranty of the safety or fitness of the described blood or blood components when used for their intended purpose.”

At the hospital the FDA regulates laboratory testing, transfusion administration, record-keeping, and reporting. After a fatal reaction the hospital must notify the FDA by telephone as soon as possible and in writing within seven days. Hospital laboratories that are accredited by one of the approved national accreditation organizations for hospitals or pathologists do not require separate establishment licenses. States with standards that meet or exceed federal standards are also exempt. The FDA’s rules are only minimum precautions and probably do not pre-empt local rules that are more stringent, although the industry favors pre-emption.

Enforcement actions by the FDA against blood banks increased six-fold from 1986 to 1989. In 1988 it increased routine inspection of all blood banks from biennial to annual, but has suspended only one establishment license. After the deficiencies at the ANRC were revealed in 1988, the FDA negotiated an agreement with ANRC to improve its operations. In 1990 an inspection of ANRC National Headquarters by the FDA revealed hundreds more errors: 230 cases

63. AABB, ANRC, & CCBC, CIRCULAR OF INFORMATION FOR THE USE OF HUMAN BLOOD AND BLOOD COMPONENTS 1, 7 (Aug. 1991) (emphasis in original).
64. 21 C.F.R. § 606.170(b) (1991); AABB, ANRC, & CCBC, supra note 63, at 4. All blood banks and transfusion services must have standard operating procedures to investigate adverse donor and recipient reactions, which the FDA reviews during annual inspections. 21 C.F.R. § 606.100(b)(9) (1991). In 1990 the FDA received reports of 53 fatal transfusion reactions from blood banks nationwide. But not all such deaths are reported accurately by hospitals. Ralph Frammolino, Medical Lab Error Linked to Man's Death, L.A. TIMES, Oct. 19, 1991, at A24, col. 1.
69. Memorandum from Paul D. Parkman, Director, Center for Biologies Evaluation and Research, U.S. Food and Drug Administration, Control of Unsuitable Blood and Blood Components, to all registered blood establishments (Apr. 6, 1988); National Affairs Symposium Covers Recent Controversial FDA Actions, AABB BLOOD BANK WEEK, supra note 5, Oct. 21, 1988, at 4; ARC and FDA Sign Voluntary Agreement to Improve Operations, CCBC NEWSLETTER, supra note 14, Sept. 9, 1988, at 4-6; agreement reprinted in Blood Supply Safety (1991), supra note 39, at 82-84.
of possible transfusion AIDS and four fatal cases of bacterial contamination that were not reported to the FDA; violations of testing procedures; failure to monitor error reports; release of suspect units; and failure to exclude high-risk donors. More inspections of blood banks in 1990-1991 disclosed more errors. One shut itself down without the FDA sending a notice of intent to revoke its license. Notices were sent to four others; two closed voluntarily, and the others either took or were taking corrective measures. The FDA concluded that the ANRC had not complied with their 1988 agreement. The ANRC launched a $120-million effort to centralize its recordkeeping and testing within fourteen new laboratories by 1994.

E. The Response of the Industry and FDA to the Risk of AIDS

It is essential to have in mind the changes in screening donors, testing blood, and warning physicians that the industry made—and


71. Under 21 C.F.R. §§ 601.5, 601.6 (1991), the FDA may temporarily suspend a blood center's license when inspections reveal grounds for revocation and a clear danger to the public. When the inspection reveals serious problems short of that, the agency must issue a notice of intent before revoking the license. The notice allows the blood center to continue to make interstate shipments, provides for a reasonable period for it to take corrective measures, and, if necessary, offers the opportunity for a public hearing. The FDA may revoke the license if the firm does not correct the violations, and it may request an injunction against a blood center that continues to operate without complying, but no request has been necessary since 1984 or 1985. Telephone Interview with Mr. Steve Maciello, supra note 51; Letter from Dr. Gerald Quinnan, supra note 51. *See also Blood Supply Safety* (1991), supra note 39, at 1-16, 24-43, 98-99, 109-20, and 130-39; *Red Cross, FDA Testify at House Oversight Hearings; Focus Is on New Problems at Portland Region*, CCBC NEWSLETTER, supra note 14, Apr. 19, 1991, at 1-5; *FDA Warns Metropolitan Washington Blood Bank of Intent to Revoke License*, CCBC NEWSLETTER, supra note 14, July 19, 1991, at 4; Hilary Stout, *Red Cross Plans Major Changes at Blood Banks*, WALL ST. J., May 21, 1991, at B4, col. 4; Edwin Chen, *Independent Blood Banks Review Safety*, L.A. TIMES, May 22, 1991, at A18, col. 4; *Red Cross Plans 14 Central Labs to Screen Blood*, L.A. TIMES, Nov. 19, 1991, at A20, col. 4. The FDA informed all blood banks of the kinds of errors that inspections and reports had revealed and reminded them of their obligation under 21 C.F.R. § 600.14 to report errors and accidents promptly to the FDA. Memorandum from Gerald V. Quinnan, Jr., Acting Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components, to all registered blood establishments (Mar. 20, 1991), reprinted in *Blood Supply Safety* (1991), supra note 39, at 93-95; Memorandum from Gerald V. Quinnan, Acting Director, Deficiencies Relating to the Manufacture of Blood and Blood Components, to all registered blood establishments (Mar. 20, 1991), reprinted in *Blood Supply Safety* (1991), supra note 39, at 125-27.
the changes that it refused to make—as the epidemic unfolded. My
chronology is summarized in the Appendix. It shows that the three
groups of blood banks made policy jointly and that the decisions of
the FDA relied heavily on their advice.

What later was called AIDS emerged in 1977, but the first case
reports among homosexual men were published by the CDC in June
and July 1981. In July 1982 the CDC published three case reports
of AIDS among hemophiliacs. Groups of experts in government
and industry usually discuss “early warning” information about new
transfusion threats. These groups include: the CDC, FDA, and Na-
tional Institutes of Health (NIH); the three blood-collecting organi-
sations, their specialized committees, and their annual meetings; ad
hoc groups; and public meetings of the FDA’s Blood Products Advis-
sory Committee (on which blood banks in recent years have held the
chairmanship and up to two of the other ten voting seats). In 1982
public concern about AIDS arose in these groups. On July 27, 1982,
an open meeting of the Public Health Service considered the impli-
cations of recent homosexual and hemophilia cases for the manufac-
ture of blood products. Included were the CDC, FDA, NIH, the
National Hemophilia Foundation, homosexual men’s groups, and
manufacturers of blood products. The report of that meeting stated
that AIDS had, among other things, “characteristics which suggest
an infectious etiology,” and a “possible mode of transmission is via
blood products.” But no recommendation was made or action
taken.

In December 1982 an infant died in San Francisco of AIDS
twenty months after transfusion for Rh incompatibility. The high-
risk donor was well at the time of donation but died of AIDS after
eighteen months. That case alarmed the CDC. It knew that re-
ported cases understated the extent of AIDS because its definition
was restrictive and borderline cases were not counted. It knew AIDS
was found among male homosexuals, intravenous drug abusers, and
persons who frequently received blood products—the same risk

72. Centers for Disease Control, Pneumocystis Pneumonia—Los Angeles, 30
MORBIDITY & MORTALITY WEEKLY REP. 250 (1981); Kapo’s Sarcoma and Pneumo-
cystis Pneumonia Among Homosexual Men-New York City and California, id. at 305-
08. This CDC publication is distributed widely.
73. Centers for Disease Control, Pneumocystis Carinii Pneumonia Among Persons
74. This conclusion was emphasized by the United States District Court in the first
in relevant part, 851 F.2d 437 (D.C. Cir. 1989), aff’d without opinion, 906 F.2d 783
(D.C. Cir. 1990). See also SHILTS, supra note 37, at 169-71.
75. Centers for Disease Control, Possible Transfusion-Associated Acquired Immune
Deficiency Syndrome (AIDS)—California, 31 MORBIDITY & MORTALITY WEEKLY
REP. 652 (1982); Arthur J. Ammann et al., Acquired Immunodeficiency in an Infant:
groups for viral hepatitis. In Atlanta on January 4, 1983, the CDC convened a national conference on a larger scale which included the groups that met in July 1982. The likelihood that AIDS was caused by a blood-borne agent dominated what some participants referred to as “that horrible meeting.”

The CDC urged blood banks either to ask donors about sexual preference or to adopt “surrogate” tests. Most hepatitis viruses could not be detected in blood tests. But certain liver abnormalities or antibody markers common in persons who are exposed to hepatitis viruses could be identified. These surrogate tests for hepatitis were controversial among blood bankers because they were only partially effective and they rejected some safe blood. But it is important to understand that hepatitis and AIDS have parallel risk groups—which was also understood in 1983—so testing for one reduces some transmission of the other. A CDC study of AIDS patients showed that one surrogate test identified all intravenous drug users, ninety percent of male homosexuals, but only about five percent of blood donors. It would cost about five dollars per unit including replacements.

In a fateful decision at Atlanta, blood bankers rejected the CDC’s recommendation to adopt that surrogate test (they changed their minds over four years later). “Some participants [at the meeting] were reluctant to accept the hypothesis that AIDS has been transmitted by whole blood in the absence of additional evidence.” The group agreed that high-risk persons should not donate, but “no consensus was reached as to the best method of doing this.” These are important events for AIDS litigation.

Until the Atlanta meeting individual blood banks were on their own in deciding how to respond to AIDS. Afterward the three blood-collecting organizations coordinated the industry’s response through

76. SHILTS, supra note 37, at 221.
joint statements. On January 13, 1983, the AABB, ANRC and CCBC said that evidence for transfusion-transmitted AIDS was “inconclusive” and “incomplete.” Direct interrogation about a donor’s sexual preference or promiscuity was an inappropriate “invasion of privacy” until more data were available.  

On March 4, 1983, a Public Health Service interagency group reached a different conclusion. It surveyed the distribution of AIDS cases that paralleled the epidemiology of the hepatitis B virus, the case of the San Francisco infant, and others under investigation. It recognized that the “[a]vailable data suggest that . . . AIDS is caused by a transmissible agent” and “[t]he likelihood of blood transmission.” On March 7, 1983, the AABB, ANRC, and CCBC jointly acknowledged that the conclusions of the Public Health Service were “similar but not identical” to their previous joint statement, but did not change their position.  

On March 24, 1983, the FDA issued weak recommendations on donor screening that reflected the industry’s position. The main risk group was defined as “sexually active homosexual or bisexual men with multiple partners.” The definition excluded symptomless homosexual men who were not promiscuous and—against the advice of CDC—persons with certain liver abnormalities that could be detected by surrogate tests. The FDA recommended confidential unit exclusion in December 1984 and signed donor consents in October 1986. It extended the risk groups to “any male who has had sex with another male since 1977” in September 1985 and to prostitutes in October 1986.
As patients learned about transfusion AIDS and the response to it by industry and the FDA, some attempted to recruit their own donors—called a “directed donation.” Presumably family or friends would provide an added margin of safety, especially in high-risk urban areas, or at least bring peace of mind. On June 22, 1983, the AABB, ANRC, and CCBC, in another joint statement, recommended that blood banks reject these requests. They believed that the public’s concern was “understandable, but excessive,” and that widespread directed donations would “seriously disrupt the nation’s blood donor system.”

One AIDS case that I discuss infra turned on such a denial.

In January 1984 two studies published in medical journals linked AIDS in transfusion recipients with donors who were in high-risk groups and had pre-AIDS blood abnormalities. In 1987 in the first transfusion AIDS case, a United States district court took these publications as conclusive evidence for when “the medical community reached a consensus as to the proposition that AIDS was transmissible by blood.”

In April and July 1984, scientific papers identified HIV (then called HTLV-III). On March 2, 1985, the FDA licensed the anti-HIV test and recommended that blood banks use it as soon as possible. The AABB required testing for anti-HIV on July 1, 1985, two months later. Some patients who became infected with the AIDS

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84. AABB, ANRC, & CCBC, Joint Statement on Directed Donations and AIDS (June 22, 1983); Joint News Release (June 22, 1983), reprinted in Blood Supply Safety, supra note 16, Exhibit G, at 116-17. See infra Section V.


87. 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); Jean L. Marx, Strong New Candidate for AIDS Agent, id. at 475; P. M. Feorino et al., Lymphadenopathy Associated Virus Infection of a Blood Donor-Recipient Pair with Acquired Immunodeficiency Syndrome, 225 SCIENCE 69 (1984).

88. Owing to the delays in producing final regulations, the FDA did not require anti-HIV testing until Jan. 5, 1988. See Kirkendall v. Harbor Ins. Co., 698 F. Supp. 768,
virus from untested blood shipped to hospitals during these two
months sued. They argued that blood banks should have recalled
untested units from hospital inventories once anti-HIV testing be-
came routine.

On January 13, 1983, the AABB, ANRC, and CCBC jointly
stated that "[f]ewer than 10 cases of AIDS with possible linkage to
transfusion have been seen despite approximately 10 million transfu-
sions [sic] per year." The anti-HIV blood test that was imple-
mented in March 1985 permitted estimates of how common HIV
infection among donors had been. The ANRC found the prevalence
of true positives in nine of its regional centers was 38:100,000, or
380 times greater than the "one in a million" estimate. Prevalence in
Los Angeles and Washington, D.C. was more than three times that
in Boston, Detroit, or Philadelphia and about ten times the average
rate for Tulsa, Oklahoma, Portland, Oregon, and Peoria, Illinois. If
the average patient got 5.4 units, each from a different donor, then
the real risk was 2,052 times the industry's prediction. Moreover, the
ANRC's survey was over two years after the FDA and blood banks
had adopted the voluntary self-exclusion rules. If those rules cut
the prevalence of HIV among donors, then the risk should have been
even lower in 1985 than in January 1983, when the one-in-a-million
estimate was made. Retrospective studies of the risk in San Fran-
cisco in 1983-84 indicate that the estimates of blood bankers at the

772, 779 (W.D. Ark. 1988), aff'd, 887 F.2d 857 (8th Cir. 1989); see also infra note 264.

89. AABB, ANRC, & CCBC, JOINT STATEMENT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME RELATED TO TRANSFUSION (Jan. 13, 1983). The three organizations may have meant that 10 million units were transfused per year. At the time, it was commonly estimated that about 3.5 million persons were transfused each year, and the average transfusion was of three to four units of whole blood or components. A Los Angeles blood banker said that the odds of getting AIDS-tainted blood were "ten million to one." As AIDS Scare Hits Nation's Blood Supply—, U.S. NEWS & WORLD REP., July 25, 1983, at 71 [hereinafter As AIDS Scare Hits Nation's Blood Supply —]. A San Francisco blood banker put the odds at about one per million in July 1983 and at less than one per 500,000 in March 1984. SHILTS, supra note 37, at 345, 433. The chairman of an AABB committee of experts told a subcommittee of the House of Representa-
tives that the risk was "less than one in a million." Statement on AIDS and Blood Transfusion Before the Subcomm. on Intergovernmental Relations and Human Re-
(statement of Joseph R. Bove, Director, Yale-New Haven Hospital Blood Bank and
Chairman, AABB Committee on Transfusion-Transmitted Diseases and FDA Blood Produk ts Advisory Committee).

blood in the high-risk communities of Houston, Miami, San Francisco, or New York.

91. Standard blood banking practice usually does not attempt to transfuse a pa-
tient with more than one component unit from the same donor. JOSEPH FELDSCHUH &
DORON WEBER, SAFE BLOOD: PURIFYING THE NATION'S BLOOD SUPPLY IN THE AGE OF
AIDS 108-09 (1990). The exception is packs of several units of platelets from a single
donor whose tissue type is compatible with the recipient's. Single-donor platelet packs
amounted to about 1% of all transfusions in 1987. Surgenor et al., supra note 23, at
1648.
time were even more inaccurate than estimates for the nation at large.  

My chronology raises several questions about industry care levels since 1983. Should it have adopted stronger donor-screening measures than the FDA recommended? Should it have adopted surrogate tests when the CDC recommended them? Should it have encouraged, or at least not discouraged, directed donations? Should it have issued warnings? Should the entire industry be liable for choosing incorrect care levels if risks were managed by joint agreements among the three blood-banking organizations?

III. THE ECONOMIC CONSEQUENCES OF ALTERNATIVE RULES OF LIABILITY

The main purpose of liability is to strengthen the incentives for responsible conduct. For most activities our society chooses among legal rules so that buyers or sellers receive signals for risk-management. Accidents cannot be eliminated, but precautions can reduce their rate and severity. Because precautions are costly, the logic of liability law is to assign the duty to take them to whoever can avoid the injury at lower cost—usually whoever has superior information about risks. That strengthens incentives to control risks or to disclose them.

In this Section I evaluate three liability rules—industry custom, strict liability, and adequate warning. Issues of negligence and causation are difficult in the transfusion cases because of their factual complexity. First I illustrate how the legal and economic principles work in nonblood situations, and then I analyze the problem of liability for transfusion.

92. One source reported that it was about 1:440 units, or about one in eighty-one patients, assuming the average transfusion was 5.4 units. Shilts, supra note 37, at 546. A retrospective study published in 1991 estimated that the risk peaked in 1982-1983 at about 1.1% per component unit transfused. Michael P. Busch et al., Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood Transfusion Before the Implementation of HIV-1 Antibody Screening, 31 TRANSFUSION 4 (1991). Their estimate of about 1% for 1983 and the first six months of 1984 was 10,000 times greater than the 1:1,000,000 estimate by San Francisco blood bankers in July 1983 and 5,000 times greater than the estimate of 1:500,000 in March 1984. See supra note 89.
A. Industry Custom

Self-regulation by blood banks plays an important role in determining standards of care. Therefore it is important to know the extent to which courts will review an industry's customary practice. The legitimacy of judicial review was established in *The T.J. Hooper*, a 1932 admiralty case. In an oft-quoted passage, Judge Hand held:

> Indeed in 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 never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.94

Judge Hand cited three railroad cases as authorities. In *Texas & Pacific Railway Co. v. Behymer* Justice Holmes had held that "[w]hat usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it usually is complied with or not." Hand traced the doctrine to a 1868 Massachusetts case of negligence by a cattle drover, but it goes back another decade at least.97

*The T.J. Hooper*'s facts are tricky. During a gale, barges towed by tugs whose captains did not have working radios were lost. Nearby tows with working radios received reports of the gale early enough to put into harbor. A natural experiment had occurred which allowed comparison between two groups of tows, and Judge Hand saw that the benefits of working radios obviously exceeded costs.

