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A CHRONOLOGICAL AND LEGAL ANALYSIS

OF THE

RICKY RAY HEMOPHILIA RELIEF FUND ACT[1]

James B. Reed, Esq.[2]

Note to the Reader: this document contains redlined portions intended to emphasize the most important 10-15% of the document.

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[1]This document is copyrighted, 1996, 1997 and 1998. It is intended by the author for use as part of U.S. Senate Labor and Human Resources Committee and House Immigration and Claims Subcommittee hearings concerning the Ricky Ray Hemophilia Relief Fund Act. This document appears in earlier draft form in the September 19, 1996 U.S. House Immigration and Claims Subcommittee, House Judiciary Committee, Hearings Report on the Ricky Ray Hemophilia Relief Fund Act. Additional copies available upon request.

[2]1989 - Chair, AIDS Litigation Working Group, the National Hemophilia Foundation; 1988 - J.D., Columbia Law School; admitted - District of Arizona, Ninth Circuit Court of Appeals, Court of Federal Claims, and the U.S. Supreme Court.

JON KYL
ARIZONA
702 HART SENATE OFFICE BUILDING
(202) 224-4521

COMMITTEES:
JUDICIARY
INTELLIGENCE
ENERGY AND NATURAL RESOURCES

United States Senate

WASHINGTON, DC 20510-0304

STATE OFFICES:
2200 EAST CAMELBACK ROAD
SUITE 120
PHOENIX, AZ 85016
(602) 840-1891

7315 NORTH ORACLE ROAD
SUITE 220
TUCSON, AZ 85704
(520) 575-8633

October 8, 1997

Senator James Jeffords
Chairman
Senate Labor and Human Resources Committee
Dirksen Room 428
Washington, DC 20510

Dear Senator Jeffords:

I respectfully request your consideration of one of my constituents, James Reed, Esq., as a witness for the upcoming Labor Committee hearings on AIDS issues, and in particular, on the Ricky Ray Hemophilia Relief Act.

Jim has severe hemophilia and contracted HIV from the infusion of concentrated blood clotting factor to treat his medical condition. He has spent the last two years lobbying, researching, and writing on the subject of potential FDA liability related to the agency's failure to protect and later to warn hemophiliacs about the existence of tainted blood supplies. His 80-page report on this issue was printed in the September 19, 1996 House Subcommittee on Immigration Claims hearings on the Ricky Ray Act. Jim has brought, in my opinion, an in-depth and well-reasoned legal analysis to what could otherwise be an emotionally charged discussion.

I believe that Jim can offer information and analysis to the Committee that is unlikely to be presented by any other witness. I know that his oral presentation would provide a helpful synthesis of his research and add greatly to the Committee's understanding of the issue. Jim has read all the primary source materials relating to these issues, and I believe he could articulate the legal position of hemophilia sufferers in a most helpful manner.

I thank you for your consideration of this request. If you have any questions, please contact me or my staffer, Tom Alexander, at 4-4521.

Sincerely,

JON KYL
United States Senator

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The views and conclusions contained in this report are exclusively those of the author, and are not intended to reflect the opinions of any of the individuals or organizations acknowledged herein, or to reflect the opinions of any other persons or entities mentioned anywhere else in this document, unless expressly stated.

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A CHRONOLOGICAL AND LEGAL ANALYSIS

OF THE

RICKY RAY HEMOPHILIA RELIEF FUND ACT

"We are carefully to preserve that life which the Author of nature has given us, for it was no idle gift." (Harvey W. Wiley, creator of the Federal Food and Drugs Act of 1906, Commencement address, Hanover College, 1867, FDA Papers, February 1972, p.1.)

"[T]he Food, Drug and Cosmetic Act is to be given a liberal construction consistent with its overriding purpose to protect the public health. . . ." United States v. An Article of Drug . . . Bacto-Unidisck. . . ., 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969).

INTRODUCTION

This report has three objectives: 1) to chronologize the events which give rise to liability on the part of the Food and Drug Administration ("FDA") for a significant amount of the Human Immunodeficiency Virus ("HIV") infection rate for the U.S. hemophilia community; 2) to describe the legal standards which govern the FDA and which this report concludes that the FDA failed to observe during critical periods of the HIV infection of the U.S. hemophilia community; and 3) to suggest a perspective of the issues designed to address the financial dimensions of the Ricky Ray Act. The conclusion of this report, that the FDA failed to observe common law standards of conduct required of it during the period of time when the hemophilia community was exposed to blood-borne HIV, coupled with the unique financial problems posed by HIV infection, in combination with the pre-existing medical and financial stresses imposed by hemophilia, supports the creation of a federal trust fund to assist persons infected with HIV as a result of clotting factor infusion, whether principally or through secondary spousal or perinatal infection, or their survivors.

EXECUTIVE SUMMARY

Four reasons support the conclusion that the FDA is at fault for high HIV infection rates of the U.S. hemophilia community. First, pasteurization technology was available to destroy viruses such as hepatitis and HIV, but the FDA did not require its use for concentrated blood plasma clotting factor VIII proteins ("concentrate") used by hemophilia patients.[3] Second, the FDA possessed sufficient information by August 1, 1982, and at the very least, by mid-January, 1983, to require patient package inserts with the concentrate products that would have warned concentrate users of the risks of HIV transmission, but the FDA did not do so. Third, the FDA did not require that commercial blood donation centers utilize donor questionaires that asked about sexual practices, even though the FDA was aware that the homosexual community was at a high risk for contracting, and therefore, transmitting, the AIDS virus. Fourth, the FDA did not require a procedure known as "surrogate testing" for HIV, which would have tested donor blood for the presence of the core antibody for hepatitis B, which frequently accompanied and therefore revealed the presence of 70-90% of the HIV present in donated blood. The National Academy of Sciences' Institute of Medicine ("IOM") and various other sources have indicated that, if the FDA had required any one of these four procedures, it probably would have prevented numerous HIV infections among hemophilia patients. This paper concludes that, if the FDA had adopted a reasonable combination of safety requirements, it would have prevented a substantial amount of the HIV infections among hemophilia patients, along with subsequent re-infections that may have accelerated the onset of AIDS. This paper will discuss the standards of FDA conduct in Section One, the pasteurization alternatives in Section Two, and the safety procedures discussed by the IOM in Section Three. Section Four discusses the availability of a treatment therapy known as cryoprecipitate that was available at the time, and which greatly reduced the risk of infection from HIV. Section Five proposes that the median midpoint of seroconversion was after January 1, 1983, and therefore, using the estimated date most favorable to the FDA, January 3, 1983, after which time no reasonable scientific uncertainty remained as to the fact that AIDS was

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[3] Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F.Supp. 1379, 1383 (N.D.Cal. 1987):

> Blood clotting, although not fully understood, may be generally described as follows. The clotting process begins when platelets in the bloodstream adhere to the site of a wound. The platelets would be dislodged, however, unless bound in place by strands of fibrin, an insoluble polymer. The formation of a network of fibrin from its soluble precursor, fibrinogen, is critical to clotting. That formation is the result of a complex series of interactions between blood proteins. Factor VIII:C is one of the agents that activate other proteins essential to this process. A deficiency in Factor VIII:C therefore prevents blood clotting.

transmitted by blood, the FDA could have prevented the seroconversion of half of the United States hemophilia population. Section Six proposes a partial theory of FDA motivations, that the FDA publicly understated the risks of blood-borne HIV in order to maintain presumptively quantitatively safe levels of nonpaid[4] donor blood. Section Seven argues that plasma with high titer for hepatitis B unnecessarily exposed the hemophilia community to HIV. Section Eight contends that the private settlement releases in the multidistrict litigation did not release the FDA from liability for breaches of duties owed to those persons who have not received either state or federal benefits for the treatment of HIV. Section Nine distinguishes the duty owed by the FDA to the hemophilia community from its duty to those persons who received blood transfusions for purposes other than to treat clotting factor disorders. Finally, Section Ten determines that the conclusions of Section Five, in combination with the Ricky Ray Act requirement that fund recipients execute a waiver of a cause of action as against the FDA, provides a budgetary offset value of this legislation that is comparable to its anticipated cost. This paper concludes that remedial legislation such as the Ricky Ray Act is appropriate.

[4]The literature and common law generally distinguish between blood for which the source is nonpaid, termed "volunteer" donors, as opposed to donors who are "paid," and who are usually not referred to a "volunteers." Doe v. Cutter Biological, Inc., 971 F.2d 375, 385 (9th Cir. 1992). Volunteer blood has been recognized for the past twenty-five years as far safer than paid blood. See Section II, timeline 1974, p. 18, infra.

SECTION ONE: THE MISSION OF THE FDA AND THE DUTY OF CARE IMPOSED UPON IT BY STATUTE AND COMMON LAW.

A. Statutory and Regulatory Duties of the FDA.

The Federal Food, Drug and Cosmetic Act ("FFDCA") of 1938 was originally signed into law by President Franklin Roosevelt, and has been amended numerous times since then. The Food and Drug Administration is established by the FFDCA to carry out and enforce that law. "Blood derivatives such as Factor VIII are prescription biologicals subject to federal regulation as both 'biological products' and 'drugs'" by the FDA.[5][6] Walls v. Armour Pharmaceutical Co., 832 F.Supp. 1467, 1483 (M.D.Fla. 1993), citing Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262, and citing Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. 21 C.F.R. § 610 (1988).[7]

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[5]The Louisiana State Court of Appeals explains that "Alpha, Armour, Baxter, and Miles were regulated by the Federal Drug Administration (FDA) which set minimum standards for plasma collection and the manufacture of blood component products." Cross v. Cutter Biological, Div. of Miles, Inc., 676 So.2d 131, 136 (La.App.4th Cir. 1996).

[6] Blood banks in general are regulated, inspected and licensed by the FDA. 212 U.S.C. §§ 321(g)(1)(B), 360(b) (1994); 42 U.S.C. §§ 262(C), (d) (1994). The Code of Federal Regulations also requires that the suitability of a blood donor shall be determined by or under the supervision of a qualified physician. See 21 C.F.R. § 640.3(a) (1995). Illinois treats blod banking similarly.

Advincula v. United Blood Services, 678 N.E.2d 1009, 1013 (Ill. 1996).

[7]The Supreme Court of New Jersey explained the scope and nature of federal regulation of blood safety for blood banks in New Jersey:

> State and federal regulations apply to both sectors of the blood-banking industry. The Food and Drug Administration (FDA), an agency of the Public Health Service (PHS) in the United States Department of Health and Human Servics (DHHS), inspects and licenses blood bnaks and other blood facilities. See 21 U.S.C.A. § 321(g)(1)(B) (broadly defining "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," which include blood and blood products); 21 U.S.C.A. § 360(b) (requiring processing establishments, including blood banks, to register with the FDA); 42 U.S.C.A. § 262(c) to (d) requiring inspection and licensing by the FDA (as delegated by secretary of DHHS) of blood or blood-product facilities that participate in interstate commerce); 21 C.F.R. § 5.10(a)(1), (5) (1995) (delegating to FDA authority vested in the secretary, DHHS, and PHS in the Food, Drug and Cosmetic Act (21 U.S.C.A. §§ 262-63); 21 C.F.R. § 607.3(b) (1995) (defining blood as a drug). In New Jersey, the Department of Health (DOH) discharges similar responsibilities. See N.J.S.A. 26:2A-1 (authorizing DOH to regulate

"Under federal law, 'labelling' is broadly defined and includes not only package inserts, but also separate communications concerning the drug, such as 'Dear Doctor' letters sent by drug manufacturers to physicians to provide information about a drug." Walls, 832 F.Supp. at 1483.

The particular sections regarding warnings are set forth in 21 CFR Ch.2, Subpart B -- Labeling Requirements for Prescription Drugs and/or Insulin, § Subsection 201.57(d) states: "Contraindications" - "Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." Subsection (e) "Warnings" states:

> Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.[8]

(emphasis added). As to the issue of warnings, this portion of the CFR is critical to understand the discussion of whether the FDA failed to meet its statutory and regulatory responsibilities.[9]

B. Common Law Standards of Liability for FDA Misconduct.

"A cause of action in tort arises out of a violation of a legal duty imposed upon an actor to avoid causing harm to others." United Blood Services v. Quintana, 827 P.2d 509, 519 (Colo. 1992). "Legal duty is defined in terms of a standard of care. The source of the duty and the corresponding standard essential to the proper discharge of the duty may originate from a judicial decision or a legislative enactment." United Blood Services, 827

> collection, processing and distribution of blood). A blood bank in New Jersey cannot operate without licenses from both the FDA and DOH. 42 U.S.C.A. §§ 262(a); N.J.S.A. 26:2A-4.

Snyder v. American Association of Blood Banks, 144 N.J. 269, 676 A.2d 1036, 1039-1040 (1996).

[8]"The forseeability, not the conclusiveness, of harm suffices to give rise to a duty of care." Snyder v. American Association of Blood Banks, 676 A.2d 1036, 1049 (N.J. 1996).

[9]The debate is encapsulized in a March 7, 1983 New York Times UPI wire, II, 7:5: "[a]lthough there is no conclusive scientific evidence that the infectious agent is transmitted by blood, health officials say 15 cases may be linked to the blood transfusions and several hemophiliacs have died after receiving transfusions." Whether such information was required to be reported to the hemophilia community, along with the additional information in this report, is the essence of the warnings issue.

P.2d at 519. Those standards are not determined by the standard of the industry at the time, particularly where a governmental agency is invested with the powers to set that standard:

> In a professional negligence case, therefore, a plaintiff should be permitted to present expert opinion testimony that the standard of care adopted by the school of practice to which the defendant adheres is unreasonably deficient by not incorporating available practices and procedures substantially more protective against the harm caused to the plaintiff than the standard of care adopted by the defendant's school of practice.

United Blood Services, 827 P.2d at 521.[10]

The FDA is governed by common law standards concerning the reasonability of its conduct. It cannot delay in carrying out its regulatory duties, once it determines that it must act. Cutler v. Hayes, 818 F.2d 879, 898 (D.C. Cir. 1987):

> The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay. Economic harm is clearly an important consideration and will, in some cases, justify court intervention, and "[d]elays that might be altogether reasonable in the sphere of economic regulation are less tolerable when human lives are at stake."

Public Citizen Health Reserch Group v. Augchter, 226 U.S.App.D.C. 413, 702 F.2d 1150 (1983) ("in the context of the OSH Act, designed to protect workers' health . . ., the Assistant Secretary's protracted course in face of potentially grave health risks cannot be characterized as reasonable"). Therefore, an evaluation of the reasonableness of FDA response time is measured, first, by whether the FDA was reasonable in deciding whether

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[10]Doe v. Miles, 927 F.2d at 191.

> The Maryland Court of Appeals recognized four common threads that are generally considered in most cases which conclude that blood and blood products are not unreasonably dangerous. These four common threads are: (1) the nonexistence of any scientific test capable of detecting the viral agent which contaminated the blood at the time of injury; (2) the great utility of the product; (3) the lack of any substitute for the the product; and (4) the relatively small risk of the disease being transmitted by the product. [ftnt: Miles Laboratories, Inc., Cutter Laboratories Div. v. Doe, 315 Md. 704, 733, 556 A.2d 1107, 1121 (1989).

or not it must conduct an investigation, and, second, whether the FDA was prompt in investigating and otherwise responding to the problem in a substantively adequate manner. This paper concludes that the FDA response was both egregious in its delay and in its quality. Because the FDA is responsible for the safety of the nation's blood supply generally, and is responsible for clotting factor VIII concentrate safety specifically,[11] it is ultimately responsible for the failure by the blood banking industry to respond effectively. In so doing, this report concludes that unnecessary HIV-contamination of the blood supply occurred, as did the New Jersey Court of Appeals:

> The Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic concludes that "[t]he initial response of the nation's blood banking industry to the possibility of contamination of the nation's blood banking by a new infectious agent was unnecessarily slow." The evidence at trial supports the jury's finding that the response was not only "unnecessarily slow" but also that it was clearly imprudent and unreasonable, resulting in unnecessary contamination of the blood supply.

Snyder v. American Association of Blood Banks, 282 N.J.Super. 23, 659 A.2d 482, 490 (N.J.Super.A.D. 1995), aff'd 1996 WL 290907 (N.J.).

C. Compensation Programs as a Remedial Device.

The Ricky Ray Act is not the first compensation program of its kind. The National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10, et seq.,[12] became

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[11]The Louisiana Court of Appeals provides a helpful descruiption of the fractionation process:

> Carl Moore, Director of Regulatory Affairs for Cutter, testified that blood is collected from a donor, the plasma is separated from the red blood cells, and the red blood cells are returned to the donor. Plasma from thousands of donors is pooled to produce Factor VIII. Hematologist Dr. Louis Aledort explained that Factor VIII is fractionated from a precipitant of frozen blood plasma known as cryoprecipitate which contains high levels of Factor VIII. Biochemist Milton Mozen, an expert in the manufacture and processing of Factor VIII, explained that cryoprecipitate is placed in a centrifuge and Factor VIII is separated and freeze dried. The patient dissolves the freeze-dried Factor VIII blood derivative and infuses it to control bleeding.

Cross v. Cutter Biological, Div. of Miles, Inc., 676 So.2d 131, 136 (La.App.4th Cir. 1996).

[12]Previously the National Childhood Vaccine Act of 1986, as amended, by the Omnibus Budget Reconciliation Act of 1987, Public Law No. 100-203, Title IV, Dec. 22, 1987, 42 U.S.C. §§ 300aa-1 et seq.

effective October 1, 1988. Section 300aa-11(c)(1) provides the elements that a petitioner must describe in a successful petition for compensation under the Act. The NVICP provides compensation for the following: (1) medical or remedial care, and a variety of custodial and rehabilitative services;[13] (2) award of $250,000 in the event of death;[14] (3)loss of earnings;[15] (4) pain and suffering;[16] and (5) reasonable attorney fees and other costs.[17] Compensation for injuries incurred before the effective date is covered by 42 U.S.C. § 300aa-15(b), and has been interpreted to require compensation for vaccine-related injuries incurred both before and after the effective date of the statute. Brown v. Secretary of DHHS, 18 ClCt. 834, 841-842 (1989). Compensation has been made under the Program for a variety of vaccines. See Brown, 18 ClCt. 834 (for injuries from paralytic polio caused by administration of oral polio vaccine); Kue v. Secretary of Department of Health & Human Services, 18 Cl.Ct. 777, 778-779 (1989) (parents of infant who died as a result of hypotonic-hyporesponsive collapse one day after administration of DPT vaccine entitled to recovery); Hanagan v. Secretary of the DHHS, 19 Cl.Ct. 7 (1989) (child who had seizures and resulting injuries after receipt of diphtheria-tetanus-pertussis vaccination entitled to compensation); Storrer v. U.S., 662 F.Supp. 18 (N.D.Ohio 1986) (swine flu vaccinee entitled to compensation for contraction of Guillain Barre Syndrome); Baker v. U.S., 660 F.Supp. 204 (D.Conn. 1987) (swine flu vaccinee - Guillain Barre Syndrome); Petty v. United States, 740 F.2d 1428 (8th Cir. 1984) (swine flu vaccinee - serum sickness).

The Act is separate from the National Influenza Immunization Program of 1976 (Swine Flu Act), Public Law 94-380, 42 U.S.C. 247b(j)-(l), as amended (1976). The burden of proof under the Swine Flu Act is the same as that required in a civil suit; a petitioner must prove that it is more likely than not that she has received her injuries from the vaccination. Baker, 660 F.Supp. at 211.[18] In short, a trust fund is an appropriate device to address similar injury in a discernable population receiving a drug subject to the regulation of the FDA. If the FDA is found at fault for those injuries, the only remaining issue is whether to use such a fund retrospectively as a class reimbursement device, or exclusively in a prospective manner for future recipients of blood-borne infections.

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[13]Section 300aa-15(a)(1).

[14]Section 300aa-15(a)(2).

[15]Section 300aa-15(a)(3).

[16]Section 300aa-15(a)(4).

[17]Section 300aa-15(e).

[18]The Baker Court found for the plaintiff and separately held proceedings with respect to the damages issue. Baker, 660 F.Supp. at 211-212.

SECTION TWO: THE FDA FAILED TO REQUIRE PASTEURIZATION OF CLOTTING FACTOR CONCENTRATE TO DESTROY BLOOD BORNE VIRUSES, AND, THEREFORE, FAILED TO REQUIRE THE USE OF TECHNOLOGY ALREADY DEVELOPED AND IN USE IN GERMANY THAT WOULD HAVE DESTROYED MOST BLOOD-BORNE HIV AND PROTECTED HEMOPHILIC USERS OF CONCENTRATE FROM CONTRACTING TRANSFUSION-ASSOCIATED AIDS.

A) A Brief History of Hepatitis and The Development of Techniques to Inactivate Blood-Borne Viruses.

The procedure for heat-treating clotting factor to destroy the hepatitis B virus also destroys the AIDS virus. The technology to do so was available and in use in Germany in 1979. The FDA did not require its use, and as a result, there was no viral inactivation technique licensed in the United States until 1983. The following information serves to establish that, before HIV was widespread in the blood supply, sufficient scientific information existed to make it unreasonable for the FDA to fail to require heat-treatment of concentrate.

1) 1945 - a World War II field study (Rappaport, Capt.) found that plasma pooled and then freeze-dried by commercial manufacturers caused fourteen times as many cases of homologous serum jaundice hepatitis, now known as serum hepatitis B, a fatal form of hepatitis affecting the liver. "On the Trail of Tainted Blood," The Philadelphia Enquirer, April 16, 1995, p.1, p.2, col.1. It was clear that pooling the plasma of blood donors into one large plasma vat allowed the hepatitis B infection of any one donor to spread throughout the pool and infect many or most of the recipients of plasma from that pool.

2) 1950 - A study by J. Garrott Allen of the University of Chicago proved that prolonged heating at 90 degrees fahrenheit for between three and six months could kill the hepatitis B virus. The Philadelphia Enquirer, supra at p.2, cols.1,2.

3) 1962 - A study by the U.S. Office of the Surgeon General confirmed the 1945 Rappaport Study's finding that pooled plasma was the cause of numerous wartime cases of hepatitis B. Furthermore, the report concluded that the larger the plasma pool, the more likely it was to cause a hepatitis B infection. Twenty two percent of the men who received pooled plasma during the Korean War received hepatitis B infections. The Philadelphia Enquirer, supra at p.2, col.1. The cause and effect relationship between pooling plasma donations into one large vat and transmitting a virus from any one donor to many recipients was, by 1962, scientifically certain.

4) 1964 - Judith Graham Poole, M.D., reports a method of obtaining a plasma residue rich in factor VIII, known as "cryoprecipitate." Pool JG, Hershgold EJ, Pappenhagen AR, "High potency antihaemophilic factor concentrate prepared from cryoglobulin precipitate," Nature, 1964, 203:312.

5) 1969 - The first freeze-dried, anti-hemophilia clotting factor ("AHF") concentrates are sold on the market, and they are not heat-treated. The Philadelphia Enquirer, supra.

6) 1970 - the National Institutes of Health introduces a study published in the Journal of the American Medical Association, that warned that just one unit of hepatitis-contaminated plasma could contaminate an entire pool. Diluted ten million times, it was still infectious. The Philadelphia Enquirer, supra at p.2, cols. 2 and 3.

7) Mid-1970's - most American hemophilia patients were taking the freeze-dried concentrate that exposed them to thousands of plasma donors through the pooled plasma concentration system. Hepatitis B becomes the leading cause of death among American hemophiliacs. The Philadelphia Enquirer, supra at p.2, col. 3.

8) Mid-1970's - The federal government allows the continued sale of concentrate without any form of heat treatment but requires patient package inserts that warn of the risk of hepatitis B. The Philadelphia Enquirer, supra.

9) By 1974, studies had found a strong association between paid donors and hepatitis B. Paid donors were poorer and lived in particular urban areas more likely infected with disease. Goldfield, M. (1974).

10) By 1974, massive plasma pooling has begun. The plasma industry:

> had devised a way to filter, concentrate, and mass produce cryoprecipitate in a freeze-dried (lyophilized) form that had a shelf life of 2 years. This product, commonly known as human antihemophilic factor concentrate or Factor VIII concentrate, was described by one manufacturer as making office treatment possible and being capable of preventing minor bleeds with prophylactic treatment.[19] The medical community and patients welcomed this convenience and eventually Factor VIII concentrates became home therapy, self-injected by the hemophiliac as needed. Thus, a new industry was born. The

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[19]Citing Shanbrom, E., Feke, T., & Tse, D. Hemophilia: Cryoprecipitate and factor IX preparation. Modern Treatment of Hemophilia with a Potent, New AHF Concentrate, 854-860.

> commercial manufacturers eventually installed equipment in their plants to mix in excess of 20,000 liters of human plasma from approximately 20,000 paid donors who submitted to the plasmapheresis process.[20]

Ring and Thomas, "Representing the Hemophiliac With AIDS," Courts, Health Science & the Law, Summer, 1991, vol.2, No.1, p. 175.[21] "Thus, single-donor cryoprecipitate (collected from volunteers as a by-product of blood banks) was used less and less as the convenience products became widely available." Id. The difference between factor VIII concentrate and other blood components, however, was that

> [u]nlike other plasma products, Factor VIII preparations were not pasteurized or treated in any manner to kill viruses presnt in the starting plasma. Because one donor could contaminate the entire pool [fn. omitted], the risk of viral transmission was increased in direct proportion to the number of donors represented in the starting plasma. Hepatitis transmission through use of Factor VIII concentrates became a known risk of the product.

Id.

11) 1976 - The federal government identifies problems associated with the use of clotting factor concentrates, citing the FDA's definition of safety for biologic products: "Safety means the relative freedom from harmful effect to persons affected by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time." The Philadelphia Enquirer, supra.

12) 1978 - German drugmaker Behringwerke AG begins pasteurizing clotting factor concentrate to kill blood-borne viruses. The stability process is described in U.S. patent # 4,297,344 (Schwinn et al, assigned to Behringwerk dated October 27, 1981); Leonard Ring, "Representing the Hemophiliac with AIDS" Courts, Health Science and the Law, Summer 1991, vol.2, No. 1, p.175.

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[20]referring to information "elicited from certain employees of manufacturers in deposition testimony taken in Poole v. Alpha, 86 C 7623 (N.D. Ill.)." Ring and Thomas, supra, at p.182, fn.14.

[21]Donor pools are far larger today. M. Sue Preston, Vice President of Quality & Regulatory Affairs, Alpha Therapeutic Corporation, testified on July 31, 1997 before the House Subcommittee on Human Resources, Committee on Government Reform and Oversight, at page 24, identified the range of donors associated with the manufacturing of the Final Lot Products for Factor VIII concentrate between May and June 1997, as 63,228 - 98,294 donors. At page 25, Ms. Preston indicated Alpha's voluntary commitment to limit "final product donor exposure to the 60,000 limit. . . ."

> The [U.S. plasma] manufacturers claimed that Factor VIII concentrates could not be heated to reduce viral transmission. This is incorrect. While the Factor VIII protein is heat labile – it loses its clotting ability when heated--a foreign manufacturer, Behringwerke of Germany, had by 1979 stabilized the Factor VIII protein so that it resisted the destructive effects of high temperatures. [fn. omitted]
>
> Thus, technology was available. In 1981, Behringwerke was granted a patent in the United States for its pasteurization process applicable to Factor VIII concentrate [fn omitted]. (Pasteurization had long been used by the U.S. manufacturers to kill virus present in albumin, another commercially made plasma product.) This technology applicable to Factor VIII concentrates was ignored by the U.S. manufacturers. The likely reason is an economic one. Pasteurization significantly reduces the yield of concentrate obtained from starting plasma. Because economics of the plasma industry dictate that you don't waste plasma fractions, reduction of yield is undesirable from a profit perspective.

Id. at p. 176. The Ninth Circuit Court of Appeals agreed.

> The technology for heat treating blood was developed in the late 1970s. The record reflects some dispute as to whether the technology was available in the early 1980s to heat treat Factor VIII specifically. However, it appears that the technology definitely was available by March 1983.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 384 (9th Cir. 1992).

13) 1982 through 1983 - U.S. pharmaceuticals begin development of the first U.S. heat-treatment method.

> In July 1982, when three cases of AIDS had been reported in hemophiliacs, the FDA urged the commerical manufacturers to focus on developing a heat treatment process for Factor VIII, ostensibly to reduce the risk of hepatitis B transmission. By November 1983, one manufacturer had received FDA approval for a dry heat process whereby the freeze-dried concentrate, already in its shipping vials, was placed en masse into large ovens and heated at a fixed temperature for a fixed number of

> hours. [footnote omitted] By February 1984, the other manufacturers had received FDA approval on similar processes, with individual variations. Also by early 1984, one of the manufacturers had not only been granted a patent [footnote omitted] but obtained FDA approval on a method of heating the freeze-dried concentrate in a solution. Thus, when requested to act, the industry responded relatively quickly.
>
> The pasteurization process patented by Behringwerke, however, remained unused by the U.S. manufacturers until 1986 despite clinical studies conducted in Germany showing that pasteurized concentrates had not transmitted hepatitis [footnote: Heimburger, N., Schwinn, H., & Mauler, R. (1980). Factor VIII concentrate--hepatitis safe; Progress in the treatment of hemophilia. Die gelben Hefte, 4, 165-174] to users. Moreover, pasteurization was known to kill hepatitis B, a hardy virus. [footnote: Supra, note 31] Today, the dry heat process is no longer used. [footnote: Mannucci, P.M., & Colombo, M. (Oct. 1, 1988). Virucidal treatment of clotting factor concentrates. Lancet, 782-785.

Ring and Thomas, supra, p. 181.

14) 1983 - The FDA approves the first heated clotting factor drug in March 1983. Baxter's method heated the clotting factor at 140 degrees Fahrenheit - as had been done with albumin since the 1940's - for 72 hours. Refinements in the process protected the clotting proteins from heat destruction, as had been done in Germany since 1979. The Philadelphia Enquirer, supra. The "dry" heat treatment process of lyophilized (dehydrated) Factor VIII clotting factor concentrate is described in U.S. Patent # 4,456,590, June 26, 1984 (Rubenstein) filed May 13, 1982. The pharmaceuticals discover from this experience with heat-treatment that HIV is even more susceptible to heat than is hepatitis.[22] Goedert, et al, The New England Journal of Medicine, October 26, 1989, 321:17: "[t]he

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[22] New England Journal of Medicine, Oct. 26, 1989, p. 1145:

> The majority of persons with hemophilia or related disorders became infected with HIV-1 through the use of commercial clotting-factor concentrates that were manufactured before the start of self-exclusion of donors with risk factors for AIDS, HIV-1 antibody screening, and the development of viral-inactivation measures such as the heat treatment of factor concentrates. (footnote omitted). The nearly complete elimination of new HIV-1 seroconversions since 1986 among persons with hemophilia demonstrates the effectiveness of these measures in preventing the transmission of HIV-1.

nearly complete elimination of new HIV-1 seroconversions since 1986 among persons with hemophilia demonstrates the effectiveness of these measures in preventing the transmission of HIV-1." [footnote: "Survey of non-U.S. hemophilia treatment centers for HIV seroconversions following therapy with heat-treated factor concentrates MMWR, 1987; 36:121-4.] See also, K. Schimpf, M.D., et al, "Absence of Anti-Human Immunodeficiency Virus Types 1 and 2 Seroconversion After the Treatment of Hemophilia A or Von Willebrand's Disease With Pasteurized Factor VIII Concentrate," The New England Journal of Medicine, October 26, 1989, pp. 1148-1152. In Israel, only heat-treated factor VIII concentrate was used as of January 1984. Shlomit Orgad, et al, "Antibodies to HIV in Israeli Hemophiliacs: Relationship Between Serological Profile and Disease Development," AIDS Research and Human Retroviruses," Volume 3, Number 3, 1987, p.323. "The decline in the rate of seroconversion [in Israel] can be attributed to the replacement of NHT fac VIII concentrate with heat-inactivated factor VIII (HT fac VIII) concentrate by November 1983." Id.

15) 1985 - FDA approves a solvent-detergent method of purging viruses from plasma developed by Bernard Horowitz and Alfred Prince of the New York Blood Center. Today that pasteurization process is a world standard of care. Horowitz later admits that the major concern and reluctance to using heat treatment as early as the German pharmaceutical was caused by a concern over losing the potency of the clotting factors. He concluded that this later proved to be less of a problem than was expected. The Philadelphia Enquirer, supra at p.2, col.4.

16) February, 1987 - J. Garrott Allen, now a retired head of surgery at Stanford, testifies at a deposition that "No medical, economic or social reason could justify ever using . . . unheated, pooled plasma or its clotting products . . . [l]arge pools are highly profitable, but they are medically bankrupt." The Philadelphia Enquirer, supra at p.2, col.4. He also testifies later that year that he first informed the U.S. army of the benefits of heat-treating plasma in 1940. The Philadelphia Enquirer, supra at p.3, col.1.

Indeed, the pharmaceuticals had possessed the ability for several years to heat-treat clotting factor, but because of their perception that it was not an effective method against hepatitis, it was not used until the presence of HIV in the blood supply was recognized.

> Heat-treated clotting factor concentrates were developed several years ago with the unfulfilled goal of decreasing hepatitis infectivity of factor concentrates. These products have been commercially available, but were not widely used until two studies showed that HIV is heat-sensitive (McDougal et at., 1985b; Spire et al., 1985). The virus was non-detectable when treated according to commercial manufacturers' various specifications (McDougal et al., 1985b).

Janine M. Jason and James W. Curran, "The Epidemiology of AIDS," Blood, Blood Products and AIDS, edited by R. Madhok, MD, C. D. Forbes, MD (Glasgow U.), and B.L. Evatt, MD (CDC), 1987, p. 9.

17) 1993 - Charles M. Heldebrant, director of research and development for pharmaceuticals for Alpha, testifies that his company never worked on killing viruses until mid-1982. The directive to begin heat treatment came not from the medical leadership of Alpha or from the FDA, but from Alpha's marketing department, which sought to stay current with its German competitor, Behringwerke. It took Alpha only 3 to 4 months to develop the process. When asked under oath what technology he had used that could not have been developed years earlier, Heldebrant replied "Absolutely nothing." The Philadelphia Enquirer, supra at p.3, col.1.[23]

The Ninth Circuit Court of Appeals concluded from similar facts that

> It is possible that had the industry concentrated on applying knowledge about heat treatment to the treatment of Factor VIII, that technology could have become available at an earlier date. Heat treatment was never used by the industry during the period at issue in these cases. Since the treatment is 100% effective in destroying HIV, the process could have been an important tool in ensuring the safety of blood products.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 384 (9th Cir. 1992).

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[23] Indeed, the "Executive Summary" of the Committee on Government Reform and Oversight's July 25, 1996, Report entitled "Protecting the Nation's Blood Supply From Infectious Agents: The Need For New Standards To Meet New Threats," explained the extent to which the slow reaction of the FDA to blood sterilization and protection techniques yet remains.

> According to testimony, FDA is also not working effectively with manufacturers to expedite the development of new screening tests and viral inactivation techniques for blood product sterilization. (ftnt. omitted) One manufacturer submitted a 510(k)(80) application for a Chagas' disease [a blood borne disease which, in immunocompromised individuals, can be severe or fatal] screening test as a medical device to FDA's Center for Devices and Radiological Health (CDRH), at the suggestion of FDA in November 1995. The company had already received approval of a 510(k) for diagnostic testing in 1994. In Novmeber 1995, FDA informed the company that the screening indication required filing a Product Licensing Application (PLA) with the Center for Biologics Evaluation and Research (CBER). As a result of this confused regulatory system, to date there is still no approved Chagas disease screening test for donated blood and plasma.

Id., p. 13.

18) 1993 - FDA Commissioner David Kessler testifies before a House subcommittee that his commission erred in its relationship with the blood industry, but that "those days are behind us." However, he also testified that when his own wife underwent surgery, she stored and then used her own blood instead of risking the use of the national blood supply. The Philadelphia Enquirer, supra at p.3, col.1.

B. Conclusion: The FDA Failed to Require a Pasteurization Process That Would Have Prevented a Substantial Amount of HIV Infection.

In sum, the technology to inactivate viral hepatitis B and, therefore, HIV, existed during the 1970s and was used commercially in Germany by 1979. Additionally, the scientific data concerning the risks of hepatitis B from paid donor blood that was pooled were well known by 1974. Nevertheless, the FDA did not require heat treatment of clotting factor concentrate to destroy viral hepatitis B. This failure to inactivate hepatitis B also allowed HIV to remain active in clotting factor concentrate, and represented a missed opportunity to prevent all but a small percentage of HIV infections among hemophilia patients. The remainder of the hemophilia population who used cryoprecipitate instead of clotting factor concentrate would have the same risk of infection as the general population relying upon standard blood supply safety procedures. Pastreurized clotting factor concentrate was preferable to cryoprecipitate, but as Sections Three and Four demonstrate, this was true only if it was pasteurized.

SECTION THREE: THE FDA'S FAILURE TO REQUIRE THE FOLLOWING PROCEDURES RESULTED IN THE EXTENSIVE HIV INFECTION OF THE U.S. HEMOPHILIA COMMUNITY: 1) WARNINGS OF THE RISKS OF AIDS ISSUED TO USERS OF CLOTTING FACTOR CONCENTRATE; 2) SURROGATE TESTING FOR HIV BY TESTING FOR THE HEPATITIS B CORE ANTIBODY TO ELIMINATE HIV-CONTAMINATED BLOOD; AND 3) BLOOD DONOR QUESTIONAIRES INQUIRING ABOUT SEXUAL PRACTICES.

The following information is intended to demonstrate the FDA's failure to take appropriate actions in the form of the above three categories of conduct suggested by the CDC and other organizations at relevant periods of time.

1) June, 1981 - the Centers for Disease Control ("CDC") identify 26 homosexual men with opportunistic diseases in Morbidity and Mortality Weekly Report.

2) January, 1982 - the CDC receives the first report of a hemophilia patient with Pneumocystis carinii pneumonia. Terence L. Chorba and Bruce L. Evatt, "Transfusion-associated AIDS," Blood, Blood Products and AIDS, edited by R. Madhok, MD, C. D. Forbes, MD (Glasgow U.), and B.L. Evatt, MD (CDC), 1987), p. 16.[24]

3) July 9, 1982 - one week prior to the July 16, 1982 Morbidity and Mortality Weekly Report of three hemophilia patients demonstrating symptoms for AIDS, the FDA sends a warning to the pharmaceutical industry concerning the Report's implication for hemophilia patients and clotting factor manufacturers. The U.S. Court of Appeals for the Ninth Circuit upheld a U.S. District of Hawaii finding that:

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[24]The expertise of the CDC in epidemiology and the pre-eminent position of the MMWR as a pathology reporter was already well-known; the CDC's expertise in AIDS reporting also would quickly become known.

> The CDC, with the help of doctors, regularly compiles publications that represent its position on advancements in AIDS research. Input from many different physicians and researchers is printed in these publications. The publications do not necessarily represent the opinions of all the different researchers; rather, the CDC will formulate what it feels is the most accurate position, then publish it.

Moore v. Armour Pharmaceutical Co., 927 F.2d 1194, 1196 (11th Cir. 1991).

> According to the record, on July 9, 1982, the Center (sic) for Disease Control issued a warning that three hemophiliacs had the syndrome that was later named AIDS. This warning focussed on the use of Factor VIII [concentrate], stating that "[a]lthough the cause of this immune dysfunction is unknown, the possibility of a transmissible agent has been suggested and concern about possible transmission through blood products has been raised." On the same day, the FDA sent a warning to the manufacturers of blood products about three hemophiliacs with the disease. That July, many physicians began warning their hemophiliac patients about AIDS.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 383 (9th Cir. 1992). One of the assumptions concerning the first date that the FDA should have been aware that hemophilia patients were at risk for AIDS infection is that the FDA read the July 16, 1982 Morbidity and Mortality Weekly Report. The finding of the Doe Court establishes two important items: 1) the FDA believed the information sufficiently noteworthy to notify manufacturers, but nevertheless did not require a warning label change or a notification of concentrate consumers; and 2) the FDA's awareness of the article prior to the publication of the July 16, 1982 MMWR also establishes that the timing FDA Consumer Magazine articles concerning the overall safety of the blood supply and minimal risk of AIDS to hemophilia patients could have been responsive to forthcoming MMWR reports. Under the federal rules of evidence, the first point is considered an admission of a party-opponent of material evidence.

4) July 16, 1982 - The first, second and third cases of Pneumocystis carinii pneumonia among persons with Hemophilia A are reported in the July 16, 1982 MMWR. Patient 1 "had frequent injections of Factor VIII concentrate for severe hemophilia for many years." Patient 2, "[a]s a patient with severe hemophilia . . . had received received frequent injections of Factor VIII concentrate for several years." Patient 3 "had frequently received parenteral Factor VIII concentrate for severe hemophilia." "[T]he second and third patients were found by the CDC through routine surveillance of requests in June and July of 1982 for drugs available only from CDC to treat P. carinii pneumonia." Terence L. Chorba and Bruce L. Evatt, "Transfusion-associated AIDS," Blood, Blood Products and AIDS, edited by R. Madhok, MD, C. D. Forbes, MD (Glasgow U.), and B.L. Evatt, MD (CDC), 1987), p. 16. Indeed, "[a]ll had been treated with large doses of commercially prepared lyophilized factor VIII concentrates as part of the treatment of their coagulation defect. Two of the three received transfusions for prophylaxis almost daily, and the third received them every four to five days." Menitove, M.D., et al, New England Journal of Medicine, January 13, 1983, 308:2, 83.

In that report, the CDC described perhaps the single most significant investigative finding in the early infection period of the hemophilia community that should have enabled the

FDA to recognize and warn of the widespread AIDS viral contamination of the clotting factor concentrate supply:

> For each patient, records of the administration of Factor VIII concentrate were reviewed to determine manufacturer and lot numbers. **No two of the patients are known to have received concentrate from the same lots.** (emphasis added)

MMWR, supra. Even that understated the extent of the varied factor VIII concentrate usage.

> One patient used concentrates prepared by six different manufacturers; another, concentrates prepared by five manufacturers; and a third, concentrates prepared by three or four. None used the same lot of factor VIII concentrate.

Menitove, et al, supra. The CDC stated in that MMWR issue, supra, that:

> Although the cause of the severe immune dysfunction is unknown, the occurence among the three hemophiliac cases suggests the possible transmission of an agent through blood products.

This conclusion was based upon the fact that:

> Inquiries concerning these initial patients' sexual activities, drug usage, ethnicity and travel or residence provided little evidence that the disease could have been acquired by contact with homosexuals, illicit drug abusers or Haitian immigrants. The hypothesis that AIDS developed in these patients as a result of an infectious agent transmitted by the blood products' administration seemed logical and research for the occurrence of disease in transfusion recipients intensified. Soon it became clear that AIDS was a major problem for blood banks and the plasma industry.

Terence L. Chorba and Bruce L. Evatt, "Transfusion-associated AIDS," Blood, Blood Products and AIDS, edited by R. Madhok, MD, C. D. Forbes, MD (Glasgow U.), and B.L. Evatt, MD (CDC), 1987, p. 16; see also, Menitove, supra, (the patients "were heterosexuals with no history of intravenous drug abuse"). This conclusion by the CDC, that a blood-borne agent might be at work, coupled with the fact that no two of the patients had received the same lots of concentrated clotting factor, meant that, as a result of the past experiences with hepatitis and

pooled plasma, the three patients might represent several hundred infections.[25] Thus, the CDC and the FDA had sufficient information to know that the entire community of severe hemophilia patients was at immediate risk of infection with the agent causing this potentially fatal immune suppression.[26]

The Superior Court of New Jersey wrote that, following the "red flag" raised by the July 16, 1982 MMWR, "[a]t least from that time forward, the CDC and others working in the field assumed as a working hypothesis that AIDS was caused by a blood-transmissible infectious agent." Snyder v. American Association of Blood Banks, 282 N.J.Super. 23, 659 A.2d 482, 486 (N.J.Super.A.D. 1995). That the AIDS virus was blood-borne was, at this time, "a belief most experts had come to share when the hemophiliac cases were reported. . . ." Snyder, 659 A.2d at 489. The Snyder Court related the testimony of CDC epidemiologist Don Francis, that "[the report of the three cases of AIDS among hemophilia patients] brought much of our speculation about the disease to . . . a conclusion about its transmissibility." Snyder, 676 A.2d at 1042 (ellipses in original).

5) July 27, 1982 - the CDC, FDA, NIH, the National Hemophilia Foundation, the American National Red Cross, various blood banking organizations, the National Gay Task Force, the New York City Health Department and the New York Inter-Hospital Study Group on the Acquired Immune Deficiency Syndrome (AIDS) and Kaposi's Sarcoma (KS) meet in New York City to discuss the significance of the occurrence of opportunistic infections with Pneumocystis carinii pneumonia (PCP) in three patients with

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[25] June 5, 1983 - NYT, "Blood Donor Policy Revised Over AIDS," XXII, 4:5:

> Each pool of Factor VIII concentrate goes to about 100 patients. For each hemophiliac diagnosed as an AIDS victim, there are 99 who received the same lot of Factor VIII concentrate. The 99 did not contract the illness but might do so. The incubation period for AIDS appears to vary from two months to two years and could strike any one of these 99 blood recipients at any time during that span. Because of the large number of donors who contribute to each pool of plasma, it is not possible to identify the infected donor.

[26] Study of the Factor VIII manufacturing process led CDC researchers to believe that a virus caused AIDS. In producing Factor VIII, fractionators would filter out larger infectious agents, such as bacteria, to reduce the likelihood of contamination. The filters, however, could not trap smaller agents, such as viruses. Dr. Francis explained that the realization that the infectious agent was a virus that could be transmitted by blood "was a red flag and concerned us greatly about the potential for blood-borne transmission of other therapeutic blood products."

Snyder v. American Assoc. of Blood Banks, 676 A.2d 1036, 1043 (N.J. 1996).

hemophilia. The meeting produced the "Summary Report on Open Meeting of PHS Committee on Opportunistic Infections in Patients with Hemophilia."[27]

Three hemophilia patients diagnosed with AIDS are discussed, and the Summary Report concludes:

> II. F. * * * Hemophilia patients use large amounts of Factor VIII (40,000 to over 65,000 factor units per year) from multiple preparations with subsequent potential exposure to material derived from thousands of donors.
>
> G. The occurence of PCP in three patients with hemophilia is disturbing, particularly since there is no previous evidence that this infection is common in hemophilia patients. The two patients who had immunologic studies performed demonstrated a T-cell abnormality similar to that among other patients in other high-risk groups with AIDS\KS. There is no known intrinsic immune disorder in hemophilia patients that would permit or promote such opportunistic infections.

Id. The FDA was already aware of the hepatitis B infection rates for hemophilia users of concentrate made from pooled plasma, and therefore realized the risk of HIV infection to patients who infused with concentrate. Indeed, the hematology community already understood the risk that factor concentrate transmitted an AIDS-causing agent, since "[c]linically, cases

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[27]The three cases were reported in the July 16, 1982 MMWR. (See Section 3, Timeline 4). For a discussion of lay hemophilia community access to CDC information or to the MMWR, see fn. 18, infra. The MMWR was a for-purchase publication whose existence and scientific/epidemiological importance was unknown to most hemophilia patients. Generally, little of the information that circulated among government officials was available to the lay public. The House Committee on Government Operations reported in The Federal Response To AIDS, November 30, 1983, p. 30:

> For the first two years of the epidemic the Department [of Health and Human Services] failed to develop a plan and budget for discharging this responsibility [for public education] in a coordinated and comprehensive way. Between 1981 and mid-1983, the public education and information dissemination effort was largely comprised of disparate meetings and conferences, occasional articles in medical journals and news releases, interviews with the press, individual phone conversations, and the publication of articles in CDC's Morbidity and Mortality Weekly Reports (MMWR). [fn. omitted] The MMWR was the most systematic dissemination vehicle used for reporting surveillance and epidemiological information, but its circulation has been severely restricted by recent budget cuts. [fn. omitted] Between August 1981 and May 1982, even the MMWR contained no information on AIDS.

occurred in persons with no other risk factors and, initially hemophiliacs who had heavy use of Factor VIII were more apt to have ARC and AIDS." Dietrich, "Epidemiology of HIV Infection," Recent Advances in Hemophilia Care, 1990, pp. 80-81. The summary report stated that "AIDS had 'characteristics which suggest an infectious etiology,' and that a 'possible mode of transmission is via blood products.'" Smith v. Cutter Biological, Inc., 823 P.2d 717, 721, fnt. 4, (Hawaii 1991). At the meeting's conclusion, the FDA did not require any of the previously-described safety measures, nor did the FDA require the clotting factor concentrate manufacturers to issue warnings to hemophilia patients through patient package inserts or other methods designed to effectively communicate warnings about the risk of AIDS to clotting factor concentrate users.[28]

6) November, 1982 - The CDC issues safety guidelines for health care workers entitled: "Acquired Immune Deficiency Syndrome (AIDS): Precautions for Clinical and Laboratory Staffs." The guidelines state:

> The etiology of the underlying immune deficiencies seen in AIDS cases is unknown. One hypothesis consistent with current observations is that a transmissible agent may be involved. If so, transmission of the agent would appear most commonly to require intimate, direct contact involving mucosal surfaces, such as sexual contact among homosexual males, or through parenteral spread, such as occurs among intravenous drug abusers and **possibly hemophilia patients using Factor VIII products.** [. . .] These patterns resemble the distribution of disease and modes of spread of hepatitis B virus, and hepatitis B virus infections occur very frequently among AIDS cases. (emphasis added)

The CDC's guidelines clearly reflected a knowledge that AIDS was transmissible by blood. For example, those guidelines included the following:

> 2. Gloves should be worn when handling **blood specimens, blood-soiled items,** body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
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> * * * *

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[28]The November 30, 1983 Committee on Government Operations Report criticized the HHS information dissemination efforts: "Until the summer of 1983, HHS did little to disseminate information about AIDS to affected communities, to health care workers, and to other occupational groups that were likely to be in contact with AIDS." The Federal Response To AIDS, House Report, Nov. 30, 1983, p. 30.

> 4. . . . Hands should also be washed thoroughly and immediately if they become contaminated with **blood**.
>
> 5. **Blood and other specimens should be labeled prominately with a special warning, such as "Blood Precautions" or "AIDS Precautions."** [. . . .] **All blood specimens should be placed in a second container, such as an impervious bag, for transport. The container or bag should be examined carefully for leaks or cracks.**
>
> 6. **Blood spills should be cleaned up promptly with a disinfectant solution, such as sodium hypochlorite (see above).**
>
> 7. **Articles soiled with blood should be placed in an impervious bag prominently labeled "AIDS Precautions" or "Blood Precautions" before being sent for reprocessing or disposal. Alternatively, such contaminated items may be placed in plastic bags of a particular color designated solely for disposal of infectious wastes by the hospital.** (emphasis added)

These guidelines reflect not merely a concern that AIDS was transmissible by blood, but a conclusion by the CDC that a blood borne agent was transmitting AIDS, and that health care workers needed to be warned and protected from blood contamination.

7) November, 1982 - The FDA did not relay the CDC's concerns to the hemophilia community and provide the same information to the known users of blood products, such as hemophiliacs, that the CDC was providing to persons who only potentially were exposed to contaminated blood, such as physicians, nurses and other hospital employees. Instead the FDA published an article that same month in its November 1982 issue of FDA Consumer concerning commercial blood banks that made no mention whatsoever of AIDS. The article contained language such as the following:

> Around these needs [for blood] has grown a sophisticated industry that uses whole blood and its major components efficiently, and relatively safely, to improve human health.

"Blood: A Fluid You Can Bank On," FDA Consumer, November 1982, vol.16, No.9, p.1. The only mention of blood borne viruses in the entire article was of hepatitis B, the risk of which the FDA Consumer minimalized.

> One problem involving blood transfusion is not yet completely solved. A viral infection of the liver called hepatitis can be

> transmitted in whole blood, plasma and some plasma products. The infection can be mild and virtually without symptoms, but more serious infections can lead to chronic liver disease, including cirrhosis. There also has been evidence linking at least one type of the disease, hepatitis B, with an increased risk of liver cancer. Hepatitis B strikes an estimated 200,000 Americans, primarily young adults, each year -- with about a tenth of the cases linked to transfusions. Of the unfortunate 1 percent of hepatitis B victims whose disease is extremely severe, about half die.
>
> Since 1972 FDA has required all blood and blood products to be tested for hepatitis B. Labels of products for transfusion must indicate whether they come from paid or volunteer donors, since blood from paid donors carries a significantly higher risk of post-transfusion hepatitis.

Id. Despite the warnings of the most prominent epidemiological research institution in the world, the CDC, the FDA ignored the CDC's warnings and published a contrary article the same month that the CDC published its blood safety guidelines concerning AIDS. The fact that the FDA acknowledged the dangers associated with paid donor blood suggests that these choices of article composition and timing of publication were intentional. That the FDA was aware of the forthcoming CDC healthcare worker guidelines is established in timeline 3.

8) December 3-4, 1982 - The Blood Products Advisory Committee (BPAC) of the Office Of Biologics, the National Center for Drugs and Biologics, the Food and Drug Administration, meets in Bethesda, Maryland. While there were approximately fifty total participants and observers at the meeting, the official members present were: Joseph R. Bove, Chairman, Elizabeth Hafleigh, Ronald D. Miller, William V. Miller, James W. Mosley, John W. Suttle, James G. White, and Dorothea Zucker-Franklin. The summary minutes for the meeting were approved and adopted on February 7, 1983. The following minutes prove particularly relevant.

> 26. Dr. Jay Menitove, Blood Center of Southeast Wisconsin, Milwaukee, WI, reported on a series of studies conducted in hemophiliacs, some of whom had received AHF concentrate and others who had only received Cryoprecipitated Antihemophilic Factor. Measuring the T4/T3 cell ratio in each group, he found that the ratio was lowered in the patients receiving AHF. Similar changes had been found in patients with AIDS. His study included 42 patients, 9 in the cryoprecipitate treated group and 33 in the AHF group. One of the 9 patients in the cryoprecipitate group had an altered T4/T3 ratio as did 16 of 33 in the AHF group. Among

the patients in the AHF group, no correlation was found suggesting a dose response relationship.

27. Dr Bruce Evatt, Centers for Disease Control, Atlanta, GA, briefed the committee on the current status of their investigations on AIDS. He stated that the epidemic is rising at an almost exponential pace, with 788 domestic cases and about 50 foreign cases reported since mid-1979. The incubation period, as determined from about 35 cases where person-to-person transmission has been documented, is about 4 to 7 months with a prodrome before diagnosis of about the same period. The epidemiologic pattern seems to be similar to that of hepatitis B. Cases are now appearing among contacts of persons in the high risk groups.

Eight hemophilia patients receiving AHF have now been reported with AIDS, 3 of which are still alive. About 5 AIDS cases have been reported within the past 18 months in patients following blood transfusions. One confirmed case was a child who recieved an exchange transfusion at birth, was healthy following that, and then developed AIDS. One donor subsequently was diagnosed with AIDS seven months after the donation. Dr. Evatts expressed concern that transfusion associated with AIDS may follow the same increasing pattern seen with hemophilia patients.

28. The foregoing information suggests that Cryoprecipitated Antihemophilic Factor (cryo) may be preferable to AHF concentrate and that AHF requirements should be modified to include an innactivation procedure during processing. Several disadvantages with either of these alternatives were discussed. With cryo, there are problems of convenience to the patient and processing distribution difficulties among others. For AHF, most techniques to reduce infectivity will reduce the yield of Factor VIII, will increase its costs and possibly cause shortages of the product. Concerns about this latter point were expressed, noting that about 10% of the present hemophilia patients without hepatitis B markers (but all new patients) might benefit if hepatitis B infectivity were eliminated. For the new patients, there is now an effective vaccine available. Some participants preferred to leave the products as they are unless it could be shown that AIDS is absolutely related to HBV, stating that problems with HBV are not that severe now.

29. As the meeting concluded, there was a sense of urgency because of the continuing spread of AIDS and because of its long incubation time. There were suggestions for immediate steps to reduce the risk since definitive answers are not yet available. These include increasing reliance on cryo, developing less infectious Factor VIII and IX products, excluding potential high risk donors, and adopting additional screening tests for infectious markers in donor blood. At the next meeting of the committee, closed sessions with the manufacturers will be scheduled to evaluate their efforts to prepare less infectious products. A meeting on tests to prevent transfusion transmitted hepatitis is also planned.

30. **The committee did not recommend any immediate changes in the biologic regulations or regulatory activities at this time.** Several investigations are being intensely pursued by the blood bank community, CDC, NIH, FDA, and the manufacturers which may lead to steps to reduce the risk to recipients of blood products. (emphasis added)

31. Although a closed meeting was scheduled for this meeting, none was held. The meeting adjourned at 3:30 p.m., December 4, 1982.

9) December 10, 1982 - The New York Times describes a report by the CDC of the fifth case of AIDS caused by a blood transfusion, including one of a hemophilia patient "who require[d] frequent transfusions of a blood clotting factor."[29] The CDC report stated

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[29]December 10, 1982 - NYT, "Infant Who Received Transfusion Dies of Immune Deficiency Illness," I,22:3:

> Altogether, the Atlanta centers have documented seven cases of the immunedeficiency disease in hemophilia patients since July. Five of the seven patients died. [. . . .]
>
> "These additional cases provide important perspectives on AIDS in U.S. hemophiliacs," the report said. "Two of the patients described here are 10 years of age or less and children with hemophilia must now be considered at risk for the disease. The number of cases continues to increase and the illness may pose a significant risk for patients with hemophilia," the report said.

The CDC considered the cases of infant transmission to be dispositive of the issue of whether AIDS was blood borne:

> The CDC reported that the children could have been infected by the "transmission of an 'AIDS agent" from mother to child, either in utero or

that "[t]his and continuing reports of AIDS among persons with hemophilia A raise serious questions about the possible transmission of AIDS through blood and blood products." What little the FDA might have failed to understand regarding the CDC's perception of the threat should have been clarified by the article.

10) December 13, 1982 - The New York Times further describes the number of children infected at that time, who clearly did not fall into the ordinary risk groups ("American Red Cross to Study Blood Donor Policy," II, 17:5):

> The American Red Cross will review its policy for selecting blood donors following reports that a 20-month-old baby may have gotten an often-fatal immune deficiency from a donor, the group's director says.
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> * * * *
>
> The syndrome, found largely among male homosexuals and drug abusers, has also been found in as many as 20 children, said Dr. James Oleske of New Jersey Hospital and St. Michael's Medical Center in Newark.

This evidence of transmission of infants was so significant that the Superior Court of New Jersey wrote that "from the point of view of CDC, the assumption that AIDS was caused by a blood-transmissible virus became a matter of high probability when it reported, in December, 1982, that an infant had died of AIDS in California after having been transfused at birth with blood from a donor who had himself subsequently died of AIDS." Snyder v. American Association of Blood Banks, 282 N.J.Super. 23, 659 A.2d 482, 486 (N.J.Super.A.D. 1995). Affirming the lower court opinion, and based on the case of that infant's seroconversion, and several others reported among infants just one week later, the Supreme Court of New Jersey wrote that "by late 1982, the pattern for AIDS transmission was clear." Snyder v. American Association of Blood Banks, 1996 WL 290907 (N.J.).[30]

> shortly after birth." That possibility, according to Dr. Francis, "really fill[ed] in all of the pieces of the puzzle of transmission here. . . . The epidemiology of HIV now looked identical to hepatitis B virus.

Snyder v. American Assoc. of Blood Banks, 676 A.2d 1036, 1044 (N.J. 1996).

[30]The Snyder Court, 676 A.2d at 1049, wrote: "[b]y 1983, ample evidence supported the conclusion that blood transmitted the AIDS virus."

11) January 1, 1983 - A retrospective of 1982 finds that:

> nine cases of the acquired immune deficiency syndrome (AIDS) were recognized in hemophiliacs. Eight of these individuals were previously healthy, and one had long-standing common variable hypogammaglobulinemia (1-3). All had classic hemophilia, and all had received antihemophilic (AHF) concentrates. These patients had in common severe deficiencies of their immune systems which included a persistent reduction in peripheral blood helper/inducer T-lymphocytes, with a reversal of the T-helper/inducer to T-suppressor/cytotoxic cell (H/S) ratio.

T. Vincent Shankey, PhD, et al, AIDS Research, vol. 1, No.1 (1983), pp. 83-90.

12) January 4, 1983 - A followup meeting to the July 27, 1982 meeting is held by the CDC in Atlanta. See "Summary Report on Workgroup to Identify Opportunities for Prevention of Acquired Immune Deficiency Syndrome - January 4, 1983".[31] Epidemiological evidence from CDC investigations strongly suggests that blood and blood products transmitted the agent causing AIDS and that the disease could also be transmitted through intimate heterosexual contact.

The conclusion that AIDS is blood-borne is based on two findings.[32] First, AIDS was

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[31]The followup to both this blood advisory meeting and the July, 1982 meeting were notoriously poor. Bruce Voeller, PhD, and 1983 President of the Mariposa Education and Research Foundation, testified at the August 1 and 2, 1983 House Hearings before the Subcommittee of the Committee on Government Operations, Federal Response to Aids, p. 173:

> Dr. Bove [Yale Medical School and Yale-New Haven Blood Bank] and I both served on the two blood and AIDS panels held by the Government, as invited guests of the three governmental agencies, and neither of us has received any followup reports whatever. We have not even received the update bulletin that Secretary Heckler announced would be put out on AIDS, and indeed, I had to subscribe on my own to the MMWR published by the CDC, as was mentioned.

(See fns. 27, 28, infra, for a discussion of the unavailability of CDC information to the lay public) If an invited panel member felt it necessary to complain about his inability to obtain printed summaries of information descussed there, or his need to use discretionary income to pay for a subscription to MMWR, one can imagine the difficulty of hemophilia community members to receive the same information about a meeting that generally they did not even know took place, or about a publication they generally did not know existed.

[32]The Supreme Court of Colorado considered testimony regarding the state of knowledge of the blood borne nature of the AIDS virus at the time.

occurring in transfusion recipients and individuals with hemophilia who had received anti-hemophilic factor ("AHF") concentrate, and second, the epidemiologic pattern of AIDS is similar to hepatitis B, another blood-borne disease.

The Superior Court of New Jersey writes that, at the January 4, 1983 emergency workshop, "[t]he [CDC's AIDS] Task Force was convinced that AIDS was blood-transmissible." Snyder v. American Association of Blood Banks, 282 N.J.Super. 23, 659 A.2d 482, 486 (N.J.Super.A.D. 1995). The Snyder Court clarifies that it was not merely the CDC who believed that the AIDS virus was transmissible: "[t]he general tenor of the evidence as a whole justifies the inference that every responsible expert in the United States was convinced well before the end of 1983, and most well before the end of 1982, that AIDS was caused by an infectious, blood-transmitted agent." Snyder, 659 A.2d at 489.[33] The New Jersey Court of Appeals elsewhere found that the Public Health Service Committee on Opportunistic Infections had issued a warning to the blood banking industry prior to the end of 1983 that AIDS was likely transmissible through blood products. Snyder v. Mekhjian, 244 N.J.Super.

> 1985. Doctor Conant filed an affidavit stating that he was prepared to testify at trial to the following matters: as of January 1983 there was ample evidence available to the medical community and to national blood banks that the AIDS virus was transmissible in blood and blood products and that transfusion recipients were at risk of contracting AIDS if adequate precautions were not taken by blood banks in screening donors and performing surrogate tests on donated blood; that as of January 1983 there was ample evidence that the highest risk groups for AIDS were homosexual males, intravenous drug users, Haitians, and hemophiliacs. . . .

United Blood Services v. Quintana, 827 P.2d 509, 512 (Colo. 1992).

[33]Legal experts in the field, however, have placed the date at which knowledgeable and responsible parties, which would include the FDA, should have acted, much earlier, and as early as January, 1982.