An adequate receiving set suitable for a coastwise tug can now be got at small cost and is reasonably reliable if kept up; obviously it is a source of great protection to their tows. Twice every day they can receive these

93. 60 F.2d 737 (2d Cir.), cert. denied, 287 U.S. 662 (1932).
94. Id. at 740.
95. 189 U.S. 468, 470 (1903) (custom of bumping and jerking cars is negligence if brakeman is required to stand on ice-covered roofs of cars). See also Wabash Ry. Co. v. McDaniels, 107 U.S. 454, 461 (1883) (railroad must take same degree of care in hiring night telegraphic operators, who can cause collisions when messages are not transmitted accurately, as in maintaining equipment and machinery); Shandrew v. Chicago, St. P., M. & O. Ry. Co., 142 F. 320, 325 (8th Cir. 1905) (tests for defects in air hose that exploded and killed brakeman, beyond tests customarily used, would have been ineffectual and impractical).
96. Maynard v. Buck, 100 Mass. 40, 48 (1868) (custom of drovers for hire to continue to end of route before returning to search for missing cattle was negligent).
97. Hibber v. McCartney, 31 Ala. 501, 508 (1858) (custom of steamboats of carrying night torch-lights cannot affect liability of owners for a loss caused by failure to protect cargo of baled cotton from sparks); Mayhew v. Sullivan Mining Co., 76 Me. 100, 111-12 (1884) (custom of cutting a ladder hole in a mining platform in active operation without providing lights, rails, or warnings was negligence). These cases and those cited infra in notes 102 and 103 were complied in Brief for Plaintiffs-Appellants, Doe v. American Red Cross Blood Services, S.C. Region, No. 88-496, 1988 AIDS LITIG. REP. 1460, 1465-66 (on certification to the Supreme Court of South Carolina from the U.S. District Court (D.S.C.)).
[weather] predictions . . . . Such a set is the ears of the tug to catch the spoken word, just as the master's binoculars are her eyes to see a storm signal ashore.\textsuperscript{98}

He held that there was "no custom at all [in the industry] as to receiving sets; some had them, some did not; the most that can be urged is that they had not yet become general."\textsuperscript{99} The trial court found that ninety percent of tugs had radios, although "many of these radio sets were the personal property of the tug master, and not supplied by the owner."\textsuperscript{100} William M. Landes and Richard A. Posner suggested the analogy of carpenters who bring their own tools. If radios were a cost-effective safety device, they argue, then "it is impossible to understand why the device is not customary in the industry—as in fact it appears to have been."\textsuperscript{101} Requiring tug owners to own radios, however, probably lowers the cost of monitoring whether ships carried them. Custom lagged only if radio ownership by tug owners was essential.

What I call the Holmes-Hand rule—that industry custom is subject to a cost-benefit test—is law in seven federal circuits. In about half the circuits the custom is treated as some evidence of due care but is not dispositive.\textsuperscript{102} In the others industry custom has been held to be negligent.\textsuperscript{103} In The T.J. Hooper the masters who did not have working radios risked harm mainly to themselves. But in most of

\textsuperscript{98} The T.J. Hooper, 60 F.2d at 739-40.
\textsuperscript{99} Id. at 740.
\textsuperscript{100} The T.J. Hooper, 53 F.2d 107, 111 (S.D.N.Y. 1931).
\textsuperscript{102} Petition of J.E. Brenneman Co., 322 F.2d 846, 855 (3d Cir. 1963) (in negligent damage to pier from fire on barge moored next to pier, custom is only evidence of a standard of care); Gill v. Hango Ship-Owners/AB, 682 F.2d 1070, 1074 (4th Cir. 1982) (in longshoreman's injury, proof of adherence to an industry practice or custom is not dispositive on issue of negligence); Baker v. S/S Cristobal, 488 F.2d 331, 333 (5th Cir. 1974) (in longshoreman's injury, compliance with customs and practices of industry is not alone due care, but is evidence of care); Anderson v. Malloy, 700 F.2d 1208, 1212 (8th Cir. 1983) (applying Missouri law) (in motel where woman was raped, evidence of deviation from accepted practice of security measures in other area hotels and motels has evidentiary value but does not establish negligence conclusively).
\textsuperscript{103} Tug Ocean Prince v. United States, 584 F.2d 1151, 1156 (2d Cir. 1978) (in accident for oil spillage from towed barge that collided with submerged rock, custom and usage do not justify negligence); Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455, 462 (4th Cir. 1960) (applying Virginia law) (custom of mislabelling length and width of nails used in orthopedic surgery, when one became stuck in patient’s leg and caused osteomyelitis, was negligent); Complaint of Paducah Towing Co., 692 F.2d 412, 426 (6th Cir. 1982) (admiralty) (industry practice in mooring a vessel does not establish reasonableness); Abernathy v. Superior Hardwoods, 704 F.2d 963, 967-68 (7th Cir. 1983) (applying Indiana law) (in truck driver’s injury at lumber mill, compliance with custom is not the standard for negligence).
these recent cases (only one of which is in admiralty) those who managed risk affected the safety of others, as occurs when blood banks manage risk for transfusion recipients. For example, in the Court of Appeals for the Second Circuit, Judge Mehrtens, in a case where oil spilled from a grounded barge, held that “[m]ethods employed in any trade, business or profession, however long continued, cannot avail to establish as safe in law that which is dangerous in fact.”104 In the Seventh Circuit Judge Posner, in a case where a lumbermill employee’s negligence injured a truckdriver, held that “compliance with custom is not a defense to negligence.”105

In *Marsh Wood Products Co. v. Babcock & Wilcox Co.*106 the Wisconsin Supreme Court upheld a jury verdict that industry custom was negligent. That 1932 case was decided six months before Judge Hand’s opinion in *The T.J. Hooper*, so neither case cites the other. But the decision is consistent with the Holmes-Hand rule. Boiler tube manufactured by defendant and sold to plaintiff exploded when subjected to about half the boiler’s allowable working pressure. The jury found that the tube ruptured because it was manufactured from defective steel that the manufacturer would have known about had it tested the steel beforehand. Plaintiffs relied on two professors of metallurgy who microscopically examined samples of tube from the boiler. The experts found enough slag and other impurities to conclude that the steel used was unfit, “imminently dangerous,” and that it caused the rupture. They testified that only by microscopic examination of each “heat,” or batch, of steel could the manufacturer determine whether the steel was sufficiently strong. Such a test, they said, would have rejected the heat of steel from which the tube that ruptured was made.

The Wisconsin Supreme Court found sufficient evidence to warrant the jury’s verdict that the manufacturer was negligent in failing to employ microscopic tests. The fact that such tests were not incorporated into Wisconsin law or the specifications of the relevant professional associations

is certainly strong evidence against the position taken by [the two experts]; but it does not dispose of their evidence as a matter of law. The fact that the custom of manufacturers generally was followed is evidence of due care, but it does not establish its exercise as a matter of law. Obviously, manufacturers cannot, by concurring in a careless or dangerous method of manufacture, establish their own standard of care.107

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106. 240 N.W. 392 (Wis. 1932).
107. *Id.* at 396; *Boyce v. Wilbur Lumber Co.*, 119 Wis. 642, 97 N.W. 563, 565 (1903). *See also* *Hogge v. SS Yorkmar*, 434 F. Supp. 715, 734 (D. Md. 1977) (in admiralty, where vessel collided with bridge, failure to use outmoded whistle signals was not conclusive, since an industry cannot establish its own standard of care).
But the trial court erred in submitting to the jury the question of whether the particular tube was manufactured negligently. The evidence supported the conclusion that the manufacturer did not have an obligation to test all tubes or a particular tube, “but merely an obligation to establish by a suitable number of these tests the fitness of a heat or quantity of steel for the purpose of making tubes.”

The court, however, did not disturb the jury’s conclusions that: (1) the manufacturer had superior information about the quality of steel used to make tube, compared to information available to boiler employees or their employer; (2) custom did not establish a standard of due care; and (3) a cost-effective way of monitoring the quality of tubes was to test the quality of steel.

Since early 1983 the three blood-collecting organizations, acting as trade associations for members, have managed transfusion risks jointly. Therefore, it would be relevant to learn how courts have dealt with negligence issues in other industries where firms manage risks jointly.

The question of joint liability of substantially all the manufacturers in an industry and its trade association was raised in *Hall v. E. I. Du Pont De Nemours & Co.* In 1972 damages were sought for eighteen separate accidents in which children were injured by blasting caps. The precise manufacturer in most instances could not be identified. Plaintiffs alleged that manufacturers knew of the danger to children, took certain inadequate steps to warn, collusively failed to add label warnings, and lobbied against legislation to require warnings.

*Hall* is a diversity case in which the United States district court ruled on preliminary motions that required it to determine whether the plaintiffs might succeed on the law and facts. For that purpose it took the “gross first approach” of “assum[ing] the existence of a national body of state tort law” based on “[a] growing consensus on

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110. The opinion covers two cases. In *Chance v. Du Pont*, plaintiffs, who could not identify manufacturers of the injury-causing caps, sued substantially the entire industry and its trade association. *Hall*, 345 F. Supp. at 359. In *Hall*, other plaintiffs sued manufacturers in addition to those that made the injury-causing caps and dropped their complaint against the trade association to maintain a diversity action. The court held that the *Hall* plaintiffs’ arbitrary selection of nonproducer defendants and their lack of need for joint liability required dismissal of the claims against nonproducer defendants and severance of the remaining claims. *Id.* at 396. Thus, the *Hall* plaintiffs sacrificed in vain the possibility of testing the Holmes-Hand rule against a trade association.
the substantive law in this country." The court held that if defendants had joint control over the risk of injury and violated a legal standard of care, then they could be jointly liable. It was not necessary for plaintiffs to show that defendants were in a joint venture or a profit-sharing plan to establish joint control over risk. Plaintiffs could establish joint control by showing express agreement or concert of action over care levels. Alternatively, they could demonstrate evidence of defendants' parallel behavior sufficient to support an inference of tacit agreement or cooperation. Plaintiffs could also submit evidence that defendants, acting independently, adhered to an industry-wide standard or customary care level. The court said that existence of industry standards would not support the imposition of joint liability in all circumstances, but that they are germane.

Plaintiffs alleged that manufacturers, through parallel practices, knew that information collected by their jointly sponsored and jointly financed trade association showed that children were injured in accidents involving blasting caps. The court argued that it was unlikely that individual manufacturers would collect information about the nationwide incidence and circumstances of blasting-cap accidents involving children. It would have been reasonable to delegate that function to a trade association. Plaintiffs also alleged that the manufacturers knew of feasible safety measures and had delegated certain design functions to their trade association; therefore, the risk to children was foreseeable. Such allegations were held to be a cause of action under strict liability and negligence principles.

Issues requiring factual development, the court held, were whether defendants collected and shared this information as a group and made joint decisions on the basis of known risks. Relevant issues included the association's size, whether it was composed of few or many firms (the blasting cap industry in this country comprised six firms), its announced and actual safety objectives, internal procedures of decision-making about safety, information-gathering procedures about accidents, and lobbying activities about safety during the period in question. In sum, the court conceptualized Hall as a case where a trial would determine whether manufacturers, jointly through their trade association, had superior information about risk. Attempts to apply Hall to cases of liability for drugs, toxins, or asbestos, however, failed owing to distinguishable facts.

111. Id. at 360. Later the claims were severed and transferred in Chance v. E. I. Du Pont De Nemours & Co., 371 F. Supp. 439 (E.D.N.Y. 1974).
113. Id. at 378. The activities of the trade association were documented in Chance, 371 F.Supp. at 441-43, 448.
114. Sindell v. Abbott Lab., 26 Cal. 3d 588, 607 P.2d 924, 935, 163 Cal. Rptr. 132, 143 (1980) (more than two hundred manufacturers made DES and they did not delegate safety functions to a trade association); Sheffield v. Eli Lilly and Co., 144 Cal. 236
Turning now to liability in medicine and other professions, custom usually is the standard of due care. Professionals are expected to exercise reasonable care and to have and use a minimum standard of knowledge and ability that is typical of members in good standing. That standard is determined by the profession’s “collective wisdom.” Whether or not it was met is established by expert testimony of like professionals. Courts usually defer to other professions and are reluctant to burden them with liability arising from “uneducated” judgments by judges and juries. Following custom in similar circumstances is not conclusive, but it is strong evidence of nonnegligence if the custom has a rational basis. If neither evidence nor common experience indicates otherwise, custom without a cost-benefit test will usually establish nonnegligence as a matter of law.

Helling v. Carey was a short-lived exception to that rule. In 1974 the Washington Supreme Court reversed a trial court's judgment for defendant ophthalmologists following a defense verdict, which was affirmed on appeal, in a malpractice action against them for failure to detect glaucoma earlier in a thirty-two-year-old woman. The professional standard was not to test patients under forty years old unless they had suspicious symptoms or complaints. The standard pressure test for glaucoma was simple, harmless, and inexpensive, but was administered only after the patient's tenth office visit over a five-year period. Failure to test this glaucomatous person caused a devastating result that could have been arrested with early detection. Citing *The T.J. Hooper*, the court held that the defendants were negligent as a matter of law.

Landes and Posner argue that it was anomalous for the court to

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117. *Id.* at 516, 519 P.2d 981, 983. In a separate opinion Justice Utter argued for strict liability and implied that his colleagues had confused strict liability with negligence. *Id.* at 517, 519 P.2d 981, 984-85 (Utter, J., concurring).
find an ophthalmologist negligent for following a standard, without striking down the standard on the basis of its expected benefits and costs. Apparently the “over forty” care level for glaucoma had long been criticized in medical texts, so the court may have achieved the right result for the wrong reason. In Washington, *Helling* was “restricted solely to its own ‘unique’ facts” by courts after being rejected by the legislature. The California Court of Appeal rejected *Helling* for malpractice. In the 1980s a few jurisdictions moved away from custom toward a reasonable care standard for malpractice. But in the blood cases, as I show *infra*, the courts usually reject the Holmes-Hand rule in favor of custom as the standard of due care.

Suppliers have weaker incentives to compare benefits and costs if custom is the standard of due care. Regulation, as an alternative to liability, in principle can attempt to implement the Holmes-Hand rule by forcing an industry to compare costs and benefits before choosing care levels, but the evidence indicates that this did not occur in blood banking. Following the holding in *Hall*, plaintiffs suing an industry of professionals under the Holmes-Hand rule would have to show that the professionals delegated the choice of care levels to their trade association, that the association had control over risk, that it chose without making cost-benefit tests, and that injury from such choices was foreseeable.

B. Strict Liability

The key to managing risk in transfusion or any other activity is to have information about risk. The crucial role such information plays in assigning liability can be illustrated best by a case in which facts and causation are simple. In *Nelson v. Hall*, a 1985 California case, a veterinary assistant sued the owner of a dog for injuries sustained to her face when bitten during the course of medical treatment. The trial court granted the defendant dog owner summary judgment, and the California Court of Appeal affirmed and denied review. California’s “Dog Bite Statute” makes the owner strictly liable

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118. LANDES & POSNER, supra note 101, at 138.
124. CAL. CIV. CODE § 3342 (West 1985); *Nelson*, 165 Cal. App. 3d at 712 n.1,
for damages to a person who is bitten while in a public place or lawfully in a private place, including the property of the dog's owner, regardless of the dog's former viciousness or the owner's knowledge of it. But the court of appeal concluded that "Amos," a hundred-pound black Labrador-German shepherd mix, was delivered to the veterinary office for treatment over which his owner had no control and that the staff assumed the risk.

Plaintiff had been an assistant for thirteen years, and for two years at that establishment. "Amos" had been treated there for six years. The staff knew that "Amos" might attempt to bite his handlers, and a notation of "careful" was on his treatment card. The staff knew that dogs undergoing sedation might bite. Dogs known to be vicious usually were muzzled during treatment. "Amos" bit the assistant while undergoing sedation without a muzzle. The assistant had been bitten less severely at least five times before, on some of the occasions by sedated dogs, and one bite had required treatment. The court held that dog bites were a known occupational risk that she had appreciated and voluntarily accepted.

Apparently the owner of "Amos" did not know of his vicious propensities or that he had tried to bite handlers before. Thus, the complaint was based on strict liability rather than negligence. The court said, however, that such knowledge could have been the basis for a negligence action. "If a dog owner purposefully or negligently conceals a particular known hazard from a veterinarian, he or she would not be relieved of liability, for this would expose the injured person to an unknown risk." 2

Responsibility for avoiding the accident in Nelson was assigned to the party with superior information, or what Rodney T. Smith and I

211 Cal. Rptr. at 670 n.1.

125. Nelson, 165 Cal. App. 3d at 788 n.4, 211 Cal. Rptr. at 673 n.4; Lipson v. Superior Court, 31 Cal. 3d 362, 444 P.2d 822, 182 Cal. Rptr. 629 (1982) (fire fighter may recover when the act resulting in his injury, such as defendant's misrepresentation of or failure to warn of known, hidden danger, is independent of the act that created the fire); Prays v. Perryman, 213 Cal. App. 3d 1133, 262 Cal. Rptr. 180 (1989) (dog groomer did not assume risk when bitten after owner took dog out of cage on leash under owner's exclusive control while groomer was deciding whether it would be safe to proceed); Harrold v. Rolling "J" Ranch, 228 Cal. App. 3d 260, 266 Cal. Rptr. 734 (1990) (experienced rider did not impliedly assume a known or ordinary risk because she was not specifically informed of the rented horse's dangerous propensity to be spooked or that it had thrown riders before); Cohen v. McIntyre, 233 Cal. App. 3d 201, 277 Cal. Rptr. 91 (1991) (veterinarian who muzzled dog that snapped at him, and was bitten after he removed muzzle while dog was under his exclusive control, voluntarily assumed a known risk even if the owner concealed the dog's propensity to bite people).
have called the underlying structure of information costs. Both parties were obligated to use or disclose what information they had. The consumer did not realize her dog had a history of biting and knew nothing of how sedated dogs behaved in veterinarian offices. She could have avoided the risk only by forgoing treatment. The assistant could have avoided injury by reading the treatment card provided for “Amos” and applying a muzzle—the cost-effective precaution. Nelson was followed in California appellate cases involving animals and job risks.