> The argument against forseeability is straightforward--until the causative agent of AIDS had been identified in mid-1984, no scientific proof existed to support the hypothesis that AIDS was caused by a blood transmissible agent. Risk, by definition, however, is the possibility of injury and not its certainty. Scientific proof speaks to certainty, not risk. By January 1982, when the first report of an AIDS-related illness following concentrate injections was publicized, the risk of AIDS was not merely forseeable but known. The legal duty to guard and warn against this specifically defined risk, therefore, came into being at this time.

Ring and Leonard, supra, p.177. Warnings, such as appropriate patient package inserts, are not dependent upon scientific certainty of injury, and therefore the FDA should have required their use at this time.

281, 582 A.2d 307, 310 (N.J.Super.A.D. 1990). At trial in the Snyder case, Dr. Don Francis of the CDC testified as to the reaction by the blood banking industry to CDC's conclusion of blood transmissibility of the AIDS virus:

> [T]he initial negativism, accepting such a thing as transfusion associated AIDS, and then the real hostility towards moving ahead and doing something, saying it was going to cost too much, it was going to cause too much trouble, was just a most unfortunate expression of AABB [American Association of Blood Banks] policy.[34]

Snyder, 659 A.2d at 487, ftnt. 1. The Snyder Court found that, unfortunately, AABB policy was:

> described by several of the expert witnesses as inordinately influential in setting national blood policy in the first half of the 1980's, a primary responsibility of the FDA, by reason of AABB's participation in the FDA's Blood Products Advisory Council and other agencies, councils, and committees charged with formulating national blood policy, and by reason, apparently, of its acknowledged expertise. Indeed, the Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic (June 1988) (HIV Report) concluded that one of the early obstacles to progress during the early years of the epidemic was the extent of governmental deference to industry views. The HIV Report states:
>
> > The Food and Drug Administration (FDA) has the responsibility to set the standards for the blood industry;

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[34]The Snyder Court wrote:

> Dr. Francis rejoined that the AABB's response was "remarkably obstructive." He recognized the response as "basically an attempt to deny that there was a threat." The AABB nonetheless persisted in arguing that surrogate testing and direct questioning would be too costly and would lead to the rejection of too much blood.

Snyder, 676 A.2d at 1045.

> however, it relies heavily on that industry for advice on what standards to set -- a relationship that presents a significant opportunity for conflicts of interest to arise.

Snyder, 659 A.2d at 488-489. FDA policy was, to a large extent, AABB policy: "In 1984, the AABB was more than a trade association. It was the governing body of a significantly self-regulated industry." Snyder, 676 A.2d 1050.

The afternoon of the January 4, 1983 meeting is "spent discussing the significance of the finding and the appropriate course of action." Summary Report, p. 1. At this meeting, the leading blood bank organizations are in attendance, and the blood industry vigorously opposes any required blood donor questionaires or testing in blood samples for hepatitis B, which frequently accompanied and therefore revealed the presence of the AIDS- causing agent in the blood.[35] The 1983 Summary Report states at page 3:

> For example, if the presence of hepatitis B core antibody is used as a laboratory surrogate screening test:
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> 1. **In CDC's specimen file, 90 percent of known definite AIDS cases are positive for anti-Hbc and would be excluded as blood donors.**[36] **(emphasis added)**

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[35] "Screening tests are conducted for hepatitis B by testing for surface antigen (an indication of active virus) and antibody to core (an indication of resolving or past infection and a surrogate marker for high-risk behavior, such as intravenous drug use)." "Blood Safety - Enhancing Safeguards Would Strengthen the Nation's Blood Supply," GAO Testimony, June 5, 1997, House Subcommittee on Human Resources, Committee on Government Reform and Oversight.

[36] Ring and Thomas, supra, p.182, further state:

> The Hepatitis B Core Antibody test according to Thomas Spira, a member of the CDC staff in 1982, would detect 90% of high risk donors. The measurement of a donor's T-cells was also proposed as a "marker" test to screen high risk donors. This test was used by Dr. Edgar Engelman, Stanford U. Blood Center, beginning in July 1, 1983. See Report to Subcommittee on Oversight, (July 13, 1983).

Under the lowest estimates by CDC officials since that time, surrogate testing for HIV by testing for the presence of the hepatitis B core antibody would have detected the presence of approximately seventy percent of the HIV among paid blood donors.[37] Nevertheless,

> The FDA refused requests to perform surrogate tests on Factor VIII concentrate. [. . . .] The FDA's position was that there was no data demonstrating that surrogate tests would prevent the spread of AIDS.

Gruca v. Alpha Therapeutic Corp., 51 F.3d 638, 644 (7th Cir. 1995). Once again, the AABB was central to this opposition to safety measures: "[t]he record reveals that the AABB led the charge against direct questioning of donors and surrogate testing." Snyder, 676 A.2d at 1055. Indeed, at the conclusion of the January 4, 1983 meeting,

> Confronted with escalating evidence that blood transmitted the AIDS virus and that surrogate testing would reveal the presence of the virus, the AABB became increasingly intransigent.

Snyder, 676 A.2d at 1045. The Snyder Court concluded that "the bottom line is that the AABB represents its interests and those of its members." Snyder, 676 A.2d at 1050. The AABB did not lessen this opposition to surrogate testing over time, despite its increasingly apparent effectiveness.[38]

While it is possible that IV drug abusers might have been reluctant to disclose their IV drug history, particularly in the case of ongoing usage, the hepatitis B core antibody test was

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[37]The Ninth Circuit Court of Appeals writes:

> The fact that surrogate testing may not have guaranteed pure blood is not necessarily a defense to liability. There is strong indication that, at a minimum, surrogate testing would have seriously curtailed the amount of HIV infected Factor VIII. A safety measure need not be perfect before its use is considered necessary to satisfy the standard of care.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 383 (9th Cir. 1992).

[38] In July 1984, the Blood Products Advisory Committee's Hepatitis B Core Antibody Testing Study Group (study group) reported its findings on the core test. The study group consisted of eleven members representing the FDA, plasma manufacturers, and major blood-industry associations, including the AABB. The majority of the study group, including the AABB, rejected the core test. It contended that the core test would lead to the rejection of too many healthy donors, was not sufficiently specific, and cost too much.

Snyder, 676 A.2d at 1047.

a unique opportunity to detect and destroy most of the HIV-infected blood donated by IV drug users, since the route of transmission for HIV most common among IV drug abusers also was a common route of transmission for hepatitis B. Hence, a tremendous opportunity to detect and eliminate HIV-infected plasma was missed.[39]

The Snyder Court allowed the jury to view a 1986 "20/20" segment presenting testimony of a former FDA official who was specific in his estimation of the blood banking industry's influence over the FDA, which was manifested in the FDA's choice not to adopt Hepatitis B core antibody testing:

> JARRIEL: [voice-over]: Dr. Dennis Donohue disagrees. He was head of the FDA's division of blood and blood products from 1980 to 1986. That division regulates the blood industry.
>
> DR. DENNIS DONOHUE, former FDA official: I thought the evidence was good that there was a correlation between anticore positive test results and those people that had been defined as being at risk for transmitting AIDS.
>
> JARRIEL: Why couldn't you insist on that being used?
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> DR. DONOHUE: Well, we discussed this at an advisory committee meeting. My personal conviction was that it should be done. The committee that addressed it again said no. I thought the committee was heavily weighted, because there was no one on it who wasn't either industry or someone closely allied to industry.
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> JARRIEL: That sounds almost clubbish.
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> DR. DONOHUE: I think it is clubbish. I think it, at times is too clubbish.

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[39]Smith v. Paslode Corp., 799 F.Supp. 960 (E.D.Mo. 1992).

> The undisputed evidence in this case shows that no volunteer blood collector used the hepatitis B core antibody test as a surrogate marker for AIDS in 1983. [. . . .] No federal agency or professional blood collection standard-setting entity, including the FDA and the AABB, ever required or recommended the use of a surrogate test for AIDS. Id. at par.9 ARC's testing policies and procedures in 1983 and 1984 satisfied the AABB standards, the FDA regulations and the United States Public Health Service recommendations.

Snyder, 659 A.2d at 493-494, ftnt. 7. The Supreme Court of New Jersey found:

> [a]s the record reflects, moreover, the AABB was a major player in both state and federal government in setting blood policy in the 1980s.
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> * * * *
>
> At stake for its members was a substantial financial interest in the regulation of the industry. In 1984, voluntary blood banks generated revenues of approximately one billion dollars.

Snyder v. American Association of Blood Banks, 1996 WL 290907 (N.J.) 1, 16-17. The New Jersey Supreme Court concluded that: "[n]othing other than its own self-interest and tragically bad judgment prevented the AABB from recommending surrogate testing." Snyder, 1996 WL, 1 at 18.

13) January 7, 1983 - The Doe decision also noted that, **on January 7, 1983, "the [American Association of Blood Banks] Committee on Transfusion Transmitted Diseases issued a statement on AIDS that observed '[t]he epidemiologic pattern is that of a blood borne agent."** Doe, 971 F.2d at 382.

14) January 13, 1983 - The New England Journal of Medicine devotes several articles to the issue of AIDS and hemophilia. A study by Lederman, et al.,[40], concluded that "[t]he epidemiology of AIDS is suggestive of a blood-borne transmissible agent." The study also implicated concentrated clotting factor as posing a greater risk of infection than infusion with cryoprecipitate.[41] The same article reported that two of the cases of PCP reported in the July 16, 1982 MMWR had resulted in fatality. The investigators found significant differences in immune system impairment in patients receiving concentrate as compared to those only receiving cryoprecipitate.

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[40]Lederman, M.D., Ratnoff, M.D., Scillian, PhD., Jones, PhD., and Schacter, PhD, "Impaired Cell-Mediated Immunity In Patients with Classic Hemophilia," NEJM, vol. 308, No. 2, p.79.

[41]Lederman, M.D., et al., fn. 33, supra. The authors summarized the study results:

> Our study was designed to examine the immune system of otherwise healthy patients with hemophilia who had received lyophilized antihemophilic-factor concentrates or cryoprecipitates and who might be at risk for the development of AIDS. In this study the results of both lymphocyte-subpopulation surface-marker assays and lymphocyte functional assays were found to be significantly abnormal in the group of patients receiving lyophilized preparations of antihemophilic factor.

> When compared with controls, hemophiliacs treated with lyophilized antihemophilic factor had a relative decrease in helper T cells, a relative and absolute increase in suppressor T cells, and a depressed helper/suppressor T ratio. [. . . .] Lymphocyte counts, cell-surface markers, and functions in the eight patients treated primarily with cryoprecipitate did not differ from those in controls.

Lederman, et al, supra, p.82. The investigators conclude:

> What are the possible explanations for the abnormalities in cell-mediated immunity among patients with hemophilia? Conceivably, abnormal cell-mediated immunity is part of the genetic hemophilia disorder, but this explanation is unlikely for several reasons. Until recently, hemophiliacs did not appear to be at greater risk for infections, other than those attributable to the adminstration of blood products. In addition, hemophiliacs treated only with cryoprecipitates had no demonstrable functional abnormalities in cell-mediated immunity. (emphasis added)

> A more likely possibility is that the immune dysfunction is acquired. Active infection with hepatitis B virus is probably not responsible, since none of the 11 patients in the LYOPH group had demonstrable hepatitis B surface antigenemia. The cause of the immunosuppression in this population is not known; among patients with AIDS, however, epidemiologic evidence would implicate a blood-borne pathogen. Whether or not this putative immunosuppressive agent is responsible for the abnormalities in cell-mediated immunity that we have observed in healthy hemophiliacs and for the opportunistic infections recently described in this population remains to be determined. (emphasis added)

Lederman, et al, supra, p.82. In the same issue of the NEJM, another study compared AIDS infection rates among patients using clotting factor concentrate versus those using cryoprecipitate.[42] The study first noted the extensive infusion histories with concentrated clotting factor for the three patients reported in the July 16, 1982 MMWR.

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[42]Menitove, M.D., Aster, M.D., Casper, M.D., Lauer, M.D., Gottschall, M.D., Williams, M.D., Gill, M.D., Wheeler, R.N., Piaskowski, B.S., Kirchner, B.S., and Montgomery, M.D., "T-Lymphocytes Subpopulations In Patients With Cryoprecipitate and Lyophylized Concentrates," The New England Journal of Medicine, vol.308, No. 2, p.83.

> All had been treated with large doses of commercially prepared lyophilized factor VIII concentrates as part of the treatment of their coagulation defect: Two of the three received transfusions for prophylaxis almost daily, and the third received them every four to five days.

Id., p.83. The article called further attention to the point subtly made in the MMWR article; the patients had all used different lots, and therefore, the AIDS-causing agent would have to be contained within not less than three different lots, potentially infecting hundreds of hemophilia patients.

> One patient used concentrates prepared by six different manufacturers; another, concentrates prepared by five manufacturers; and a third, concentrates prepared by three or four. None used the same lot of factor VIII concentrate. Another case of P.carinii pneumonia and one of cryptospirilliosis occurring in patients with hemophilia A are currently being investigated (Evatt BL; personal communication).

Id. Once again, the difference in infection rates between users of clotting factor concentrate and cryoprecipitate was patently obvious.

> The clustering of AIDS in patients with common sexual contacts and the occurrence of P.carinii pneumonia among users of factor VIII concentrates have led to speculation that AIDS may be transmitted to patients with hemophilia through factor VIII infusions. [footnote omitted] To evaluate this possibility we performed immunologic studies on healthy patients with hemophilia treated either with cryoprecipitate obtained from volunteer blood donors with commercially prepared, lyophilized factor VIII concentrates. Eight of 22 patients had abnormal T4/T8 ratios. None of the cryoprecipitate users and 57 per cent of the users of commercially prepared lyophilized concentrates had abnormal T4/T8 ratios ($P < 0.003$).

Id. The study concluded:

> Our data are consistent with the possibility that commercially prepared lyophilized factor VIII concentrates can induce an AIDS-like picture, but a large number of patients must be studied before a definite conclusion can be drawn. . . . we urge those involved in the care of patients who use factor VIII concentrate to follow them

carefully for stigmata of AIDS and changes in immunologic status.

Id at p.85. Hemophilia patients infusing with concentrate were actually under study for serologic conversion, without any awareness of the risks readily apparent at that time to readers of one of the most respected American medical journals.

Most astonishing in this issue of NEJM is the candor of the introductory article, summarizing the two studies contained in that issue and drawing a dramatic conclusion regarding the future of hemophilia care. First, the article made the obvious conclusion, which the interior studies nonetheless made reluctantly:

> Patients receiving lyophilized commercial concentrates of factor VIII appeared more likely than those receiving cryoprecipitates to have abnormalities of T-cell subpopulations. In view of this finding, current modes of treatment must be scrutinized. **Concentrates are prepared from pooled plasma from 2000 to 5000 donors, lyophilized, and packaged in vials containing 200 to 1200 IU (1 IU is equivlent to the activity in 1 ml of normal plasma) [footnote omitted]. Cryoprecipitate, on the other hand, is prepared in the blood bank from the plasma of individual donors; each bag finally contains about 100 units of factor VIII in a relatively small volume.** The commerical preparation is more concentrated than the cryoprecipitate, and its unitage is more reliable, but the advantage of the cryoprecipitate is that the recipient is exposed to only one donor per bag. In the hemophiliacs studied, [footnotes omitted, referring to the interior articles] the difference between those receiving concentrate and those receiving cryoprecipitate does not seem to be explained by the fact that there was less treatment in the latter group, but one may wonder whether exposure to fewer donors is crucial. (emphasis added)

Jane F. Desforges, M.D., "AIDS and Preventive Treatment in Hemophilia," The New England Journal of Medicine, Jan. 13, 1983, 308:2, p.95. The size of those pools was even larger, in all probability:[43] "[i]n the case of commercially prepared products made from pooled human plasma, the donor/recipient ratio, on the average, is 20,000 to 1." Ring and Thomas, "Representing the Hemophiliac With AIDS," Courts, Health Science & the Law, Summer,

[43]See footnote 21 for the current estimates of donor pool sizes, which currently contain a minimum size for Alpha Therapeutic Corporation of 60,000 donors.

1991, vol.2, No.1, p. 174.[44] Desforges balanced both the convenience to the patient and the relative stress that a return to cryoprecipitate infusion therapy would place upon the nation's blood banks, and nonetheless concluded that a return to cryoprecipitate as the treatment of choice should be considered by patients undergoing the risk of infection.

> Ease in obtaining the commercially prepared lyophilized concentrates of factor VIII has made the ambulatory program possible. The average patient requres about 40,0000 units yearly, and provision of this amount of cryoprecipitate to each of the nation's 12,000 hemophiliacs would certainly stress the capacity of blood banks. It would also be difficult to design a home-infusion program with cryoprecipitate therapy, since the material must be stored in the frozen state. The present program has been extremely successful and would be given up by physicians and patients only with great reluctance. **Yet it is time to consider doing so, even though we may not have enough evidence to demand such a radical change.** (emphasis added)

Id. The study concluded with an entirely new perspective upon the treatment of hemophilia.

> The fact that hemophiliacs are at risk for AIDS is becoming clear. If the use of cryoprecipitate will minimize this risk, the current home-infusion program needs to be revised. The studies reported in this issue demonstrate in vitro abnormalities of immunoregulation, but the numbers are too small for definitive comparison of the risks of different modes of treatment. Unfortunately, the data are consistent with a greater potential for AIDS in the population treated with concentrate. Physicians involved in the care of hemophiliacs must now be alert to this risk. Preventing the complications of the present treatment may have to take precedence over preventing the complications of hemophilia itself. (emphasis added)

Id. This information was clearly sufficient to demand FDA action, which should have included, at a minimum, warnings to the community.[45]

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[44]"The commercial manufacturers eventually installed equipment in their plants to mix in excess of 20,000 liters of human plasma from approximately 20,000 paid donors who submitted to the plasmapheresis process." Ring and Thomas, supra, p. 175; see fn. 13, supra.

[45]The connection between concentrate usage and HIV was demonstrated time and again. Goedert, et al, "Antibodies Reactive With Human T Cell Leukemia Viruses in the Serum of Hemophiliacs Receiving Factor VIII Concentrate," Blood, vol. 65, No. 2, (February), 1985, pp. 492-495, described their study results:

15) January 24, 1983 - the American Association of Blood Banks' Committee on Transfusion Transmitted Diseases issues a report authored by Joseph R. Bove, M.D., at the time the director of the Yale Blood Bank, and the Chair of the FDA Blood Products Advisory Committee. In that report, Dr. Bove makes several startling statements.

First, Dr. Bove states: "There is little doubt in my mind that additional transfusion related cases and additional cases in patients with hemophilia will surface."

Nevertheless, in that same report, Dr. Bove writes:

> Blood banks that wish to sell plasma for further fractionation already face the need to do something. Perhaps our Committee should prepare guidelines with suggested wording for them to use. We are reluctant to do this since **we do not want anything that we do now to be interpreted by society (or by legal authorities) as agreeing with the concept - as yet unproven - that AIDS can be spread by blood.** (emphasis added)

This statement is truly remarkable in view of the statement **which Dr. Bove makes earlier in the same report.**

> Since we met, however, an additional child with AIDS has been admitted to a Texas hospital. At birth the child had received seven transfusions, one of which came from a donor who now seems to have AIDS. **This case increases the possibility that AIDS may be spread by blood.** (emphasis added)

16) January, February, July and December 1983 - the FDA's Blood Products Advisory Committee meets to discuss blood collection and processing policies, including

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> These data demonstrate that HTLV III antibodies are detectable in the majority of hemophilia A patients, particularly those heavily treated with factor VIII concentate. As of Oct (sic) 15, 1984, 49 hemophiliacs who did not have other risk factors have been accepted as AIDS cases by the Centers for Disease Control, including 45 patients with hemophilia A (classical hemophilia, factor VIII deficiency) and two with hemophilia B (factor IX deficiency). Estimating the hemophilia population from a 1980 Department of Health, Education, and Welfare survey, the cumulative attack rate of AIDS is six times greater for patients with hemophilia A (3.6 per 1,000 hemophiliacs). All 49 of these hemophiliacs with AIDS had been treated with lyophilized clotting factor concentrates. . . .

Id., pp. 493-494.

possible implementation of a surrogate test for HIV. According to the 1995 Study by the Institute of Medicine, the BPAC improperly did the following:

> a) accepted estimates that the risks of AIDS from blood transfusion was low ("one in a million"); and
>
> b) accepted advice that control strategies such as automatic withdrawal of AHF concentrate lots containing blood from donors suspected of having AIDS, or a switch from AHF concentrate to cryoprecipitate in mild or moderate hemophiliacs would be ineffective, too costly, or too risky.
>
> c) as a result, blood policy changed little in 1983.

This failure on the part of the FDA to act appears directly responsible for infection of hemophilia patients. The Institute of Medicine Report concludes:

> **a) earlier implementation of either [donor screening questions about sexual preferences, particularly homosexual activies, and the use of an available surrogate test for hepatitis B core antigen (anti-HBc)] probably would have reduced the number of individuals infected with HIV through blood and blood products."**
>
> [and]
>
> b) when confronted with a range of options for using donor screening and deferral to reduce the probability of spreading HIV though the blood supply, **blood bank officials and federal authorities consistently chose the least aggressive option that was justifiable.** In adopting the limited approach, policymakers often passed over options that might have initially slowed the spread of HIV to individuals with hemophilia and other recipients of blood and products, for example, screening male donors for a history of sexual activity with other males and screening donated blood for the anti-HBc antibody. The Committee believes that it was reasonable to require blood banks to implement these two screening procedures in January 1983. The FDA's failure to require this is evidence that the agency did not adequately use its regulatory authority and therefore missed an opportunity to protect the public health." (emphasis added).

The questionaires eventually used only went so far as to discuss high risk groups such as intravenous drug users, recent immigrants from Haiti, and those with early symptoms of AIDS or exposure to patients with AIDS; direct questions about high-risk sexual practices were not required.[46] None of the donors were required to be directly questioned by blood bank workers.[47]

17) February 6, 1983 - In the context of an article which might otherwise have alerted the hemophilia community or at least the lay press to the risks attendant the use of concentrated clotting factor, the Food and Drug Administration openly denied a linkage between blood and AIDS.

> In the spring of 1982, the C.D.C. received its first reports of AIDS in hemophiliacs. Some of these patients were probably exposed to the AIDS agent in a blood-clotting medication called factor VIII concentrate that is made from the blood of thousands of donors. Anywhere from 2,500 to 22,000 blood donors are used to make just one lot of this widely used product; one lot treats about 100 patients. To date, the C.D.C. has received a total of eight confirmed reports of hemophiliacs with AIDS, six of whom have died. All used factor VIII concentrate rather than an older, less convenient blood product called cryoprecipitate, which is made from the blood of a handful of donors. **In view of the AIDS threat some hemophilia experts are urging a return to cryoprecipitate, especially in mild or newly diagnosed cases.**
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[46]Unquestionably, issues of donor privacy entered into the decision-making process. However, "[t]o the extent that the conference participants permitted their own political and social views (however enlightened) to influence a public health decision, they acted irresponsibly." Doe v. American National Red Cross, 866 F.Supp. 242, 246 (D.Md. 1994).

[47]These questionaires were entirely voluntary. The U.S. District Court for the Eastern District of Missouri provided an example:

> [I]n early 1983, Regional Blood Services began providing potential donors with a pamphlet entitled "What You Should Know About Giving Blood" and an insert entitled "An important message to all blood donors." Id. Donors were instructed to read the pamphlet and [the accompanying] insert before donating blood. Moreover, donors were told they would be required to sign a statement indicating that they understood the information contained in the pamphlet and insert.

Smith v. Paslode Corp., 799 F.Supp. 960 (E.D.Mo. 1992).

> One way to try to stop the syndrome from spreading is to keep the AIDS agent out of the nation's blood supply, if, indeed, a blood-borne virus is the culprit. Even that is still uncertain. **"It's not clear at all that there's a new blood-borne virus involved," says Dr. David Aronson, director of the coagulation branch of the division of blood and blood products of the Food and Drug Administration. "I can't see anything different in the death patterns of hemophiliacs now from four years ago." As early as 1979, he says, five to 10 hemophiliacs a year were dying of unusual infections and cancers that today would be called AIDS, although the disease had not yet been identified. He theorizes that anticlotting medication itself might have an immune-suppressant effect. Dr. Aronson thinks the AIDS threat to hemophiliacs has been overstated. "It's more of a threat to change their treatment without thinking things through," he says.** (emphasis added)[48]

NYT, "AIDS - A New Disease's Deadly Odyssey," VI, p.28. Dr. Aronson's conclusion of the similarity of causes of death from PCP and those of hemophilia patients years earlier were clearly incorrect, since PCP had not been diagnosed in the hemophilia community previously.[49] Nevertheless, in the same article, once again Dr. Bove, Chair of the FDA Blood Products Advisory Committee, ignored the evidence of AIDS in hemophilia patients and minimized the risk of transmission from blood transfusion:

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[48]The very article disproved Dr. Aronson's argument. PCP was not known among hemophilia patients prior to the appearance of AIDS in the 1980s:

> Like Kaposi's sarcoma, Pneumocystis pneumonia was considered a rare disease. It also affected patients whose immune systems were severely compromised: cancer-chemotherapy patients and organ-transplant recipients.
>
> Now, a new group of patients was developing the disease. "Without even trying, we found 11 cases of Pneumocystis in young men," recalls Dr. Henry Masur, an infectious-disease expert then at New York Hospital-Cornell Medical Center and now at the National Institutes of Health. Within a year of diagnosis, eight of the eleven men were dead.

NYT, "AIDS - A New Disease's Deadly Odyssey," Feb. 6, 1983, VI, p.29.

[49] The two most prominent AIDS-associated diseases were pneumocystis pneumonia and Kaposi's sarcoma. Before their occurrence in AIDS patients, both pneumocystis pneumonia and Kaposi's sarcoma had been extremely rare.

Snyder, 676 A.2d at 1042.

> "In the two years since AIDS was first identified," Dr. Bove says, "20 million people have been transfused, and some must have gotten blood from donors with AIDS. But we don't see an epidemic of AIDS spread by blood." Dr. Bove contends that a number of AIDS patients in San Francisco have been identified as blood donors, and to date, the only confirmed case of transfusion-related AIDS there occurred in the baby who received an Rh transfusion.

NYT, Feb. 6, 1983, VI, p.36. Dr. Bove made this public comment just twelve days after informing the FDA BPAC that he expected additional cases of AIDS to occur in hemophilia patients. Dr. Evatt of the CDC took immediate issue with Dr. Bove in the same article on different grounds:

> "What Dr. Bove is not taking into account is the incubation period of AIDS," says Dr. Bruce L. Evatt, director of the division of host factors at the C.D.C. Although the risk now appears to be less than one AIDS case per million transfusions, he says, it may increase significantly.

Id.

18) March 4, 1983 - In the March 4, 1983 edition of MMWR, the CDC writes that "Recently, 11 cases of unexplained, life-threatening opportunistic infections and cellular immune deficiency have been diagnosed in patients with hemophilia." "Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations," Morbidity and Mortality Weekly Report, March 4, 1983, 32:101-03. The CDC further concluded "Blood products or blood appear responsible for AIDS among hemophilia patients who require clotting factor replacement therapy" and that "[w]ork should continue toward development of safer blood products for use by hemophilia patients."[50]

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[50]The risk of AIDS viral infection from blood transfusion had become so apparent by this time that even the lay press discussed the possibilities of eliminating the blood-borne risk:

> The discovery of a hormone imbalance associated with an often-fatal disease that was first observed among homosexuals two years ago may eventually lead to a simple test to reveal its presence quickly in patients and to prevent its spread through blood transfusions, a researcher said yesterday.

New York Times, "Immune Disease: A New Test?" March 8, 1983, III, 8:3.

19) March 24, 1983 - "[T]he Food and Drug Administration issued a memorandum to 'all establishments collecting human blood for transfusion' and a separate memorandum to 'all establishments collecting source plasma.' The Food and Drug Adminstration at that point in time had not issued any regulations regarding AIDS, and the March 1983 memorandum consisted of recommendations only." United Blood Services v. Quintana, 827 P.2d 509, 515 (Colo. 1992).

20) May 1, 1983 - The New York Times reports the discovery of a virus in the blood of persons with AIDS.

> Evidence of an unusual virus has been found in up to one-third of blood samples from some victims of acquired immune deficiency syndrome, or AIDS, an immunological disorder that has killed about half of the 1,352 people known to have acquired it, according to the federal scientist in charge of investigating the epidemic.
>
> Although scientists studying the disease are excited about the new research findings, they cautioned that the link between the virus and the disorder is far from certain and that they have no proof the virus causes AIDS. Other organisms are under study.
>
> The virus is called human T-cell leukemia virus, or HTLV. It was detected in 25 to 35 percent of blood specimens of AIDS victims that were sent for testing at Harvard, according to Dr. James Curran, the epidemiologists heading the investigation at the Federal Centers for Disease Control In Atlanta. The virus was found in less than 5 percent of blood specimens from individuals who do not have AIDS and whose blood was used for purposes of scientific control, Dr. Curran said in an interview.

Lawrence K. Altman, "Rare Virus May Have Link With Immunological Illness," NYT, May 1, 1983, I, 26:1.

21) May 19, 1983 - The lay press attempts to call the attention of the government to the issue. ABC News aired a "20/20" episode which discussed AIDS, its threat to the blood supply and to hemophilia patients, and the relative nonresponsiveness of the federal government to the issue as a whole.

> **GERALDO RIVERA** [voice-over]: Bothered by the apparently slow initial response to the AIDS epidemic, both [Representative] Waxman of California and Senator Moynihan of New York have

> introduced legislation requesting $40 million a year for public health emergencies like AIDS. But Dr. Edward Brandt, the assistant secretary of health, is opposed.
>
> **DR. BRANDT:** I oppose those measures because they're not needed.
>
> **RIVERA** [voice-over] And Dr. Brandt is the Reagan administration official to whom all public health agencies report.

22) June, 1983 - The apparent complacency by the FDA Consumer magazine concerning AIDS continued. In contrast to strong, but, within the hemophilia community, almost unknown, warnings by the CDC, the FDA Consumer merely noted:

> The [AIDS] syndrome also has been observed in hemophilia patients who require routine injections of antihemophilic factor. The factor is produced from the pooled blood of many donors.

"Updates: Alert on AIDS", FDA Consumer, June 1983, p. 2.

23) June 5, 1983 - Despite the failure by the FDA to act, the New York City Health Department was increasing certain that AIDS was blood-borne, and that hemophilia patients were at particular risk:

> Among the most vulnerable blood recipients are the thousands of hemophiliacs who rely on large amounts of plasma, processed into what is termed Factor VIII concentrate. Statistics reveal that AIDS-like illnesses were the second-leading cause of death among hemophiliacs nation-wide in the last year.
>
> "There is little doubt that we are dealing with an infectious agent that is transmitted through the blood and through sexual contacts," said Dr. David Sencer, New York City's Health Commissioner.

NYT, "Blood Donor Policy Revised Over AIDS," XXII, 4:5.

24) June 17, 1983 - The epidemiological pattern of AIDS as a blood borne virus continued, still without FDA action:

> Thirteen hemophiliacs, who require regular blood transfusions, have also been infected, as well as 90 people who seem, at first

glance, to fall into none of those classes of risk. In addition, 21 children, hemophiliacs or the babies of AIDS victims, have sickened, and some have died.

Cases Double in 6 Months

The figures are revised regularly, and health authorities say they lag half a month or more behind the actual caseload, in part because only a few states, including New York, require doctors to report AIDS victims. The national caseload continues to grow, roughly doubling every six months.

Dr. Harold Jaffe, investigating AIDS at the Centers for Disease Control, says the disease progressed to include a dozen people whose only apparent exposure was in receiving blood transfusions in surgery.

NYT, "AIDS Spreads Pain and Fear Among Ill and Healthy Alike," II, 4:2.

25) July 28, 1983 - The lay press reports on the inadequate public information telephone line, which meant that the hemophilia population did not have an adequate public information source to which to turn:

The Government's special telephone information number on acquired immune deficiency syndrome, or AIDS, has been swamped with 8,000 to 10,000 calls a day, so the system will be expanded from three to eight lines.

NYT, "AIDS Phone Line Expanding," I,12:5.