The influential Restatement (Second) of Torts also assigns liability by comparing the information held by the consumer and the supplier. Under Restatement section 402A, strict liability “applies only where the product is, at the time it leaves the seller’s hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.” An unreasonably dangerous product is one that is “dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.”

127. Willenberg v. Superior Court, 185 Cal. App. 3d 185, 229 Cal. Rptr. 625 (1986) (veterinarian leaped upon by dog from examination table as he entered office assumed a risk inherent in his job); Ordway v. Superior Court, 198 Cal. App. 3d 98, 243 Cal. Rptr. 536 (1988) (jockey injured during a race assumed risk of infractions of rough riding rules, which are within the ordinary expectations of participants); King v. Magnolia Homeowners Association, 205 Cal. App. 3d 1312, 253 Cal. Rptr. 140 (1988) (air conditioner repairman injured on falling from ladder after scaling it a second time understood danger and assumed risk); Von Beltz v. Stuntman, Inc., 207 Cal. App. 3d 1467, 255 Cal. Rptr. 755 (1989) (stuntwoman in motion picture was responsible for portion of catastrophic injury caused by failure to request safety belts, but did not assume risk caused by director's decision, between first and second takes, to double speed of stunt without informing her); Ford v. Gouin, 227 Cal. App. 3d 1175, 266 Cal. Rptr. 870 (1990) (experienced water skier, who skied barefoot and backward down a narrow channel that he was familiar with, assumed the risk that the driver of the boat might veer from a straight course and cause the skier to hit his head on an overhanging branch); Knight v. Jewett, 232 Cal. App. 3d 1142, 275 Cal. Rptr. 292 (1991) (woman injured in touch football game, playing without an agreement of rules beforehand and after rough play occurred, voluntarily and knowingly assumed risks that are within the ordinary expectations of participants); Hacker v. City of Glendale, 228 Cal. App. 3d 1013, 279 Cal. Rptr. 371 (1991) (professional tree trimmer voluntarily assumed the risk of electrocution because he had general knowledge of the risk and understood that high-voltage lines passed through the tree he was hired to trim); Donahue v. San Francisco Housing Authority, 230 Cal. App. 3d 135, 281 Cal. Rptr. 446 (1991), rev. granted No. S021823, 284 Cal. Rptr. 510 (1991) (fire inspector who had inspected a building many times and who noticed that concrete steps were wet and muddied understood and voluntarily assumed the risk of falling whether or not he realized that the steps lacked non-slip adhesive treads).
128. Restatement (Second) of Torts, § 402A (1965).
129. Id. § 402A cmt. g.
130. Id. § 402A cmt. i.
C. Adequate Warnings

When and how well blood banks warned physicians of the risk of transfusion AIDS has been raised in litigation. Therefore, it is important to know the duties to warn that courts have imposed on other firms and industries in factually simpler cases. The general rule is that if a supplier has better information about foreseeable product risk than consumers do, and risk cannot be reduced cost-effectively, then its duty to the consumer is discharged by issuing a warning. The rule applies whether the supplier is a single firm or an industry acting jointly.

In Canifax v. Hercules Powder Co., a 1965 California action in strict liability and negligence, five workers were killed or injured in a dynamite explosion in an exploration tunnel at a dam site. Defendant argued that it was generally known to users and sellers that dynamite fuse was usually manufactured to burn at the rate of one foot in forty seconds, although some fuse was made to burn faster. A safety order required that a three-foot sample of each lot of fuse be tested for its burn rate in open air by the State of California. Fuse was sold in rolls of three thousand feet without its burn rate printed on either the fuse or its paper wrapper.

The California Court of Appeal reversed a motion for summary judgment granted to defendants. Defendants had not shown that consumers were aware that manufacturers did not customarily give warnings of burn rates, that it was common knowledge in the industry that fuse was customarily manufactured to burn at the rate of one foot every forty seconds, that the fuse that caused the explosion was manufactured to that specification and was not one of the rarer fuses that burned faster, or that it was the custom of manufacturers to make fuse to burn at a given rate.

That custom, in any event, would not necessarily establish a standard of care meeting the test of reasonability to be applied when the case is tried. The existence of the state safety order may be evidence that it was reasonable for suppliers of fuse in some instances not to warn regarding fuse timing. It is not, however, conclusive.132

The case was remanded for trial to determine whether defendants had a duty to warn under either strict liability or negligence.

Hall v. Du Pont also raised the issue of whether a group of manufacturers acting jointly had a duty to warn. The district court, again generalizing from an assumed national body of tort law, held that

132. Id. at 55, 46 Cal. Rptr. at 559.
blasting cap manufacturers were not entitled to judgment as a matter of law on whether they met the duty to warn.

An "unreasonable risk" in any given situation depends on the balancing of probability and seriousness of harm if care is not exercised against the costs of taking precautions.

Activity involving a small likelihood of death or serious injury may require greater and more costly precautions than that involving a higher probability of lesser harm.\(^{133}\)

Children were not the intended users of blasting caps, but they may have been foreseeable users.\(^{134}\) The court held that there is "no sharp boundary between foreseeability—i.e., probability of harm—under negligence and under strict liability principles." Under strict liability, "the range of intervening acts which will insulate the defendants from liability will be even narrower than under negligence principles."\(^{135}\) The industry warned adults through printed notices on, and inserted in, packages of blasting caps. Plaintiffs had to show that a failure to warn children constituted a breach that was a "cause in fact" and a "proximate cause" of the accidents. What kinds of warnings would be effective for children required "a full factual presentation."\(^{136}\)

The duty to warn in the Restatement's strict liability rule also depends on information. A supplier who "has reason to anticipate that danger may result from a particular use . . . may be required to give adequate warning of the danger . . . , and a product sold without such warning is in a defective condition."\(^{137}\)

Where . . . the product contains an ingredient . . . whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.\(^{138}\)

**D. Liability for Blood Transfusion**\(^{139}\)

In transfusion the information problem is similar to that in Nelson v. Hall but more complex. The problem must be divided into what

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134. Id. at 365.
135. Id. at 369-70.
136. Id. at 367. The court defined a "cause in fact" as a warning that could have averted the particular accident and "proximate cause" as the absence of intervening events that would have prevented a finding of liability. Id.
137. RESTATEMENT (SECOND) OF TORTS, § 402A cmt. h (1965).
138. Id. § 402A cmt. j (emphasis added).
139. The analysis in this section is adapted from ECKERT & SMITH, supra note 126. Similar conclusions were reached with a different analysis in Reuben A. Kessel, Transfused Blood, Serum Hepatitis, and the Coase Theorem, 17 J. L. & ECON. 265 (1974); Marc A. Franklin, Tort Liability for Hepatitis: An Analysis and a Proposal, 24 STAN. L. REV. 439, 466, 479-80 (1972); and Comment, Liability Without Fault and the
the patient knows, what the treating physician knows, and what the blood bank knows.

Most patients start with zero information about the organization and operation of blood banks that I described in Section II. Patients normally deal with physicians and hospitals, not blood banks. Many will not know even the name or location of their regional blood supplier, let alone the routine precautions it takes. For patients who are skeptical of the safety of blood-bank blood, the costs of learning about the costs and benefits of alternative precautions would usually be high and in an emergency would be prohibitive. Consumers in general, when facing high information costs, are not likely even to know what safety improvements—such as additional screening or testing—to bargain over. Patients rely on their hospital to choose a suitable blood bank, their physician to inform them of risks, and the blood bank to do its job prudently.

Assuming that a patient understood the true risk of transfusion and believed it was too high, how could the patient reduce it? An elective surgery could be postponed or perhaps forgone. The surgeon could be instructed to transfuse only if essential (which might slow recovery). Switching hospitals in the same region probably would not reduce risk, since most regions are served by a single blood bank. Some patients would probably switch to a hospital in a different region with a reputation for safer blood. But each of these adjustments is costly.

One relatively inexpensive way for patients to attempt to reduce the risk would be to choose donors themselves. Such a request signals the blood bank that some patients believe that their potential damages are high and that extra precautions are cost-effective. But the possibility of directed donors was limited by the industry’s strong opposition. Others deposited their own (autologous) blood in advance of surgery, but by 1987 autologous blood grew to only three


140. See Kessel, supra note 139, at 282.
141. LANDES & POSNER, supra note 101, at 132.
142. Most producers do not have this information without some signal from consumers. See Eckert & Smith, supra note 126. An additional complexity is whether a consumer is willing to pay the extra cost or is willing only to have their insurer billed. Private and governmental insurers sometimes are unwilling to pay for new procedures until their effectiveness is documented, and such information was not available early in the AIDS epidemic. See infra note 279 and accompanying text.
percent of all collections. Neither procedure is practical for emergencies or when extensive transfusion is necessary (e.g., for some chemotherapies, massive gastrointestinal bleeding, and some surgeries). Thus, other than choosing donors, switching regions, or forgoing treatment, patients can do nothing to reduce risks.

What patients know about risks, aside from what they read and learn on their own, depends on what their physicians and hospitals know and tell them. Under the rule of Canterbury v. Spence, a leading case in medical malpractice, the physician has a duty to warn the patient—voluntarily, specifically, and in nontechnical terms—of all “material” risks the patient needs to know to make an informed choice between the proposed treatment and alternatives. The physician is not required to disclose every known risk and has no duty to disclose in emergencies or to patients who are distraught or incompetent. But “[a] very small chance of death or serious disablement may well be significant.” A duty to disclose may apply also when the physician knows the patient attaches significance to a particular risk, whether or not the physician believes it to be material.

The knowledge or warnings that physicians can transmit to patients depends in part on what is published or communicated to them by specialists in blood banking and expert government agencies. Blood is both a biologic and a prescription drug. Under the learned intermediary doctrine, the manufacturer of a prescription drug, or a blood bank, has a duty to warn only the physician. The physician, in deciding on use, takes into account “the propensities of the drug, as well as the susceptibilities of his patient.”

Blood bankers, as I noted in Section II, have lower costs of acquiring “early warning” information about new transfusion threats than

143. Not all hospitals offer the service, and it usually costs more than blood-bank blood. Surgenor et al., supra note 23, at 1648.
145. The Canterbury rule that physicians must disclose all material risks may be replacing the rule that physicians must disclose only what is customary practice in the community. Lambert v. Park, 597 F.2d 236, 239 (10th Cir. 1979) (applying Oklahoma law) (what is material, not custom, is the standard of care); McNeill v. United States, 519 F.2d 283, 288 (D.S.C. 1981) (applying Federal Tort Claims Act and South Carolina law) (geographical standard of care, if it exists, is not conclusive). See Keeton et al., supra note 115, § 32 at 188, 191, 194-96; see also Keeton et al., supra note 121, § 32 at 30.
hospitals, physicians, or patients. Their three trade associations are in regular contact with each other, the CDC, the FDA, and other cognizant federal agencies. These organizations can disseminate new risk information quickly to member banks through bulletins, annual meetings, and continuing education workshops. Most of these groups were involved in the series of meetings that spread information about AIDS in 1982-1983; non-A, non-B hepatitis in 1985-1987; HTLV-I and HTLV-II in 1988; parasites in 1989; and HIV-2 and bacterial infections in 1990.

Blood bankers know that their early information about transfusion threats is superior to that of hospitals, physicians, and patients. They also know the extent to which contaminated blood injures a human being. They know that hospitals, physicians, and patients rely on them to provide blood that is safe. They know that donors in certain groups and some geographical areas are at greater risk for disease, and they know that their knowledge about viral risks is superior to that of donors. They know that they can discover viral defects in blood at a cost below that of anyone else in the process. They know which tests detect various agents or their markers and that they can learn at relatively low cost which tests are cost-effective. They know that the blood they ship to hospitals will be put to its intended use and purpose. They know that the condition in which it was collected and shipped usually will not be altered. They know it will be used without inspection for viral defects by patient or physician (who are not qualified to inspect it anyway). They know that when faced with a prospective epidemic, the productivity of early precautions is high.

Industry custom in blood banking rarely emerges from experimentation and emulation by independent competitors. Minimum standards are set by the FDA, which relies heavily on industry experts.

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151. Plaintiffs who sue donors for negligence (in addition to hospital and blood banks) do not have a cause of action against the donors unless the donors knew or had reason to know prior to donation that they were infected. Hubbell v. South Nassau Communities Hosp., 46 Misc. 2d 847, 260 N.Y.S.2d 539 (1965).

152. Alteration of a product by the consumer is a defense available to the manufacturer. For example, a consumer who tethered the rear legs of a ladder without the manufacturer's approval and used it on soft ground contrary to instructions that were printed on the ladder could not recover for injuries. Erickson v. Sears, Roebuck & Co., 240 Cal. App. 2d 793, 50 Cal. Rptr. 143 (1966). Normally blood is used in the state that it is supplied by the blood center, although occasionally it is manipulated at the hospital laboratory to reduce the threat of dangerous reactions.

153. For the same point concerning liability generally, see Eckert & Smith, supra note 126.
for advice. The AABB sets its own standards and accredits members, and since 1983 the three blood-collecting organizations have jointly set policy on matters that affect their liability for transfusion AIDS. Individual blood banks appear to have delegated control over certain care levels—and thus over transfusion risks—to the three blood-collecting organizations jointly in a manner similar to that of the blasting-cap manufacturers in *Hall*. The AABB’s counsel has stated that professional standards are “[t]he most obvious place [for a court] to look for the rules.” The AABB says that its accreditation program “provides a measure of protection” against lawsuits. One might conclude that its standards are chosen at least partly with regard to liability.

The basis for giving blood-banking organizations so much influence is that their information about risk and care levels is superior to that of any single blood bank or anyone else. In AIDS litigation, which I describe *infra*, defendant blood banks have argued that industry custom should be the standard of due care. That is tantamount to arguing that the group that sets industry standards has expert status and superior information about risk. Industry custom may be a reasonable rule if consumers and suppliers have identical information, but clearly that is not the case for transfusion. Whether the industry set cost-effective care levels early in the epidemic when they would have been most effective can be determined only after a factual inquiry such as in *The T.J. Hooper* or *Marsh Wood Products*. Whether the industry exercised joint control over risk as in *Hall*, and issued adequate early warnings as in *Canifax*, also can be determined only after a factual inquiry (which I discuss in Section V).

### IV. The Blood Cases

Blood cases are complex because causation is difficult to discover and establish. Obvious symptoms of hepatitis, if they appear at all, can take several months to develop. Meanwhile the patient could be exposed to more virus through other transfusions, skin cuts, travel to high-risk areas, or other contacts. Symptoms of HIV infection take years to develop, and some transfusion patients may belong to other high-risk groups. Certain groups of donors are more likely to transmit either hepatitis viruses or HIV. Specific laboratory tests for viruses in blood banking are rare, and indirect or surrogate tests—including those for antibodies—have error rates. It may be difficult to show in court that such a test could have prevented an infection.

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AIDS Blood-Transfusion Cases
SAN DIEGO LAW REVIEW

A. Pre-AIDS Cases

The standards for transfusion liability that were applied to AIDS cases in the 1980s emerged in cases of transfusion hepatitis in the 1960s and 1970s. These cases have been analyzed elsewhere. My discussion emphasizes that courts in some states without “blood shield laws” held blood banks strictly liable owing to their superior information about risk. That led blood banks to lobby for and secure statutory shields nationwide.

1. Implied Warranty

The first exemption from implied warranty occurred in a 1954 New York action, Perlmutter v. Beth David Hospital. Under implied warranty a seller is liable for harms from goods that are not of merchantable quality or fit for their intended purpose. The plaintiff sought recovery for damages from hepatitis on the theory that it was a sale under New York sales law for a hospital to supply her with tainted blood for a separate fee. She claimed that defendant knew the purpose for which the blood would be used, that she relied on defendant’s skill and judgment in supplying safe blood, and that the sale triggered the implied warranty imposed by the statute. The hospital moved to dismiss on the ground that the transaction did not constitute a sale. The New York Supreme Court denied the motion, and its appellate division affirmed. But the New York Court of Appeals reversed. What the patient had bargained and contracted with the hospital to provide, the court said, was medical services that were exempt from implied warranty. The medicines, drugs, or blood she received were not separate sales transactions and were “incidental to” and “not divisible” from her medical treatment. Moreover, no blood tests were available in 1954 to detect hepatitis viruses, and plaintiff did not allege negligence. Making the hospital liable regardless of fault, the court held, would be tantamount to making it an


Perlmutter was a four-to-three decision, and it was not clear that it would be followed. Accordingly, associations of blood banks, hospitals, and physicians began to lobby legislatures for statutes that declared blood to be a "service" rather than a product or a sale, which was exempt from implied warranty. By 1965 three states had enacted exemptions.168

By 1966 four jurisdictions had adopted Perlmutter for hospitals and two jurisdictions extended it to blood banks that furnished blood to the hospitals for a separate fee.169 The Perlmutter majority was more sensitive to factual distinctions than were the courts that extended it to blood banks. Hospitals have higher costs of screening donors and testing blood than blood banks. Accordingly, the Perlmutter majority made a reasonable decision for a hospital under either a strict liability or a negligence standard, and presumably would have recast its argument had a blood bank been the defendant.160 Nevertheless, a narrow ruling for a hospital was extended to cases with different facts and triggered heavy lobbying by blood banks for shield laws.