26) August 1, 1983 - Marcus Conant, professor of dermatology at the University of California Medical Center at San Francisco, and president of the board of directors of the National AIDS-KS Foundation, testifies before the House Subcommittee of the Committee on Government Operations, in FEDERAL RESPONSE TO AIDS, p.101, that AIDS was unquestionably blood-borne and that the federal response was overwhelmingly inadequate:

The first aspect is that we are dealing with a new sexually-transmitted blood-borne agent, probably a retrovirus, and that we have at our disposal the intellect, the abilities, the capabilities of isolating a virus, producing a vaccine and protecting a population not yet exposed who are at risk.

Dr. Conant further testified at those hearings:

> The final statistic in this grim litany is that nearly 60 percent of the people who contract AIDS die from it. The disease, quite simply, is the most lethal infectious killer known to modern medicine, and it is on a rampage in this country.
>
> In the face of this appalling specter, one would expect the government of the United States, the world's most affluent and technically advanced nation, to be sparing no resource in its fight stop AIDS. But as a physician and researcher who has worked with this problem from the beginning, I have to characterize the federal response to AIDS as bordering on the negligent.

Id. He testifies further on this point at p. 100:

> As a second point, I suggested that you have been misled; that we have all been misled.
>
> We heard a moment ago that the Government had only recently become aware of this problem.
>
> I was invited to attend the first meeting held at Bethesda, National Institutes of Health, in the fall of 1981.
>
> Everyone attending those meetings knew at that time what we were facing. We knew the type of disease we thought this was, a transmissible agent, probably blood-borne.(emphasis added)

Id, pp. 103-104. Dr. Conant was not alone in this estimation. The California Superior Court writes: "[a]s early as November 5, 1982, it was thought that the transmission of the agent would appear to most commonly require intimate direct contact involving . . . possibly hemophelia (sic) patients using blood clotting products." Raytheon Company v. Fair Employment and Housing Commission, 1988 WL 241125 (Cal. Superior), 1, 19.[51][52] One

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[51] Doe v. Cutter, 971 F.2d at 381.

> Thus, although it is true that the virus was not isolated until 1984, there is evidence supporting appellants' claim that the industry strongly suspected the new disease was caused by a blood borne virus before 1984 and that means of testing the blood supply were both available and considered.

example cited by Dr. Conant was the failure of the government to demand blood screening, as compared to merely donor questionaires.

> Every American has an interest in seeing to it that the nation's blood supply is protected. Efforts must be made to develop reliable, scientific method of screening that supply for infectious agents such as AIDS. In recent months, as it has become suspected that AIDS may be transmitted through blood transfusions, the vast majority of gay men have taken themselves out of the pool of blood donors for the duration of this health emergency. Most blood banks have also cut back on blood drives in gay neighborhoods. But a policy of protecting the blood supply by screening donors, rather than blood, is ultimately shortsighted and ineffective. [. . . .] As far as the nation's blood supply is concerned, the emphasis must therefore shift from the donor to the blood.

Id, p.113. Two conclusions emerge from this testimony: donor questionaires for sexual practices would have been effective if adopted earlier; and the advantages of surrogate testing for the presence of HIV was so obvious, based on the available scientific evidence, that even those physicians not trained in hematology knew by mid-Summer, 1983, at the very latest, that surrogate testing was necessary.

27) August 5, 1983 - The New York Times reports that "[t]he number of cases of acquired immune deficiency syndrome that are reported weekly has more than doubled in the last six months," according to the CDC. The NYT article reported an increase in the number of new weekly reports of the disease to 53 a week in July, as compared to 24 a week in January and 11 per week in July 1982. The NYT article also reported the CDC's conclusion that "[o]ther groups considered high risks for the disease are people who take narcotics intravenously, recent Haitian immigrants and hemophiliacs. [. . . .] [R]esearchers suspect it is spread through personal contact and by blood products."

28) August 22, 1983 - The hemophilia community held few options with regard to obtaining information from sources other than their physicians or from patient package inserts. The federal AIDS hotline, established July 1, 1983, is reported as receiving eight

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[52]The Supreme Court of New Jersey similarly concluded:

> The risk was also forseeable. Epidemiologists at the CDC believed as early as 1982 that the AIDS virus could be transmitted by blood and blood products.

Snyder, 676 A.2d at 1049.

thousand calls per day on a total of eight lines. Only five thousand per day actually get through, with the remaining three thousand only getting busy signals. "Federal AIDS Hot Line Is Swamped by Callers," New York Times, August 22, 1983, I, 14:6. Critics said "the hot line should expand and provide workers with more training, but [Shelley Lengel of the United States Public Health Service] said there were no plans to expand the system because 'it wouldn't be cost-effective."

29) August 28, 1983 - The New York blood banking community, in the midst of attempting to quell what they perceive to be unwarranted concerns over AIDS, the blood supply, and particularly the risk of infection from donating blood, actually systematically attempt to deny family members the opportunity to donate blood for particular use with other family members anticipating surgery:

> [B]oth the American Association of Blood Banks and the American Red Cross have come out strongly against designated donations.
>
> "We have had several people coming into the hospital for elective surgery who have said that they would like a family member to donate blood for their use," said Dr. William Schraft, director of the New Rochelle Hospital Medical Center's laboratories and blood bank. Dr. Schraft said he has tried to convince these patients that "our blood comes from the community and is good and that anyone suspected of having AIDS has been screened out."

NYT, August 28, 1983, Section 23, p.23, Col. 1.

30) August 31, 1983 - The American Red Cross recalls more than 5,500 vials of factor VIII concentrate because one donor had died of AIDS. "However, the Red Cross stressed that there is no scientific proof that AIDS can be transmitted by blood products." (emphasis added). The article did not contain any comment by the FDA.

31) September 2, 1983 - The New York Times reports the appearance of an AIDS cancer virus in the blood of hemophilia patients.

> Traces of a cancer virus detected in AIDS victims have been found in hemophiliacs, researchers reported yesterday.
>
> Doctors from the Harvard School of Public Health reported 12 percent of 172 hemophiliacs without AIDS showed antibodies against the virus, an indication they were infected with the virus at one point. Only 1 percent of a control group had it.

* * * *

> He said that finding the cause could help in research to fight the disease, which involves a breakdown of the body's immune system. Medical researchers believe the disease is transmitted by blood contamination and sexual contact.

UPI, "Virus Linked to AIDS is Found in Hemophiliacs," NYT, September 2, 1983, I, 13:1. Besides providing additional motivation for the FDA to reconsider its earlier estimates of the size of the HIV-infected U.S. hemophilia population, the findings also undercut the median midpoint of seroconversion estimates of September, 1982 by Eyster, Section Five, infra.

32) September, 1983 - The CDC and the FDA both publish information concerning hemophilia and HIV, but once again, the FDA minimizes the risk and ignores the implications of CDC recommendations to health care workers. In its September 1983 issue of FDA Consumer, the FDA fails to report the March 4, 1983 CDC conclusions that AIDS is transmissible by blood and that hemophilia patients using clotting factor concentrate were at risk because of the method of pooling the plasma. The article instead presents the prospect of a blood borne agent as almost mere speculation:

> The best evidence for transmission of AIDS through blood products is the occurrence of AIDS in a small number of hemophilia patients receiving large amounts of factor VIII, a clotting substance in blood.

"What the Experts Know About AIDS", FDA Consumer, September 1983, p.16. The article went on again to minimalize the risk to concentrated clotting factor users and to emphasize the effectiveness of federal government efforts.

> Factor VIII is extracted and concentrated from pooled blood plasmas donated by thousands of people, and it appears that in some **rare instances** the plasma has carried AIDS.
>
> To insure the safety of plasma derivatives, FDA has collaborated with the U.S. Centers for Disease Control in examining 200 separate lots of clotting factor concentrate manufactured by the four major U.S. manufacturers and found none that contained detectable infectious viruses. (emphasis added)

FDA Consumer, supra at p. 17. The latter statement is some of the best evidence of the FDA's intentional distortion of the risks to concentrate users. The statement is intended to be reassuring, but fails to mention that that was no direct test for the AIDS virus in existence at

that time.[53] Testing for the HTLV virus was still under investigation, and could not have been among the viruses which the FDA sought to detect. The other marker for AIDS, alpha interpheron, was for the first time reported as used in hemophilia patients in the August 31, 1983 NYT.

Further, in a devastating indictment of the FDA's timing of its articles concerning hemophilia and HIV,[54] Science magazine published an HTLV study, reported in the

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[53]The September 8, 1983 New York Times quoted M. Elaine Eyster, M.D., of the Pennsylvania State University Medical School: "We do not have a test for AIDS." (I, p.20, col. 6). See Doe v. Miles Laboratories, Inc., 927 F.2d 187, 190 (4th Cir. 1991) ("Not until March 2, 1985, did the Secretary of Health and Human Services license the Enzyme-Linked Immunosorbent Assay ('ELISA test') as the first test to screen blood and plasma for HIV antibodies").

> . . . at the time the Koyne was administered in September of 1983, there was no way to determine whether a particular unit of blood was contaminated with the HIV virus. The parties agree that an approved test to identify the presence of the HIV virus was not available until 1985 with the development of the ELISA test.

Doe v. Miles, 927 F.2d at 191. "An additional test for AIDS, called the 'Western Blot test' was licensed for use by the FDA in mid-1987. Thereafter, the Western Blot test became the standard confirmatory test." Doe v. Cutter Biological, A Div. of Miles, Inc., 852 F.Supp. 909 (D.Idaho 1994)..

[54]Furthermore, the FDA is responsible for disseminating information and for requiring warnings that are reasonable in the context of information appearing in the media concerning relevant medical information. The United States District Court for the Northern District Of Iowa sought to determine whether the United States was liable for injuries from vaccination for the swine flu vaccine under a theory of strict products liability. Brazzell v. United States, 633 F.Supp. 62 (N.D. Iowa 1985). That theory of torts incurs potential liability for a manufacturer of a product regardless of the risk of forseeability of a particular injury. Accordingly, the hemophilia community could pursue a separate tort theory of negligence against the FDA if exempted under the Federal Tort Claims Act, 28 U.S.C. §§ 2671, et seq., since the CDC's warnings and documented cases of AIDS arguably made the risk forseeable, and accordingly would not need to rely exclusively upon a strict liability theory.

In determining whether the FDA's required warnings concerning the 1976 swine flu vaccine were inadequate, the U.S. District Court for the Northern District of Iowa took into account the media's presentation of the issues.

> Prior to her doctor's appointment to receive the swine flu shot, plaintiff read newspapers and magazines that said there was a strong possibility of a swine flu epidemic. Plaintiff also saw the President on television, supposedly getting the first shot in the government's immunization program (partial transcript of proceedings, pp. 24-25, 77-78). In light of her prior health problems, plaintiff believed that taking the flu shot was the "lesser of two evils" (partial transcript of proceedings, p. 25).

September 2, 1983 NYT, that found traces of antibodies to a rare form of leukemia in 12% of hemophilia patients, as compared to 1% of a control group. Previous studies had found 36% of men with AIDS had such viral antibodies called HTLV. Additionally, not all of the 172 hemophilia patients tested in the study had severe hemophilia. Since the severe portion of the community infused much more than the remainder of the patients, those figures frequently could have been expected to be low for severe patients. Accordingly, there was physical evidence of a statistically significant rate of infection of the hemophilia population without immediate symptoms. This justified notification of AIDS risks to concentrate users, but the FDA was silent.

In stark contrast with the FDA article, that same month the CDC issued additional health care guidelines, this time for dental workers, morticians and persons performing postmortem examinations. "Acquired Immunodeficiency Syndrome (AIDS): Precautions for Health-Care Workers and Allied Professionals," Morbidity and Mortality Weekly Report, September 2, 1983, 32:450-51. In that issue of MMWR, the CDC states that "AIDS appears to be transmitted by intimate sexual contact or by percutaneous inoculation of blood or blood products," and that

> Caution should be exercised in handling secretions or excretions, particularly blood and body fluids, from the following: (1) patients who meet the existing surveillance definition of AIDS [footnote omitted]; (2) patients with chronic, generalized lymphadenopathy, unexplained weight loss, and/or prolonged unexplained fever when the patient's history suggests an epidemiologic risk for AIDS [footnote omitted]; and (3) all hospitalized patients with possible AIDS.

Id.

33) September 9, 1983 - Science Magazine, "Antibodies to Human T-Cell Leukemia Virus Membrane Antigens (HTLV-MA) in Hemophiliacs," p. 1061, 1063, reports on the prevalence in asymptomatic hemophilia patients of antibodies to a virus common in AIDS patients, and concludes:

> Hemophiliacs represent one of the major risk groups for development of AIDS (2, 3, 10). They may receive blood elements from tens of thousands of donors in a relatively brief period of time

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Brazzell v. United States, 633 F.Supp. 62, 66 (N.D. Iowa 1985), remanded for reconsideration on strict liability grounds, Brazzell v. United States, 788 F.2d 1352 (8th Cir. 1986); reversed and remanded on strict products liability grounds, Brazzell v. U.S., 880 F.2d 84 (8th Cir. 1989). The Brazzell holding is quite applicable in the case of the FDA's response to HIV and factor concentrate, since the FDA itself was a willing participant in the media's low estimation of the risks of HIV from blood transfusion.

> and they frequently receive both blood and blood products (10). The likelihood that blood from healthy HTLV-carrier individuals may be present in the donor pool thus seems high. (emphasis added)

34) September, 1983 - Armour submits a request to the FDA for the first time to change its Factor VIII labels to include an AIDS warning. Walls v. Armour Pharmaceutical Co., 832 F.Supp. 1467, 1484 (M.D.Fla. 1993). Not until January 25, 1984 did the FDA approve this labeling change. Walls, 832 F.Supp. at 1484.

35) November 2, 1983 - New York Times, II, 24:1. The FDA announces Cutter Laboratories' withdrawal of 16 lots of clotting factor containing plasma donated by a man who died of AIDS the previous month. Without describing any of the risks posed to users of clotting factor concentrate, Dennis Donohue, director of the FDA's division of blood products in the Office of Biologics, said that the man " 'lied' when asked by the center if he belonged to any of the high-risk groups that have been primarily identified with AIDS." Instead of providing a warning to hemophilia patients of AIDS infection risks from the use of concentrated factor, the article instead provided a forum for Cutter to minimize the risk:

> "We did this to assure the country's 15,000 to 20,000 hemophiliacs that we were taking every precaution even though there is no evidence that AIDS is transmitted this way," Mr. Modersbach [spokesman for Cutter] said.

The event demonstrated clearly the need for redundancy in the protective measures taken; the donor in question, according to Dr. Donohue, "gave blood plasma at least 50 times in the last 11 months to a commercial blood center in Austin, Texas. The withdrawal involved about 64,000 doses." Certainly, that such a level of damage could be achieved simply by "lying" had to be considered insufficient protective measures by the FDA.

36) December, 1983 - The FDA approves warnings of the risk of AIDS on the labels of Factor VIII concentrate for the first time. Gruca v. Alpha Therapeutic Corp., 51 F.3d 638, 644 (7th Cir. 1995).

37) February 1984 - Armour begins inserting warning into the Factor VIII product advising that AIDS might be transmissible by blood or blood components. Wall, 832 F.Supp. at 1484. Cutter follows in 1984 with its own labels. Ray v. Cutter Laboratories, Div. of Miles, Inc., 744 F.Supp. 1124 (M.D.Fla. 1990).

38) May, 1984 - Armour begins marketing heat-treated Factor VIII concentrate. Walls, 832 F.Supp. at 1496.

39) June, 1984 - The FDA Consumer magazine publishes an article concerning hemophilia care that clearly betrayed the FDA's bias against the CDC's conclusions and in favor of the continued use of clotting factor concentrates by hemophilia patients, as opposed to other options at less risk for transmission of the AIDS virus. J. Couric, "Hemophilia Has Outlasted The Czars," FDA Consumer, June 1984, p.18. Once again, the FDA minimalized the risk of contracting AIDS through clotting factor concentrate infusions.

> The bad news is that a few hemophiliacs have contracted acquired immune deficiency syndrome (AIDS) from blood plasma they received. While the number of hemophiliacs in the United States is estimated at 20,000, only a small fraction of 1 percent of those have become victims of AIDS, the notorious ailment that breaks down the body's immune system. (See "What The Experts Know About AIDS" in the September 1983 issues of FDA Consumer.)

FDA Consumer, supra, p.19. In the Eight Circuit Court of Appeal opinion in Petty v. United States, 740 F.2d 1428, 1437 (8th Cir. 1984), infra., such a warning in the context of the FDA's swine flu vaccines, had it appeared with the product, would have been legally inadequate.

> The disclosure here was merely a broad, generic statement. The alleged warning here did more to dilute the seriousness of the risks at stake than it did to apprise the recipients of the existence of those risks. Indeed, it appears that assuring participation was the motivation behind the phraseology decisions rather than an effort to inform the recipients of the risks.

In short, as a matter of federal law, the FDA has previously been found to have intentionally underestimated the risks of the use of certain drugs in order to encourage their use. The FDA's practice in FDA Consumer Magazine is similar in that respect.[55]

Regardless of the truth of the FDA's statement in that issue, the risk of infection was enormous as a result of the pooled plasma, which could spread one infection through an entire lot of clotting factor destined for hundreds of hemophilia patients. The FDA was quite familiar with these risks from pooled plasma as demonstrated by the September 1983 FDA Consumer magazine article and the general state of medical knowledge concerning the risks to the

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[55]The language of the Eighth Circuit Petty decision is similar in other respects. Although the Petty decision obviously dealt with FDA warnings accompanying the drug, and the facts regarding FDA alerts on factor concentrate were in a magazine of general distribution, the standard of what type of warning constitutes an adequate presentation of risks to the patient is similar and informative. The Petty Court wrote at pp. 1438-1439: "[t]he [swine flu vaccine] warning was inadequate in part because of the calculated ambiguity of its terms and because it was couched in terms that lulled the recipient into a false sense of security."

hemophilia community of hepatitis as a result of pooled plasma. The Philadelphia Enquirer, supra at p.2, cols. 2 and 3.

The FDA's statement as to the level of infection reveals its bias in several ways. First, the FDA was aware that half of the twenty thousand persons with bleeding disorders only required occasional clotting factor infusions, if at all. Thus, by comparing the number of AIDS cases with the entire community of hemophilia patients, the FDA statistically diluted the apparent risks of infection. Secondly, the CDC, and therefore, the FDA, was aware that there was a latency period between the date of infection and the date on which symptoms for disease would first appear.[56] This latency period had already led experts one year before to make their infamous predictions of an iceberg phenomenon, that the cases of AIDS occurring at that point were merely the visible tip of an iceberg of thousands more infections.[57] Therefore, the mere fact that a limited number of patients had symptoms of AIDS did not mean that many were not already infected and many more were at risk of infection through clotting factor concentrate infusions.[58] Third, the FDA was aware of the passive nature of CDC reporting,

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[56]Even the National Hemophilia Foundation, a lay organization, knew that there was a latency period. Alan Brownstein, NHF Executive Director, testified at the August 1, 1983 House Hearings before the Subcommittee of the Committee on Government Operations, FEDERAL RESPONSE TO AIDS, that "mothers [of hemophilic children] . . . call up and say 'I infused my child last night, and I am afraid that that infusion had AIDS in it,' but we know that that is not possible to determine, knowing the incubation period. . . ." The FDA was also aware of the incubation period, and thus the fact that those few patients probably represented at least hundreds more infections.

[57]James Lipsett, M.D., City of Hope National Medical Center, and Executive Committee member of the Southern California Physicians for Human Rights, testified at the March 17, 1983 Senate hearings before the Committee on Labor and Human Resources, Biomedical Research, Training, and Medical Library Assistance Amendments of 1983, p.41, that "one cannot help but wonder if this new phenomenon is just the tip of the iceberg." And one year earlier, at the April 13, 1982 House hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, Kaposi's Sarcoma and Related Oportunistic Infections, James Curran, M.D., coordinator, CDC Task Force on Kaposi's Sarcoma and Opportunistic Infections, stated that, at a time when only 300 cases of Kaposi's Sarcoma had been reported to the CDC, "[i]t may represent the tip of an iceberg of a problem affecting thousand of individuals."

[58]Dr. Marcus Conant, supra, testified on August 1, 1983 before the House Subcommittee of the Committee on Government Operations that the incubation period for AIDS is . . . 18 months." Dr. Curran is summarized in the May 24,1983 edition of the New York Times, I, 25:1, as stating that the AIDS induction period, "which can take anywhere from six months to three years after exposure before the illness shows up -- inhibits any predictions about the future course of AIDS." Curran stated that the "induction period means it's [AIDS] not going to explode across the country quickly. But is also means that the implications won't be fully known for several years, maybe a decade." Mathilde Krim, Ph.D, Sloan-Kettering Institute for Cancer Research In New York, testified, at p.139, at the same hearings that

> In view of the likely long incubation period and a few cases which have apparently resulted from blood transfusions or alleged casual contact, no one can say for sure, at this point in the history of this epidemic, how many may be just "at risk" and how many are already doomed.

which did not actively seek out cases of AIDS, including among hemophilia patients, but waited until they were reported to them.

40) October 26, 1984 - 52 cases of AIDS among hemophilia patients are reported in MMWR. In stark contrast to the FDA's failure to present any statistical support for potential infection rates, as opposed to cases of full blown diagnostic AIDS, the CDC pointed to a potentially serious route of transmission through concentrated clotting factor. The CDC investigated the use of clotting factor concentrate and reported:

> CDC has investigated the blood product usage of the majority of these cases. In nine cases, factor VIII concentrates have been the only blood product reportedly used in the 5 years before diagnosis of AIDS. These nine persons had no risk factor for AIDS other than hemophilia. The factor VIII-deficient patient with Kaposi's sarcoma had not used factor VIII concentrate products but had used large volumes of plasma and factor IX concentrates.

"Update: Acquired Immunodeficiency Syndrome (AIDS) in Persons With Hemophilia," Morbidity and Mortality Weekly Report, October 26, 1984; 33:589-91. Although these publications are beyond the date when many, if not most hemophilia patients who received HIV infections were exposed for the first time, it assists in clarifying the improper behavior by the FDA with regard to information disclosure, which included: 1) failing to distinguish between potential infection rates and actual cases having progressed to AIDS; 2) continual use of language tending to minimize the apparent risk of infection through the use of clotting factor concentrate; 3) failing to present the massive differences in actual donor exposures in the use of cryoprecipitate as opposed to clotting factor concentrate; 4) consistently failing to report CDC findings and recommendations, and instead countering the MMWR reports concerning AIDS with FDA Consumer articles which emphasized the safety of current methods of hemophilia care;[59] and 5) relying upon a lay organization in the form of the National

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[59]Even Joseph R. Bove, MD, Professor of Laboratory Medicine, Yale Medical School, and Director, Blood Bank, Yale-New Haven Hospital, who produced now infamously low and erroneous estimates of the risks of AIDS for patients infusing with concentrated clotting factor, acknowledged both the vital importance of CDC information and the singular importance of FDA regulatory authority:

> We look to CDC for ongoing up-to-date information on which we can base future decisions about the Nation's blood supply; to NIH for research leadership and support; to FDA for whatever regulatory authority may be needed; and to the Congress, ladies and gentlemen, for financial and emotional support.

Federal Response to AIDS, August 2, 1983, p. 164. James Curran, coordinator of the CDC's task force on Kaposi's Sarcoma, also made clear at the April 13, 1982 House hearings the importance of the CDC's role in disease prevention.

Hemophilia Foundation without reference to more qualified sources such as the CDC.[60] Under such circumstances, the U.S. District Court for Idaho found:

> [t]hus, during the time period within which John Doe was likely to have been infected by contaminated Factor VIII (i.e., prior to August 1984), nothing in the record establishes that the FDA had

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[60] The FDA's failure at that time even to acknowledge publicly the CDC's findings, guidelines and recommendations, must be considered unreasonable in light of the unanimous deference given the epidemiologic research expertise of the CDC. In a devastating criticism of the FDA's failure to communicate the findings and conclusions of the CDC, Bove concluded at that hearing:

> I think we need an ongoing and open line of information from the CDC, which is currently the locus from which the case reporting stems to the public. I think those of us who are in the blood-collecting industry, who have responsibility for the Nation's blood-collecting systems, need to know exactly how many suspected cases there are, where they are, and at what stage the investigation is.
>
> Do we have suspect donors? **I think that information ought to be available not only to us in the blood-collecting group, but to the public. This is really public health information, and I think the people of this country need to know as quickly as possible what our CDC knows about the risks.**
>
> [Representative] Weiss. Why do you believe that information has not been forthcoming?
>
> Dr. Bove. I can't answer that, Congressman. I think you have to ask others, but I know that there is a feeling on my part, and I suspect on the part of others, that the kind of openness about the information we think we need has not been available from CDC.
>
> Mr. Weiss. One of you, though I don't know who, testified that the Morbidity and Mortality Weekly Report was changed from a free distribution to a paid-for distribution, and I gather from the testimony that this was done to comply with budget restraints. (emphasis added)

Id, p.166. Although Dr. Bove stated his belief that the CDC supplied information to the National Hemophilia Foundation concerning the number of hemophilia cases of AIDS (p.167), the conflicts of interest within the NHF described by the IOM report, and of which the FDA was clearly aware, meant that that information was not transmitted to the hemophilia community. Dr. Bove's testimony is to the effect that, absent NHF transmittal, there were no other readily accessible avenues available to the public to receive this information from the CDC. If the CDC's concerns were not reflected in FDA regulations, the public remained unaware of risks of which the CDC was fully aware. Finally, Dr. Bove's conclusions about the openness of information from the CDC should be considered in light of the constant appearance of MMWR articles concerning AIDS, while Dr. Bove had informed the BPAC that such risks of blood-borne AIDS should be minimized in FDA public statements.

> imposed any standards, scientific procedures or techniques which would have insured the safety of Factor VIII concentrates.

Doe v. Cutter Biological, 852 F.Supp. at 922. The FDA failed to discharge its statutory duties, and thousands of HIV infections among the U.S. hemophilia community, and countless other subsequent re-infections, needlessly occurred.

SECTION FOUR: THE FDA FAILED TO DISCUSS OR RECOMMEND THE USE OF CRYOPRECIPITATE AS AN ALTERNATIVE TO THE USE OF FACTOR VIII CONCENTRATE IN NON-LIFE-THREATENING CIRCUMSTANCES.

A. The Medical Community Was Aware That Cryoprecipitate Was An Alternative to Concentrated Clotting Factor in Most Situations.

This section argues that alternative methods of treatment were available in the form of cryoprecipitate, but that the FDA kept the focus of treatment choices upon concentrate usage versus no treatment. In so doing, the FDA did not timely inform the hemophilia community of the greatly reduced risk of infection from the AIDS virus through the use of cryoprecipitate.

It was in the June 1984 FDA Consumer Magazine, probably well after the point in time when the majority of hemophilia patients who were ultimately infected had already received their first HIV exposure, that the FDA publicly first discussed the alternatives to clotting factor concentrate available to the hemophilia community. It was those alternatives discussed in the article which the hemophilia community might have utilized if possessed with full knowledge of the risks of AIDS. The FDA noted the alternatives to infusion with clotting factor concentrate:

> For those with severe hemophilia, two extracts of plasma are used. One, called concentrate, is in freeze-dried form. It can be stored at room temperature for up to six months or in a refrigerator for up to 24 months. The other, cryoprecipitate, is prepared from fresh blood and must be kept in the refrigerator.

FDA Consumer, June, 1984 at p. 19, col.2. Cryoprecipitate, discovered in 1965, is a residue of blood plasma that contains a less potent concentration of clotting factor. It comes directly from a donor and is not "pooled" together with plasma concentrate from many donors in the manner in which clotting factor was concentrated after 1970 in order to mass produce the medicine. Since cryoprecipitate must be thawed before injection and has considerably more volume than concentrate, an infusion takes close to one hour, as compared to fifteen minutes for an injection of freeze-dried and rehydrated clotting factor concentrate. However, in 1983, cryoprecipitate exposes an adult male patient weighing 150 pounds to only about twenty donors for a treatment raising his clotting factor level to 50% or more, as compared to an exposure of up to twenty thousand donors through the use of concentrated clotting factor. The level of exposures per treatment of cryoprecipitate for children was less than ten donors.

Piet J. Hagen, former editor of the Dutch Hemophilia Journal and a world expert on blood supply systems and technology, provides an effective insight into the medical community's awareness of the relative risks of viral infection associated with cryoprecipitate, as compared with clotting factor concentrate. Hagen's 1982 book, Blood: Gift or Merchandise, presents a glimpse into the understanding of those relative risks maintained by experts.

> Factor VIII is one of the proteins that play a part in the process of coagulation. Since 1964, factor VIII has been obtained from whole plasma by cryoprecipitation. When fresh-frozen plasma is allowed to thaw at 4C, a cold-insoluble precipitate remains that consists of the coagulation factor VIII and some fibrinogen. The remaining plasma may be used for transfusion or fractionation.
>
> The so-called cryoprecipitate is recovered from a single donation. For clinical use, preparations are made from small pools of several single donations. The advantage of this processing technique is that little factor VIII activity is lost and the risk of transmission of viral hepatitis is minimal.
>
> Although cyroprecipitate is still in use on a large scale, more-concentrated products are available too. The advantage of intermediate or high purity concentrates of factor VIII is that they have a greater specific activity and contain relatively less fibrinogen. The volume to be injected is small, so that treatment of patients is less time-consuming. On the other hand, it has to be emphasized that the yield of factor VIII activity per donation processed is significantly lower. Therefore the production of these concentrates requires much more plasma and is relatively expensive. Another disadvantage is that the risk of hepatitis is greater because these concentrates are prepared from very large donor pools. This risk, however, has diminshed in recent years.

Id., p.15. It is clear that, in 1981, the hematology community, which would include the FDA and the CDC, understood both that cryoprecipitate was a practical and workable alternative to concentrated Factor VIII in all but the more advanced hemorrhages or those hemorrhages in particularly vulnerable areas, such as the cerebellum and viscera,[61] and

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[61]Goedert, et al, "Antibodies Reactive With Human T Cell Leukemia Viruses in the Serum of Hemophiliacs Receiving Factor VIII Concentrates," Blood, Vol 65, No. 2 (February), 1985, pp. 492-495: cryoprecipitate is "difficult to use during surgery or serious hemorrhage, when high levels of clotting factors must be achieved and maintained."

that the use of cryoprecipitate would lessen the risk of viral transmission by reducing the exposure to the number of donors. This was not an unreasonable option, since Hagen reports that France used cryoprecipitate extensively: "[i]n 1981, 64% of factor VIII products was utilized in the form of cryoprecipitate and 36% in the form of concentrate." Hagen, supra, p.149. Information concerning the lower risks of viral transmission with cryoprecipitate, coupled with the knowledge of the presence of HIV in the blood supply, should have been made available to the hemophilia community in 1982.[62]

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62 Not all hemophilia treaters embraced commercial Factor VIII concentrates. Some doctors restricted patient use to treatment of serious bleeding incidents. And some doctors continued to use cryoprecipitate, refusing to subject their patients to the known and unknown risks of transmissable disease.