Florida courts were the first to reject extending Perlmutter to a blood bank. In an important 1966 case, Russell v. Community Blood Bank,161 the facts, plaintiff's theory of recovery, and trial court holding were essentially the same as in Perlmutter. Florida had neither a shield law nor a common-law case in point. The Florida District Court of Appeal, reversing a motion to dismiss, held that "[i]t seems to us a distortion to take what is, at least arguably, a sale, twist it into the shape of a service, and then employ this transformed material in erecting the framework of a major policy decision."162 The court argued that the rationale underlying Perlmutter and other cases denying liability was not the sales-service distinction. It was whether public policy should hold hospitals or blood banks liable for defective blood that was "unavoidably unsafe" owing to the presence of viruses that were undetectable with existing laboratory tests.163

The Restatement published the previous year raised the issue of whether or not a product was "unavoidably unsafe."164 Restatement

158. Franklin, supra note 139, at 475 n.204.
160. The Blood Transfusion Association, possibly a blood bank, was a third-party defendant to the action, but the hospital was the appellant and the majority and dissenting opinions address only the issue of the liability of a hospital. See Perlmutter v. Beth David Hosp., 129 N.Y.S. 232, 123 N.E.2d 792 (N.Y. 1954).
162. Id. at 752.
163. Id. at 752-53.
section 402A assigns strict liability to the seller for physical harm caused by defects whether the product is processed or is supplied untreated in its natural state (like uncooked, untreated poisonous mushrooms). A defective condition "may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product." The product must "reach the user or consumer without substantial change in the condition in which it is sold" and without subsequent mishandling or alteration by the consumer. Restatement comment k exempts such "unavoidably unsafe" products as prescription drugs or vaccines with dangerous side effects for some persons in spite of proper preparation and warnings. A properly prepared product is one for which the manufacturer has made all expenditures on safety that are justified by the gains to society from reduced accidents. If warnings are adequate, then consumers assume remaining risks.

The Florida District Court of Appeals held that a blood bank could be subject to implied warranty, but it could use comment k as a defense by proving that the particular defect was undetectable and unremovable. On appeal, the Florida Supreme Court agreed that the plaintiff had stated a cause of action in implied warranty and that the motion to dismiss was rejected correctly. But it held that it was premature for the court of appeals to delve into the matter of whether hepatitis viruses were detectable. Whether a method of detection existed and whether it would constitute a legal defense were questions of fact that should not be settled by a pronouncement of law.

In an important concurring opinion, Justice Roberts argued that blood containing undetectable hepatitis virus was adulterated and unreasonably dangerous, not unavoidably unsafe. He distinguished the case of a retail druggist who was sued by a patient for the harmful effects of a prescription that the druggist filled with a prepackaged drug. Under comment k the druggist could not be liable for

165. Restatement (Second) of Torts § 402A cmt. e.
166. Id. cmt. h.
167. Id. § 402A(1)(b) cmt. g.
168. Id. cmt. k.
171. Id. at 118-21 (Roberts, J., concurring).
breach of implied warranty as long as the drug was unadulterated.\textsuperscript{172} The druggist could have done nothing to reduce liability. Sellers are not liable for useful and desirable products, Justice Roberts argued, that are “attended with a known risk to the consumer,” as long as they are properly prepared with adequate warnings. But manufacturers of adulterated products that “produce a harmful effect upon any consumer” —such as toxins in tinned meats or nails in paper-wrapped candy bars—were liable under implied warranty whether or not they could have known of the defect.\textsuperscript{173} Blood containing viruses that were dangerous to any consumer was adulterated, Justice Roberts maintained (and, I might add, more dangerous than nails in a wrapped candy bar), and an exception to the rule could be created only by the legislature.

The Florida Legislature did enact a shield law, but Florida courts applied the \textit{Russell} rule to pre-existing cases. A hospital operating a blood bank that transfused infective blood was liable for breach of warranty similar to that of a regular blood bank.\textsuperscript{174} In 1973 the Florida Supreme Court adopted Justice Roberts’s rejection of the comment \textit{k} defense by a blood bank.\textsuperscript{175} Appellate courts in three other states held that whether a recognized method to detect hepatitis viruses was available was a factual issue to be settled at trial and that it was erroneous for trial courts to decide it with a pronouncement of law.\textsuperscript{176} But many more jurisdictions held that detectability mattered, thereby avoiding \textit{Restatement} strict liability judicially.\textsuperscript{177}

\begin{itemize}
  \item \textsuperscript{172} McLeod v. W. S. Merrell Co., Division of Richardson-Merrell, Inc., 174 So. 2d 736 (Fla. 1965).
  \item \textsuperscript{174} Mercy Hosp. v. Benitez, 257 So. 2d 51 (Fla. Dist. Ct. App. 1972) (per curiam).
  \item \textsuperscript{175} Rostocki v. Southwest Blood Bank, 276 So. 2d 475, 476-77 (Fla. 1973).
2. **Strict Liability in Tort**

Strict liability emerged in a 1970 hepatitis case in Illinois, *Cunningham v. MacNeal Memorial Hospital.*[^178] The trial court granted the hospital summary judgment on the ground that strict liability in tort, which the Illinois Supreme Court adopted in a 1965 automobile case, did not apply to blood. The appellate court reversed, and the supreme court affirmed. It held that unaltered but dangerous blood, as with untreated poisonous mushrooms, was a product under *Restatement* section 402A. "There can be no question," the court said, "that blood containing hepatitis virus is 'in a defective condition unreasonably dangerous to the user or consumer.'"[^179] The court expressly followed *Russell* even though ten jurisdictions had adopted *Perlmutter* for hospitals or blood banks and legislatures in some twenty-five states had enacted shield laws. It held that supplying infective blood for consideration was a sale that made the blood bank or hospital strictly liable. It recognized the factual difference between hospitals and blood banks, but held that a hospital was in the chain of distribution even if providing blood was only part of its total service.[^180]

Following the concurring opinion of Justice Roberts in *Russell*, the Illinois court rejected the *Restatement's* comment k defense. It held that the "unavoidably unsafe" exception was limited to "products which are not impure and which, even if properly prepared, inherently involve substantial risk of injury to the user." Whether or not viruses were detectable was "of absolutely no moment." The consequences of injury from dangerous blood should not "fall upon the individual consumer who is entirely without fault"[^181] (or, I would add, information).

After *Cunningham* blood banks, hospitals, and physicians in 1971


[^179]: 47 Ill. 2d at 492, 266 N.E.2d 897, 901.

[^180]: Id. at 492, 266 N.E.2d 897, 903-04.
obtained a shield law from the Illinois Legislature.\textsuperscript{182} In 1971 a shield against any civil liability save negligence was enacted in Washington State.\textsuperscript{183} An action for damages from hepatitis, \textit{Reilly v. King County Central Blood Bank, Inc.},\textsuperscript{184} was brought before the effective date of the statute. The trial court granted summary judgment for the blood bank. But the Washington Court of Appeals, following \textit{Cunningham}, held that a nonprofit blood bank supplying blood for a fee was a sale subject to strict liability in tort. By 1972 forty-one states had statutes declaring blood to be a service rather than a product or exempting it from strict liability in either contract or tort.\textsuperscript{185}

In a 1981 action for hepatitis against a Louisiana hospital and blood bank, \textit{DeBattista v. Argonaut-Southwest Insurance Co.},\textsuperscript{186} the trial court granted defendant’s motion to dismiss. It found no causation or negligence, and the Louisiana Civil Code exempted blood banks from implied warranty.\textsuperscript{187} The court of appeals affirmed, but a split Louisiana Supreme Court reversed. The civil code provision defining blood as a medical service exempt from implied warranty of merchantability and fitness, the majority held, did not govern the tort liability of blood banks. Evidence regarding the cause of plaintiff’s hepatitis was circumstantial but sufficient to indicate that the transfusion was the cause.\textsuperscript{188} At the time tests for hepatitis B were

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  \item \textsuperscript{182} Franklin, \textit{supra} note 139, at 475 n.205.
  \item \textsuperscript{183} Garvey v. St. Elizabeth Hosp., 103 Wash. 2d 756, 757, 697 P.2d 248, 249 (1985).
  \item \textsuperscript{184} 6 Wash. App. 172, 174, 492 P.2d 246, 248 (Wash. Ct. App. 1971) (en banc).
  \item \textsuperscript{185} Franklin, \textit{supra} note 139, at 474-76.
  \item \textsuperscript{187} Juneau v. Interstate Blood Bank, 333 So. 2d 354 (La. Ct. App.), \textit{cert. denied}, 337 So. 2d 220 (La. 1976) (exemption of blood bank from strict liability for implied warranties was constitutional).
  \item \textsuperscript{188} This case illustrates the occasional complexities of showing causation for viral transfusion disease. Mrs. DeBattista was given three units of blood on Feb. 14, 1973, had hepatitis B symptoms one month later, and was hospitalized for severe hepatitis after one more month. The test for hepatitis B antigen on one of her donors was negative, but he was rejected when he tested positive on attempting to donate sixty days later. It was subsequently learned that he was schizophrenic and had lied about a history of syphilis at the first donation. Mrs. DeBattista’s sister had contracted hepatitis B by transfusion at the same hospital one year earlier and the two visited regularly thereafter. Mrs. DeBattista’s severe hepatitis symptoms emerged about the same time as her donor’s attempt to donate a second time. The trial court found no negligence by the blood bank and did not expressly determine whether her hepatitis was transmitted by transfusion. The court of appeals, taking into account her sister’s hepatitis and the possibility that her donor could have been infected between the first and second visits to the blood bank, held that the plaintiff failed to establish causation by a preponderance of the evidence. The Louisiana Supreme Court, noting that the court of appeals may have reversed the trial court’s “implicit factual finding,” reconsidered the evidence and reversed because the transfusion was “the most reasonable cause” of her disease. \textit{DeBattista v. Argonaut-Southwest Ins. Co.}, 385 So. 2d 518, 521 (La. Ct. App. 1980), \textit{rev’d}, 403 So. 2d 26, 28-29 (La. 1981).
\end{itemize}
only thirty percent effective, so the issue was whether the blood bank was liable without a finding of negligence.

The supreme court adopted the Restatement's definition of strict liability that already was established in Louisiana products liability law. "'Unreasonably dangerous' means," the court said, "simply that the article which injured the plaintiff was dangerous to an extent beyond that which would be contemplated by an ordinary consumer" having "the ordinary knowledge common to the community as to its characteristics." Hepatitis-contaminated blood is unreasonably dangerous because "[t]he risks involved in receiving a transfusion of blood in this condition are certainly greater than a reasonable consumer would expect."189 That view is consistent with the blood bank's lower costs of discovering defects. But the legislature "overruled" the court's opinion "within weeks" after it was rendered and before it was published. Blood banks were exempted from "[s]trict liability or liability of any kind without negligence" for disease transmitted by "any infectious agent undetectable by appropriate medical and scientific laboratory tests."190

It is clear that courts in four states, absent shield laws, would have held blood banks strictly liable in either contract or tort. But strict liability for blood banks in even a few states also affects banks in other states that sell, barter, or exchange with them. AABB's counsel observed in 1985 that

AABB's executive director acknowledged that "blood banking enjoys protection unique to any other product or industry in the world [sic]. As far as I know, there is no other product that is immune from

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strict liability."¹⁹² By mid-1990 blood bankers had obtained statutory shields in all but one state.¹⁹³

3. Negligence

Numerous jurisdictions during the pre-AIDS era declared that blood banks or hospitals were not exempt from negligence in principle.¹⁹⁴ But as a practical matter they were, as long as their conduct at the time was consistent with the standard of professional care.¹⁹⁵ Courts defer to other professions as a rule,¹⁹⁶ so blood banks were not held to the usual negligence criterion—the "reasonable man" or cost-benefit standard—of what an ordinarily prudent person would have done in similar circumstances.¹⁹⁷

Post-transfusion hepatitis was common before AIDS,¹⁹⁸ but the literature reveals fewer than a dozen appellate cases in negligence. A licensed blood bank could be held negligent if it could not show that it followed FDA minimum rules and its own standard operating procedures in asking donors about their health and risk factors.¹⁹⁹ Warning physicians about hepatitis risks in printed messages on blood containers and in circulars distributed to hospitals was held to

¹⁹². Statement of Gilbert M. Clark, in Legal Issues in Transfusion Medicine, supra note 54, at 110; Franklin, supra note 139, at 475 n.205.
¹⁹³. See supra note 8.
¹⁹⁶. See supra note 115 and accompanying text.
¹⁹⁷. United States v. Carroll Towing Co., 159 F.2d 169 (2d Cir.), reh'g denied, 160 F.2d 482 (2d Cir. 1947).
¹⁹⁹. See cases cited supra note 194.
be adequate. Three courts held that physicians did not have to warn patients of hepatitis because the risk of death was "relatively minor." One jurisdiction held that a blood bank could use the Restatement's comment k defense if it had warned physicians by the best methods then known.

Blood banks were not negligent if they tested according to the AABB and FDA standards. Plaintiffs could not establish a standard of care with testimony from one or two experts who favored using additional routine tests. In 1973 a Montana blood bank was held not negligent in failing to use a surrogate test for hepatitis that measured certain liver abnormalities (called SGOT). The blood bank established that it had followed the AABB and FDA rules, that no blood bank in the country used the test routinely, that no professional group ever recommended the test for that purpose, and that, in spite of controversy over its utility, industry experts concluded it was not a useful or meaningful test for screening blood donors.


205. Id. at 361, 506 P.2d 449, 452. Montana subsequently exempted blood banks from liability if they used the tests according to the latest AABB recommendations. MONT. CODE. ANN. § 50-33-104 (1987), cited in Comment, Hospital and Blood Bank Liability to Patients Who Contract AIDS Through Blood Transfusions, supra note 156, at 890 n.75.
B. The AIDS Cases

The statutory and case law that emerged in the era when hepatitis was the worst transfusion disease was extended to AIDS. Statutory shields remained intact for strict liability. Following FDA minimum rules and industry custom usually remained the standard of due care in negligence actions.

I. Strict Liability

Case law in six states and the District of Columbia has held that blood that transmits AIDS is not a product for the purpose of strict liability in contract or tort. The District of Columbia never had a

206. I followed approximately 136 lawsuits from published opinions, newspaper accounts, and the pleadings, judgments, orders, and memoranda published in the AIDS Litigation Reporter through Apr. 10, 1992. I focused on 32 cases (24%) against private, nongovernmental blood banks (or hospitals that operated their own blood banks or provided blood banking services) that were disposed of either on summary judgment or after a trial. I eliminated 10 cases (7%) that were settled without making public the details. I also ignored cases that defendants won because of expiration of timely claims under statute of limitations. I confined the study to plaintiffs whose only risk for AIDS, based on the documents I read, was the transfusion of blood or components, each unit of which was collected from a donor at a blood bank. That eliminated another 30 cases (22%) in which the plaintiff had a history of transfusions of blood derivative products for a chronic coagulation disorder and sued the manufacturer. These products are prescription medicines made in batches from pooled plasma often from thousands of donors. Persons with lifelong clotting disorders may ingest products from multiple batches of several manufacturers. Another factual distinction between the blood products cases and the blood bank cases is that manufactured products can be heated to kill viruses without destroying the product's effectiveness. When manufacturers began heating procedures is an issue raised in actions against them but not in actions against blood banks. See Note, Hepatitis, AIDS and the Blood Product Exemption from Strict Products Liability in California: A Reassessment, supra note 156; Comment, Strict Liability for Blood Derivative Manufacturers: Statutory Shield Incompatible with Public Health Responsibility, supra note 156.


statutory shield for hepatitis or AIDS. Its common-law hepatitis shield for hospitals emerged in a 1979 case. The trial court, following Perlmutter, granted the defendant summary judgment on theories of strict liability in contract and tort. The District of Columbia Court of Appeals affirmed on the basis of the Restatement's comment k defense concerning the undetectability of the hepatitis virus. It also made the policy judgment that screening donors too carefully could harm "the public interest in assuring the ready availability of blood." In 1987 the shield was extended to blood banks in Kozup v. Georgetown University. The United States District Court for the District of Columbia held that the shield for hospitals applied logically to blood banks "with equal if not greater force." The AIDS-causing agent had not been scientifically identified by the time of transfusion in this case, so comment k, the court held, applied equally to AIDS and hepatitis. Judgment for the blood bank also kept the law tidy. "This result is consonant with that of nearly every jurisdiction, and avoids the aberrational result that the [American Red Cross] would be strictly liable in the District of Columbia for conduct that would not be actionable in 49 of our 50 states." In 1989 the Maryland Court of Appeals ruled on questions certified from the United States district court concerning a strict liability action for AIDS from a 1983 transfusion. In 1986 Maryland's shield for hepatitis was amended to insulate blood from strict liability in contract or tort "for injection or transfusion into an individual for any purpose," which was characterized as a "service." The court of appeals refused to construe the 1986 amendment retroactively since the intent of the legislature was unclear. But in 1976 Maryland courts had adopted Restatement section 402A in an automobile case. By implication, the court held, Maryland courts also adopted the

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209. Id. at 1133-34. The court rejected the use of implied warranty in Russell on the incorrect presumption that the blood bank was a commercial organization. Id. at 1132. See Community Blood Bank v. Russell, 196 So. 2d 115, 120 (Fla. 1967).
comments to section 402A. The 1986 amendment was “tantamount to legislative acceptance of the basic substance of Comment k” as long as blood was tested by the highest known standards. “[M]anifestly,” the court held, “the seller was not in a better position than the victim, or the victim’s physician, to take precautions against the unknowable defect in the product.”

Although most jurisdictions have allowed blood banks to use the comment k defense in either strict liability or negligence actions, I would argue that it was done without understanding the heart of the transfusion information problem. For example, the Maryland Court of Appeals, in the passage just quoted, concluded that the information about transfusion risks available to physicians was no better than that available to blood bankers. I argue that both logic and the behavior of blood bankers suggest that they have lower information costs both about ways to screen out higher-risk donors and about how to test blood most effectively. Although viruses themselves were undetectable, blood bankers knew of indirect tests for abnormalities associated with viral infection that would reject at least some dangerous donors. Such tests are feasible, whether or not their use is customary. Moreover, blood is shipped to the hospital in essentially its natural state and usually is transfused without alteration. A Circular of Information about risks is sent by blood banks to hospitals and physicians, not the other way around. Justice Roberts correctly argued in 1967 for limiting comment k to unadulterated, properly prepared drugs or other products with adequate warnings that remain dangerous to some persons, and for not applying it to infective blood that is dangerous to everybody. Comment k weakens the incentives of blood bankers to compare the costs and benefits of more careful screening and testing.

2. Negligence

Whether blood banks screened donors, tested blood, and warned physicians with sufficient care before the anti-HIV test was licensed

213. Id. at 704, 733, 556 A.2d at 1107, 1121. See also Howell v. Spokane & Inland Empire Blood Bank, 114 Wash. 2d 42, 785 P.2d 815 (1990) (en banc).

214. My argument here is limited to the issues raised in these cases. But contaminated blood in one sense may not be different from, for example, a properly prepared prescription drug with serious side effects for some consumers. Just as blood banks have relatively low costs of reducing transfusion risks by screening donors or testing blood more carefully, so drug manufacturers probably have relatively low costs of identifying characteristics of high-risk consumers (such as those who smoke cigarettes or take certain other prescription drugs) by spending resources on further research and testing. If the Restatement’s comment k distorts the incentives of manufacturers to test, then they may not supply the additional warnings needed to protect certain consumers, thereby making “properly prepared” products riskier.
in March 1985 has been their greatest potential liability. In seventeen of the twenty-three cases in my sample that raised these issues, blood banks prevailed—seven on summary judgment\(^{215}\) and ten after trials (nine of them to juries).\(^{216}\) They lost four screening and testing


cases after trials. They won three cases arising from failure to cooperate with plaintiffs’ request for a directed donation.

The ANRC lost a summary judgment motion that was later vacated as moot. They won three cases arising from failure to cooperate with plaintiffs’ request for a directed donation.
They lost two of three for failing to recall untested units in hospital inventories when routine anti-HIV testing began. The usual standard of due care in the AIDS cases, as with the hepatitis cases, was industry custom and FDA rules.

3. The Kozup Case: Warning, Screening, and Testing

*Kozup v. Georgetown University* was the first transfusion AIDS case to be decided, and it became an important precedent. The case was a diversity action in the United States District Court for the District of Columbia. Matthew Kozup was given three transfusions on January 12-13, 1983, at two days of age. The blood was donated to the ANRC in October 1982 by an individual who appeared healthy at the time but died later of AIDS. Matthew died at age five, allegedly of AIDS complications. His parents sued the hospital for battery and the hospital and ANRC jointly for negligence. They alleged that defendants should have realized on January 12, 1983, that AIDS was a transfusion risk and that defendants negligently failed to obtain informed consent, to screen and test blood adequately, or to suggest a directed donation. The district court granted defendants' motion for summary judgment on all counts. The Court of Appeals for the District of Columbia Circuit reversed and remanded on the battery count only.

categories. See *supra* note 216.


222. The district court's opinion did not state the date of the donation. Even if it was October 31, 1982, the unit would have been about ten weeks old and therefore out of date by today's FDA rules if transfused on January 12-13, 1983. Judging by the opinion, this issue was not raised in the case.
The district court’s decision was premised on what I see as four serious errors: (1) a factual error concerning the risk of transfusion AIDS in early 1983; (2) an error in determining causation; and (3) an egregious factual error made (4) in applying the wrong negligence standard.

The district court dismissed the informed consent and battery counts because AIDS was not a “material” risk that physicians were required to warn of in January 1983. Under the material risk rule of Canterbury,

As of January, 1983, only a single case of possible transfusion-related AIDS had been diagnosed [in a patient without other risk factors], and that only weeks before Matthew received the contaminated blood. This single case stands in contrast to the approximately 3.5 million blood donations [sic] annually. A risk of one in 3.5 million cannot be said to be material to a reasonable patient in Matthew Kozup’s situation.

The court found that a professional consensus that AIDS was transmissible by blood was not reached until January 1984, when two studies linking several AIDS patients with donors having AIDS blood abnormalities were published in medical journals.

Thus, what doctors “knew or should have known” about the risk of AIDS in blood transfusion therapy [in January 1983] was virtually nothing: this remote possibility cannot, as a matter of law, have amounted to a “material risk” within the meaning of that term as set forth in Canterbury.

The court held that no reasonable jury could conclude on the facts that, had the Kozups been informed of a “one in 3.5 million possibility of contracting AIDS,” any reasonable person in their position would have refused transfusions that were absolutely necessary to save their child’s life.

223. See supra notes 144-46 and accompanying text.

224. Kozup v. Georgetown Univ., 663 F. Supp. 1048, 1053 (D.D.C. 1987) (citation omitted). Twice the district court confused transfusions with donations. At one juncture it stated that “some 10,000,000 transfusions had been performed in 1982.” Id. at 1052. Later it said that in 1982 there were “approximately 3.5 million blood donations annually.” Id. at 1053. Although the numbers of transfusions and donations are not known precisely, it was reported circa 1983 that about 3.5 million persons were transfused each year and that the average transfusion consisted of 3-4 units, so the number of units donated was perhaps 10,000,000. AMERICAN BLOOD COMMISSION. FACT SHEET: BLOOD AND ITS USE, cited in Eckert, supra note 22, at 1 n.1.

225. Kozup, 663 F. Supp. at 1054. The district court held that under the “learned intermediary rule” ANRC owed a duty to warn physicians only. Plaintiffs had no right to be informed by hospital physicians of AIDS risks in January 1983, so whatever information ANRC gave the hospital about AIDS was held to be “irrelevant” to the Kozups’ choice. Id. at 1054-55.

226. Id. at 1054. Whether a reasonable parent would have rejected transfusions in these circumstances, the Court of Appeals for the District of Columbia held, was the standard for summary judgment for the tort of lack of informed consent but, in the absence of any consent whatsoever, not for battery. A trial was required to determine if the transfusions were necessary to save Matthew's life and whether his parents had given
To determine what risk was material under Canterbury, the district court made an apples-oranges comparison between a known surgical risk of one percent and the unknown risk in early 1983 of what was likely to be an infectious disease. The working hypothesis since mid-1982 was that AIDS, as with hepatitis B, was transmitted through sex, drug abuse, and blood by a virus or other infectious agent. All infectious diseases have incubation periods in which carriers are asymptomatic. If AIDS was infectious, then the court should have understood that physicians would realize—and most heads of blood banks are physicians—that the true risk in early 1983 exceeded one in 3.5 million. And it did. A 1984 study showed that five other cases had been diagnosed by December 1982. Moreover, the risk of AIDS on January 12-13, 1983, should have been greater than in mid-1985 when the ANRC published the risk estimate that appears in Table 1. On that basis the district court’s estimate of the January 1983 risk at “one in 3.5 million” was too low by 1,330 times. This is hindsight information, but it was published before the Kozup decision was rendered.

The district court also erred in analyzing causation. The Kozups alleged that the ANRC should have screened high-risk donors and tested for surrogate markers of hepatitis infection. Surrogate tests are important in AIDS litigation for two reasons: first, because AIDS and hepatitis have parallel risk groups, and second, because on January 4, 1983, the CDC recommended that blood banks use one of the tests—eight days before Matthew Kozup’s transfusion. Evidence from key CDC officials about why they recommended that surrogate test would be important to plaintiffs, but the federal government has prohibited them from being deposed in all but one case.

Apparently stored blood samples indicated that Matthew’s donor would have been negative at the time of donation on the surrogate test that the CDC recommended. “Thus, the critical element of causation,” the court held, “wherein plaintiffs must show that the consent for them. Kozup, 851 F.2d at 439-40.

227. Curran et al., supra note 85, at 72.
228. See supra note 90 and accompanying text and infra Appendix.
229. See supra notes 75-77 and accompanying text and infra Appendix.
230. The Department of Health and Human Services may prohibit testimony if the number of requests would prevent CDC officials from doing their job. The CDC provides plaintiffs with the documents they request, but remains neutral. Moore v. Armour Pharmaceutical Co., 129 F.R.D. 551, 555 (N.D. Ga. 1990).
ARC's failure to implement this test caused Matthew to become infected, is absent." Whether the donor would have been negative on the test that plaintiff claimed ANRC should have used became "the critical element of causation," without which, the court held, plaintiff's case faced an "insurmountable hurdle." In effect, the court converted a rule requiring a preponderance of the evidence—that the existence of a contested fact was more likely than not—to a rule requiring that the contested fact be a certainty before a blood bank could be negligent for failing to use the test. Apparently the court did not understand that medical tests have error rates and that there was some probability of obtaining a false negative on this test.

Plaintiffs claimed that the industry, by not using surrogate tests, had not adhered to the "standard of reasonable prudence" required in The T.J. Hooper and its precedents. The district court expressly rejected the Holmes-Hand rule because it would amount to holding the ANRC to "a unique super-standard" and to abandoning "[t]raditional yardsticks of negligence such as industry practice or the standard of care of a reasonable practitioner." To make what would have been non-negligent conduct for other blood banks negligence for the ANRC would be "unfair and impractical." The court did not discuss whether the test would have identified a sufficient number of infectious persons to be worthwhile for the industry to adopt, i.e., whether it would have passed a cost-benefit test. The standard in Marsh Wood Products was to test each batch of steel, not all boiler tubes from each batch or a particular tube. Blood is not a batch product, so each unit must be tested individually, but the logic of testing for contaminated blood is the same as for defective steel. Although individual errors may occur, the issue is whether enough contamination is detected to justify the expense.

Rejecting the Holmes-Hand rule led the district court to ignore evidence about which experts had the best information about transfusion risks. Scientists specializing in epidemiology are likely to have superior information about the nature of epidemics than are blood bankers or anyone else. The CDC, with federal responsibility for epidemiology, was so concerned about transfusion AIDS risks in January 1983 that it warned the industry and urged precautions publicly. Physicians routinely rely on the CDC for information about disease risks, but the Kozup court, by adopting custom as the standard of due care, treated the CDC's view as no more important than anyone else's.

If custom was the standard of due care, then the district court had

232. Id. at 1057-58; see supra notes 93, 95 and accompanying text.
233. 240 N.W. 392 (Wis. 1932). See supra notes 106-08 and accompanying text.
to determine when custom changed. Accordingly, it prepared a chronology of how it believed professional opinion changed from the year before Matthew's transfusion to the year after. Matthew's donor visited the blood bank in October 1982, three months before CDC recommended surrogate testing. No organization of blood bankers, hospitals, or federal health-care regulators recommended surrogate testing in October 1982. "The medical community," the court said, "was not yet convinced that AIDS had an asymptomatic carrier state, a necessary predicate to a conclusion that AIDS might be transmissible by blood." The suspected transfusion cases before October 1982 "lent support only to an hypothesis about the cause or transmission of AIDS. They were far from sufficient to permit any conclusions."234

The court's most egregious error was failing to notice that a Public Health Service interagency group, in a document of March 4, 1983, which the court cited in its opinion, concluded that "[a]vailable data suggest that . . . AIDS is caused by a transmissible agent" and "[t]he likelihood of blood transmission."235 In April 1983 a Department of Health and Human Services press release said that "[a]lthough the cause of AIDS is not known, researchers believe it is transmitted by an infectious agent."236 These facts suggest the likelihood that a medical consensus emerged before January 1984. The court's error affects several cases for transfusions after March 1983 in which other courts relied on the Kozup chronology.

Other publications reinforce the likelihood that a consensus emerged before January 1984. One of the two papers on which the court relied was accompanied by an editorial by a blood-banking expert, which the court did not cite, stating that "[a]lthough the data from the [CDC] were not published until today, they had been extensively discussed, and the concept that AIDS may be spread by transfusion has been with us for over a year."237 That expert later said in another publication that cases in high-risk groups reported in 1981 and 1982 "provided the beginning evidence that AIDS could

234. Kozup, 663 F. Supp. at 1056. Two experts testified that blood banks should have used the surrogate test, but they did not advocate it in January 1983, and one of them attended the Atlanta meeting where the CDC recommended it. "These two individuals' opinions," the court said, "cannot alone create a standard of care or a prima facie case of negligence, where they are entirely in opposition to the standard prevailing at every hospital and blood bank in the nation." Id. at 1057.
235. See supra note 80 and accompanying text.
237. Bove, supra note 85, at 116. See also Curran et al., supra note 85.
be related to a viral agent that was capable of contaminating the national blood and plasma supply.\textsuperscript{238} That paper was published a year before the Kozup decision.

The core question, which Kozup and subsequent decisions have ignored, is why the experts in blood banking and the FDA were so slow to agree with the CDC. Another way of asking that question is to ask what their statistical decision rule was for adopting a new precaution. Two hypotheses were possible. The null hypothesis was that AIDS was not caused by a blood-borne agent and therefore that no additional precautions were necessary. The alternative hypothesis was that AIDS was caused by a blood-borne agent and additional screening and testing was necessary. Assume blood bankers demanded sufficient evidence so that they would reject the null hypothesis mistakenly—what statisticians call a Type I error—no more than 5 percent of the time. That is, if the events in question were repeated they would arise by chance only once in twenty times. A .05 decision rule is weighted in favor of taking no action. It is a common rule, but it is not sacrosanct. The choice of a rule depends on the type of error that the decision maker wishes to minimize.\textsuperscript{239} For example one might choose a significance level of .10 or .20 if the potential cost to society of rejecting the null hypothesis mistakenly was extremely high. None of the documents I have seen indicates what the decision rule of the blood bankers and their regulators was, but they must have had one. They understand statistics and routinely deal with laboratory tests for which the probabilities of false-positive and false-negative errors are calculated.\textsuperscript{240}

The industry and the FDA chose “not testing” as the null hypothesis, and then chose a demanding criterion for rejecting it. It is not clear whether the industry and the FDA honestly disagreed with the CDC over the probability that AIDS was a blood-borne virus, or whether they agreed on the probabilities but had different attitudes toward gambling. Blood banks could have hedged the risk by recalling units shipped to hospitals before January 1983, recommending that transfusions be limited to emergencies until inventory was tested

\textsuperscript{238} Bove, supra note 77, at 140. The public had a better appreciation of the cause of the epidemic than some experts. A national news magazine reported in July 1983 of “the growing realization that this mysterious killer ... is transmitted through blood,” and that “[s]cientists suspect that AIDS is caused by a new virus or virus particle or an old agent that has changed and become virulent.” The infectious-agent hypothesis was the only causation hypothesis that the article reported. \textit{As AIDS Scare Hits Nation's Blood Supply—}, supra note 89, at 71.


\textsuperscript{240} See, e.g., Ward et al., supra note 10, at 477; Stephen L. Sivak & Gary P. Wormser, \textit{Predictive Value of a Screening Test for Antibodies to HTLV-III}, 85 AM. J. CLIN. PATH. 700 (1986).
by surrogates and asking the public for fresh donations. But the standard of care from hepatitis cases—custom without a cost-benefit test—did not encourage them to incur these extra costs.

The standards and facts of the Kozup decision became precedent for subsequent litigation over care levels for donor screening and blood testing. In an Arkansas diversity case the United States district court was sustained on an appeal for adopting Kozup’s requirement that the effectiveness of stronger donor screening measures or surrogate testing had to be established as a certainty rather than by a preponderance of the evidence.241 In a San Francisco jury trial the plaintiff may have lost because, according to the defendant’s trial brief, one of her donors tested negative on the surrogate test on a subsequent occasion, and therefore the earlier donation may have tested negative.242 Reportedly, the same blood bank settled one case where the donor was positive on the surrogate test.243 In a Michigan


243. Porter v. Irwin Memorial Blood Bank, No. 867372, Attorney’s Estate Reaches Private Settlement over His AIDS Death, 1989 AIDS LITIG. REP. 2029 (Cal. Super. Ct., San Francisco County 1988). The transfusion occurred in March 1983 and the unit was collected in February 1983. Apparently it was tested for a surrogate test as part of a “blinded” experiment in which the donor was not supposed to be identified. (Irwin did not begin routine testing with the surrogate until May 1984.) The blood bank failed to dispose of certain records that allowed the donor to be identified five years later in the lawsuit. Irwin Settles Case Out-of-Court, AABB BLOOD BANK WEEK, supra note 5, Feb. 3, 1989, at 6; Irwin Settles Case Out-of-Court (Revisited), AABB BLOOD BANK WEEK, supra note 5, Feb. 17, 1989, at 2; Cary Groner, Surrogate Blood Tests Take Center Stage in AIDS News, HEALTHWEEK, May 30, 1989, at 1, 65. In Borchelt v. Irwin Memorial Blood Bank, No. 8193 (Cal. Super. Ct., San Francisco County filed Aug. 15, 1985), the blood bank director, according to a newspaper report, testified that the implicated donor was positive on the surrogate test. Robin Evans, Blood Bank Chief Admits Reluctance to Screen Donors, SAN FRANCISCO PROGRESS, Aug. 1, 1986. But in the settlement plaintiffs “acknowledged that the screening procedures used by the blood
case the blood bank and hospital defendants won on summary judgment because the plaintiff could not show that using additional blood tests would have screened out her donor.244

Other courts adopted the Kozup standard of industry custom without a cost-benefit test. The South Carolina Supreme Court certified that the standard of care was industry custom nationwide.246 Blood banks in the San Francisco area had introduced routine surrogate testing six months before that transfusion, but that was not sufficient to establish a standard of care in South Carolina.246 The concept of "medical consensus" identified by the Kozup court proved to be highly elastic when applied to other cases. Courts rejected the Holmes-Hand rule whether the blood was donated the month of the consensus,247 five months after,248 one year after,249 or more than a

bank were appropriate." Transfusion-Associated AIDS Lawsuit Resolved in San Francisco, AABB BLOOD BANK WEEK, supra note 5, Aug. 15, 1986, at 1-3.


246. Doe v. American Red Cross Blood Servs., S.C. Region, 125 F.R.D. 637, 638, 641 n.4 (D.S.C. 1989). A California appellate court used the South Carolina case as part of its basis for rejecting the Holmes-Hand rule. A judgment for the San Francisco blood bank on the issue of negligent screening and testing was affirmed because it met or exceeded industry custom, which in California, the court held, is the standard of care for professionals. Expert testimony must be weighed against custom, and if the expert testifies that more should have been required than anyone in the industry was willing to do, then custom is controlling. The court said, "[p]laintiffs' case for anti-HBe [surrogate] testing thus boils down to the proposition that the entire blood banking profession was negligent. We find that proposition to be untenable." Osborn v. Irwin Memorial Blood Bank, No. 891642 (Cal. Super. Ct., San Francisco County Dec. 1, 1988), aff'd in relevant part, 92 D.A.R. 4890, 4902-05 (Apr. 13, 1992); CA Sup. Court Affirms Vacation of Verdict Against Irwin Memorial, AIDS LITIG. REP 8536-37 (1992). See supra note 234.