> For example, some doctors at University Hospitals of Cleveland Hemophilia Treatment Center continued treating patients with cryoprecipitate, the single donor transfusion obtained from volunteers. Dr. Oscar Ratnoff, University Hospitals, advocated use of cryoprecipitate; he published his successful results with this therapy. [footnote: Lederman, M.M., Ratnoff, O.D., Scillian, J.J., Jones, P.K., & Schacter, B.: Impaired. See also Ratnoff, O.D. (1984)]. Some complications of the therapy of classic hemophilia T. Clinical Medicine, 103, 653. (1983). Cell-mediated immunity in patients with classic hemophilia. New England Journal of Medicine, 308, 79-83. Dr. Ratnoff also reported in late 1982 that his patients did not exhibit immune system changes which were being reported in patients treated with concentrates. [footnote: Id. See also Lederman, M.M., Ratnoff, O.D., Evatt, B.L., et al. (1985). Acquisition of antibody to lymphadenopathy-associated virus in patients with classic hemophilia. Annals of Internal Medicine, 102, 753]. These were significant data since at the time there was speculation that hemophiliacs who used Factor VIII concentrates and who were developing AIDS-defining illnesses did not have a blood transmissible disease. Rather, it was hypothesized that they were simply responding to foreign antigen overload. [footnote: Menitove, J.E., Aster, R.H., Casper, J.T., et al. (1983). T-lymphocyte subpopulations in patients with hemophilia treated with cryoprecipitate and lyophilized concentrates. New England Journal of Medicine, 308, 83-86. Landay, A. Poon M-C, Abo, T., et al. (1983). Immunologic studies in asymptomatic hemphilia patients. Relationship to AIDS. Journal of Clinical Investigation, 71: 1500] Because Dr. Ratnoff's data showed no immune abnormalities in hemophiliacs treated with cryoprecipitate, [footnote: Id.] this should have heightened suspicions that concentrates were carriers of the causative agent of AIDS. Unfortunately, Dr. Ratnoff' data, along with other supporting publications, [Supra, note 35] were largely ignored.
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> Ring and Leonard, supra, p.178.

Additionally, in the very first issue of the journal AIDS Research, published in January, 1983, T. Vincent Shankey, PhD and M. Elaine Eyster, MD, of Pennsylvania State University Medical School reported:

> During the year 1982, nine cases of the acquired immune deficiency syndrome (AIDS) were recognized in hemophiliacs. Eight of these individuals were previously healthy, and one had long-standing common variable hypogammaglobulinemia (1-3). All had classic hemophilia, and all had received antihemophilic factor (AHF) concentrates.
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> * * * *
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> Recent evidence indicates that healthy hemophilia patients receiving AHF concentrates have alterations of their immune systems. These changes include decreased T-helper/suppressor ratios, and lymphadenopathy. These alterations are seen in healthy hemophiliacs treated with AHF concentrates, prepared from pools of 5,000 or more donors, but not in those treated with cryoprecipitate prepared from single donors. Furthermore, H/S ratios decrease significantly with the use of more vials of AHF, indicating that concentrate therapy is related to low H/S ratios. (emphasis added)

Shankey, et al., supra. As opposed to the NHF's statements, these infections resulting exclusively from concentrate usage were not due to "relative use patterns," but to the increased opportunity of infection as a result of a wider variety of "alloantigens":

> In a related fashion, we propose that alloantigens in AHF concentrates could provide an important inducing event which subsequently allows a viral agent (or agents) to infect a compromised host. Thus, AHF concentrates produced from thousands of individual donors provide a very large number of different alloantigenic specificities. In contrast, hemophilia patients receiving cryoprecipitate receive substantially fewer alloantigens.

Shankey, Phd, and Eyster, MD, "The Acquired Immune Deficiency Syndrome (AIDS) In Hemophiliacs: A Hypothesis." AIDS Research, Vol. 1, 1983, p.83, 84.[63]

Once again, the FDA knew the risk to the hemophilia community of AIDS infection as a result of concentrated clotting factor as compared to cryoprecipitate, but the FDA issued no warnings."

> Hemophiliacs are considered prey to AIDS because they must receive blood substances, and a debate rages over whether treatment of hemophiliacs should be done with cryoprecipitate or concentrate. Cryoprecipitate is derived from the blood of a few donors [ten to fifteen], while the concentrate comes from the pooling of many [two thousand to twenty thousand], thus increasing the likelihood of possible infection.

FDA Consumer, supra at p. 19, col.3. Without a single mention of CDC warnings concerning concentrated clotting factor, the FDA article presented only the conclusions of the National Hemophilia Foundation, a non-medically-licensed, volunteer organization, which the Institute of Medicine report found had "financial and other relationships" with "the plasma fractionation industry [which] created a conflict of interest that seriously compromised the perceived independence of NHF's recommendations." IOM Report at p.7.

The FDA Consumer magazine wrote:

> Commenting on the debate of fresh versus freeze-dried blood substances, the National Hemophilia Foundation of New York says: "there is no specific evidence indicating that there is a greater risk with concentrate than with cryoprecipitate or fresh frozen plasma. While all of the patients with hemophilia who have developed AIDS have been treated with concentrate, the

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[63]The Seventh Circuit Court of Appeals explained that a related theory was advanced in 1995:

> The plaintiffs presented expert scientific testimony at trial that, under the theory of antigenic stimulation, an infected person's exposure to additional HIV, other viruses, or foreign proteins, shortens this asymptomatic period, provokes increased replication of HIV, and leads to a quicker death from an AIDS-related illness. The plaintiffs asserted that, under this theory, Poole's death was hastened through his use of Factor VIII concentrate manufactured by the defendants after his initial HIV infection.

Gruca v. Alpha Therapeutic Corp., 51 F.3d 638, 641 (7th Cir. 1995).

> proportion of severe hemophiliacs treated exclusively with other products is so small that this observation is expected from the relative use patterns. . . ."

FDA Consumer, supra at p. 19, col.3.

Even with this unreasonable perception in light of the scientific information concerning transmissibility and the magnification of risks from pooled plasma, the FDA Consumer noted that the National Hemophilia Foundation recommended the use of cryoprecipitate for previously untransfused patients:

> The Medical and Scientific Council of the National Hemophilia Foundation has recommended that cryoprecipitate be used instead of concentrate in treating certain patients -- those under age 4, those newly diagnosed, and patients with mild hemophilia. The foundation is emphatic in its advice that the fear of contracting AIDS should not cause hemophiliacs to refuse treatment. That could cause crippling or dangerous hemorrhaging.

FDA Consumer, supra at p. 19, col.3. In placing the emphasis on concentrate usage versus no treatment, instead of cryoprecipitate versus concentrate usage, the FDA and the NHF created a straw man argument; few hemophiliacs would have refused treatment, but certainly many would have improved their chances of avoiding AIDS by infusing with cryoprecipitate instead of clotting factor if they had only been presented with the relative risk reduction opportunities.

> If one accepts the premise that commercially manufactured Factor VIII concentrate was a life-saving necessity in the life of a hemophiliac, the risk versus benefit argument is persuasive. Single-donor cryoprecipitate, however, was the life-saving, life-extending revolution in treatment. Factor VIII concentrates simply made treatment somewhat more precise since the number of Factor VIII units present in a vial are presumed to be assayed and identified on the label. The primary improvement, however, was convenience. Once this is understood, the risk versus benefit argument should receive closer scrutiny.

Ring and Thomas, "Representing the Hemophiliac With AIDS," Courts, Health Science & the Law, Summer, 1991, vol.2, No.1, p. 175. By recommending the use of cryoprecipitate for patients who had previously used little or no clotting factor concentrate, the NHF, and the FDA, by reiterating and emphasizing the NHF's recommendation by failing to report countervailing CDC findings, presented a grossly self-contradictory policy. Both the FDA

and the NHF implicitly acknowledged the risks of AIDS from clotting factor concentrate usage for previously untransfused patients, while at the same time continuing to recommend its use for those already exposed to its potential viruses.

Indeed, the FDA knew that the National Hemophilia Foundation believed that clotting factor concentrate posed a special risk of AIDS transmission, because the NHF Executive Director, Alan Brownstein testified at the August 1 and 2, 1983 hearings before the House Subcommittee on Government Operations that "[t]he recognition that AIDS appears to be transmitted through clotting factor concentrates has had a profound effect on hemophiliacs and their families throughout the country." Brownstein, House Integovernmental Relations and Human Resources Subcommittee of the Committe on Governmental Operations, Federal Response to AIDS, 98th Congress, August 1 and 2, 1983, p. 57.

If hemophilia patients had continued to treat with cryoprecipitate until the introduction into the U.S. market of heat-treated, HIV-purified clotting factor in 1984, a mere two year period from the July, 1982 CDC conference, hemophiliacs would have overwhelmingly reduced their exposure to HIV. The Goedert, et al, study, reported in 65:2 Blood, p. 493, found that, while 74% of 69 hemophilia A patients who had received factor VIII concentrate, but not factor IX concentrate, had antibodies against HTLV III, and 90% of the 48 patients receiving factor VIII concentrate at least twice a month had HTLV III antibodies, none of the 22 hemophilia patients treated only with fresh frozen plasma or cryoprecipitate had HTLV III antibodies.[64] Every single type of internal hemorrhage could have been treated with cryoprecipitate, with the exception of cranial or visceral bleeds that required clotting factor levels of 100%, possible only with clotting factor concentrate. Even with such occasional hemorrhages, severe hemophiliacs could have minimized their exposure by using clotting factor exclusively to treat hemorrhages, mild hemophiliacs would never have required the use of concentrate. Thus, an historically successful and viable treatment alternative to clotting factor concentrate, one which overwhelmingly reduced the possibility of HIV infection, was available to the hemophilia community.

In short, the FDA intentionally distorted the facts concerning the risk of AIDS transmission from the use of clotting factor concentrated clotting factor, and did so in a manner designed to encourage the use of concentrate as opposed to other forms of treatment such as cryoprecipitate.

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[64]This data is consistent with that available internationally. A study of 66 Israeli hemophilia patients for antibodies to HIV in blood samples collected between 1978 and 1985. HIV antibodies were detected in 40 patients. 38 of 45 patients treated with nonheat-treated factor VIII concentrate developed antibodies to HIV, as compared to only one seroconversion of 16 patients treated with cryoprecipitate and fresh plasma only. Shlomit Orgad, et al, "Antibodies to HIV in Israeli Hemophiliacs: Relationship Between Serological Profile and Disease Development," AIDS Research and Human Retroviruses," Volume 3, Number 3, 1987, p.323.

B. A Legal Presumption Exists That the Hemophilia Community Would Have Acted Upon FDA Warnings And Appropriately Utilized Cryoprecipitate In Circumstances That Were Not Life-Threatening.

Two obvious questions arise; were hemophiliacs really seeking this information at the time, and what would they have done with the correct information had they received it? Despite the relative dearth of information on those two issues, due to the absence of FDA and, accordingly, industry disclosure of risk, there is sufficient information to support the proposition the hemophilia community would have adopted cryoprecipitate as the treatment of choice until heat-treated product was available.

First, the hemophilia community sought out information relating to HIV risk, and remained uninformed as a result of the absence of FDA leadership. National Hemophilia Foundation Executive Director Alan Brownstein testified at the August 1 and 2, 1983 hearings before the House Subcommittee on Government Operations that patients and family members immediately sought information concerning the risk of AIDS through concentrate usage:

> Many physicians and treatment centers are deluged with calls from apprehensive patients and families seeking information and, of course, reassurance. A number of physicians themselves are concerned and disagreement exists among experts as to whether or not treatment should be modified. Some have suggested that the potential for reducing the risk of AIDS would be increased if cryoprecipitate, which is derived from smaller donor pools, was used instead of the dominant replacement therapy now in use - AHF (antihemophilic) concentrates, which are derived from much larger donor pools. Yet, there is serious question raised as to whether or not this would represent a safer alternative and, of course, the patients are caught in between as the uncertainty among physicians compounds the distress.

Testimony of Alan Brownstein, Executive Dir., National Hemophilia Foundation Testimony submitted to the House of Representatives Integovernmental Relations and Human Resources Subcommittee to the Committe on Geovernmental Operations, Federal Response to AIDS, 98TH Congress, August 1 and 2, 1983, p. 55.

There are two simple issues presented by that testimony: 1) hemophilia patients were seeking information about the risks of AIDS from factor concentrate infusion; and 2) physicians were becoming aware of the risks posed by the larger plasma donor pools utilized with factor VIII concentrate. The fact that most hemophilia patients were not

informed of these risks is quite apparent from the FDA's public statements and the conclusions of the IOM report. Physicians and the FDA may have been uncertain about what ultimately the best therapy was, in view of the risks present from AIDS, but this was not a reason not to inform the community about those risks and allow them to make the decisions themselves. Clearly, the hemophilia community could not have obtained worse results with their own risk assessment than that which the FDA performed on their behalf.

As to the second question, whether the community would have used cryoprecipitate instead of concentrate, the evidence of a few cases indicates that a substantial portion of the population would have used cryoprecipitate if merely armed with the proper information concerning risk. Patients understandably were unaware that cryoprecipitate usage could decrease the potential risk of transfusion-associated AIDS by as much as 99.9%, the difference in risk between the largest donor pools for factor concentrate, up to 20,000 persons, and the smallest donor pools for cryoprecipitate, as low as twenty persons. In the absence of any explanation of the different risks between clotting factor concentrate and cryoprecipitate, some hemophilia patients apparently abandoned any form of plasma usage:

> Some patients have abandoned appropriate use of blood products because they fear contracting AIDS. This is based on anecdotal reports from patients and physicians, particularly orthopedists, who have reported increased joint damage resulting from inadequately treated bleeding episodes. This concern is further documented by reported reductions in blood clotting factor sales from industry and reduced blood clotting factor use from treatment centers.

Brownstein, supra, p.54. If patients had been informed that they did not need to abandon treatment altogether in order to almost statistically eliminate their risk of transfusion-associated AIDS by converting their treatment choice to cryoprecipitate until heat treatment was available for factor concentrate in the U.S., those patients in all likelihood would not have abandoned the use of plasma component therapy altogether. That is precisely the argument that the Ninth Circuit Court of Appeals found to present a question of fact for the jury, and therefore reversed the prior entry of summary judgment in favor of the pharmaceutical defendants:

> Appellants claim that had they known about the risk they would have altered their lifestyles in order to curtail the frequency of the necessity of clotting factor and that they would have switched from Factor VIII to cryoprecipitate.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 384 (9th Cir. 1992). The IOM report concludes that the NHF's public stance was due to its conflicts of interests between its

commitment to the hemophilia community and its inappropriately close association, financial and otherwise, with the pharmaceutical industry.

The U. S. Court of Appeals for the Eighth Circuit affirmed a ruling by the U.S. District Court for the Northern District of Iowa, applying Iowa tort law, that a rebuttable presumption exists that the plaintiff drug recipient would have read and acted upon a proper warning by the Food and Drug Administration of the potential effects of the swine flu vaccine. Petty v. United States, 592 F.Supp. 687, 690-691 (N.D. Iowa 1983). The same swine flu vaccine cases supply a legal presumption that hemophilia patients would have changed their treatment to cryoprecipitate. The District Court first established that the warning was insufficient under Iowa law.[65] The Petty Court then remarked upon the context within which these insufficient notices were provided, one in which the FDA emphasized the absence of any acceptable practice other than immunization:

> [T]he hardsell approach to immunization taken here had the natural effect of firmly planting within the recipient's mind the imperative need for receiving the shot. The approach taken by those charged with the administration of this program had the distinct effect of de-emphasizing the importance of making individual determinations as to the advisability of undergoing the risks of immunization.

Petty, 592 F.Supp. at 691. The similarities with the FDA's presentation of clotting factor concentrate as the only available treatment therapy are clear and apparent.

The Petty Court then adopted a rule of rebuttable presumption of the proper use of warnings:

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[65]The Petty Court writes:

> In order to create the presumption that informed consent was given pursuant to this statute [Iowa informed consent law, Code of Iowa Sec. 147.137], the form must set forth in general terms the nature and purpose of the procedure, together with the known risks, if any, of death, brain damage, quadraplegia, paraplegia, the loss or loss of function of any organ or limb, . . . with the probability of each such risk if reasonably determinable, Code of Iowa Sec. 147.1347(1). The consent form given to the plaintiff failed to set forth the known risk of loss of function of any organ or limb. This symptom of serum sickness is one major element of plaintiff's damages. Thus, the Iowa informed consent law could not relieve the defendant of its liability for failure to warn of known dangers.

Petty, 592 F.Supp. at 690.

This Court concludes that the Supreme Court of Iowa, if faced with this problem, would adopt the approach of Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), wherein the Court presumed that an adequate warning would have been read and that the recipient would have acted on the warning [ftnt 4: "See also Sterling Drug v. Cornish, 370 F.2d 82 (8th Cir.1966)"]:

> Where a consumer, whose injury the manufacturer should have reasonably foreseen, is injured by a product sold without a required warning, a rebuttable presumption will arise that the consumer would have read any warning provided by the manufacturer, and acted so as to minimize the risks. In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.

Petty, 592 F.Supp. at 691.[66] The Eighth Circuit Court of Appeals upheld the District Court's holding in its entirety, and elaborated on the inadequacy of the warning, ruling that, under Iowa law, it is not sufficient to merely contend that death may result from some causes; instead, the warning must describe each separate forseeable cause.

> We reject the government's contention that a reference to death satisfies its duty to warn for another reason also. Were this

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[66]The rule regarding product warnings is particularly important in those jurisdictions having adopted Comment K of Section 402A of the Restatement (Second) of Torts, regarding strict products liability law. Comment K states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

Petty, 592 F.Supp. at 692 (emphasis and ellipses in original).

> undifferentiated warning found to satisfy the duty to warn, which under Iowa law requires disclosure of all risks reasonably foreseeable, then the duty to warn would become very hollow indeed. Death can result from virtually any treatment. Moreover, the risk of death may be conceptually remote, whereas a more specific warning detailing the known risk of serum sickness and its symptoms would alert recipients more concretely to the risks that they actually were assuming.

Petty, 740 F.2d at 1437.

The threshhold for establishing forseeability sufficient to call for warnings is not a high one. The involvement of the CDC in epidemiological studies has carried significant weight with the courts. The U.S. District Court for the Northern DIstrict of Ohio found sufficient causation of Guillain Barre Syndrome ("GBS"), a rare neurological disorder which occurred in more than a thousand swine flu vaccination recipients, where the CDC found a statistical relationship between the two:

> Shortly after the initiation of the swine flu immunization program, the Center (sic) for Disease control (CDC) began a surveillance program to determine whether there was a statistical relationship between the swine flu vaccination and GBS. Preliminary data indicated that such a relationship existed and a moratorium on vaccinations was declared.

Storrer v. U.S., 662 F.Supp. 18, 22 (N.D. Ohio 1986). The difference of opinion among experts did not matter; the Storrer Court accepted the conclusions of the CDC. Storrer, 662 F.Supp. at 22.

Citing both Iowa and California law, the Eighth Circuit described the elements of proper warning under Iowa's patient standard rule:

> [A]n individual must be advised of the inherent and potential hazards of the proposed treatment, any alternative methods of treatment, the risks attendant to such alternatives, and the likely results of remaining untreated.

Petty, 740 F.2d at 1436. The availability of alternative therapies, similar to the option of cryoprecipitate, was critical to the finding that the FDA failed to adequately warn of the risks of the swine flu vaccine:

> There were viable alternatives for Petty, yet he received treatment without a warning apprising him of the risks and benefits and without an initial individualized balancing of the risks and benefits by a learned intermediary.

Petty, 740 F.2d at 1438. The Eighth Circuit Court succinctly concluded this issue:

> Finally, we find that the vagueness of the generic warning is not mitigated by the invitation to ask questions. In some situations and for some individual idiosyncrasies, it may be necessary to rely on recipients' questions to complete the picture of risks and benefits or to clarify issues raised. This was not such a situation. Here the warning that was given was insufficient to spark the concerns that would have engendered questions.

Petty, 740 F.2d at 1437.

The basis for the statement that hemophilia patients and family members would have made reasonable treatment decisions based on the availability of scientific information is based on the demonstrated competence of the community in managing their home care in the preceding decade. So capable were hemophilia patients and family members at diagnosing and appropriately self-infusing at home, without the assistance or advice of physicians or nurses, that in the six year period from 1975 until 1981, hemophilia patients decreased the number of annual hospital days per year from 9.4 to 1.8, decreased their unemployment rate from 36% to 12.8%, and reduced the number of days lost from work or school each year by 75%. Brownstein, supra. Of the approximately 9,500 severe hemophiliacs enrolled in federally subsidized treatment centers, their care dropped in cost from $15,800 per patient per year in 1975 to $5,932 in 1981. Id. While it is true that a major reason was the availability and convenience of clotting factor concentrate, the successful use of that program would not have been possible without a community educated in risk assessment, bleeding diagnosis and execution of appropriate treatment choices. While the episodes of bleeding, and therefore the complications from arthritis, might have been more extensive during the two year period until relatively safe, pasteurized concentrate was available in the U.S. market, that option was preferable to AIDS and widespread fatalities. It was not a choice made available to the hemophilia community, and it should have been.

SECTION FIVE: THE MEDIAN MIDPOINT OF SEROCONVERSION OF THE HEMOPHILIA COMMUNITY WAS AFTER JANUARY 1, 1983, AND THUS, PROMPT ACTION BY THE FDA COULD HAVE PREVENTED SEVERAL THOUSAND INFECTIONS.

This section argues that the median midpoint of seroconversion of the hemophilia population[67] occurred during 1983, and thus the FDA is responsible for at 3,500 seroconversions in the hemophilia community. This section will examine those estimates and attempt to describe the concensus of the research on the issue. This section will begin its analysis with those estimates arguing for the dates of seroconversion in late 1982, and then consider estimates of 1983 median midpoints.

According to a 1987 study arguing for the earliest median midpoint of seroconversion among published studies of U.S. hemophilia patients, the 3501st hemophiliac out of approximately 7,000 became infected by September of 1982. In that investigation by Eyster, M.D., et al, Annals of Internal Medicine, July 1987, 107:1, p.1, the date of the median infection point of the U.S. hemophilia A population was prior to September, 1982, since 83 of the 111 patients studied had HIV antibodies in their serum at study entry in September, 1982. It should be noted that this is the earliest estimated date of the midpoint of seroconversion, and that other qualified researchers place the date several months, even as much as one year, later. Even by Eyster's estimates, greater than half of the U.S. hemophilia A community, which comprises the largest portion of hemophiliacs in the U.S. and the largest portion of infected hemophiliacs, was still uninfected at the conclusion of the July 17, 1982 CDC meeting, when it was reported that hemophiliacs were

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[67] NEJM, Oct. 26, 1989, p.1142, gives the method by which the midpoints of seroconversion were obtained:

> For the actuarial analyses of the marker data, the dates of HIV-1 infection were estimated as the midpoint in time between the last negative and first positive specimens for subjects with previously frozen serum samples. An alternative method of estimating the seroconversion date had little effect on the calculated incidence of AIDS. (footnote omitted) Data after November 1, 1988, were censored, and standard actuarial methods were used to quantify the incidence rates of intermediate markers and AIDS. (footnote omitted) Annual incidence rates were estimated as the conditional probabilities of the development of AIDS during annual intervals after the seroconversion date. [. . . .] Because of the uncertainty about the date of HIV-1 infection in the subjects who did not have stored serum samples, the evaluation of AIDS incidence rates, cofactors, and markers concentrated on HIV-1-infected subjects with midpoint seroconversion dates. Qualitatively similar results (not shown) were found in the subjects with imprecise seroconversion dates, but such data may be much less reliable in the study of time-dependent covariates. (footnote omitted).

becoming infected with an AIDS-causing agent, and that clotting factor concentrate exposed them to thousands of donors. Thus, prompt FDA action still could have prevented over half of the U.S. hemophilic seroconversions.

There are clear problems with the consistently early seroconversion midpoint dates proposed by Eyster, et al. In a different study, but one which advanced the same conclusion of a 1982 date of the median midpoint of seroconversion, Eyster herself admits that the high seroconversion rates for patients in the University of Pennsylvania patient pool might be the result of differences in levels of treatment sought.

> It is possible that the early seroconverters were already ill during 1979 to 1982, requiring more clinic visits and providing more serum samples for HTLV-III testing, whereas the healthy patients might have visited the clinic less often and provided fewer samples for detecting early seroconversion.[68]

Eyster, et al, "Development and Early Natural History of HTLV-III Antibodies in Persons with Hemophilia," The Journal of the American Medical Association, April 19, 1985, p.2222.

Additionally, the location of the patients in a large northeastern state affects the reliability of the study's conclusions. Many of the Pennsylvania patients reasonably could have used clotting factor manufactured from large plasma pools containing donations from New York City plasma donors. New York City demonstrated a proportionately higher incidence of AIDS in the early 1980's, and hemophilia patients in the New York City area also demonstrated an earlier median seroconversion midpoint date than other geographic locations in the United States.[69] Nebraska is a an example of how these rates of

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[68]Eyster herself rejects that conclusion, arguing that "in view of the slightly higher doses of factor VIII concentrate received by the early seroconverters, it seems more likely that they visited the clinic for problems related to severe hemophilia and also had a greater probability of using one of the earliest factor VIII concentrate lots contaminated with HTLV-III." Id., p.2222. This conclusion, however is faulty: numerous studies have linked seroconversion rates with amount of factor used, which Eyster herself admits. Therefore, the greater the amount of factor consumed, the greater the risk of seroconversion. Accordingly, the appearance of these patients in the clinic for treatment of categorically different symptoms from other patients seems more likely than their appearance merely because bleeding caused slightly elevated amounts of factor usage.

[69]"The FDA identified New York City, San Francisco, Los Angeles and Miami as high risk "hot spots." Cross v. Cutter Biological, 94-1477 (La.App. 4 Cir. 5/29/96), 1996 WL 293728 (La.App. 4 Cir.), at 2.

infection, and the progression from infection to full-blown AIDS, were actually less in central, as opposed to coastal, parts of the country.[70]

Further, under Eyster's prediction of the incubation time for the virus, a period of approximately two years, the appearance of AIDS symptoms should have occurred in 1985.

> From this study, it would appear that very few if any cases of seroconversion for HTLV-III antibodies occurred in patients with hemophilia before 1979, and that the rate of seroconversion increased rapidly in 1981-1982. Thus, the interval is at least two years between the earliest seroconversion and the appearance of AIDS in hemophiliacs in late 1981 and early 1982. This interval was illustrated by our two patients who developed AIDS or AIDS-like illness. As the majority of hemophiliacs receiving factor VIII concentrate appear to have developed HTLV-III antibodies during 1981 and 1982, it is possible that the peak incidence of AIDS in hemophiliacs may not be apparent until 1985 or later.

Id., p.2222. The evidence is obvious that the anticipated onset of AIDS-like symptoms in the community did not occur in 1985 or shortly thereafter, as predicted by Eyster. This fact is not explained by a longer latency period among hemophilia patients; the bell curve for immune suppression among asymptomatic hemophilia patients is the same in duration

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[70]David J. Volsky, PhD, "HTLV-III/LAV Antibodies and Virus In Hemophilia Patients in Nebraska: Survey and Initiation of a Prospective Study," AIDS Research, vol. 2, No. 1, (1986), p.52.

> In the period of June, 1983 through May, 1984, the incidence rate of AIDS in persons with hemophilia A in selected areas of the United States was similar to that of homosexual men in New York City or San Francisco (10). Antibodies against HTLV-III/LAV were reported in 64% of hemophiliacs in Denmark (11), 72% of hemophiliacs in Georgia (12), and 85% of patients with hemophilia A in California (13).
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> We have recently attempted to correlate a clinical state with seropositivity to HTLV-III/LAV among hemophiliacs registered in the Nebraska Regional Hemophilia Center (14). Although 56% of patients with hemophilia A were HTLV-III/LAV-seropositive, none of them have shown signs of progression toward AIDS.

and shape as with homosexual men - it is merely later in time.[71] Indeed, the significant infection rate among the hemophilia community of Hepatitis B, and the additional compromises of the immune systems of hemophilia patients brought on by constant infusions with medications that were 90% foreign protein, all point to an accelerated progression to AIDS as compared to the homosexual community. Accordingly, Eyster's contentions concerning median midpoint dates of seroconversion are at odds with the dates of progression among hemophilia patients from infection to full blown AIDS.

Not only is Eyster's midpoint estimation controverted by the rate at which seropositive hemophilia patients developed symptoms for AIDS, but it is also controverted by the ultimate estimated number of seropositive hemophilia patients. There were approximately ten thousand severe hemophilia patients in the United States during the years at issue; of these patients, only approximately seven thousand were infected. It is likely that at least ninety percent of severe hemophilia patients used clotting factor concentrate on more than one occasion between 1980 and 1987.[72] By the beginning of 1986, pasteurization of concentrate was sufficiently standard in care to assume that few

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[71]Once again, Eyster herself admits as much:

> All of the hemophiliacs who seroconverted before 1981 manifested lymphadenopathy and/or a low T-helper cell count (<400 cells/cu mm). In contrast, the hemophiliacs in whom HTLV-III antibodies appeared after 1981 are thus far essentially normal on these two AIDS-related clinical and immunological parameters. Lymphadenopathy and/or low T-helper cell counts are present in virtually all homosexual men who were seropositive in 1982 and who lived in central New York City, where AIDS first appeared during 1979. In recent years similar findings have been noted in hemophiliacs who receive clotting factor concentrate. These findings suggest that the first one or two years after development of HTLV-III antibodies may be relatively free of AIDS-related conditions but that lymphadenopathy, a low T-helper cell count, or some other related condition such as thrombocytopenia will be found in most persons three to five years after seroconversion.

Id., p.2222. Eyster does qualify the comparison, citing "[t]he cumulative incidence of AIDS in homosexual men with HTLV-III antibodies is only on the order of 5% to 20% (J.J. Goedert, MD, unpublished data, February 1985), and in this study of hemophiliacs with HTLV-III antibodies, the cumulative incidence of AIDS and AIDS-like illnesses, during more than three years of observation, has been lower, on the order of 2% to 4%." Id.

[72]A commonly used estimate for the number of severe hemophilic patients in the United States in 1983 is approximately ten thousand. It is unlikely that more than one thousand of those patients could have avoided the need for blood component therapy between January 1, 1982 and December 31, 1984, given the tendency of severe patients to hemorrhage more easily and profusely. Since, as also previously noted, concentrated Factor VIII remained the standard of treatment despite the occurrences of AIDS, most of those patients would have availed themselves of that form of treatment.

seroconversions occurred after that time among concentrate users.[73] Therefore, the timeframe within which one may assume infections occurred is between the beginning of 1980 and the end of 1985. Eyster estimates that over half of the infected population possessed antibodies by October of 1982, just before the midpoint date of that six year period. However, it is clear that the amount of HIV in the blood supply (the "viral load") was progressively, and perhaps geometrically,[74] increasing through the end of 1983, when gay donors began self-selecting out of donor pools.[75][76]

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[73] See Dateline 14, Section Two of this document, infra.

[74] Two main routes of HIV transmission to the blood supply were through IV drug abusers and gay men with multiple sexual partners. See Timeline 10, p.35, supra. Since many paid donors were repetitive contributers as a result of that financial incentive, all of these factors point to a geometric progression of HIV in the blood supply. That is all the more likely as a result of the long incubation period of HIV (See Fns. 57 and 58, pp. 63-64, supra) which would have extended the time period during which infected blood donors would have continued to engage in high risk behavior, potentially infecting others donors.

[75]

> The majority of persons with hemophilia or related disorders became infected with HIV-1 through the use of commercial clotting-factor concentrates that were manufactured before the start of self-exclusion of donors with risk factors for AIDS, HIV-1 antibody screening, and the development of viral-inactivation measures such as the heat treatment of factor concentrates. [footnote omitted]

Goedert, et al, The New England Journal of Medicine, October 26, 1989, 321:17. See also, K. Schimpf, M.D., et al, "Absence of Anti-Human Immunodeficiency Virus Types 1 and 2 Seroconversion After the Treatment of Hemophilia A or Von Willebrand's Disease With Pasteurized Factor VIII Concentrate," The New England Journal of Medicine, October 26, 1989, pp. 1148-1152.

> In March 1983 the Food and Drug Administration first issued recommendations for the so-called self-deferral of blood donors who belonged to any defined risk group. In addition, medical examinations, including screening for lymph-node enlargement and unexplained loss of weight, became part of predonation medical checkups.

See also Dateline 22, Section Three of this document, testimony of Conant, MD.

[76] There is sufficient evidence to establish that the prevalence of HIV in the blood supply was greater each month through 1984, and, accordingly, that the number of seroconversions should have been increasing each month. Indeed, a monthly, or at least quarterly increase in the number of seroconversions is consistent with the number of cases of AIDS.

> The first cases were recognized less than two years ago by the epidemiologists in Atlanta who, by tracking the medical histories backward, determined that while a few cases had occurred in 1978 and 1979, the surge occurred in 1980 and the incidence has been doubling every six months since.

The New England Journal of Medicine, October 26, 1989, 321:17, "A Prospective Study of Human Immunodeficiency Virus Type 1 Infection And the Development of AIDS in Subjects with Hemophilia," (Goedert, et al), gave its best estimate of the midpoint of seroconversion as follows:

> When we studied the subjects with midpoint estimates further (Fig. 1), we found that the first subject with severe hemophilia A seroconverted at the end of 1978, with a steadily increasing prevalence of HIV-1 antibodies during 1979 and 1980, a rapidly increasing prevalence from 1981 through mid-1983, and a leveling off by the end of 1984.[77] The first subject with a clotting disorder other than severe hemophilia A seroconverted at the end of 1979; there was a slow increase in prevalence during 1980 and 1981 and a steadier increase from 1982 through 1986 (Fig. 1). The maximum-likelihood estimate of the curve of HIV-1 incidence was very close to that of the midpoint estimate (Fig. 1), suggesting that the 319 subjects with midpoint estimates were representative of the entire cohort.

For patients with severe hemophilia A, the study placed the maximum likelihood estimate derived from all 1128 subjects whose clotting disorder, type and severity were known, as occuring in the middle of 1983. The midpoint estimate for just those subjects providing samples documented to be HIV-negative (328 subjects) was mid-1982. For those patients with other clotting disorders, the median midpoint estimate for the 231 subjects with HIV-negative study samples was the end of the first third of 1984. The median midpoint estimate for all subjects (469) regardless of HIV-negative sample availability was the middle of 1984.

Sydney H. Schanberg, "A Baffling Epidemic," NYT, May 24, 1983, I, 25:1. See also Dateline 23, Section Three of this document.

[77]NEJM, Oct. 26, 1989, p.1142:

> As is typical of the gene frequencies of clotting disorders, our cohort of 1219 subjects was dominated by the 659 subjects with severe hemophilia A (factor VIII deficiency), 76.5 percent of whom had HIV-1 antibodies (Table 1). There were also important HIV-1 infection rates of 46 and 25 percent among the 249 subjects with moderate and mild hemophilia A, respectively, and of 8 to 42 percent among the 148 with hemophilia B (factor IX deficiency) (Table 1). Ten of our 72 subjects with von Willebrand's disease or other rare clotting disorders have antibodies to HIV-1 (Table 1). For each type of disorder, the prevalence of HIV-1 antibodies was directly associated with the degree of severity.

Shelby Dietrich, M.D., hematologist at the Southern California Hemophilia Treatement Center, presented her conclusion of the HIV seroconversion midpoint date during the proceedings of the Symposium on Recent Advances in Hemophilia Care, held in Los Angeles, April 13-15, 1989, and published in "Epidemiology of HIV Infection," Recent Advances in Hemophilia Care, 1990, pp. 80-81.

> Studies of anti-HIV seroconversion (Eyster et al, 1987, Ragni et al, 1987) reveal that seroconversion began in 1979 and by the end of 1984 70% to 85% of hemophiliacs were anti-HIV positive. **The mid-point of sero-conversion is January 1, 1983.** (emphasis added)

James Curran, who led the investigative effort by the CDC in the early 1980s, reflected the uncertainty of these studies and the increasing tendency by experts to identify the midpoint of seroconversion at an increasingly later date in 1983.

> A large number of epidemiologic studies are currently underway to investigate the spectrum, course, and cofactors involved in HIV infection. These projects are preliminary, given the long incubation period for this disease (Lui et al., 1986) and the recency of seroconversion for most at-risk populations. For example, two independent studies suggest that over half of the factor concentrate recipients in the US acquired antibody to HIV between 1981 and the end of 1983 (Evatt et al., 1985; Eyster et al., 1985).

Janine M. Jason and James W. Curran, "The Epidemiology of AIDS," Blood, Blood Products and AIDS, editied by R. Madhok, MD, C. D. Forbes, MD (Glasgow U.), and B.L. Evatt, MD (CDC), 1987, p. 6.

Japan provides helpful data on the probable median seroconversion midpoint date for the U.S. hemophilia community. The median midpoint of Japanese hemophilia patients is reflective of the U.S. midpoint date because

> [h]emodialysis patients usually receive transfusion from a limited number of Japanese donors but hemophiliacs receive infusion of commercial factor VIII concentrates prepared from pooled plasma mainly, if not exclusively, of American donors. This is likely to be the reason for the occurrence of HTLV-III/LAV infection among the Japanese hemophiliacs but not in other groups of individuals studied.

Yoshio Koyanagi, et al, "Detection of Antibodies to Human T-Lymphotropic Viruses Type I and III In Japanese Hemophiliacs," AIDS Research, 1:5 (1984), p. 353, 357. A subsequent AIDS Research article, "Clinical, Immunological, And Virological Aspects In Japanese Hemophiliacs and AIDS Patients," 2:Supplement 1 (1986), p.S141, reported that "[m]ore than 90% of antihemophilic factor concentrate has been imported from abroad, mainly from the United States."[78] In this study, sera was collected from sixty-five hemophilia patients (58 hemophilia A, six hemophilia B and 1 with Von Willebrand's Disease), 85 hemodialysis patients and 304 healthy Japanese workers. Of the sixty-five hemophilia patients whose sera was collected during 1982 through the first half of 1984, all of whom "had received infusion of commercial factor VIII concentrate," only ten possessed antibodies to HTLV-III." Id., p. 355. All eighty-five of the hemodialysis patients were negative for antibodies to HTLV-III, as were all 304 Japanese workers. Id. As the study reported, "[i]nterestingly, a sample obtained in 1983 from a hemophiliac was negative for anti-HTLV-III, while another sample obtained in 1984 from the same patient was positive, indicating the occurrence of seroconversion during the period." Id.

These variances with Eyster's early estimates cannot be explained by differences with Japan in population size or frequency of factor concentrate infusion; at the time of the

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[78]Piet J. Hagen explains the reason for the large plasma importation need in Japan:

> Green Cross [the current parent company of Alpha Therapeutic Corporation] was founded in 1950 as Japan's first (commercial) blood bank. In 1964, however, the government decided to transfer the collection of blood to the (Japanese) Red Cross because of the high incidence of hepatitis associated with paid-donor blood. On the basis of this decision, the Green Cross Corporation terminated its commercial collection of blood. From that time onward it only fractionates plasma collected by the Japanese Red Cross and from foreign (commercial) sources.

Hagen, Blood: Gift or Merchandise, Alan R. Liss, Inc., (1982), p.122. Japan purchased Alpha Therapeutic Corporation expressly to obtain such a plasma supply:

> The Alpha Therapeutic Corporation was established in the United States in 1978, when Green Cross acquired Abbott's Scientific Products Division. Green Cross paid $24 million for Abbott's fractionation plant, which had a capacity of 300,000 liters of plasma in 1979. [. . . .] The reason Green Cross bought Abbott's plasma division was to get a share in the American plasma supply, and to gain entry to U.S. and European markets. As mentioned before, commercial collection of blood is not allowed in Japan. Of the 193,000 liters of plasma used in Japan in 1977, 90,000 liters had to be imported. Therefore, it was attractive to Green Cross to establish a company in the United States. Through Alpha, which operated 29 plasmapheresis centers in 1980, its supply of plasma was secured.

Id. at p.122.

study, there were an "estimated 4,000 patients with hemophilia A (15) and an annual consumption of 218,000,000 units of factor VIII concentrates." Id. at p.357. Further, the later midpoint of seroconversion theorists have consistently taken the position that the later conversion dates were consistent regardless of the size of the local population or its location, i.e., in states such as Georgia and California.[79] This evidence supports the occurrence of a midpoint of seroconversion in the United States of not earlier than 1983.

A study of Chinese patients with hemophilia also support a later date for the U.S. hemophilia median midpoint of seroconversion. Yi Zeng, et al., "Detection of Antibody To LAV/HTLV-III in Sera From Hemophiliacs in China," AIDS Research, 2:Supp.1, (1986), p.S147, reports that, while AIDS was first reported in China in 1981 (Id.), the use of ELISA, Western blots and immunofluorescence techniques revealed LAV/HTLV-III seropositivity in only 4 of 28 hemophiliacs treated with Factor VIII. Of those 28 patients, 18 had used Armour Company-produced factor VIII concentrate in the Zhejiang Province, 8 had used Alpha-produced factor VIII concentrate in Beijing, and 2 had used factor VIII product that was not clearly identified in the study as concentrate, as opposed to cryoprecipitate. All four of the seropositive patients were from the Zhejiang Province and had used Armour concentrate, and as of publication, none of them had yet demonstrated symptoms for AIDS. Once again, the low seroconversion rates for Chinese patients using American-manufactured factor VIII concentrate, along with the expectation of that symptoms of AIDS would appear within 2 years after infection for at least half of the infected patients,[80] do not support the early U.S. seroconversion midpoint predictions of Eyster.

A study of hemophilia patients in Spain support a median midpoint of seroconversion in the U.S. of not earlier than 1983. M. Ollero, et al, "Antibodies to the AIDS-Associated Retrovirus In Hemophiliacs and Other Individuals From Southern Spain: Lack of Correlation With Lymphocytes Sub-Populations," AIDS Research, 1:6, (1984/85), pp.439-445. The investigators studied 54 hemophilia patients, all of whom received factor VIII

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[79]David J. Volsky, PhD, "HTLV-III/LAV Antibodies and Virus In Hemophilia Patients in Nebraska: Survey and Initiation of a Prospective Study," AIDS Research, vol. 2, No. 1, (1986), p.52.

> In the period of June, 1983 through May, 1984, the incidence rate of AIDS in persons with hemophilia A in selected areas of the United States was similar to that of homosexual men in New York City or San Francisco (10). Antibodies against HTLV-III/LAV were reported in 64% of hemophiliacs in Denmark (11), 72% of hemophiliacs in Georgia (12), and 85% of patients with hemophilia A in California (13).

[80]Eyster, et al, "Development and Early Natural History of HTLV-III Antibodies in Persons with Hemophilia," JAMA, 235:15, April 19, 1985, p.2219, contends: "the latency period between exposure and appearance of AIDS ranges from five months to five years, with a mean of about two years."

concentrate manufactured exclusively in the United States. Id., p.439, 440. "Sera was collected from individuals with either hemophilia A or hemophilia B from March 1982 to December 1984. From 20 patients at least two or more serum samples from different years were available." Id. at p.440. The study reported:

> When sera from different years were tested, 2/7 patients' sera collected in 1982 were antibody positive (28.5%), 14/28 (50%) in 1983, and 19/39 (48.7%) in 1984. When the multiple sera specimens from 20 patients from different years were tested, the results showed that three patients seroconverted to a positive state from 1983 to 1984 and three individuals who were initially positive for antibody to ARV became negative in the same period of time. This latter finding could indicate a reduced exposure to ARV antigens in the clotting factor preparation and a lack of infection of these individuals by the AIDS virus.

Id., p. 441. Once again, this data is consistent with a post-1983 median midpoint of seroconversion for populations using U.S.-manufactured factor VIII concentrate.

Hemophilia patients in Israel provided the most support for Eyster's predictions of early seroconversion, and yet concluded that not even half of the patients studied possessed HIV antibodies by 1983: "Of 40 seropositive [hemophilia] patients, 1 (2.5%) had antibodies by 1980, 4 (10%) by 1982, 14 (35%) by 1983, 10 (25.0%) by 1984, and 11 (27.5%) by May 1985." Shlomit Orgad, et al, "Antibodies to HIV in Israeli Hemophiliacs: Relationship Between Serological Profile and Disease Development," AIDS Research and Human Retroviruses," Volume 3, Number 3, 1987, p.323. The study does not indicate how much of the factor concentrate was manufactured in the U.S.; however, "only 1 of the patients who received locally prepared blood products developed antibodies to HIV." Id. The distinction between foreign manufactured and domestic product clearly existed, and the results indicate that most of the concentrate utilized was purchased outside of Israel.

Studies within the United States also tend to disprove a median seroconversion midpoint before 1983. A study by M. Essex, et al,[81] which included among its authors the CDC's Evatt, collected serum samples from 45 hemophilia patients from Atlanta, Georgia,[82] 41 from Birmingham, Alabama, and 39 from Los Angeles, California. The

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[81]Essex, et al, "Antibodies to Human T-Cell Leukemia Virus Membrane Antigens (HTLV-MA) in Hemophiliacs," Science, September 9, 1983, pp.1061-1063.

[82]Georgia, somewhat surprisingly, "was among the first states to report AIDS in a patient with hemophilia (1983); California did not report a case until one year later." Evatt, et al, "Coincidental Appearance of LAV/HTLV-III Antibodies In Hemophiliacs and the Onset of the AIDS Epidemic," The New England Journal

study also analyzed samples from New York City, but because they were collected between 1978 and 1982, they are not particularly helpful. The other samples were all collected in late 1982 or early 1983. Id. The study tested for antibodies to cell membrane antigens associated with "HTLV-MA," which antibodies had been found in 36% of a group of AIDS patients. Id. The antibodies appeared among only 5-13% of the three geographic groups described. Id. at 221. 67% of hemophilia patients with AIDS or severe lymphadenopathy in the study possessed the antibody, and none of the 47 healthy lab or hospital workers possessed the antibody. Id. New York patient serum actually possessed the highest percentage of positive results at 19% (Id.), which continues to support the conclusion that Eyster's claims of a 1982 midpoint of seroconversion are flawed by testing serum obtained predominantly from New York and Pennsylvania patients voluntarily seeking medical treatment, presumably partly due to symptoms of suppressed immune systems.

California, by comparison, appears to have a median midpoint of seroconversion of not before mid-1983. In a study of 21 patients with hemophilia A in a California clinic, "[a]mong most of the 21 patients with hemophilia A in California, seroconversion did not occur until 1982, and then rapidly increased in 1983. By 1984, more than 85 per cent of the group had antibody to LAV [lymphadenopathy-associated virus]." Evatt, et al, "Coincidental Appearance of LAV/HTLV-III Antibodies In Hemophiliacs and the Onset of the AIDS Epidemic," The New England Journal of Medicine, vol. 312, No. 8, Feb. 21, 1985, p. 484.

In short, almost every seroconversion and re-infection of the U.S. hemophilia population which occurred after January, 1983, and possibly after July, 1982, was preventable by FDA acting upon the information in its possession. There appear to be over 3,500 initial HIV exposures in the U.S. hemophilia population which occurred after the January 4, 1983 CDC/FDA Workgroup meeting on AIDS. The later the date of the median point of seroconversion, the greater the direct responsibility the FDA has for the infection of the hemophilia community. The Ninth Circuit has indicated that merely the existence of conflicting evidence of the date of seroconversion "underscores the inappropriateness of a grant of summary judgment as to this issue." Doe v. Cutter Biological, Inc., 971 F.2d 375, 381 (9th Cir. 1992). Accordingly, most of the infected hemophilic plaintiffs would be entitled to bring that issue before a jury in any action against the FDA.

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of Medicine, vol. 312, No. 8, Feb. 21, 1985, p. 484.

SECTION SIX: A SURVEY OF FDA PUBLIC STATEMENTS LEADS TO THE CONCLUSION THAT THE FDA UNDERSTATED THE RISK OF BLOOD-BORNE HIV IN ORDER TO MAINTAIN A PRESUMABLY SAFE LEVEL OF THE NONPAID VOLUNTEER DONOR BLOOD SUPPLY.

The ultimate reasons for the inadequate response by the FDA to the evidence of AIDS contamination of the U.S. blood supply, along with the FDA's refusal to acknowledge or warn of the special risks posed to hemophilia sufferers as a result of blood clotting factor concentrate, are uncertain. A number of reasons for FDA inactivity have been suggested by the IOM Report, including turf battles with the CDC and conflicts of interest within the FDA that resulted in improper overreliance upon the blood industry for information and advice. It is also possible that the FDA was concerned about the possible effect upon blood donations if the general public were to link a risk of AIDS with the national blood supply. There was, indeed, a blood shortage in 1983 related to public confusion over the relative risks of obtaining AIDS from receiving, as opposed to donating, blood. An examination of newspaper accounts at that time make such a motivation by the FDA quite likely.

This section will examine New York Times reports of the apparent public perception of a cause and effect relationship between blood donation and AIDS infection, and therefore the declines in blood donation as a result of a public fear of AIDS. This provides a basis for one possible FDA motivation, a perception that a public campaign to disassociate AIDS from blood would the prevent a national blood shortage. Once again, this section relies upon a simple chronological presentation of the facts.

First, the possibility that the FDA used such a rationale is supported by the use of that same rationale by the blood banking community in the Supreme Court of the State of Washington: "The [Puget Sound] Blood Center and its alled amici seek a decision based upon public policy, arguing that the public's interest in an adequate blood supply outweighs any interest of plaintiff." Doe v. Puget Sound Blood Center, 117 Wash.2d 772, 377, 819 P.2d 370 (Wash. 1991). In the dissent, it is noted that

> The blood banks urge this court to establish a general rule of nondisclosure of donor identity as a matter of public policy. Puget Sound Blood Center points to five factors which identify the need for such a policy: [. . . .] (5) the unfounded belief of many people, that the blood donation process itself may expose one to the human immunodeficiency virus, has lessened the donor population.

Puget Sound, 819 P.2d at 384. This same theme appears in the following newspaper accounts as well.

First, the New York Blood Center already had taken the position that little or no risk of AIDS from blood transfusions existed, despite the serious inaccuracies in their public statements. The New York Times reports on June 6, 1983:

> The New York City Health Department's chief epidemiologist and the director of the Greater New York Blood Program say hospital patients face little risk of contracting a disorder that destroys the body's immunological defenses.
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> In a joint statement yesterday, Dr. Johanna Pindyck, vice president and director of the blood program, and Dr. Stephen Friedman, the city's top epidemiologist, said: "While there is a possibility that AIDS may be transmitted through blood, the data do not suggest that blood transfusions from volunteer donors are an important route for such spread. The measures that have been instituted by the health authorities and blood collection agencies further reduce the possiblity of such spread."
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> Dr. Pindyck said 10 cases of AIDS were linked to the 10 million blood transfusions in the country in the last three years. In nine of the cases, the donors appeared to be free of AIDS symptoms, she said. As a consequence, she added, **"there does not seem to be any conclusive evidence that AIDS is spread by blood transfusions." If it were, she said, the risks are less than one in a million** -- or much less than forgoing a transfusion that could be lifesaving.
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> She said the safety of blood supplies was being assured by screening out donors from high-risk AIDS groups -- homosexuals, intravenous drug users, Haitians and anyone having intimate contact with members of such groups. (emphasis added)

New York Times, June 6, 1983, "AIDS Risk Held Slight for Those On Transfusions," II, 1:6.

Further, the New York Times, on June 17, 1983, reports that the fear of contracting AIDS from donating blood was nationwide:

> In Houston, some people refuse to donate blood lest they contract AIDS from the needles at the blood bank.

New York Times, June 17, 1983, "AIDS Spreads Pain and Fear Among Ill and Healthy Alike," A1, col.5.

This effort to diminish the perceived risk of AIDS from blood infusion by comparing it to annual total blood infusions received has a measurable effect, as the media begins to recite it:

> The report failed to stress that, based on what is known to date, the risk to the public seems negligible. In reality, only 14 AIDS cases have been linked even tenuously by the Federal Centers for Disease Control to the 10 million blood transfusions performed in the last three years.

Jay Weinstein, "Fighting Panic on AIDS," New York Times, July 26, 1983, I, 21:1.

The decline in regional blood donations becomes significant by June 25, 1983, when the New York Times reports that:

> Blood supplies in New York and New Jersey have slipped below their normal summer levels, blood bank officials said. They said this was the result of a number of factors, including the unfounded fear that AIDS can be contracted by donating blood.
>
> There has been a 12 percent decline in donations through the Greater New York Blood Program, said Gary Isler, a spokesman for the program. The decline comes earlier than the expected annual shortages in July and August.
>
> Blood bank officials emphasized that the needles used to take blood were not used more than once and that this eliminated the possibility that a person with acquired immune deficiency syndrome might pass on the disorder to another donor.

New York Times, June 25, 1983, "Donors' Fears Result in Blood Bank Drops," I,26:3.

The New York Times reports on June 26, 1983 ("Groups Setting Up Own Blood Banks," I,26:1) that:

> Medical reports in recent months have questioned the possible role blood tranfusions may play in transmitting AIDS. As a result, the number of calls from metropolitan New York residents wanting to give their blood to relatives and friends has grown, officials said.
>
> * * * *
>
> In addition, blood banks in the area say that concern by potential donors over AIDS has contributed to a decline in blood supplies. The blood-bank officials say such concern is unwarranted, since needles used to draw blood from a donor are not reused. (emphasis added)

The same article reports the effort by Joseph Bove, chair of the FDA's Blood Products Advisory Committee, to downplay the risks of infection from blood transfusion.

> Any many local hospitals, such as Yale-New Haven Hospital, are refusing to honor requests by people who want to designate their own blood donors. "We do not permit it," said Dr. Joseph Bove, a staff member at the hospital. "It's not done in any hospital in Connecticut.
>
> Dr. Bove, along with representatives of all the other blood banks in the area, said that the chance of contracting AIDS, or acquired immune deficiency syndrome, through a transfusion was extremely remote. It is believed to be spread through sex or injections with contaminated needles. The risk for a person in need of blood going without a transfusion far outweighs any possible health risk from accepting blood, he said.

Further, this same article revealed the intense concern of the blood banking community to avoid a concerted effort to set up autologous or known-donor blood donation centers:

> But blood-bank officials in the New York metropolitan area have expressed concern about the impact of groups like the Roslyn association, which work outside the usual blood supply networks.

"Blood Banks Would Be Destroyed"

> "If people started to set up pools like Roslyn, we'd see little pockets of donors and eventually the blood banks would be destroyed," said Martin Lowy, administrative director of the Greater New York Blood Program, which serves 262 hospitals in metropolitan New York and New Jersey.

This loss of patient rights to designate a donor is extraordinary, and today, unimaginable. But FDA's discouragement in 1983 of designated donors was consistent with Dr. Bove's desire to "delink" AIDS and blood in the mind of the public.

New York City's then-Mayor Edward Koch found the public perception of the risk of contracting AIDS from blood donations so significant that he donated blood to dispell the belief.

> To counteract the idea that AIDS can be spread by donating blood, Mayor Koch gave a pint of his own, type A positive, yesterday.
>
> "There is misinformation going around that if you give blood you can contract AIDS," he stated. "That's ridiculous."

New York Times, July 6, 1983, "Mayor Gives Blood to Make a Point," II, 3:2.

The public perception of the risk of AIDS from giving, and not merely receiving blood, was so commonplace by mid-summer that the effort to combat it had climbed into the editorial pages of the New York Times. That effort included denying the existence of scientific evidence of a blood borne agent transmitting AIDS.

> "People have gotten it in their heads that giving blood increases the risk of getting this terrible mystery disease. That shows how incoherent fear can be. In fact, it's not certain that contracting AIDS is related to blood at all. And even if there is a danger, it's from receiving blood, not from giving it."
>
> But a lot of people won't listen long enough to understand that -- a lot of people. The blood bank says that donations in the first 10 days of July have dropped off 25 percent compared with the same period last year, and the blood supply is down alarmingly. It's dumb and dangerous. Unfounded fear provoked by one health disaster is pushing us into another one. (emphasis in original)

New York Times, July 14, 1983, "Dumb -- and Dangerous," I, 22:1. This staff editorial of the New York Times is a portion of the media context in which the FDA's failure to act must be judged.

By this time in mid-summer, the blood shortage in the New York area had become severe.

> The director of the Greater New York Blood Program said yesterday that blood supplies remained critically low and that hospitals in the metropolitan region were being advised that type O negative blood should be used only in emergency cases.
>
> "We have asked hospitals to forgo all surgery requiring O negative that is not an emergency, " said the director, Dr. Johanna Pindyck.
>
> If the blood shortage persists, she said, the 262 hospitals served by the program will be requested to ration other types for emergency cases.
>
> According to Dr. Pindyck, there has been a sharp drop in donations in the last six weeks, apparently because of a fear among potential donors of contracting acquired immune deficiency syndrome, or AIDS, a disorder that destroys the body's immune defenses.
>
> **'Seems to Be Getting Worse'**
>
> She said the shortage, of more than 10 percent, showed no signs of abating. "If anything," she said, "the problem seems to be getting worse."
>
> * * * *
>
> Dr. Pindyck said that her program had less than 200 units of type O negative on reserve yesterday, hundreds of units short of its need. O positive and negative are sent to accidents or disasters because, once the Rh factor is accounted for, the two types can generally be given to anyone. A shortage of O negative is particularly life threatening to any woman with that type at or below childbearing age, because a transfusion of an opposite type could induce a deadly factor in a child born to her.

> Health officials are trying to assure potential donors there is no risk of acquiring AIDS by giving blood. They say needles used to draw blood are used once and destroyed.

New York Times, July 15, 1983, "Blood Supplies Said to Remain Perilously Low," II, 3:6.

At this time, the public and private efforts to ease concern over the risk of infection from blood donation begin to have an effect. This effort, however, appeared to have been at the cost of informing recipients of donor blood of the real risks of AIDS infection. The New York Times reports on July 17, 1983, ("Blood Donations Up As Fear Over AIDS From Needles Eases," I:20:4) that:

> Fears that acquired immune deficiency syndrome, or AIDS, could be transmitted by needles used to collect blood have eased, alleviating the concerns of health officials about blood shortages.
>
> * * * *
>
> "In the middle of June, many regions seemed to be having a lot of trouble with donation," said Dr. Alfred Katz, executive director of Red Cross blood services. "A major contributer to this seemed to be a little bit of confusion about AIDS. That seems to have turned around. Most regions seemed to end the month in pretty good shape."
>
> Some potential donors had been afraid they could get AIDS from needles used to collect blood, according to health officials. Most of the 1,700 AIDS cases reported this year in the United States have been among homosexual and bisexual men or those who take drugs by intravenous injection. **There have been rare cases in which the disease has been spread though transfusions of AIDS-contaminated blood.** (emphasis added)

Once again, the plasma manufacturing community minimizes the risk of AIDS infection from donated blood, in the context of an effort to increase blood donations and maintain supply levels. That the Public Health Service was concerned about the blood supply levels was obvious, and equally implicit is its cooperation in minimizing the risk of infection from blood donations:

> Public health information -- and misinformation -- has a powerful effect on society, and the few highly inflammatory news reports

> on AIDS have done considerable damage. In one report, for example, 19 million network television viewers were told that the threat of AIDS extends to "every single one of us who may need a blood transfusion because of an accident or an operation. You heard right: There is now a steadily growing fear that the nation's entire blood supply may be threatened by AIDS." The report failed to stress that, based on what is known to date, the risk to the public seems negligible. **In reality, only 14 AIDS cases have been linked even tenuously by the Federal Centers for Disease Control to the 10 million blood transfusions performed in the last three years.**
>
> **After such reports there was a temporary decline in blood donations, creating what Federal officials characterize as "a serious national health problem."** We also learned of patients deferring elective surgery and stockpiling their blood and of communities establishing private blood banks to avoid what they perceived as a threat of contamination. (emphasis added)

New York Times, July 26, 1983, "Fighting Panic On AIDS," I, 21:1, (editorial).

As the New York City area turns the corner on the shortage by the beginning of August, spokespersons for the blood banks continue to point to public perceptions of the risk of infection from donating blood as the cause of the shortage.

> Dr. Pyndick [New York Blood Program Director] said the [blood] shortage had been eased by informing the public that giving blood did not pose any risk of contracting acquired immune deficiency syndrome, or AIDS, because the needles were used once and thrown away.
>
> The misconception that AIDS can be contracted through donating blood, coupled with the normal decrease in blood donations in July and August, brought the supply of type O-negative blood to under a day's worth on July 15, Dr. Pindyck said. O-negative is used as a barometer of blood supplies because it can be given to anyone in emergencies, regardless of their blood type.
>
> Blood donations decrease in the summer because there are no blood drives at universities and many of the employees who usually donate at work are on vacation, the director said.

> But by yesterday, the New York blood program had collected enough O-negative blood to last two and a half to three days. This is 10 percent less than the program had last July, the director, and a little over half of the ideal supply of four to five days' worth.

New York Times, August 1, 1983, "Blood Shortage Is Said to Ease in City Region," II, 1:6.

Elsewhere, the New York Times reports:

> According to Mr. Scahill [spokesperson, Greater New York Blood Program], yearly blood donations within the seven-county Hudson Valley division, which, in addition to Westchester, includes Rockland, Putnam, Dutchess, Orange, Sullivan and Ulster Counties, average 172 pints a day. During the summer, that number is generally anywhere from 5 to 7 percent lower. This year, however, the decrease was 14 to 16 percent and Mr. Scahill said that "some of that extra 9 percent has to be attributed to AIDS," or acquired immune deficency syndrome.
>
> Specifically, he said that many people felt that AIDS could be spread from the needles used to draw blood. Officials have tried to dispel what they say is an erroneous belief, pointing out that each needle is used only once then discarded, but they concede that their efforts have not totally succeeded.
>
> "There are still some new and would-be donors who are unsure," Mr. Scahill said, but added that "we're climbing back" in terms of donations. He credited this, in part, to "the coverage in the media regarding the safety of giving blood." Still, he warned that "any number of factors could reverse the positive steps we've taken" and indicated that the situation still remained potentially dangerous.
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> * * * *
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> Clair G. Lambert, director of public relations for Yonkers General Hospital, said, "It's safe to say that there has been a definite drop-off in donations at our hospital probably caused by the hysteria of AIDS."

New York Times, August 28, 1983, Section 23, 23:1. The connections between public concern over AIDS infection from donating blood, the drop in regional blood supplies, and government efforts to minimize the evidence of blood transmissibility are clear from even this limited review of the accounts of New York City voluntary blood donation solicitation efforts.

The difficulty with a media presentation regarding the safety of giving blood, as opposed to receiving it, is that the distinction appears to have been lost on some potential donors:

> [Mr. Scahill, spokesman for the Greater New York Blood Program] said that many people felt that AIDS could be spread from the needles used to draw blood. Officials have tried to dispel what they say is an erroneous belief, pointing out that each needle is used only once then discarded, but they conceded that their efforts have not totally succeeded.

Gary Kriss, New York Times, August 28, 1983, 23, p. 23:1. The apparent response by the blood industry was to extend the reassurances from the activities related to blood which were considered categorically safe, to the categorical safety of the national blood supply itself:

> [B]oth the American Association of Blood Banks and the American Red Cross have come out strongly against designated donations.
>
> "We have had several people coming into the hospital for elective surgery who have said that they would like a family member to donate blood for their use," said Dr. William Schraft, director of the New Rochelle Hospital Medical Center's laboratories and blood bank. Dr. Schraft said he has tried to convince these patients that "our blood comes from the community and is good and that anyone suspected of AIDS has been screened out."

Id. This shift in information from safe blood activities to safe blood provide the linkage between blood shortages and inaccurate assurances knowingly made to the public about the safety of the national blood supply. The active role which the FDA played in this process demonstrates at least a portion of its motivation in diminishing the stated risk to the hemophilia community of AIDS, in order to conform the statistics regarding AIDS among factor concentrate consumers to the overall desire to stabilize blood donor levels.

The question then arises whether the FDA, or any other Public Health Service agency, could use misinformation of the hemophilia community in order to downplay a perceived connection between AIDS and blood transfusions. Using the standard of informed consent required in clinical studies, such extraneous, tertiary concerns are not allowable exceptions under 21 CFR § 50.23 to the standard requirement of obtaining informed consent; indeed, such considerations are prohibited under 21 CFR § 56.111(a)(2):

> Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possbile effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

This is the standard of exceptions to informed consent regarding considerations secondary to the safety of the study participants. In the drug safety and efficacy studies regulated by the CFRs, the study participants do not assume that there are drug benefits at the same level, if at all, which the public assumes to exist for a licensed pharmaceutical product. Hence, the prohibition in the Code of Federal Regulations against the consideration of tertiary benefits of a clinical trial, where those benefits are separate from the immediate efficacy and safety concerns of the drug, ought to apply doubly where the public assumes that the drug is safe. Accordingly, the FDA should not consider, and legally cannot, the benefits to the general public from maintaining a stable nonpaid volunteer blood supply level when determining whether to inform hemophilia patients of the risk of contracting AIDS from clotting factor concentrate usage. Nevertheless, it appears that this was a motivating factor in the FDA's decision not to inform patients of the risk of AIDS from concentrate infusion.