248. Memorandum and Order, Shelby v. St. Luke's Episcopal Hosp., No. H-86-3780 (S.D. Tex. 1988); Shelby v. Gulf Coast Regional Blood Center, No. H-87-901, 1988 AIDS LITIG. REP. 701-04 (S.D. Tex. 1988) (applying Texas law). The court held that the defendants followed industry custom and FDA standards. It stated that these standards "required extensive questioning of donors regarding all known sexual contacts and other factors that might make the donor susceptible to carrying the AIDS virus." That was an error; only in December 1990 did the FDA recommend that donors be questioned about all risk behaviors. The court rejected the Holmes-Hand rule because "no test for the HIV virus was available at the time the blood in question was transfused." That was another error; the test that blood banks use is for the antibody to HIV, not for the virus itself which is a more complex and lengthier laboratory procedure. The antibody test has an error rate, as discussed supra notes 13 and 47-50 and accompanying text.

year after. 250

Plaintiffs won on summary judgment in a District of Columbia case arising from a transfusion in July 1984, two months after blood banks in the San Francisco Bay area began surrogate testing. Whether such tests were reasonable and prudent in the District of Columbia was held to be a jury question. The court could not say "as a matter of law, that no reasonable juror could conclude, on the basis of the evidence . . . , that the Red Cross violated the applicable standard of care." The bench ruling, which was followed by a settlement, then was vacated as moot. 251 Plaintiff won the appeal of a summary judgment in Florida. A material fact over whether the blood bank met the standard of care in 1987 was in dispute, and plaintiff did not have to prove that the defect was detectable or removable by reasonable scientific procedures to recover in negligence. 252

Plaintiffs have won where the court instructed the jury to decide not on the basis of industry custom but on what they believed a reasonably prudent blood bank would have done under similar circumstances. In one case the donor testified that he was a monogamous homosexual who had donated more than twenty times before testing positive for anti-HIV. The blood bank argued that it followed the FDA recommendations and industry custom of the period in advising only men with multiple sex partners to self-exclude. Plaintiffs' experts testified that it was naive to think that homosexuals in supposedly monogamous relationships were not at risk, and that donors


According to an interview of an attorney for the ANRC, no ANRC case has gone to trial. All have either been disposed of on motions for summary judgment or demurrers or have been settled. Slind-Flor, supra note 6, at 37.

should have been interrogated directly. In another case the donor said that he would have disclosed that he had multiple homosexual partners had he been asked the question directly. The jury also decided that the blood bank could have screened out two-thirds of HIV-positive blood by using one surrogate test.

In a Colorado case the trial court's ruling that the standard of care should be professional rather than ordinary negligence was reversed on appeal. The appellate court held that not only is "the profession essentially allowed to establish its own standard of care, but also it is, in all practical respects, immunized by that standard of care." The "blood banking industry itself," the court said, "lacks the defining characteristics of a profession which serve to police and promote the standards, customs, and practices which define a professional standard of care." Government regulations and industry custom were "merely evidence" of the standard. "Moreover, there was undisputed evidence that the defendant may have unduly lagged behind contemporary professional knowledge in the adoption of new donor and blood screening procedures." In what may prove to be a major development, the Colorado Supreme Court held that professional negligence was the standard of care and that industry custom was evidence but not conclusive proof of due care. The industry could not establish its own standard of care. In a new trial the plaintiffs would be allowed to present to the jury expert testimony to challenge whether industry custom met the Holmes-Hand Rule.


In the retrial, the plaintiffs were allowed to present experts who were sufficiently familiar with the standard of care in blood banking even though they were outside the blood-banking industry. One expert was Dr. Donald P. Francis, a retired CDC official, who had not been allowed to testify while employed by the government (see supra note 230). According to newspaper reports, he testified that the blood bankers rejected his warning in December 1982 that five AIDS cases had been linked to transfusion and that the number of cases was doubling every six months. Blood bankers also rejected his warning in January 1983 to take additional precautions (see supra note 77). New Quitana Trial to Start Next Week; Jury to Decide If Entire Blood Services Industry Had Negligent
Plaintiffs have also won where blood banks violated industry custom or FDA rules. One allowed a drug addict to donate. At another blood bank, a donor apparently was deferred once because he tested positive for antibody to syphilis and then twice owing to a hepatitis vaccination. Both conditions indicated higher risk. Subsequently he was allowed to donate three HIV-infected units out of six attempts between 1982 and 1985.

4. The Osborn Case: Directed Donation

In early 1983 hospitals and blood banks generally did not offer directed donations for patients who feared AIDS. Because of industry custom the Kozup court granted Georgetown Hospital summary judgment on that count.

In Osborn v. Irwin Memorial Blood Bank a California child developed AIDS as a result of a transfusion of twelve units during heart surgery at one month of age in February 1983. His parents claimed that they had read articles in newspapers about AIDS and were concerned about the possibility of contaminated blood. They claimed that family and friends were willing to donate for the child directly, and that the blood bank rejected their request on policy grounds. They claimed to have learned later that the blood bank allowed directed donations under some circumstances, even though it


discouraged them generally, which the blood bank denied. The blood bank would have claimed that too much time was required to collect the necessary quantity of the child's unusual blood group, but the court did not allow it to explain that to the jury, which found for plaintiff. Subsequently, the court narrowed the grounds for the judgment to negligent misrepresentation and reduced the award. On appeal the decision was reversed and remanded for a new trial. The appellate court held that evidence associated with the child's blood group was relevant to proximate cause and that the blood bank's misrepresentation would not have affected the outcome if it was not feasible to obtain a sufficient number of directed donations of that blood group in time. In another California case with similar facts the jury rejected a claim against the same blood bank for negligent misrepresentation of its directed donation policy, which was affirmed on appeal.


During the trial, the court ruled that the blood bank was not a provider of health services under California law. Therefore, since the case was tried as one of negligence rather than medical malpractice, defendant could not introduce evidence on the standard of care or take advantage of California's statutory cap on medical malpractice awards. After the verdict the judge reduced the jury's award because it apparently had not followed instructions, and the judge reversed his ruling that the blood bank was not a health care provider subject to the award caps. Memorandum of Points and Authorities in Support of Motion to Set Aside Judgment and Enter a Different Judgment, Osborn v. Irwin Memorial Blood Bank, No. 891642, 1989 AIDS Litig. Rep. 2242 (Cal. Super. Ct., San Francisco County Dec. 1, 1988); Reply Memorandum of Points and Authorities in Support of Motion to Set Aside Judgment and Enter a Different Judgment, Osborn, id. at 2249; Further Brief in Opposition to Application of MICRA Limits, Osborn, id. at 2255; Supplemental Memorandum of Points and Authorities Explaining How MICRA Applies to This Case, Osborn, id. at 2259; Order Granting Motion to Set Aside Judgment and to Correct Judgment to Conform with Law (Feb. 7, 1989), Osborn, id. at 2306; Verdict Against Irwin Modified but Upheld, AABB Blood Bank Week, supra note 5, Feb. 3, 1989, at 6; P. Robert Rigney, Jr., Legal Update: Blood Banks Achieve Mixed Results in AIDS Cases as Some Win, Some Lose, Both Sides Appeal, AABB News Briefs, Feb. 1989, at 2-3.


5. The Kirkendall Case: Testing Inventory

The FDA licensed the anti-HIV test on March 2, 1985 and recommended that blood banks "begin performing the test as soon as supplies are commercially available." The AABB did not require it until July 1, 1985. The FDA acknowledged that testing was voluntary until a regulation became effective and that an "appropriate phase-in period" was necessary for laboratory staff to become proficient. Shipments of test kits began at once, but blood banks received them at different times. While staff were being trained, blood banks continued under standard procedures to collect and ship to hospitals units that were not tested for anti-HIV. Three plaintiffs who received AIDS-contaminated blood claimed that blood banks were negligent in failing to test all units in their inventories that were donated before routine testing began and in failing to recall units in hospital inventories that were shipped before routine testing began. The FDA requires banks to keep the necessary records for recalls.

In Kirkendall v. Harbor Insurance Co. the contaminated unit was donated and shipped about a week before the blood bank received its first test kits. It was returned to the blood bank after twelve days, shipped out again the next day—three days before routine testing began—and transfused a week later. The United States district court held that the blood bank "could not have predicted that any of the 1,753 units of blood products in its inventory on March 23, 1985, would have tested positive for AIDS antibodies. The overwhelming statistical probability was that not one unit . . . would test positive." But that is wrong. The probability that one of a group of units was positive was small, but it was not zero as the


268. The FDA sets limits on the "shelf life" of each blood component, so many blood banks ship older units first.

district court implied. After testing, the probability that any given unit would be positive is either zero or one (assuming a fully accurate test). The court confused the *ex ante* expectation of finding a positive unit before testing was available with the *ex post* information that testing would provide. It is also important to keep in mind the difference between a small probability of an event and small damages. The small probability of a disaster may yield large expected damages.

The court held that industry custom was the standard for negligence. The blood bank “theoretically” could have tested all inventory units that were about to reach their expiration dates during a key five-day period. But that would have delayed testing new units, disrupted supply, and “caused a greater risk to blood recipients than was present in the supplying of untested blood.” The blood bank could have avoided shipping untested units if, “as plaintiff urge[d], [it had] advised all sixteen of its serviced hospitals to delay all elective and non-emergency surgery until all blood could be tested.” But the defendant was not negligent because no blood bank tested inventory and the FDA did not recommend it explicitly. Relying on *Kozup* the court expressly rejected the reasoning of *The T.J. Hooper*. “Only if the entire blood banking industry was negligent in the manner in which HIV testing was implemented and carried out . . . could the court conclude that [this defendant] acted negligently.”

The Court of Appeals for the Eighth Circuit affirmed, but held that it was “inapposite” for the district court to rely on *Kozup*, which did not concern antibody testing. Quoting Justice Holmes and applying the Holmes-Hand rule, the court of appeals held that the FDA’s recommendation to begin testing as soon as supplies became commercially available imposed a duty on blood banks to do just that. Thus “industry practice at the time . . . does not govern

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273. *Id.* See supra notes 93-103 and accompanying text.
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[defendant's] conduct with respect to blood that it had in inventory.'\(^{274}\) The court of appeals held that the blood bank did not violate its duty because it had the unit for only one day after kits arrived. But plaintiffs won jury verdicts in two other inventory cases.\(^{276}\)

V. FACTUAL TERRAIN OF THE HOLMES-HAND RULE

Generally, blood banks have prevailed in negligence actions when industry custom was the standard of due care. That standard assumes that the groups setting care levels have expert status and superior information about risk. The criterion for joint liability in Hall was whether blasting-cap suppliers controlled risk jointly. The court believed it was "unlikely" that individual suppliers would collect information about nationwide accident rates and that it was "entirely reasonable that [they] . . . should delegate this function to a jointly-sponsored and jointly-financed association."\(^{276}\) Joint liability of the three blood-collecting organizations for setting the wrong industry standards has yet to be litigated. My purpose here is to set out the various issues involved, and if possible to identify which facts would be dispositive.

A factual inquiry probably would focus on two questions. First, did the three blood-collecting organizations either claim superior

\(^{274}\) Kirkendall, 887 F.2d at 860-61.


knowledge or jointly control risk for patients? Second, did they compare costs and benefits before setting care levels jointly? They have issued at least nine joint statements since early 1983.17 I will assume each is dispositive evidence of the Hall criteria for joint control of risk—sharing information, concert of action, or express or tacit agreement. The joint statement of January 13, 1983, for example, came about through concert of action. The AABB's representative described the "time and energy" that went into "reach[ing] a consensus" through "several iterations." He expressed the "hope to keep it up" and the "believe[f] that the three of us can, together, work out whatever new problems may arise. We plan frequent conference calls to keep each other informed."278 The key elements of each joint statement are its date and the risk it controlled—directed donation, inventory testing, surrogate testing, or warning.

A. Directed Donations

Requests for directed donations signal that patients expect relatively high damages and seek to reduce them. Their willingness to pay the extra costs, assuming that the costs may be billed to them,279 indicates that they think the procedure is cost-effective. On June 22, 1983 the AABB, ANRC, and CCBC issued a joint statement opposing directed donations.280 Risk for transfusions to patients who were refused a directed donation was controlled by the individual blood

277. AABB, ANRC, & CCBC, JOINT STATEMENT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME RELATED TO TRANSFUSION (Jan. 13, 1983); AABB, ANRC, & CCBC, JOINT STATEMENT ON PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME RELATED TO TRANSFUSION (Mar. 7, 1983); AABB, ANRC, & CCBC, JOINT STATEMENT ON DIRECTED DONATIONS AND AIDS (June 22, 1983); AABB, ANRC, & CCBC, LOOK-BACK: NOTIFICATION OF PREVIOUS RECIPIENTS OF BLOOD AND COMPONENTS FROM DONORS WHO NOW HAVE A CONFIRMED POSITIVE TEST FOR ANTI-HTLV-III (June 16, 1986); AABB, ANRC, & CCBC, INTERIM GUIDELINES FOR TESTING DONATED BLOOD FOR HTLV-I ANTIBODIES (Nov. 4, 1988); AABB, ANRC, & CCBC, JOINT STATEMENT ON HIV ANTIGEN TESTING (Apr. 5, 1989); AABB, ANRC, & CCBC, JOINT STATEMENT ON THE INTRODUCTION OF TESTING VOLUNTEER DONORS FOR HEPATITIS C VIRUS INFECTION (Apr. 30, 1990); AABB, ANRC, & CCBC, JOINT STATEMENT ON SCREENING BLOOD FOR EVIDENCE OF HIV-2 INFECTION (Apr. 30, 1990); AABB, ANRC, & CCBC, JOINT STATEMENT ON DONOR STATUS OF MILITARY PERSONNEL RETURNING FROM THE PERSIAN GULF AREA (Apr. 3, 1991).


279. See supra note 142. In California the extra charges for a directed donation must be based on costs and may not exceed the charges for an autologous donation. CAL. HEALTH & SAFETY CODE § 1628(e) (West 1989). Screening the additional candidates for directed donors that the family sends to the blood bank may increase operating costs. However, units that are either not suitable for, or used by, the directed recipient and that are released to the general donor pool may lower costs.

bank before June 1983 and by the blood bank and the three associations jointly after June 1983. That is consistent with the action against the San Francisco blood bank concerning its policy on directed donations in January 1983.281 A year later it allowed directed donations.282 Within five years six states forced blood banks to allow them.283

One would think that directed donations would benefit blood banks as well as patients. Patients who provided donors, or who declined the chance to provide them, presumably would assume the risk.284 But the industry's policy was defended by experts in each of the three organizations.285 On political grounds they thought that it was unfair to let some patients choose donors when others might not have enough information or friends to get them. On economic grounds they feared that directed donations would cause a drop in regular donations, "seriously disrupt" the blood supply, and perhaps cause blood banks to be "destroyed."286 These arguments had nothing to do with the costs and benefits of a standard of care, and meeting a standard is not relieved simply because the old way of doing business is no longer profitable. But the standard that emerged from the hepatitis cases—industry custom—gave blood banks relatively weak incentives to let patients assume the risk if operating costs rose as a result.

On medical grounds the experts argued that patients could not select donors any better than blood banks because donors might not be

281. See supra notes 260-62 and accompanying text. Presumably an additional element of proof would be that the intended donor was not in a high-risk group for HIV at the time of transfusion. Patti J. Miller et al., Potential Liability for Transfusion-Associated AIDS: In Reply, 255 J. A.M.A. 196 (1986).


286. AABB, ANRC, & CCBC, Joint Statement on Directed Donations and AIDS (June 22, 1983); Westphal, supra note 285; Joseph R. Bove, Directed Donations, in Legal Issues in Transfusion Medicine, supra note 52, at 70-74; Eckert, supra note 22, at 68.
truthful about risk factors among family and friends. They believed that the extra logistical problems involved would increase the risk of a patient getting the wrong blood. They also claimed that no body of evidence showed that directed donors were safer than regular donors. These arguments were relevant to their claims to superior knowledge about care levels and amounted to assertions that the expected costs of the procedure exceeded its unknown benefits.

Blood banks began studies to test the “directed-donor-is-riskier” hypothesis in 1984-1985. These studies were published in 1986-1989. One of the three blood-collecting organizations published a study in 1989 based on data collected at twenty banks between September 1987 and March 1988. Another study found statistically the same rate of rejection of regular versus directed donors for markers for hepatitis viruses and HIV. The others found a significantly higher rate of markers for hepatitis viruses among the directed donors but no difference in the incidence of anti-HIV. These results indicated that, on average, patients were no worse than blood banks in choosing donors after 1984. That result was contrary to what the industry expected, but did not lead it to change its policy. Moreover, patients may have been more effective than blood banks in choosing donors before 1984-1985, when the AIDS risk was greatest. One study also showed that directed donations increased donations on net—another result contrary to the industry’s expectation.

B. Testing Inventories

Neither the industry nor the FDA declared that, once routine anti-HIV testing began, blood banks had to test inventories and recall untested units from hospitals. Absent such a declaration, the


288. Id. at 136; Ruth R. Cordell et al., Experience with 11,916 Designated Donors, 26 TRANSFUSION 484 (1986); Pearl T. Toy et al., Higher Non-A, Non-B Hepatitis Surrogate Marker Rates in Designated Donor Units, 28 TRANSFUSION 17s (1988 Abstract Supp.).


291. Blood bankers attributed the higher rates of hepatitis markers among directed donors to the higher fraction of first-time donors among them. Yalon & Perkins, supra note 287, at 131-32.

292. Id. at 134.

293. See supra notes 264-65 and accompanying text.
AABB, ANRC, and CCBC may have concluded that members were shielded from negligence by the standard of due care in the hepatitis cases—industry custom without a cost-benefit comparison. But blood banks lost two of the three inventory cases. In affirming the case that the blood bank won, the Court of Appeals for the Eighth Circuit held that the FDA recommendation to test as soon as test kits were commercially available applied to inventory.

Industry custom for inventory testing subsequently changed. When tests for other viruses were adopted in 1988 and 1990, joint statements recommended testing inventory or replacing it with tested material. In 1990 some blood banks suggested that physicians and hospitals consider postponing elective surgeries until blood was tested. One bank recalled the units shipped over a seven-week period because of a possible error in testing.

C. Donor Screening and Surrogate Testing

Since at least 1982 the working hypothesis in government and industry was that transfusion AIDS was caused by an infectious blood-borne agent. The crucial question is whether the industry, in light of the dominant hypothesis, took screening and testing precautions that struck a favorable balance between benefits and costs. The Kozup court held that the failure to take extra precautions in early 1983 was not negligent because the medical community did not reach a consensus on the hypothesis until January 1984. If consensus was not reached earlier, however, it was because of objections by the blood bankers.

294. See supra note 275.
296. The standard for antibody to HTLV-I was to test inventory within thirty days of beginning routine testing. AABB, ANRC, & CCBC, INTERIM GUIDELINES FOR TESTING DONATED BLOOD FOR HTLV-I ANTIBODIES (Nov. 4, 1988); AABB, 1989 ANNUAL REPORT 11 (1990). The standard for antibody to hepatitis C was to test the most recently collected units first, which is in reverse of the common practice of shipping the older units to hospitals first. AABB, ANRC, & CCBC, JOINT STATEMENT ON THE INTRODUCTION OF TESTING VOLUNTEER BLOOD DONORS FOR HEPATITIS C VIRUS INFECTION (Apr. 30, 1990); Joint Statement Advises on Planning for HCV Testing, AABB NEWS BRIEFS, Feb. 1990, at 1; AABB, 1990 ANNUAL REPORT 8 (1991).
299. See supra notes 73-76 and accompanying text and infra Appendix.
On January 4, 1983, the CDC recommended either more careful donor screening or surrogate testing. On January 13, 1983, the AABB, ANRC, and CCBC opposed both in a joint statement. Claiming superior knowledge, they believed that “[d]irect or indirect questions about a donor’s sexual preference are inappropriate” or ineffective. They were concerned that direct questioning could provoke some persons to donate regardless of their health. Until more data were available, they and the FDA believed—and it was nothing more than a belief—that it was necessary for only highly promiscuous homosexual or bisexual men to exclude themselves.

The blood bankers were concerned over the amount of safe blood surrogate tests would reject and that they would need new donors to replace. They assumed that the benefits of surrogates would be less than the increase in their operating costs. Groups of male homosexuals opposed stronger donor screening with sexual-orientation questions, but they favored surrogate testing. Nevertheless the blood bankers rejected the CDC’s recommendation until surrogates had been evaluated around the country. One surrogate, however, had been used routinely as a screen for hepatitis by four blood banks since 1981-1983. Apparently these decisions were based on a comparison of the costs and benefits of reducing risk.

300. See supra notes 77-79 and accompanying text and infra Appendix.  
301. AABB, ANRC, & CCBC, JOINT STATEMENT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME RELATED TO TRANSFUSION (Jan. 13, 1983). Apparently the statement was prepared at a meeting of the AABB’s Committee on Transfusion Transmitted Diseases on Jan. 6, 1983. Present were representatives of the three blood-collecting organizations, the CDC, the FDA, and certain groups who were included in the July 1982 meeting and the Atlanta meeting (see infra Appendix). Memorandum from Edward O. Carr, AABB, President, Joint Statement on Acquired Immune Deficiency Syndrome (AIDS) Related to Transfusion, to AABB Institutional and Associate Institutional Members (Jan. 13, 1983).  
302. See supra note 37 and accompanying text. The director of the New York Blood Center said in 1986 that “[w]e never encouraged—as a matter of fact for many years have discouraged—donations in the gay community. This was done not as a public policy, but by not seeking donations in any organized groups.” Statement of Johanna Pindyck, Vice President, New York Blood Center, in LEGAL ISSUES IN TRANSFUSION MEDICINE, supra note 52, at 51.  
303. It was not until September 1985 that FDA expressly excluded any male who has had sex with another male even once since 1977. See supra note 83 and accompanying text.  
305. Two major studies published in 1981 estimated that testing for elevated levels of alanine aminotransferase (ALT) would eliminate between 29% and 40% of post-transfusion hepatitis cases and half the worst cases, at a loss of between 1.6% and 3.0% of donors. Richard D. Aach et al., Serum Alanine Aminotransferase of Donors in Relation to the Risk of Non-A, Non-B Hepatitis in Recipients: The Transfusion-Transmitted Viruses Study, 304 NEW ENG. J. MED. 989 (1981); Harvey J. Alter et al., Donor Transaminase and Recipient Hepatitis: Impact on Blood Transfusion Services, 246 J. A.M.A.  

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On July 1, 1983, the Stanford University Blood Bank implemented a surrogate test for AIDS based on an abnormality in certain white blood cells (called T-cells) that is characteristic of many healthy persons and almost all AIDS patients. The test was not perfect and cost six dollars per unit, but it identified some infective donors who were allowed to donate at other blood banks. The head of the ANRC's blood service opposed the T-cell test because of its cost and the amount of blood it would reject. Another blood banker criticized Stanford's action as a "marketing tool for a medical center" that was "distasteful." In September 1984 the blood bank at Tulane University Medical Center adopted the T-cell test. In May 1984 the blood bank in San Francisco adopted as a surrogate for AIDS the hepatitis test that the CDC recommended in 1983, and a month later the ANRC's regional center in San Jose followed suit. Later the San Francisco bank discovered that the CDC's prediction in 1983 that the test would reject blood that was infected with HIV had been correct. Two more blood banks began to use the test in early 1986. A study showing that the test also


308. Dylan Landis, Tulane Ignores Critics in Planning AIDS Test, TIMES-PICAYUNE, Sept. 14, 1984, at A-1. Tulane used the test until June 1, 1987 even though the anti-HIV test was implemented on April 1, 1985. Letter from Charlee Verrett, Manager of Blood Services, Tulane Medical Center Hospital and Clinic, to Ross D. Eckert (Jan. 3, 1991).
310. Blood Bank Will Use Second Test in Drive to Reduce AIDS Risk, WALL ST. J., March 30, 1984, at 19, at col. 5. About 40% of donors who tested positive for anti-HIV also were positive on the surrogate test. Pekkanen, supra note 19, at 40; Busch et al., supra note 92, at 7; Thomas F. Zuck, Silent Sequences and the Safety of Blood Transfusions, 108 ANNALS OF INTERNAL MED. 895, 896 (1988).
detected donors exposed to viral hepatitis led an FDA advisory panel in 1986 to recommend that blood banks use two surrogates for hepatitis. In 1987 the AABB finally agreed. In 1991 the FDA recommended that blood banks use one test.

The surrogate testing controversy offers more evidence about how the AABB, ANRC, and CCBC set care levels jointly. They discounted the advice of experts who were outside the industry’s councils, whether at the CDC or at blood banks, and who recommended new precautions. An abstract of a study on the T-cell surrogate for AIDS at the Stanford University Blood Bank was submitted for presentation at the 1983 AABB annual meeting, but it was rejected. An abstract of a study showing the effectiveness of T-cell testing was submitted for presentation at the 1989 AABB annual meeting, but it was also rejected.

The industry’s 1983 joint statement on directed donations was typical in that it put the burden of proof on those advocating extra precautions. That bias was apparent in the earlier controversy over a test for cytomegalovirus. The test was inexpensive and prevented

311. Hernandez v. Nueces County Medical Soc’y Community Blood Bank, 779 S.W.2d 867, 870 (Tex. Ct. App. 1989). In 1986 it was estimated that testing for antibody to the hepatitis B core antigen would cut hepatitis cases by 43% with a loss of 4% of donors. Deloris E. Koziol et al., Antbody to Hepatitis B Core Antigen as a Paradoxical Marker for Non-A, Non-B Hepatitis Agents in Donated Blood, 104 ANNALS INTERNAL MED. 488 (1986).

312. AABB Issues Guidelines on Surrogate Testing for NANB Hepatitis, AABB BLOOD BANK WEEK, supra note 5, Aug. 15, 1986, at 1, 3; FDA Advisory Committee Supports AABB Policies on Surrogate Testing, Confidential Unit Exclusion System, AABB BLOOD BANK WEEK, supra note 5, Sept. 12, 1986, at 1-2; Board Delays Enforcement of Requirement for Core Testing, AABB BLOOD BANK WEEK, supra note 5, Nov. 21, 1986, at 1; Workshop Affirms Efficacy of Anti-Core Test for NANB Hepatitis, AABB BLOOD BANK WEEK, supra note 5, Jan. 23, 1987, at 1; AABB Reaffirms Decision to Require ALT and Anti-HBc Testing, AABB BLOOD BANK WEEK, supra note 5, Feb. 20, 1987, at 1. See also AABB Tells Members They May Delay Implementation of Anti-HBc Testing, CCBC NEWSLETTER, supra note 14, Nov. 21, 1986, at 1; Bove, supra note 77, at 143; and infra Appendix.

313. Memorandum from Gerald V. Quinnan, Jr., Acting Director, Center for Biologies Evaluation and Research, U.S. Food and Drug Administration, FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc), to all registered blood establishments (Sept. 10, 1991).


315. The technique used at Stanford was estimated to capture 11 of 17 HIV-1 positive units. See M. Gonzalez et al., Retrospective Analysis of CD4:CD8 In Preventing HIV-1 Transmission, submission form for abstracts, AABB Annual Meetings, 1989; Letters and Enclosures from F. Carl Grumet, Professor of Pathology, Stanford University School of Medicine to Ross D. Eckert (Nov. 15, 1989 & Dec. 29, 1989).

316. See supra note 84 and accompanying text.

317. See supra note 17 and accompanying text.
devastating illness in premature infants." But the AABB approved it only after several years of debate, limited its use to regions "[w]here transfusion-associated [CMV] disease is a problem," and did not recommend it for transplant patients. In 1988 the medical director of the Stanford University Blood Bank said that "until very recently the industry has steadfastly resisted the addition of new tests, requiring that the utility of any candidate test must be proven over and over again before it can even be considered for mandatory use."

D. Warnings

According to Hall, whether an industry must warn under either strict liability or negligence depends upon whether benefits outweigh costs. An activity involving a small likelihood of death may require more careful warnings than an activity involving a higher probability of a lesser harm. In Canifax suppliers were required to warn if the risk was not common knowledge. The Restatement does not relieve suppliers of the duty to warn, whether or not products are "unreasonably dangerous" under comment k. Even if the comment k defense logically fit blood, which it does not, blood banks would not

319. AABB STANDARDS § G6.600. See also Paul J. Schmidt, Revisions to Standards for Blood Banks and Transfusion Services Announced, AABB NEWS BRIEFS, June 1982, at 4-5; Cytomegalovirus Infection and Blood Transfusion, AABB NEWS BRIEFS, June 1984, at 1; Letter and Enclosures from F. Carl Grumet, Professor of Pathology, Stanford University School of Medicine, to Ross D. Eckert (Dec. 29, 1989).
320. Engleman, supra note 314, at 6-7. In 1986 Bove stated that "[a]lthough the data [supporting the CMV test] . . . seemed unambiguous and decisive enough to mandate an immediate change in blood bank practice, neither the [FDA, AABB, or ANRC] . . . took decisive action. Blood banks always have been conservative about the addition of new tests or restrictions without adequate documentation of their need." Apparently the dominant view was that CMV-related infection was confined to certain local areas. A study showing causation was published in 1983, and "mounting pressure from neonatologists, forced most blood banks to adopt some program to reduce the risk . . . in selected newborn infants." Bove, supra note 77, at 126. By 1983 "[s]everal relatively simple and inexpensive tests [had] been developed." Cytomegalovirus Infection and Blood Transfusion, supra note 319, at 2.
323. Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1089-91 (5th Cir. 1973) (applying Texas law) (expert manufacturers had duty to warn employees of possible hazards of asbestos); Reyes v. Wyeth Lab., 498 F.2d 1264, 1274-76 (5th Cir. 1974) (applying Texas law) (manufacturers of prescription drugs have duty to warn prescribing physicians, and drugs with proper warnings are not unreasonably dangerous).
be relieved of a duty to warn.

In 1986 the three blood-collecting organizations issued a joint statement agreeing to notify hospitals of possible transfusion-transmitted HIV infections.324 When a donor is found to be positive for anti-HIV, the blood bank “looks back” through its records for previous donations by that person and notifies the hospital(s) to which the unit(s) were shipped. The hospital or treating physician then notifies the patient(s). That puts the blood bank in the unenviable position of providing information that may identify future plaintiffs in actions against it. Blood banks adopted the policy out of a concern that an unaware transfusion recipient could transmit HIV infection to spouses or others. But they probably have a duty to warn learned intermediaries of subsequently discovered dangers.326 Warnings are low-cost ways to enable consumers to attempt to reduce damages. Patients cannot make informed decisions about whether to postpone or forgo treatment unless physicians inform them of hazards and benefits. Physicians are more likely to inform patients properly if blood banks inform physicians properly. Blood bankers are specialists; they presumably are held to the knowledge and skill of experts, who are supposed to keep up with scientific developments.329 Their committees set industry standards. In 1988 in another context a blood banker and former FDA official appeared to claim expert status for blood bankers:

Who should educate physicians? The risks of blood transfusions . . . are small parts of the enormous volume of literature on modern technology thrust upon physicians. Blood bankers are suited to assume the tasks of education because of their special interests in these areas.327

The risk of transfusion AIDS was foreseeable by blood bankers as early as July 1982 at least, and on January 4, 1983, the CDC warned them publicly.328 The ANRC's assistant legal counsel argued

324. AABB, ANRC, & CCBC, Look-Back: Notification of Previous Recipients of Blood and Components From Donors Who Now Have a Confirmed Positive Test for Anti-HTLV-III (June 16, 1986). The AABB supplied members with model letters to heads of hospitals and transfusion services and forms on which to record information about the patients who received the units in question. Memorandum from Eugene M. Berkman, President, AABB, "Look-back" Program to Trace Recipients of Blood from Donors Now Found to Be HTLV-III Antibody Positive, to AABB Institutional and Associate Institutional Members (June 16, 1986) (with attachments).

325. Tresemer v. Barke, 86 Cal. App. 3d 656, 150 Cal. Rptr. 384 (1978) (physician's failure to warn a patient that an intrauterine device had been withdrawn from the market, and the risk was foreseeable, was malpractice). In 1985 the AABB's legal counsel noted the implications of that case for blood banks. Willett, supra note 54, at 65-67, 199.


327. Zuck, supra note 310, at 896.

328. See supra note 77 and accompanying text and infra Appendix.
that the joint statement of January 13, 1983 was a warning to physicians. The statement declared that “the cause of AIDS is unknown,” that “evidence for its transmission by blood is inconclusive,” “still unproven,” and only a “possibility,” but was of “sufficient concern” to warrant “[a]dditional caution in the use of blood.” It made recommendations to blood banks and explained why the AABB, ANRC, and CCBC believed that strong screening and surrogate testing were unnecessary. It urged blood bankers to “extend education campaigns to physicians to balance the decision to use each blood component against the risks of transfusion” and recommended that autologous blood (prereposited units of a patient’s own blood) “should be considered more frequently, especially in elective surgery.” The statement shows that blood bankers believed they had superior information and that they controlled risk to patients. It also contained a gross underestimate of the risk of transfusion AIDS relative to what later studies showed. Whether it was a warning to physicians is debatable, although one court took it as a warning.

For some time the three blood banking organizations have jointly prepared the Circular of Information, which is distributed to hospitals and physicians. In 1986 the ANRC’s assistant legal counsel stated that the Circular was revised in July 1985 to disclose HIV risks. The document she cites was not on file at the FDA in 1990. In any event the key issue is whether the AABB, ANRC, and CCBC issued a clear warning to physicians before 1985. For my part, I could not find one, and I note that in 1985 AABB’s legal counsel said:

I think that the difference [before 1985] was that physicians may well not have appreciated the degree of the risk of AIDS that attended blood transfusion. That’s conjecture on my part and is something that’s better answered by experts. I hope they won’t have to take the stand and do it, but that’s my impression now.

330. See supra note 79, 89-92 and accompanying text.
332. See supra note 63.
333. Lipton, supra note 329, at 139 n.40.
335. Willett, supra note 54, at 65.
VI. RETHINKING THE BLOOD SHIELD LAWS

Attorneys for blood banks anticipated that the negligence rule from the hepatitis cases—industry custom without a cost-benefit test—would be the standard of due care for AIDS.336 Apart from the inventory-testing cases (for which no express standard was set) and a few other exceptions, they were mainly correct. But the industry custom cases raise problems if interests other than the well-being of blood banks are at stake.

First, some witnesses may have complex incentives. As a rule, only blood bankers may testify as experts on the prevailing professional standard of care at blood banks,337 even though the outcome of the trial could indirectly affect the future liability of the expert’s blood bank. Also, plaintiffs who join blood banks and hospitals as defendants may encourage cooperation among parties whose interests might otherwise diverge—on warnings, for example.338

Second, courts misunderstand facts. In Kozup, the key case, the court misunderstood the risk of an infectious disease, constructed an erroneous chronology of the industry’s response to AIDS, and did not realize that blood tests have error rates.

Third, the industry custom standard renders the key issue of whether the industry adopted a cost-beneficial standard of care moot. Industry custom means that courts review only gross negligence or those blood bank practices for which standards do not exist. Standard-setting is relegated to the FDA and to an influential industry that acts jointly and usually puts the burden of proof on those who advocate new precautions.

I conclude that the problems of using a negligence rule to induce blood bankers to make cost-benefit calculations before jointly setting care levels are so great that a rule of strict liability is worth reconsidering. Though blood bankers, like the veterinary assistant in Nelson, are the party in the best position to take the cost-effective precaution, they are protected against strict liability by a chain of

336. Lipton, supra note 329, at 144; Willett, supra note 54, at 95. See also Rabkin & Rabkin, supra note 177, at 2243.


338. In 1986, an attorney for a blood products manufacturer said that “[t]hus far we’ve been able to avoid the blood organizations fighting among themselves and with the prescribing physicians. That sort of fighting will make the case for plaintiffs.” ABC Board Reviews New Donor Group, Confidential Unit Exclusion, AABB BLOOD BANK WEEK, supra note 5, Dec. 19, 1986, at 3.
fications that most state legislatures and jurisdictions accept: (1) that blood bankers have no better information about transfusion risks than physicians or patients; (2) that donor screening cannot substitute for laboratory testing; and (3) that the Restatement’s comment k applies because blood is like a vaccine. None of these assumptions has any support by logic or by empirical evidence.