SECTION SEVEN: THE COMMENTS AT THE HOUSE HEARINGS ON THE RICKY RAY ACT REGARDING PLASMA WITH HIGH TITER FOR HEPATITIS B DEMONSTRATE THAT THE FDA AND THE FRACTIONATORS WERE AWARE THAT THE FRACTIONATORS SOUGHT AND OBTAINED PLASMA FROM PERSONS WITH HIGH RISK OF EXPOSURE TO AN AIDS-CAUSING AGENT.

An important dialogue emerged in the House Hearings on September 19, 1996, regarding the solicitation of plasma from persons exposed to hepatitis B.[83] Dana Kuhn made the argument that discovery in the multidistrict litigation had produced evidence that the pharmaceutical community had intentional collected and utilized the plasma of gay men in an effort to create a hepatitis B vaccine. Immigration and Claims Subcommittee Chairman Lamar Smith invited comments on the issue, writing to Mr. Reilly on February 7, 1997 that:

> testimony was given by a witness that the plasma industry intentionally mixed high titer plasma pools with screened plasma pools for production of hemophilia factor concentrate in order to cut production costs.
>
> Clearly, if that statement is accurate, it would strongly influence congressional and historical perception of the industry's culpability in the HIV-infection of the hemophilia community.

U.S. House Immigration and Claims Subcommittee, House Judiciary Committee, September 19, 1996 Hearings Report on the Ricky Ray Hemophilia Relief Fund Act, "Letter to Douglas C. Bell, International Plasma Products Industry Association," p. 292.

Robert Reilly of the International Plasma Products Industry Association diverted the discussion from the true issue, whether disproportionately high percentages of the plasma of gay men were contributed to plasma pools as a result of concerted efforts to obtain the plasma that was high in titer for hepatitis B. In the process, Mr. Reilly calls attention to the significant difference between the testing that the industry performed to screen against hepatitis B, and the hepatitis B test which it should have used as a surrogate marker for the presence of HIV.

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[83]It is beyond reasonable dispute that the pharmaceutical industry primarily sought this plasma particularly from the homosexual plasma donation community.

Mr. Reilly contends that the fractionators sought only plasma high in titer for hepatitis B surface antibody, which guards the host against hepatitis B, as opposed to plasma high in titer for hepatitis B antigen, which is the infective agent for hepatitis B. Mr. Reilly then contends that screening prevented the inclusion of the latter from main plasma pools:

> The plasma used by the fractionators to process factor concentrate was, and is, screened for the hepatitis B surface antigen, which is the serologic marker most closely associated with potential hepatitis B infectivity. All plasma units were screened for (among other things) hepatitis B surface antigen and were rejected if they were antigen positive.

Ricky Ray Act Hearings, supra, "Letter from Robert Reilly to Chairman Lamar Smith," March 17, 1997, p. 293, 295. Mr. Reilly concedes that the plasma of individuals with plasma high in titer for hepatitis B was solicited, and that it was added to main plasma pools, but contends that the screening for hepatitis B antigen both avoided exposures from contaminated factor and actually contributed to the plasma consumer's hepatitis B antibody level. This misstates the risk which Mr. Kuhn attempted to present.

The issue is not whether the pharmaceuticals unnecessarily risked unnecessary hepatitis B infection of hemophilia patients, but whether it was irresponsible to continue to solicit the plasma of persons in the same epidemiologic path as the AIDS-causing agent. The epidemiologic similarity between hepatitis B and HIV had already been established as a result of the transfusion AIDS cases during the second half of 1982. Further, the CDC had overwhelmingly established by January 3, 1983, the ability of the hepatitis B core antibody test to reveal the likelihood of exposure to HIV, as opposed to Mr. Reilly's acknowledged inability to detect the likely presence of HIV, or even a of history of viral hepatitis, through the hepatitis B surface antibody test.[84] Currently, "[s]creening tests are conducted hepatitis B by testing for surface antigen (an indication of active virus) and antibody to core (an indication of resolving or past infection and a surrogate marker for high risk behavior, such as intravenous drug use. . . ." Statement of Bernice Steinhardt, Dir. Health Services Quality, "Blood Safety: Enhancing Safeguards Would Strengthen the Nation's Blood Supply," Testimony before the Subcommittee on Human Resources, Committee on Government Reform and Oversight, June, 5, 1997, p. 9, fn. 8.

Mr. Reilly, in the course of directing the focus as to whether the pharmaceutical industry had unnecessarily exposed factor concentrate consumers, as opposed to whether the hemophilia community had been unnecessarily exposed to HIV, called this argument "at

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[84]"[T]he FDA has confirmed that the presence of hepatitis B surface antibody in the absence of a clinical history or medical diagnosis does not constitute a 'history of viral hepatitis' which would require rejection of a donated unit of blood or plasma." Reilly Letter, supra, p. 295.

best, misunderstanding (sic) and, at worst, inflammatory rhetoric and unfounded accusations." Reilly Letter, supra, p. 296. Health care workers in early 1983 disagreed with this conclusion. The UPI wire service reported:

> A new hepatitis B vaccine made from blood plasma, which it is feared may contain an agent of the often-deadly acquired immune deficiency syndrome, or AIDS, is safe and highly effective, two physicians from the Food And Drug Administration say.
>
> Some health-care workers have refused to be vaccinated because some of the plasma is obtained from hepatitis B-positive male homosexuals, the primary victims of AIDS disease. The cause of AIDS is not known, but there is concern that it may be caused by an agent that can be transmitted through blood or blood products.
>
> Dr. Robert J. Gerety and Dr. Edward Tabor of the Federal agency, writing in the current journal of the American Medical Association, called the vaccine highly purified and safe.

New York Times, Feb. 11, 1983, I, 14:6. Certainly, consumers of the concentrated plasma components had an equal interest in the risk posed to them, and particularly in light of additional risk posed by the concentration of the plasma proteins. In short, there is nothing either inflammatory or unfounded in pointing to the irresponsibility of adding plasma obtained from a demographic at known high risk for AIDS, despite the uncertain and unrelated benefits from the presence of hepatitis B antibodies. The comments of Drs. Gerety and Tabor of the FDA demonstrate that the FDA was aware of this procedure. Accordingly, yet another basis for FDA liability is available to the hemophilia community.

SECTION EIGHT: APPEARANCES TO THE CONTRARY, THE PRIVATE SETTLEMENT WAIVER DOES NOT WAIVE A CAUSE OF ACTION AGAINST THE FDA BY EACH AND EVERY PRIVATE SETTLEMENT FUND RECIPIENT, AND THUS, A POTENTIAL CAUSE OF ACTION AGAINST THE FDA REMAINS INTACT FOR APPROXIMATELY FIVE THOUSAND PLAINTIFFS.

A. Introduction.

The private settlement waiver contains a waiver of a cause of action. It would appear from a cursory reading of that clause that the defendant pharmaceuticals intended it as a defense to any future causes of action against the FDA. However, under the laws of Illinois, this waiver should waive a claim only by recipients of prior federal assistance, namely, Medicare, Medicaid or Social Security Insurance.

The extremely broad language of the exculpatory clause appears intended to obtain a waiver of a cause of action regardless of the prior federal benefit status of the private settlement fund recipient. However, because of the limited allowances provided drafters of exculpatory clauses, particularly when the beneficiary is a state actor, and further when there is disparate bargaining power, such clauses are narrowly construed against the released party. Further, only former recipients of medicare, medicaid or social security benefits for HIV care received any consideration for the waiver in the form of subrogation rights waivers by the U.S. Department of Justice; accordingly, the waiver lacks mutual consideration and, therefore, enforceability, in all other cases. Because the waiver against the federal government is ancillary to the scope and objective of the main settlement release form, the courts may enforce the waiver only against those former federal assistance recipients, and allow all other parties to continue with a cause of action against the FDA, subject to other defenses ordinarily available.

B. The Language of the Release.

The private settlement release ("the Release") contains a clause clearly intended to achieve broad exculpatory objectives with regard to the federal government in general, and the FDA in particular. That clause reads in relevant part:

> 5. Releasors agree to waive, release, and discharge any and all rights they may have to assert claims, causes of action, and administrative or other proceedings arising out of Claimaint's use of Factor Concentrates, as defined in the Agreement, including, but not limited to, the use, administration, regulation, processing, and distribution of Factor Concentrates, against the

> United States of America, its federal employees, representatives, agents, agencies and instrumentalities, and each and every individual State, Commonwealth, Territory or Possession which by agreement with the Fractionators has released its claims against Releasors to reimbursement and subrogation related to the Agreement. Releasors do not, however, waive any rights that they may have to any entitlement or right to compensation which may be provided after May 1, 1997 by the legislature of any state, federal or other government.

In short, the drafters of this Release appear to have sought a classwide release in favor of the FDA. The waiver's permission for private settlement claimants to receive Ricky Ray Act proceeds can hardly be characterized as a right which the pharmaceuticals could either provide or take away. The waiver does not accomplish its intended purpose under Illinois law,[85] however, with this waiver enforceable only as against prior Medicare, Medicaid or Social Security Insurance recipients, with the remainder of the Release remaining in effect classwide.

C. The Courts Will Construe the Waiver In Light of Its Intended Purpose, i.e. To Resolve Claims Only As Against the Fractionators.

There is no reasonable dispute that the purpose of the private settlement was to resolve claims as against the fractionators named as defendants in the Factor VIII Concentrate Multidistrict Litigation (MDL) in the Northern District of Illinois. The Food and Drug Administration is not a defendant to that action, nor is any other government body, state or federal. The federal government appears in the settlement agreement only in order to obtain waivers of subrogation rights by the U.S. government for benefits provided through Medicare, Medicaid or Social Security for the treatment of HIV-related illness. These are the circumstances within which the Illinois courts would consider the release.

First, the rules applicable to contracts apply equally to settlement agreements:

> A settlement agreement is a contract and as such, "the construction and enforcement of settlement agreements are governed by principles of local law applicable to contracts generally. Florida Educational Association v. Atkinson, 481 F.2d 662, 663 (5th Cir. 1973). When interpreting a contract

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[85]Under the "Erie doctrine," the MDL litigation, or any subsequent court interpreting the Release Agreement, would rely upon Illinois law to interpret its enforceability. Erie Railroad v. Tompkins Railroad, 304 U.S. 487 (1941).

> under Illinois law, "[t]he intent of the parties to a contract must be determined with reference to the contract as a whole, nor merely by reference to particular words or isolated phrases, but by reviewing each part in light of the others." LaThrop v. Bell Federal Savings & Loan Assoc., 68 Ill.2d 375, 378, 12 Ill.Dec. 565, 568, 370 N.E.2d 188, 191 (1977).

Air Line Stewards , Etc. v. Trans World Airlines, 713 F.2d 319, 321 (7th Cir. 1983). Accordingly, a central principle of contract interpretation, to look to the circumstances of the document's execution, equally applies to the Release:

> The language employed to express the terms of the contract in this regard being fairly and reasonably susceptible of two interpretations, it is proper and necessary to look to the evidence pertaining to the respective positions of the parties, the purpose sought to be accomplished and all of the facts and circumstances surrounding the execution of the contract, as well as to the evidence showing its practical performance by the parties themselves, to ascertain their real meaning and intention.

Knowles Foundry & Mach. Co. v. National Plate G. Co., 301 Ill.App. 128, 21 N.E.2d 913, 924 (1939).[86] Any court interpreting the release therefore will note that the FDA is not a party to the lawsuit, and will consider that the intention, and reasonable expectation, of the parties was to waive a cause of action only against the fractionators by the Release.

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[86]See also SKK, Inc. v. Cambridge Systems Group, Inc., 723 F.2d 553, 555 (7th Cir. 1983) ("consideration of the facts and circumstances surrounding the negotiation of the agreement, the nature of the product and enterprises involved, and the conduct of the principals was most appropriate to aid the district court in determining the intention and meaning of the agreement [citations omitted]"); and see also Florida East Coast Railway Co. v. CSX Transportation, Inc., 42 F.3d 1125, 1129 (7th Cir. 1994), rhg. den. ("A court's underlying goal when interpreting a contract must always be to ascertain the intent of the parties"); ("the language of a contract cannot be properly understood if it is read without attention to the circumstances under which it was written"); ("[c]ontracts are presumed to be written in contemplation of the existing applicable law"); and see also American Pecco Corp. v. Concrete Building Sys. Co., 392 F.Supp. 789, 793 (N.D. Ill., E.D. 1975) ("It is well settled in Illinois that the court will look to substance and not form when determining the relationship of the parties to an agreement [citation omitted]"); Green v. Aerosol Research Company, 374 F.2d 791, 794 (7th Cir. 1967) ("[w]here any doubt does arise as to the sense or meaning of a contract, resort may properly be had to the circumstances surrounding its execution"); Keeshin v. Levin, 31 Ill.App.3d 790, 334 N.E.2d 898, 904 (1975), as mod. on rhg. ("[t]he primary criterion for determining the question is the intention of the parties as determined by a fair construction of the terms and provisions of the contract itself, by the subject matter to which it has reference, and by the circumstances of the particular transaction giving rise to the question"), citing 17 Am.Jur.2d, § 325; and see also Boesl v. Suburban Trust & Savings Bank, 642 F.Supp. 1503, 1511 (N.D. Ill., E.D. 1986) ("[t]he overriding purpose in construing a contract is to give effect to the intent of the parties at the time the contract was made" [citations omitted]).

In that interpretive spirit, the courts look to the contract as a whole, and not to select sentences, clauses or words. Boesl v. Suburban Trust & Savings Bank, 642 F.Supp. 1503, 1511 (N.D. Ill., E.D. 1986) ("[t]he intent of the parties must be determined with reference to the contract as a whole, not merely by reference to particular words or isolated phrases, but by reviewing each part in light of the others"); People Ex Rel. Harris v. Board of Governors of Federal Reserve, 751 F.Supp. 1323, 1329 (N.D.Ill. 1991) ("[t]he intent of the parties to a contract should be determined with reference to the contract as a whole, not merely by reference to particular words or isolated phrases [citations omitted]"). The courts will seek to interpret discrete portions of a contract both by discerning the consistency of that interpretation with the general purpose of the contract, and by anticipating the result of that understanding with the outcome for the contract participants:

> The meaning of the Agreement here must be ascertained from a common sense reading of it as a whole, and particular clauses in a contract are subordinate to the general intent. [citations omitted] See also West's Ann.Cal.Civil Code § 1653 ("Words in a contract which are wholly inconsistent with the nature or with the main intention of the parties are to be rejected"). Thus, the court will view the language of the Agreement in light of its nature as a whole and not use a disjointed, single-paragraph, strict construction approach. [citation omitted]
>
> An interpretation of the Agreement which would make it extraordinary, harsh, unjust, inequitable or which would result in absurdity, should be avoided unless plainly mandated by it terms. [citation omitted]

In Re Amica, Inc., 135 B.R. 534, 548 (N.D.Ill. 1992). The courts seek to harmonize individual contract portions both with the other sections of the contract[87] and with the document's ultimate intention as the parties reasonably understand it. Aronson v. K. Arakelian, Inc., 154 F.2d 231, 233 (7th Cir. 1946) ("a contract will not be presumed to have imposed an absurd or impossible condition on one of the parties, but will be interpreted as the parties must be supposed to have understood the conditions").

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[87] Medcom Holding v. Baxter Travenol Laboratories, 984 F.2d 223, 226 (7th Cir. 1993) ("[u]nder Illinois law, '[t]he intent of the parties to a contract must be determined with reference to the contract as a whole, not merely by reference to particular words or isolated phrases, but by viewing each part in light of the other" [citations omitted]); Carrico v. Delp, 141 Ill.App.3d 684, 490 N.E.2d 972, 976 (4th Dist. 1986) ("[t]he intent [of the parties] should not be gathered from any clause or provision standing by itself, but each provision should be viewed in light of the others" [citation omitted]); Martindell v. Lake Shore National Bank, 15 Ill.2d 272, 689, 154 N.E.2d 683, 689 (1958) ("[t]he intention of the parties is not to be gathered from detached portions of a contract or from any clause or provision standing by itself, but each part of the instrument should be viewed in the light of the other parts" [citations omitted]).

Finally, when interpreting a contract, the courts seek not only to give meaning to the various portions in a fashion harmonious both internally and with regard to the objective achieved, but also in a way that attributes reasonable and proper motives to the parties. Carrico v. Delp, 141 Ill.App.3d 684, 490 N.E.2d 972, 976 (4th Dist. 1986) ("[i]f an instrument is susceptible of two conflicting constructions, one of which imputes bad faith to one of the parties and the other does not, the latter construction should be adopted" [citation omitted])[88]; see also Chartrand Equipment Company v. Admiral Insurance Company, 609 F.Supp. 810, 812 (S.D.Ill. 1985) ("every contract imposes upon each party a duty of good faith and fair dealing").

D. Illinois Courts Disfavor Exculpatory Clauses, And Would Hold That The Release Does Not Waive Causes of Action Against the FDA By All Settlement Claimants.

Contractual clauses whereby one party attempts to negotiate a release from its liability for its conduct otherwise giving rise to a cause of action is a contract strategy generally held in disfavor by the Illinois courts. LaSalle Nat. Trust v. Board of Directors, 287 Ill.App.3d 449, 677 N.E.2d 1378, 1383 (1st Dist. 1997) ("[g]enerally, exculpatory clauses 'are not favored and are strictly construed and must have clear, explicit and unequivocal language showing that it was the intent of the parties" [citation omitted]).[89] In an action in which the State of Illinois attempted to invoke an exculpatory clause in its favor, the Illinois Court of Claims held:

> **[I]t is our conclusion that such a provision cannot be used by the State, as counsel for respondent contends, to relieve itself of liability for negligence. We do not believe that an exculpatory clause is enforceable where, as here, the matter is one of public concern, and the party seeking exculpation is in a dominant position. [citations omitted] (emphasis added)**

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[88] Martindell v. Lake Shore National Bank, 15 Ill.2d 272, 689, 154 N.E.2d 683, 689 (1958) ("where an instrument is susceptible of two conflicting constructions, one which imputes bad faith to one of the parties and the other does not, the latter construction should be adopted").

[89] Chicago & N.W.Ry. Co. v. Chicago Packaged Fuel Co., 195 F.2d 467, 470 (7th Cir. 1952) ("an indemnity contract will not be construed as indemnifying one against his own negligence, unless such a construction is required by clear and explicit language in the contract"); LaSalle National Trust, N.A., v. Board of Directors, 287 Ill.App.3d 449, 677 N.E.2d 1378, 1383 (1997) ("[g]enerally, exculpatory clauses are 'not favored and are strictly construed and must have clear, explicit and unequivocal language showing that it was the intent of the parties'" [citation omitted]); Reuben H. Donnelley v. Krasny Supply Co., 227 Ill.App.3d 414, 592 N.E.2d 8, 11 ("[e]xculpatory clauses are not favored and must be strictly construed against the benefitting party [citation omitted]").

Parkhill Truck Company, Claimant, v. State of Illinois, Respondent, 25 Ill.Ct.Cl. 172 (1965). Such cases establish that one factor which militates against enforcement against the entire hemophilia settlement claimant group of the waiver of FDA conduct is the inability of consumer settlement participants to bargain over the terms of the waiver. The courts find a disparity in bargaining power between contract participants particularly to excuse enforcement of an exculpatory clause. Reuben H. Donnelley v. Drasny Supply Co., 227 Ill.App.3d 414, 592 N.E.2d 8 at 11 ("courts will not interfere with contracts containing exculpatory clauses, unless there is a defect in the contract negotiation process such that a disparity in bargaining power denied a party a meaningful choice").[90]

The Seventh Circuit has articulated the stringent requirements for such clauses:

> Under Illinois law, three prerequisites must be met before an exculpatory clause will be deemed to defeat a claim.
>
> (1) The exculpatory clause must be strictly construed;
>
> (2) With every intendment against the party who seeks immunity from liability; and
>
> (3) The clause must spell out the intention of the parties with the greatest of particularity.
>
> Exculpatory contracts or clauses are also subject to the general contract rule that they are construed most strongly against their maker, "and expecially so when printed upon the [maker's] form."

Berwind Corp. v. Litton Industries, Inc., 532 F.2d 1, 4 (7th Cir. 1976), rhg. den. The Northern District of Illinois has similar adopted a rule which strictly construes such clauses against their exculpatory effect:

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[90]For contracts generally, the Reuben H. Donnelley Court, 592 N.E.2d at 11, has stated:

> A contract is unconscionable where it is improvident, oppressive or totally one-sided. [citation omitted] Relevant factors include gross disparity in bargaining positions of the parties together with terms unreasonably favorable to the stronger party. [citation omitted] Courts may look at the commercial experience of the parties in determining whether the aggrieved party had a meaningful choice when faced with unreasonably unfavorable terms. [citation omitted]

> Illinois courts have long recognized the validity of exculpatory clauses that relieve a party from liability, unless "(1) it would be against the settled public policy of the state to do so, or (2) there is something in the social relationship of the parties militating against upholding the agreement." Jackson v. First National Bank, 415 Ill. 453, 460, 114 N.E. 2d 721, 725 (1953). See also Evra Corp. v. Swiss Bank Corp., 522 F.Supp. 820, 832 (N.D. Ill. 1981). Such a clause, however, must be stricly construed against the party seeking immunity from liability, and the intentions of the parties should be delineated "with the greatest of particularity." Berwind Corporation v. Litton Industries, 532 F.2d 1, 4 (7th Cir. 1976)

Diedrich v. Wright, 550 F.Supp. 805, 808 (N.D. Ill., E.D. 1982);[91] see also Calarco v. YMCA of Greater Metropolitan, 149 Ill.App.3d 1037, 501 N.E.2d 268, 273 (2nd Dist. 1986) ("the language of an agreement must clearly notify the prospective releasor of the effect of signing the agreement" [citation omitted]); see also Ohio Bell Tel. Co. v. Public Utilities Comm'n, 301 U.S. 292, 307 (1937) ("[w]e do not presume acquiescence in the loss of fundamental rights"); and Sethness-Greenleaf, Inc., v. Green River Corporation, 65 F.3d 64 (7th Cir. 1965) ("waiver in contract law is the intentional relinquishment of a known right" [citations omitted]).

In particular, the Illinois courts construe the clause against the party whom it favors:

> Plaintiff's principal contention is that an exculpatory clause will be strictly construed against the party whom it favors, and other terms of the instrument may be considered in weighing the parties' intent with regard to the clause. We agree with this statement. (Moss v. Hunding, 27 Ill.App.2d 189, 169 N.E.2d p.399), the rule of construction to be applied here is that "[a]n agreement protecting one from the consequences of his own negligence must be in clear and explicit language or expressed in unequivocal terms."

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91 Under Illinois law, a court need not enforce a contractual clause exempting a party from liability for its own negligence unless "it is clear from the contract that the parties' intent was to shift the risk of loss" and it would not be against the "settled public policy of the state to do so. . . ." Rutter v. Arlington Park Jockey Club, 510 F.2d 1065 (7th Cir. 1975); citing Jackson v. First National Bank, 415 Ill. 453, 460, 114 N.E.2d 721, 725 (1953).

Evra Corp. v. Swiss Bank Corp., 522 F.Supp. 820, 832 (N.D. Ill., E.D. 1981)

Owen v. Vic Tanny's Enterprises, 48 Ill.App.2d 344, 199 N.E.2d 280, 281 (1st Dist. 1964). This is particularly the case where the clause is drafted by the party seeking excuse from its conduct. Arkwright Mutual Insurance Co. v. Garrett & West, Inc., 790 F.Supp. 1386, 1388 (N.D.Ill., E.D. 1992) ("[g]enerally, Illinois courts construe exculpatory clauses strictly against the benefitting party, particularly if that party is also the one who drafted the release [citation omitted]").[92] see also Gay v. S.N. Nielsen Company, 18 Ill.App.2d 368, 152 N.E.2d 468, 472 (2nd Dist. 1958) ("when indemnity provisions are ambiguous or equivocal, they should be strictly construed against the indemnitee and especially so when printed upon the indemnitee's form").

E. The FDA's Anticipated Invocation of the Waiver Does Not Meet the Common Law Requirement of Contract Consideration.

Given the clear authority that the Release is to be interpreted as a settlement contract, it is subject to the same formation requirements as any normal contract. Those requirements are as follows:

> A contract is formed only after there is an offer, acceptance and consideration. [citation omitted] Consideration is any act or promise which is of benefit to one party or detriment to the other. [citation omitted] If there is a failure of consideration, there is no contract. [citation omitted] The burden of proof is on the party seeking to enforce the agreement. [citation omitted]

Serpe v. Williams, 776 F.Supp. 1285, 1287-1288 (N.D.Ill. 1991).[93] The requirement of

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[92] Such [exculpatory] clauses are not favored [citation omitted] and are to be strictly construed against the party they benefit [citation omitted], particularly when that party was also the draftsman [citation omitted]. Such clauses must spell out the intention of the parties with great particularity and will not be construed to defeat a claim which is not explicitly covered by their terms. [citations omitted].

Scott & Fetzer Co. Montgomery Ward & Co., 112 Ill.2d 378, 493 N.E.2d 1022, 1029-1030 (1986); see also Macek v. Schooner's Inc., 224 Ill.App.3d 103, 586 N.E.2d 442, 444 (1st Dist. 1991) ("[e]xculpatory clauses in contracts must contain clear, explicit and unequivocal language in order to absolve a party from liability for negligence. [citation omitted] Under Illinois law, exculpatory contracts are not favored and are strictly construed against the maker" [citation omitted]); and see Rayner Covering v. Danvers Farmers Elevator, 226 Ill.App.3d 507, 589 N.E.2d 1034, 1037 (2nd Dist. 1992) ("exculpatory or limitation of damages clauses are not favored and must be strictly construed against a benefitting party" [citation omitted]).

[93] Martin-Trigona v. Bloomington Federal, Etc., 101 Ill.App.3d 943, 428 N.E.2d 1028, 1031 (1st Dist. 1981) ("[a]llegations demonstrating the existence of a contract must contain facts indicating an offer, acceptance, and consideration" [citations omitted]); Lewis-Kearns v. Mayflower Transit, Inc., 932 F.Supp.

consideration, i.e., a benefit provided or a detriment suffered by each party to the contract, must be observed in the Release. Calo, Inc. v. AMF Pinspotters, Inc., 31 Ill.App.2d 2, 5, 176 N.E.2d 1, 5 (1st Dist. 1961) ("[w]here a bilateral contract is in the contemplation of the parties, in order to have a completed contract there must be reciprocal promises").

In this case, under a theory of the Release that contemplates all settlement claimants to have waived a cause of action against the FDA for HIV infection, there is categorically no consideration provided by the federal government to settlement claimants who have never received state or federal benefits for care related to an HIV infection. Waivers of causes of action are acceptable consideration, but only where the parties mutually possess causes of action: "[c]ertainly, the consideration alleged, mutual promises to forbear prosecution of actions which are reasonably believed meritorious by the parties, can support a contract." Martin-Trigona v. Bloomington Federal, Etc., 101 Ill.App.3d 943, 428 N.E.2d 1028, 1031 (1st Dist. 1981) (citations omitted) (emphasis added). In this case, the Federal government has no cause of action against consumers who have not received past federal or state benefits related to HIV care, and therefore, there is a clear failure of consideration under an interpretation of the Release that seeks to expand the waiver to cover the entire claimant population:

> Generally, courts will not inquire into the sufficiency of the consideration which supports a contract. [citation omitted] However, where the amount of the consideration is so grossly inadequate as to shock the conscience of the court, the contract will fail.

O'Neill v. Delaney, 92 Ill.App.3d 292, 415 N.E.2d 1260, 1265.

F. The Courts May Enforce the Remaining Portions of the Release Without Enforcing a Waiver Of Causes of Action Against the FDA Against Each and Every Claimant.

First, the courts are compelled to enforce a contract in part rather than void it in its entirety. Mid-Ill Truck Equipment Co. v. Tatum, 13 Ill.App.3d 671, 300 N.E.2d 571 (1973) ("partial failure of consideration or performance is not a complete defense to an action on a contract"); Braye v. Archer-Daniels-Midland Co., 175 Ill.2d 201, 676 N.E.2d 1295, 1303 (1997) ("we recognize that a construction of a contract which renders the agreement enforceable rather than void is preferred" [citation omitted]). A theory available to the courts to enforce the remainder of the Release while reading out of the document the

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1061, 1070 (N.D. Ill, E.D. 1996) ("[f]or a contract to be created, the plaintiff must show an offer, acceptance, and consideration. Further, the terms of the contract must be reasonably certain"), citing Caporale v. Mar Les, Inc., 656 F.2d 242 (7th Cir. 1981).

waiver against the federal goverment for some claimants is the theory of divisible contracts. Chemetron Corporation v. McLouth Steel Corporation, 381 F.Supp. 245, (N.D. Ill., E.D. 1974) ("[a] divisible contract is, for example, one that is composed of independent monthly parts, the performance of any one of which will bind the other party pro tanto [citation omitted]").

The court may sever the unenforceable or unconscionable portions of a divisible contract and enforce the remainder. In re Chemtoy Corp., 19 B.R. 475, 481 (N.D.Ill. 1982) ("a contract is considered severable where one party's performance consists of several distinct and separate items and the price to be paid by the other party is apportioned to each of the items to be performed [citations omitted]").

> If the part to be performed by one party consists of several distinct and separate items, and the price to be paid by the other is apportioned to each item to be performed, or is left to be implied by law, such a contract will generally be held to be severable. [citing Keeler v. Clifford, 165 Ill. 544, 547, 46 N.E. 248, 249]

Keeshin, 334 N.E.2d at 905. The court may divine the availability of its power to sever the contract by infering such an intent by the parties:

> The question of whether a contract is severable is based on a determination of the intent of the parties. The factors considered are whether performance by one of the parties consists of separate and distinct functions and whether the price paid by the other party is apportioned to each function performed. [citations omitted]

Derby Meadows Utility v. Inter-Continental, 202 Ill.App.3d 345, 559 N.E.2d 986, 992 (1990). If the parties simply did not agree on a portion of the contract, then this is sufficient to empower the court to sever the unenforceable section.[94]

The point is that the court may determine that the waiver is ancillary to the central purpose of the contract, and in fact serves no purpose for the majority of the settlement claimants, who have received no form of state or federal assistance for their HIV care.

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[94]Dwyer v. Graham, 110 Ill.App.3d 316, 442 N.E.2d 298, 303 (1982) ("no evidence of a meeting of the minds on this point was presented by defendant. The contract clearly provided for the performance of separate agreements at a price apportioned to each agreement. [citation omitted] Accordingly, the issue of severability was properly tried by the trial court").

If the FDA insists that the waiver is intended to protect it from causes of action by all claimants, the courts are well within their rights to sever the waiver from the Release for those claimants.

G. The FDA Will Meet With No Success In Claiming That Either It, or the Claimants Who Receive the Benefits of the Federal Government's Waiver of its Subrogation Rights, Are Intended Third Party Beneficiaries to the Release by the Remaining Claimants.

At this juncture, the only argumentative option remaining to the FDA would be a somewhat desparate one, that is, an alleged status as a third party beneficiary to the Release between the defendants and the settlement claimants. A part of that strategy would undoubtedly include the contention that claimants who actually are vulnerable to federal government subrogation claims also are intended beneficiaries of the other releases. Both arguments fail as a result of the absence of any evidence of such intent by the majority of claimants.

First, this section has established the principle that waivers and exculpatory clauses are to be strictly construed against their enforcement and in favor of the party allegedly relinquishing their rights. Additional Illinois establishes this basic:

> Banco's attempted recovery as a third-party beneficiary of the Sales Agreement is similarly unavailing. As E.B. Harper & Co. v. Nortek, Inc., 104 F.3d 913, 920 n.4 (7th Cir. 1997) (citations to earlier quoted cases omitted) has recently emphasized, Illinois law precludes such third party claims absent a manifest intent on the fact of the contract to benefit the third party directly:
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> > In order for a third party to have a right to sue, "the contract must be undertaken for the plaintiff's direct benefit and the contract itself must affirmatively make this intention clear." If the intent is not express on the fact of the contract, "its implication at least "must be so strong as to be practically an express declaration."
>
> Illinois law further creates "a strong presumption that the parties to a contract intend for its provisions to apply only to them and

> not to third parties" (Stichter v. Zuidema, 269 Ill.App. 3d 455, 461, 206 I..Dec. 929, 933, 646 N.E.2d 296, 300 (3d Dist. 1995)).