Perhaps the most influential argument that led courts and legislatures to adopt shields is the fear that strict liability would curtail blood supplies.\textsuperscript{339} I interpret this theory to mean that the litigation damages that blood banks would sustain without an exemption from strict liability would be so great that they would cease to operate. In other words, blood banks—after adopting the better screening, testing, or warnings that strict liability required—could not raise the price of their products sufficiently to continue making a profit. It is not clear to me, however, why this argument applies to blood banking uniquely. Other industries continue to operate in spite of the higher costs that strict liability causes—whether they are competitive or monopolistic, for-profit or not-for-profit.\textsuperscript{340} At any rate, the purpose of a strict liability rule is not to minimize industry operating costs. Its purpose is to strengthen the incentives of producers to compare the costs and benefits of precautions whenever they have superior information about risk and to remove impediments to disclosing useful information to consumers.\textsuperscript{341} The argument that blood banks cannot survive with strict liability is tantamount to arguing that they cannot survive if consumers are fully informed about transfusion


\textsuperscript{340} The failure of blood banks to provide the correct level of safety—that is, the standard of care that consumers value in excess of its extra cost—does not appear to be related to their typical positions as regional monopolies. Monopolists charge monopoly prices, but the theory of monopoly does not imply that profit-seeking monopolists will fail to provide increments in product quality that consumers are willing to pay for. Moreover, it is not clear that the not-for-profit status of blood banks is relevant. As the AABB’s executive director said, “Think of us as tax-exempt rather than not-for-profit. We have to make a profit.” Quoted in Andrea Rock, Inside the Billion-Dollar Business of Blood, Money, Mar. 1986, at 153, 158.

\textsuperscript{341} Eckert & Smith, supra note 126.
risk.

Under the industry custom rule at the present, blood bankers screen donors relatively lightly and rely on laboratory tests for antibody reactions, which have error rates. They use a pool of about 9 million donors, who give an average of 1.5 times per year. About one-fifth of this group are first-time donors, who are more likely to transmit disease. In 1987 repeat women donors were nine times less risky than first-time males, but women constituted only 42% of the pool.

Since under the strict liability rule the legal risk of using such a huge donor pool would increase, blood bankers would find it rewarding to screen donors more carefully. Either they can test inside the laboratory for antibody reactions or they can “test” more extensively outside the laboratory for donor characteristics associated with lower risk. What I and others have proposed are donor registries—limited panels of low-risk repeat donors who are in good health to begin with, who maintain their health, who have not been transfused since 1977, who agree to a confidential and more detailed medical history (including questions about promiscuity), who have not had a venereal disease, and who agree to more extensive testing of their blood, if necessary, than was routine at blood banks in 1991. Registry donors would give as often as good health allowed and would be replaced only when necessary with new, equally well screened and tested persons from the same low-risk groups.

One difference between registries and the donor screening recommendations that the FDA issued in 1990 is that the FDA excludes persons who have exchanged money or drugs for sex, have had syphilis or gonorrhea (but not other venereal diseases), or who have received a transfusion of blood or blood products within the past twelve months. In registries these events or behaviors (and others) would establish lifetime exclusions. The FDA’s decision to recommend that blood banks ask donors directly about all risk behaviors,

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342. See supra note 39 and accompanying text describing the FDA donor screening recommendations of December 1990.
343. Yearly attrition of donors in the ANRC system is about 15%. S. Gerald Sandler, The Case for Enrolling and Testing, but Not Collecting, During a Donor's First Visit, Presentation at the 28th Annual Meeting of the Council of Community Blood Centers, Clearwater, Fla. (Feb. 18-22, 1990), at 3. First-time donors are riskier because repeated medical history screening sometimes reveals information justifying exclusion that the donor forgot to mention previously. Yalon & Perkins, supra note 287, at 132; Leitman et al., supra note 42.
344. Cumming et al., supra note 32, at 944-45.
345. Eckert, supra note 22, at 14-26; Kessel, supra note 139, at 272-76, 287 n.71.
346. A survey by CDC in early 1990 revealed that between 1977 and 1985, 5% of adults (about 9 million) had received a blood transfusion and 1% (1.8 million) did not know whether they had been transfused. CDC Reports New Information on AIDS and Blood Donation, CCBC Newsletter, supra note 14, Oct. 26, 1990, at 4-7.
however, is a step in the right direction.

Available evidence shows that stronger donor screening culls infectious blood when dangerous viruses cannot be detected by specific laboratory tests. For instance, in the 1960s and 1970s the Mayo Medical Center in Rochester, Minnesota—in a rural area of about 120,000 residents and employees—utilized a “small, selected, targeted and tested donor pool.”[^4^] It rejected random or walk-in volunteers that regular blood banks accepted. Registered donors, many of whom received cash or other awards, gave three to four times per year. In 1976 donors who were hepatitis B carriers at the Mayo clinic were about one-eighth as common as at the nearby ANRC regional center, which was the safest Red Cross blood in the United States at the time.[^3^][^4^][^8^] In a 1976 report to the Congress the Comptroller General found similar results at other hospitals that used registries.[^4^][^6^][^9^] These arrangements once were common and are of the kind that strict liability would encourage. That makes it difficult for me to believe that strict liability would cause blood banks to close.

Even such a simple factor as geography can reduce HIV risk. In the fifty states in the year ending February 1992, 44,474 AIDS cases for all risks were reported to the CDC. Figure 2 shows that 28,726 or about 65% were concentrated in six states: New York (7,910), California (8,317), Florida (5,585), Texas (3,061), New Jersey (2,212), and Illinois (1,641). Six other states had 86 cases or about 0.19%: Montana (26), Alaska (23), Vermont (14), Wyoming (14), South Dakota (5), and North Dakota (4).[^35^][^4^] The distribution of blood donors with anti-HIV in 1986-1987 by state on a per capita basis in Figure 3 shows a similar pattern. In California in 1987-1988, for example, blood donors with anti-HIV were about twice as likely to be found among men than women and about twice as likely

[^347^]: Howard F. Taswell, Directed, Paid and Self Donors, in Competition in Blood Services 147 (AABB ed. 1987). Noncash volunteer donors required more blood bank personnel, higher solicitation costs, longer hours of operations, and resulted in less blood harvester per donor. Unit costs were about half as much with cash donors, compared to noncash volunteers. Id. at 144-46.


to be found in Los Angeles and San Francisco as in the rest of the state. In 1987-1989 the rate of HIV infection among San Francisco blood donors was 1.5 times the national average. Metropolitan areas under 500,000 population reported 10% of all AIDS cases before 1985 but 19% in 1988. In summary, although geography has become a less effective marker for risk as the HIV epidemic has advanced, it remains reasonably accurate. It is not, however, a panacea. In some rural areas viral hepatitis and diseases spread by bites from ticks and fleas are relatively common, so careful donor screening remains essential.

FIGURE 2
Adult-adolescent and pediatric AIDS cases, reported March 1991 through February 1992, United States


353. Centers for Disease Control, First 100,000 Cases of AIDS, supra note 3, at 561.
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FIGURE 3
HIV antibody prevalence (percent positive) in blood donors, combined data from adjacent centers, by state, July 1986-June 1987


A blood bank's "critical decisions," Marc Franklin argued, "are where to conduct its business and which donors it will seek out and use.\textsuperscript{354} Locating blood banks in cities where the incidence of viral hepatitis was high—when direct tests for viruses were poor, and without using registries—was a fateful decision.\textsuperscript{355} The effect of introducing strict liability would be to lead blood banks in higher-risk areas to become centers for distributing to hospitals blood that is

\textsuperscript{354} Franklin, supra note 139, at 466.
\textsuperscript{355} The high rates of transfusion hepatitis in the 1960s and 1970s are usually attributed to paying donors cash, but were in fact caused by the location of blood banks and by inadequate donor screening. See Eckert, supra note 22, at ch. 2.
imported from lower-risk areas. In the era before preservatives extended shelf life it was probably necessary to collect blood near hospitals. Blood is now regularly shipped within the AABB, ANRC, and CCBC “exchanges.” Los Angeles imports blood from Oklahoma, and New York imports it from Florida and Europe. In 1991 about one blood donation in ten crossed state lines. Hence, strict liability would cause changes that are only a matter of degree.

Experience indicates that blood bankers respond to changes in liability rules. For example, blood banks lost two inventory-testing cases and were reversed in principle on the appeal of the case that they won. Later, when new tests were introduced, the industry adopted stronger rules for testing inventory. By the same token, I expect that donor screening practices would improve if strict liability became the rule.

VII. CONCLUSIONS

Blood safety in the United States is determined by blood bankers and by politicians in state legislatures and in the FDA. Their strategy has been to displace the ex post private damage action with ex ante incentive controls through a combination of industry self-regulation and direct FDA regulation. State laws shield blood banks from strict liability. In negligence cases the standard of due care is usually industry custom. Under this relatively weak rule blood banks have won most of the AIDS cases, including the most important ones. The FDA relies heavily on the industry for advice in setting key risk-management standards. The probability of requiring a transfusion in a given year is so low that it does not pay the average consumer to learn more about blood safety or to try to influence regulation. The gains of lobbying exceed costs for the blood banks, so they have influence over the politicians in state legislatures and at


357. See supra note 296 and accompanying text. One commentator has argued that the availability of an effective laboratory test for anti-HIV undermines the premise of blood shield statutes and justifies strict liability. Note, AIDS; Blood Bank Liability, supra note 258, at 372-73.
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The precautions that the industry and the FDA have taken since AIDS emerged have been viewed by a presidential commission as too little and too late. But neither the industry nor the FDA concedes any errors, and the mechanism by which each makes decisions has not changed materially. The industry continues to be conservative in adding new precautions. It believes that its response to AIDS was appropriate and that the public has an unrealistic expectation of blood safety.

I argue that industry self-regulation and direct FDA controls have been a poor substitute for liability. Since blood bankers have superior information on how to reduce transfusion risks by screening donors, testing blood, and warning physicians, it would be appropriate for them to be subject to strict liability. Since their three trade associations claim expert status, set key care levels, and jointly control risks, joint liability for negligence should be considered. The resulting factual inquiry would help to determine whether they chose cost-beneficial care levels.

The future course of litigation against individual blood banks is unclear. Among potential plaintiffs, about seven percent of those with transfusion AIDS are children. Their economic damages, according to theories based on lost earnings, are speculative. That may weaken the incentives of attorneys to take their cases. Some states extend statutes of limitations and statutory caps for malpractice awards to blood banks, which further weakens such incentives. Attorneys of defendants may specialize in blood cases more than those

358. This outcome is common in regulated industries. See George J. Stigler, The Theory of Economic Regulation, 2 Bell J. Econ. & Mgmt. Sci. 3 (1971); Sam Peltzman, Toward a More General Theory of Regulation, 19 J. Law & Econ. 211 (1976).


361. Owing to HIV's long latency, plaintiffs may not have claims if blood banks are considered providers of medical services and if statutes of limitations for medical malpractice toll from the date treatment for the primary illness was terminated rather than from when the HIV infection was discovered. Kaiser v. Memorial Blood Center, 721 F. Supp. 1073 (D.Minn. 1989). In New York, HIV in blood is considered a toxic substance, and the statute of limitations tolls from the date that the injury was discovered. DiMarco v. Hudson Valley Blood Servs., 542 N.Y.S.2d 521 (N.Y. App. Div. 1989). Twenty-five states cap malpractice damage awards, usually for noneconomic damages.
of plaintiffs. But two courts broke with the precedent of granting defendant blood banks an order to protect the confidentiality of their internal documents. That may lower the cost of bringing new lawsuits.

Even if the debate over liability for transfusion AIDS is nearly over, our society is at a crossroads. The supply of viruses and parasites is not likely to decline. Strict liability for blood banks would encourage them to solicit donors in low-risk areas and to screen them more carefully. Most major cities do not produce the wheat or lettuce that they consume. Why should they collect blood locally if it can be obtained more safely through inter-regional transactions?

Perhaps their experience with AIDS will lead blood bankers to choose different care levels before the next deadly virus arrives. But in 1983 they preferred the risks of controversy and litigation to the extra costs of precautions or clear warnings. Plaintiffs and defendants bear their own costs, so litigation is expensive for defendants even when they triumph. In 1989 apparently some blood bankers were concerned about the adequacy of their malpractice insurance and were sour about lawsuits and public criticism. An FDA blood-banking official said, before he became the executive director of the AABB, that "one hears recurrently about how the fun has gone out of blood banking, of the lack of appreciation of the public and the media." Will the gratitude that blood bankers seem to crave for

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362. Vansant v. American Red Cross, No. 4881 (Pa. Court of Common Pleas, Sept. Term, 1989); PA Court Rejects Protective Order for Red Cross Documents, 1990 AIDS Litig. Rep. 4602-03; Motion of the American Red Cross for Protective Order, id. at 4630; Memorandum of the American Red Cross in Support of Its Motion for a Protective Order, id. at 4632; Plaintiffs' Response to American Red Cross' Motion for Protective Order, id. at 4615; Order, Bradway v. American Nat'l Red Cross, No. 1:89-CV-1073-MHS, 1990 AIDS Litig. Rep. 5124 (N.D. Ga. Aug. 16, 1990); GA CT: Red Cross Must Reveal Documents but not Donor Names, id. at 5097-98.


supplying what once was viewed as the “gift of life,” plus concern over malpractice insurance, be enough to get them to take cost-beneficial precautions against the next blood-borne virus or parasite? We may find out only after it arrives.

APPENDIX. AUTHOR’S CHRONOLOGY OF THE RESPONSE TO AIDS THREAT.

EVEN Ts LEADING UP TO THE CDC’S WARNING

1977
This is the earliest date that AIDS is believed to be transmissible.

June and July 1981
The first cases among homosexual men of what was later called AIDS are reported in a CDC publication.

July 1982
Three cases among hemophiliacs are reported in a CDC publication.

July 1982
The New York Blood Center implements a surrogate blood test for hepatitis.

July 27, 1982
An open meeting of the Public Health Service for blood bankers and others is held to discuss the hemophilia cases. Various theories of AIDS are discussed, including its characteristics that suggested the possibility of a blood-borne infectious agent. The meeting results in neither recommendation nor action.

December 1982
The death of a San Francisco infant after transfusion from a donor who later died after being diagnosed with AIDS is reported in a CDC publication.

January 4, 1983
The CDC convenes a meeting in Atlanta of blood bankers and others to warn of likelihood that AIDS is caused by a blood-borne agent. Blood bankers reject the CDC’s recommendation either to ask donors directly about risk behavior or to adopt for AIDS another surrogate test for hepatitis. No conclusion is reached about how to exclude high-risk donors.
RESPONSE OF THE FDA AND BLOOD BANKS TO THE CDC'S WARNING

January 13, 1983
The AABB, ANRC, and CCBC issue a joint statement on high-risk donors. They conclude that evidence for a blood-borne cause of AIDS is incomplete and that donors should not be asked directly about risk behavior.

March 4, 1983
A Public Health Service (PHS) interagency group states in a CDC publication that available evidence suggests that AIDS is caused by an agent that is probably transmitted by blood.

March 7, 1983
The AABB, ANRC, and CCBC issue a new joint statement that acknowledges the differences between their first joint statement and the report of the PHS interagency group.

March 24, 1983
The FDA issues donor screening recommendations that identify risk groups conservatively and are consistent with first joint statement of the blood banks.

April 1, 1983
The blood bank in Oklahoma City implements the surrogate test for hepatitis adopted in 1982 by the New York Blood Center. By the end of 1983 about four banks are using this test routinely.

June 22, 1983
The AABB, ANRC, and CCBC issue a joint statement opposing directed donations.

July 1, 1983
The Stanford University Blood Bank implements its T-cell surrogate test for AIDS.

January 1984
A published study links seven AIDS patients to transfusions from high-risk donors with pre-AIDS blood abnormalities. Later a United States district court takes this as dispositive evidence as to when the scientific and medical communities reached a consensus that AIDS could be blood-borne.

April 1984
Scientific papers identify the AIDS-causing agent (then called HTLV-III, now called HIV).

May 1, 1984
The San Francisco blood bank implements as a screen for AIDS
the surrogate hepatitis test that the CDC recommended on January 4, 1983. The ANRC's regional blood center in San Jose followed suit in June 1984.

September 13, 1984
The Tulane University Medical Center blood bank adopts the T-cell surrogate test for AIDS that Stanford University Blood Bank adopted in 1983.

March 2, 1985
The FDA licenses the first test kits to screen blood for the antibody to HIV (anti-HIV).

RESPONSE SINCE THE ADOPTION OF THE BLOOD TEST FOR ANTI-HIV

July 1, 1985
The AABB requires members to test for anti-HIV.

August 1985
The ANRC publishes its initial experience with the anti-HIV test for over 1,000,000 donors in all ANRC regional centers. The prevalence of HIV turns out to be two to three orders of magnitude greater than the earlier estimates of blood bankers.

December 15, 1986
The FDA recommends that blood banks adopt the confidential unit exclusion procedure.

July 1, 1987
The AABB requires that members implement the surrogate hepatitis test adopted in 1982 by the New York Blood Center as well as the surrogate hepatitis test recommended for AIDS by the CDC on January 4, 1983.

January 5, 1988
The FDA requires all blood banks to test for anti-HIV.

June 24, 1988
The Presidential Commission on the HIV epidemic concludes that the blood banking industry's response to the AIDS threat was "unnecessarily slow," that the industry was hesitant on economic grounds to promote strategies to minimize the use of transfusion therapies, and that the FDA "relies heavily" on the industry for advice on which standards to set.

December 5, 1990
The FDA removes Haitian immigrants from its list of high-risk
donor groups and recommends that blood banks interrogate donors directly about risk behaviors.