Banco Del Estado v. Navistar International Transportation Corp., 954 F.Supp. 1275, 1283-1284 (N.D.Ill., E.D. 1997). While this principle clearly holds against the status of the FDA as an intended third party beneficiary, it also supports the proposition that **each claimant is not a third party beneficiary to any other claimant's contract of release of the fractionators from liability.** Instead, despite the fact that the defendant fractionators established a classwide settlement, each executed release is a separate contract between that claimant and the fractionators, independent of any other executed release:

> The law regarding third party beneficiaries is well established in Illinois and this circuit. Under Illinois law, parties to a contract are presumed to bargain for themselves and only incidently for third persons. [citation omitted] Those parties not in privity to a contract may only sue to enforce the contract when the language of the contract clearly manifests an intent by the contracting parties to confer a direct benefit on the third party. [citations omitted] "A third party's rights to enforce a contract 'rests upon the liability of the promisor, and this liability must affirmatively appear from the language of the instrument when properly interpreted and construed.'" [citations omitted]

General Electric Capital v. Equifax Services, Inc., 797 F.Supp. 1432, 1445 (N.D. Ill. 1992); see also General Electric Capital, 797 F.Supp. at 1447 ("the question of whether a contractual benefit is direct or incidental depends on the contracting parties intent and must be determined on a case-by-case basis. This is so because the contracting parties intent must be determined from the text of the contract itself").

Any finding to the contrary must clearly establish the intent of the parties to confer such an intent.[95]

> To determine whether one is a third-party beneficiary to a contract, the court must look to the contract itself and determine the intent of the parties. [citation omitted] The burden of proof

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[95]Smith v. Clark Equipment Co., 136 Ill.App.3d 800, 483 N.E.2d 1006, 1009 (1st Dist. 1985) ("[i]n order for a third party to maintain a suit for breach of contract, the contract must be entered into for the direct benefit of the third party and the liability of the promisor must affirmatively appear from the language of the instrument"); see also Smith v. Clark Equipment Co., 136 Ill.App.3d 800, 483 N.E.2d 1006, 1009 (1st Dist. 1985) ("[a] party's status with respect to a contract depends on the intention of the parties as expressed by the language of the document and the circumstances surrounding the parties at the time of its execution").

> is properly shouldered by the party trying to establish third-party beneficiary status. . . . [citation omitted]

Serpe, 776 F.Supp. at 1289. Only in the absence of intent may the courts look to the circumstances of the contract. M & J Diesel Locomotive Filter Corp. v. Nettleton, 56 Ill.App.2d 146, 205 N.E.2d 659, 661 (2nd Dist. 1965) ("[r]ules of construction require that where the identity of the parties to the contract is not clear, all of the facts and circumstances surrounding the making of the contract may be considered to determine who are the actual parties" [citations omitted]). In this case, the result is obvious; the FDA is not a party defendant in the MDL, and there is no basis for contending that the majority of claimants, having received no federal benefit for their HIV care, intended to waive whatever cause of action they might maintain against for their HIV infection. Absence such evidence, the FDA cannot successfully claim third party beneficiary status.[96] Accordingly, should this legislative attempt to resolve the issue of FDA liability for the HIV infection of the hemophilia community fail, the option of litigation remains for the majority of that community.

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[96]Kanter v. City of Chicago, 1 Ill.App.2d 420, 117 N.E.2d 790, 791 (incidental benefit arising to third party from contract is not sufficient to warrant action as third party beneficiary, it being essential that there be a clear liability of promisor directly to third person).

SECTION NINE: DISTINCTIONS BETWEEN THE HEMOPHILIA COMMUNITY AND OTHER BLOOD TRANFUSION-TRANSMITTED HIV INFECTION RECIPIENTS CALL FOR PROMPT PASSAGE OF THE RICKY RAY ACT IN ITS PRESENT FORM.

Some opponents of this legislation may incorrectly perceive that it inappropriately excludes as compensation recipients those persons who received an HIV infection as a result of a blood transfusion for purposes other than for treatment of clotting factor disorders. This section considers that issue and concludes that sufficient distinctions exist between these two infected communities to institute compensation procedures for the clotting factor disorder community alone.

There is no reasonable dispute that during the period from July, 1982 through and including December 31, 1986, some recipients of blood tranfusions in the United States, in addition to and independent of hemophilia patients, received HIV infections from blood transfusions. Many of those individuals perceive themselves as deserving of compensation from the federal government on the theory that they would not have voluntarily received that blood infusion had they received information within the FDA's knowledge and duty to disclose to whole blood or blood component recipients. It indeed is beyond reasonable dispute that there exist such consumers with such valid claims. Those individuals share certain characteristics with the hemophilia community, but also represent a consumer population to whom the FDA owed a different standard of care, which it breached to a lesser degree. Finally, the complications caused by AIDS, within the context of existing medical disability within which those manifestations occur, are clearly different between the two blood component recipient populations. As a result, despite the unarguable merits of the claims of certain blood transfusion-transmitted AIDS recipients, those allegations against the FDA are sufficiently distinct as to call for separate legislative attention, for reasons which follow.

First, the hemophilic and nonhemophilic transfusion-transmitted AIDS recipients do share several entitlements to a duty owed by the FDA, and a similar breach of that duty. First, both communities were, in the early 1980s, dependent upon the safety of the national human blood supply.[97] As a result, the FDA's early estimates of a "one in a million chance" of contracting AIDS from a blood transfusion affected both communities. The FDA was aware of the latency period of up to eighteen months after infection occurred and before symptoms emerged, and therefore knew that the chances of HIV infection were presumably far greater than what the FDA publicly claimed. Based on that latency period, it is reasonable for the FDA to have disclosed to the general public a risk of infection from a single infusion of whole blood from a single donor at a level ten to fifty times higher than

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[97]Recombinant factor, made from the blood components of animals such as pigs (porcine product) was not available, even on an experimental basis, until the late 1980s.

a "one in a million chance." Accordingly, by withholding information about latency periods and their effect upon transmission risk estimates, the FDA increased that risk (the "risk multiplier") to both hemophilic and nonhemophilic transfusion recipients. Both communities shared the same risk multiplier at that first level of access to the national blood supply in the early 1980s.

Both communities also would have benefitted from surrogate testing for HIV by detecting and destroying blood containing core antibodies for Hepatitis B.

Finally, the two communities share a segmenting of the populations in terms of availability of options. The hemophilia community had three options available: concentrate, cryoprecipitate, or no blood component therapy. For only the mildest hemorrhages was the last option available, and yet the second option would have been available in many, if not most, cases, for even the most severely hemophilic patient. In contrast, the nonhemophilic community also had three options: general blood supply exposure, autologous or "known donor" prior blood collection and infusion, or no blood replacement at all. For patients with elective, deferrable surgery, the last two options were available. For patients requiring immediate, life-saving blood replacement, such as vehicular traffic or workplace accident victims, typically only the first option was available.

Here, however, the communities begin to diverge in characteristics. Whereas the hemophilic community typically infused concentrate numerous times for various reasons as the principal treatment therapy, those using blood therapy as a treatment secondary to other invasive medical procedures, such as heart surgery, are frequently quite aware of the specific circumstances of their infection. Hence, those persons who do not qualify for compensation because their exposure to AIDS-infected blood was unavoidable are frequently easily identifiable in the nonhemophilic community, but frequently not identifiable in the hemophilic community except among the more moderate bleeding disorder members. As a result of the numerous blood component infusions which they typically receive, hemophilia patients, as individual plaintiffs, have a greater difficulty than other blood transfusion recipients in establishing proximate causation against a particular pharmaceutical or the FDA.

An additional point of divergence is the second risk multiplier imposed upon the hemophilic community as a result of the FDA's failure to reveal the existence of economies of scale, created by large manufacturer plasma pools of 2,000 to 20,000 donors. Since the risk multiplier is easily calculated based upon the number of blood donors to which a blood recipient is exposed, hemophilic patients unknowingly incurred a risk of HIV-infection from factor concentrate that was 200 to 2,000 times greater than the general public. The Ninth Circuit writes:

> Factor VIII involves a higher concentration of blood donations and therefore involves a higher risk of transmission than the risk associated with a single blood transfusion obtained from a single donor.

Doe v. Cutter Biological, Inc., 971 F.2d 375, 381 (9th Cir. 1992). Most hemophilic patients should reasonably have assumed that the concentrate of at least ten separate donors was required in order to sustain an infusion sufficient to raise clotting factor levels to roughly 50%. Accordingly, hemophilic patients believed that their risk of HIV-infection was greater than for the general public only based on two factors: 1) hemophilic patients received more blood component infusions annually, and thus were exposed to greater numbers of different donors; and 2) an infusion of a blood component such as factor VIII required several more donors per infusion than a whole blood or albumin infusion.[98] At worst, a typical hemophilia patient perceived an exposure of up to ten separate donors, or approximately the same amount as with an infusion of cryoprecipitate.

Accordingly, both the hemophilic and nonhemophilic transfusion recipients suffered, as a result of any use of the national blood supply, one risk multiplier of ten to fifty times. However, as a result of the FDA's failure to disclose the potential duration of latency periods for HIV infections, the hemophilic community uniquely suffered an additional risk multiplier of 200 to 2,000, due to the FDA's failure to disclose the existence, extent and attendant risks of manufacturer plasma pooling. That the FDA was aware of the pooling is beyond dispute: 1) the FDA conducted regular site inspections; 2) the FDA understood the existence of plasma pooling as a result of its experiences with hemophilia and hepatitis B; 3) the FDA was privy to that knowledge as a result of the Blood Product Advisory Committee's predominantly industrial membership; and 4) the CDC and experts in the field routinely informed the FDA through their publications and scholarship. Accordingly, the hemophilia community suffered a breach of duty by the FDA that was 200 to 2,000 times greater than for the general public.

Additionally, the FDA owed particular duties to the hemophilia community as a result of the classification of Factor VIII as prescription drug.[99] Those additional safety

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[98]For treatment of shock from significant and rapid fluid loss.

[99]"Blood derivatives such as Factor VIII are prescription biologicals subject to federal regulation as both 'biological products' and 'drugs'" by the FDA. Walls v. Armour Pharmaceutical Co., 832 F.Supp. 1467, 1483 (M.D.Fla. 1993), citing Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262, and citing Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. 21 C.F.R. § 610 (1988).

schedules and warning requirements were uniquely required of the FDA in favor of concentrate consumers, as opposed to the first tier precautions and warnings for blood. Once again, the hemophilic and nonhemophilic communities both share the same, front-end, first tier duty owed them by the FDA as a result of blood regulation, but the hemophilia community was owed an additional duty as a result of the FDA's knowledge of plasma pooling, and blood component refinement as a prescription drug. The FDA breached those duties.

Further, because of the additional processing attendant a prescription drug, as opposed to a simple blood transfusion, there was additional opportunity for the pharmaceuticals, and therefore, the FDA, to intervene:

> Factor VIII is a "product" produced from blood, whereas blood transfusions involve transferring whole blood directly to recipients. Therefore, Factor VIII manufacturers may have had a greater ability to intervene and take precautions in the production of Factor VIII in order to prevent the transmission of disease than did the entities responsible for administering blood banks.

Doe v. Cutter, 971 F.2d at 380.

Even further, the FDA's efforts at information dissemination would have been far easier, and therefore more effective, in the hemophilia community, than with the larger community of potential blood component recipients for reasons other than treatment of clotting disorders. The Ninth Circuit Court of Appeals writes:

> Factor VIII is manufactured by only four producers, as opposed to hundreds of blood banks and medical entities involved in the taking and storing of blood donations. Information about the threat of AIDS and various strategies to meet the threat could have easily been discussed and coordinated by the four appellees. With blood banks, by contrast, such pooling of information would have been extremely difficult.

Doe v. Cutter, 971 F.2d at 379-380. Accordingly, the FDA had a greater opportunity, and therefore, a greater obligation, to disseminate accurate information to the hemophilia community.

Finally, the effects of AIDS upon the hemophilia community have been far more devastating, both statistically, qualitatively and financially, than for any other U.S. community impacted by AIDS. First, approximately seventy percent of the severe

hemophilia community contracted HIV, and forty to fifty percent of that infected population has thus far died. Second, hemophilic patients are medically excluded from entire categories of antiviral therapies as a result of spontaneous hemorrhages caused by those treatment regimes. Third, the complications of AIDS come in addition to prolific internal hemorrhaging and attendant arthritis, which is frequently aggravated by weakened musculature due to HIV-related wasting. Fourth and finally, the financial dimensions of HIV are more dramatic for hemophilic patients for three reasons: 1) complications from hemophilia frequently creating pre-existing limited employment options and, accordingly, health, life and disability insurance options, all of which had already diminished patients' financial well-being; 2) new monoclonal and recombinant dna clotting factor concentrate purification techniques now required as a result of HIV, both guarantee a maximum co-pay and deductible; and 3) those higher purified therapies make insurers more likely to deny individual enrollment eligibility, blanket coverage for concentrate, and approval for particular claims. There can be no question that the hemophilia community is particularly devastated by HIV and AIDS, and that this factor alone might justify a legislative distinction from any other transfusion-transmitted AIDS recipient community.

The most reasonable conclusion is that the two communities contracting HIV-infections from blood usage potentially both have valid categories of claims against the FDA, but are also sufficiently distinct in liability and damages claims as to require disparate legislative consideration. Accordingly, the existence of other transfusion-transmitted AIDS communities and organizations in the United States should neither expand nor delay this legislation.

SECTION TEN: THERE EXISTS AMPLE JUSTIFICATION FOR THE HEMOPHILIA COMMUNITY'S REQUEST FOR THE CREATION OF A FEDERAL TRUST FUND FOR PERSONS INFECTED BY HIV-CONTAMINATED CONCENTRATED CLOTTING FACTOR OR THEIR INFECTED SPOUSES, CHILDREN OR OTHER SURVIVORS.

A. A Demographic Theory of Federal Disaster Relief Assistance Justifies the Act.

The hemophilia community believes that it can overcome the economic objections to the legislation, with the first defense being that of federal disaster relief. First, this crisis among the nation's hemophilia community satisfies in all respects the requirements for federal disaster relief. It is caused by forces beyond the control of the affected community, it is devastating enough in nature to be of national concern, and it crosses state boundaries so as to require a federal effort to ensure a consistency of aid. The important issue to note is that this disaster is **demographic** and not **geographic**. Geographic distasters are those that usually receive federal funding and are easy to conceptualize, i.e., a hurricane or other natural disaster. Instead, this disaster is demographic, i.e., occurring within, but not geographically throughout, a population. It is a category of disaster much more difficult to conceptualize, but it nevertheless meets federal guidelines for relief.

Should the Congress determine that the problem was unavoidable, then by definition it was beyond the control of man and is a natural disaster. If the Congress determines that it was avoidable, then it was by definition of the type against which the FDA should have protected the hemophilia community or at least warned of its dangers. The characterization of the disaster in the latter form would justify the provision of funding under subpoint B.

B. The FDA's Misconduct Has Incurred Liability for the Federal Government, Regardless of the Availability of Funds.

1. Such misconduct does not require a budgetary offset in order to justify the enactment of the Ricky Ray Act.

For all of the reasons previously discussed, the FDA has incurred liability for the federal government by its negligence in the execution of its statutory responsibilities. The FDA misconduct is a budgetary condition precedent and thus represents a financial obligation of the government that is not optional, but has already been incurred. As such, the FDA's responsibility is not diminished by budgetary concerns.

Additionally, the Federal Tort Claims Act prevents the hemophilia community from suing the FDA for misconduct without a special legislative exemption of the FDA from the

Act's protections. Accordingly, the federal government has eliminated any alternative means for the hemophilia community to seek reimbursement from the FDA directly for their injuries.

2. Notwithstanding the absence of a philosophical need to justify a budgetary offset, the waiver provision in the Act for any claims against the federal government represents a savings to the government that substantially offsets the cost of the legislation.

The Ricky Ray Act contains a waiver of any claims as against the federal government by any person accepting payment under the Act. The value of this waiver approximately offsets the anticipated cost of this legislation. Each claim of HIV infection is certainly valued at, at least, one million dollars in damages. If the hemophilia community were granted an exemption to sue the FDA under the Federal Tort Claims Act, the FDA would be named as a defendant with approximately four defendant pharmaceuticals.[100] Its shared liability in each suit would probably be not less than 20%, or $200,000, for each suit. These are conservative estimates, both as to the damages level of any one suit, and as to the FDA's potential share of liability, since proper FDA action uniquely could have entirely prevented those infections where causation is established.

Given this liability level, the recent estimates of the midpoint of seroconversion as sometime during 1983, establish that the FDA could have prevented more than 3,500 infections if it had acted properly after the January, 1983 FDA/CDC meeting. Legal experts in this area have placed the date at which knowledgable and responsible parties, which would include the FDA, should have acted as early as January, 1982. Ring and Leonard, supra, p.177. Accordingly, the date when the FDA should have conducted Hepatitis B core antibody testing, according to the Institute of Medicine, is not necessarily the earliest possible date when the FDA should have acted with warnings. Warnings, such as appropriate patient package inserts, are not dependent upon scientific certainty of injury, and therefore the FDA should have required their use earlier than January of 1983; instead, warnings were not first approved until January of 1984, and not at the request of the FDA, but voluntarily by a pharmaceutical.

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100 [U]nder the theory of alternative tort liability, if several defendants act negligently and it is not possible to determine which defendant caused plaintiff's injury, the burden shifts to the defendants to prove that they did not cause the injury. This approach was developed by the California Supreme Court in the classic case of Summers v. Tice, 33 Cal.2d 80, 199 P.2d 1 (1948).

Doe v. Cutter Biological, et al., 971 F.2d 375 (9th Cir. 1992).

If the FDA had done nothing more than issue warnings after the July, 1982 blood advisory meeting, it is possible it could have prevented over five thousand infections out of the approximately 7,000 which occurred, using as the approximate number of claimants, or their estates, discovered in the Northern District of Chicago federal lawsuit In Re Factor VIII Or IX Concentrate Blood Products Litigation,. Accordingly, it is not unreasonable to assume that the FDA currently has approximately seven hundred million and 00/00 dollars ($700,000,000.00) in liability to the hemophilia community. Using only a median midpoint of seroconversion of January 1, 1983, as the date by which the FDA had a legal duty to begin a proper response to the evidence of HIV infection, the FDA is still responsible for at least 3,500 infections valued at, at least, $200,000 each, respresenting a monetary liability by the FDA of $700,000,000. The Senate version of the Ricky Ray Act, at its current requested distribution of $125,000 per recipient, would require a total distribution of approximately eight hundred and seventy-five million and 00/00 dollars ($875,000,000.00); the House version reduces that payment to $100,000.00 per claimant. Accordingly, under the Senate version of this legislation, at the same time as the federal government debits the federal budget for $875,000,000.00 for the payouts requested, it would also reduce an existing debit in the form of liability to the hemophilia community of an amount within $175,000,000.00 of the anticipated costs of this legislation. Under this theory of the legislation, were the federal government to have considered and revealed in the annual federal budget the claims by the U.S. hemophilia community for wrongful HIV infection as a potential existing liability, in the same way as American corporations are required to disclose existing liabilities to investors in annual reports, the payment of the Ricky Ray Act would result in a net outlay of only approximately $175,000,000.00.

Since the FDA is singularly responsible for the impossibility of actually establishing the median midpoint of sercoversion date with reasonable scientific certainty, the evidentiary presumption as to the number of persons who were infected as a result of the FDA's failure to act should be construed against the FDA. However, the fact that over half of the infected population has survived to this date, and the fact that many infected hemophilia patients are not yet symptomatic, provides increasing evidence that the midpoint of servoconversion was as late as the end of 1983, which reasonably could increase the value of the statutory offset to well over one billion dollars.

3. The theory that the FDA should have required pasteurization technology not later than by 1981 solves any concerns about establishing the median midpoint of seroconversion, and increases the value of the statutory waiver offset to an amount well in excess of one billion dollars.

The theory of FDA liability based upon its failure to require pasteurization eliminates the need to establish the midpoint of seroconversion. If the Congress finds that the FDA was

negligent in failing to require pasteurization by 1981, the Congress must find that the FDA negligently allowed the infection of nearly the entire hemophilia community. Those several thousands of infections valued at FDA liability of $200,000 per infection establish a statutory waiver offset of approximately one and one-half billion dollars. However, given that pasteurization would unquestionably have prevented all of the subsequent infections, the FDA's share of liability certainly would rise to at least 50% or more, with a statutory waiver offset consequently of over three billion dollars. Since it was unreasonable for the FDA to have failed to require the pasteurization of concentrated clotting factor, in light of the FDA's knowledge concerning hepatitis B, the risks of pooled plasma, and the availability of heat-treatment technology, it is reasonable to assume the existence of a budgetary offset of three billion dollars. This is clearly sufficient to justify the legislation.

C. The FDA Should Be Deterred From Future Misconduct If the Congress Wishes to Protect Vital National Health Interests Affecting All Americans.

1. Systemic Problems As Yet Remain Within the FDA Regarding Blood Safety.

The national blood supply represents a vital national interest, and this legislation would deter the FDA from continuing a sometimes complacent attitude toward its safety. The problems with blood supply safety regulation did not begin, and they have not ended, with AIDS. Accordingly, a financial penalty against the federal government on behalf of the FDA would assist the FDA in improving its approach to blood supply safety issues.

Bernice Steinhardt, Director of Health Services Quality and Public Health Issues for the GAO, submitted the June 5, 1997 GAO report the House Subcommittee on Human Resources, Committee on Government Reform and Oversight, regarding the FDA's blood safety oversight. The Report found that particular problems remain in the FDA's supervision of blood safety, and specifically, in the FDA's response to reports pursuant to the CBER Errors and Accidents Reports System (CEARS), established in 1996. At page 9, that report considered lookback tracing and notification and stated:

> Facilities also vary in their policies for notifying recipients who have received blood from donors who later test positive for viruses and for conducting lookback, that is, tracing and removing units from implicated donors that remain in inventory. FDA requires these practices for HIV and recommends - but does not require - quarantine and destruction of units in inventory from donors who subsequently have repeatedly reactive tests for hepatitis B, hepatitis C, and HTLV. FDA has made no recommendations about

> notifying recipients who may have received blood infected with these other viruses.

At page 13, the study found significant delays in the FDA's response to CBERs:

> Further, we found that the timeliness of FDA actions in response to reports is also a problem. Our analysis of FDA's recall database showed that in 60 percent of cases, 7 months or more elapsed between the time of report submission and the district office's recommendation to CBER that a recall should be considered. The average time for CBER review was 9 weeks, but reviews sometimes took as long as a year. The total time from report submission to recall confirmation and public announcement ranged from a little over 1 month to 2-2.5 years, with an average of nearly 9.5 months; in 70 percent of cases, the time was 7 months or more.

Additionally, the GAO disclosed problems that particularly affect hemophilia consumers:

> We found no significant differences in FDA's processing time based on the severity of the case. That is, more serious cases were not processed faster than less serious ones. Given the long time FDA takes to go through its formal recall process, blood product safety could be compromised. Clearly, the longer it takes to initiate a recall, the more likely it is that all the product will have already been transfused.

GAO Testimony, supra, p. 14. Unfortunately, the FDA's self-regulation and commitment to change appears continually limited by priorities other than the public health and safety:

> FDA has been aware of a number of these problems for several years and has initiated some actions to address them. In other cases, the agency has said that our recommendations would be too costly or unnecessary.

GAO Testimony, supra, p.19. It would appear that the FDA requires additional incentives for the FDA safety standards that citizens are entitled to expect of it under the relevant CFRs. Because cost is a significant item of consideration for the FDA, the penalty of financial compensation for parties injured by its conduct or failure to regulate, or relief from sovereign immunity to sue the FDA, would provide a needed additional savings incentive.

2. Creutzfeldt Jacob Disease, a fatal neurological disorder potentially blood transmissible, provides yet another example of FDA informational abuses.

A recent example of continuing FDA difficulties in accurate information dissemination is found in donor blood potentially contaminated with a possible blood borne agent causing Creutzfeldt Jacob Disease ("CJD"), a fatal neurological disorder.[101]

A late 1994 series of voluntary withdrawals created an opportunity for the FDA to disclose the risks to hemophilia from infusion with clotting factor concentrate potentially contaminated with an agent transmitting CJD. The November 17, 1994 Food and Drug Administration "Talking Paper"[102] minimalized the risk that CJD is blood-to-blood transmissible. The Paper makes the statement that "there has never been a reported case of transmission of CJD by blood or plasma products and it is not known whether CJD can be transmitted by blood." While this was true for human to human contact in the very limit number of studies undertaken at that time, CJD, even by November, 1994, had been transmitted to mice and to guineapigs from blood taken from CJD patients. Lancet, October 19, 1985, p. 896; Lancet, ii, p. 1074. The FDA made reference to the animal studies only on the second page of the Paper, with the limiting language that CJD can be blood-borne to animals "if innoculated directly into the animals' brains." Cerebral innoculation, however, had never been demonstrated to be the only possible target location for CJD transmission, but simply represented the only location utilized in a published study. Subsequent studies may very well establish that animals can receive CJD from intravenous injection, and epidemiological evidence soon may establish the transmissability among humans through blood transfusion.

The fractionators typically referred to two "look back" studies[103] at the time, without mentioning that most of the persons who received blood transfusions in those two studies were admittedly already ill and died from other causes, despite the possible transmission of viraemia. Additionally, CJD more frequently occurs in older patients, and, therefore, latency periods may not be as relevant as the age of the patient when CJD appears. Whereas some CJD patients have been children, this is also the case with HIV; it is not improbable that CJD occurs most readily in young and old patients, when the blood-brain barrier is less stable. Finally, the latency period was suspected at the time as far longer than for HIV, and now is commonly

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[101]CJD is transmitted by a "prion," or distorted protein, instead of by a virus. Because the viral inactivation techniques commonly used with clotting factor concentrate are intended to screen out only viruses, and accept protein material, they are ineffective against the method of transmission presumed of CJD.

[102]"Voluntary Market Withdrawal of Blood Products," FDA TALK PAPER, T94-55, Nov. 17, 1994.

[103]Lancet, June 18, 1994, vol. 343, p. 1575-76; Lancet, Jan. 29, 1994, vol. 343, p. 298-99.

suspected to be as long as thirty years. Most hemophilia patients would have found this information relevant.

Consistent with the conclusion of this paper that the FDA improperly took the issue of the national blood supply level into account in the early 1980s in determing whether to issue warnings to hemophilia patients of the risks attendant Factor VIII concentrate usage, the "Executive Summary" of the Committee Report on Government Reform and Oversight's July 25, 1996, "Protecting the Nation's Blood Supply From Infectious Agents: The Need For New Standards To Meet New Threats," explained the extent to which the BPAC improperly considered ancillary issues of blood supply levels:

> FDA's BPAC first met to discuss the potential risk of CJD transmission through blood in December 1994, voting 14 to 1 in favor of withdrawing blood components collected from donors who subsequently developed CJD. **But calling the CJD risk theoretical and expressing concern about possibly creating shortages of plasma products**, the committee voted against the recall of plasma derivatives despite impassioned pleas from hemophilic representatives. BPAC voted 9 to 14 in favor of indefinite lookback (ftnt. omitted) and informing recipients of blood components from blood donors who subsequently developed CJD. However, the committee voted 10 to 14 against such notification of plasma derivative recipients.
>
> On June 22, 1995 FDA covened the ad hoc Special Advisory Panel on CJD. The panel endorsed the recommendations made at BPAC's December 1994 meeting to recall blood components made from blood donors who subsequently developed CJD and notification of recipients of these products.
>
> In August 1995 FDA Commissioner Kessler asked 11 of 13 members of the BPAC to resign due to perceived potential conflicts of interest involving their employment in regulated establishments such as hospital blood banks and regional blood centers. The Commissioner's action followed much criticized BPAC decisions on CJD and p24 antigen testing. (ftnt. omitted)

Id., p. 14 (emphasis added). While legislation now requires patient population BPAC members, the FDA BPAC once again apparently based its estimates of the risks of infectivity of a known fatal disorder upon a separate industrial agenda that had little or nothing to do with the risks posed to consumers of plasma products.

3. Hepatitis A Also Has Appeared In Patients Using Clotting Factor Concentrate.

Blood contaminations have also continued with three new infections of hepatitis A among hemophilia patients using concentrate, as reported in the January 19, 1996 MMWR. Hepatitis A, while perhaps representing a comparitively less dangerous form of viral hepatitis, is possibly the most inexcusable. Hepatitis A is typically spread by fecal contamination, which should be inconceivable in the manufacture of blood clotting factor concentrate. The Government Reform Committee Report refers once again to an inadequate response by the BPAC to Hepatitis A outbreaks:

> In another area, the BPAC again failed to reach a final decision on am important public health issue. In March, 1994, the National Hemophilia Foundation (NHF) recommended to BPAC that manufacturers of plasma products update their product package inserts to include the risks of Parvovirus B19 and Hepatitis A attendant to use of these products. The issue was again considered in March 1996 but no decision was ever made. The National Hemophilia Foundation believes that specific warnings of possible infectious disease transmission via clotting factor concentrates, although needed to ensure informed treatment decisions, are not on the package insert because the BPAC has been unable to make a decision on the matter. (ftnt. omitted)

Id., p. 13. Again, this is unacceptable conduct regarding information which end users of clotting factor concentrate are entitled to possess. The FDA can and should do better, and this legislation provides a financial incentive for them to do so.

CONCLUSION

The FDA actively obstructed the flow of information from the CDC to the hemophilia community. It reassured the public that the risk of AIDS infection from blood was low, and in order to make that reassurance consistent with evidence of AIDS among hemophilia patients, the FDA stated that the existence of AIDS among hemophilia patients was statistically minimal and not reflective of the overall risks to the hemophilia community. The FDA exclusively regulates the safety of the blood supply to the exclusion of state regulatory powers, which it expressly pre-empts to the extent that they conflict, and the FDA establishes the minimum blood supply safety levels nationally. Additionally, assurances that federal efforts are the most complete, scientifically sound and effective curtailed private efforts to monitor the safety of the blood supply. However, its actions were against the best available scientific evidence and were irresponsible in light of the purpose of the FDA and the public's reliance upon its carrying out of its public health charge. The hemophilia community was directly injured as a result to a devastating degree.

The overwhelming challenges presented to the hemophilia community by the infection of patients with the most severe form of hemophilia are difficult to comprehend in an empathetic sense. Some anti-viral treatments are ineffective for hemophilia patients, and many other therapies possess anticoagulant properties and, therefore, are difficult for persons with clotting factor disorders to withstand. For this community, HIV follows upon a medical disorder already severely debilitating, both physically and financially. As Shelby Dietrich, M.D., concluded at the 1989 Los Angeles symposium:

> The spread of HIV infection among hemophiliacs via contaminated blood components and blood products has had devastating medical, social and economic effects, the dimensions of which remain unmeasurable. At least three-fourths of heavily treated classic hemophiliacs are infected with HIV [. . .] The curve of progression to AIDS is open-ended. [. . .] Infected hemophiliacs have two co-existing chronic illnesses demanding comprehensive and continuing care.

Recent Advances in Hemophilia Care, pp. 84-85. The damage caused by the FDA's inaction and failure to convey accurate information is clear; over seven thousand hemophilia patients and family members were infected with HIV, and over three thousand of those persons thus far have died. On average, one hemophilia patient or a subsequently infected family member dies every second day in the United States from AIDS. In such a small community of only fifteen to twenty thousand members, it is difficult to exaggerate the negative consequences of the FDA's conduct. The facts and applicable law strongly support decisions by the Senate Labor and Human Resources Committee and the House Judiciary Committee to approve the Ricky Ray Act, and for both the U.S. House and Senate to pass this legislation.