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THE INADEQUATE RESPONSE OF THE FDA

TO THE CRISIS OF AIDS IN THE BLOOD SUPPLY

I. Introduction

The response of the blood industry and the Food and Drug Administration (FDA) to the problem of acquired immune deficiency syndrome (AIDS)¹ in the nation's² blood supply has been called inadequate and abysmal,³

¹AIDS is a disease in which certain white blood cells, the T-helper cells, are gradually depleted, thereby causing an individual's immune system to break down. Linda M. Dorney, *Culpable Conduct with Impunity: The Blood Industry and the FDA's Responsibility for the Spread of AIDS Through Blood Products*, 3 Ohio N.U.J. Pharmacy & L. 129, 138 (1991).

²This paper only covers the problem of AIDS in the American blood supply and does not address the problems that occurred in France involving AIDS-contaminated blood. In October of 1992, three former French governmental officials were convicted of failing to stop the distribution of HIV-infected blood clotting factors to hemophiliacs in 1985. *Three Physicians Convicted in French 'Blood-Supply' Trial* Science, Oct. 30, 1992; *Transfusion of Death*, The Washington Post, May 29, 1993 at D1. France's National Center of Blood Transfusion (CNTS) was aware that the blood clotting factors were contaminated with the AIDS virus in March of 1985. *Bad Blood in France*, Time, July 8, 1991 at 48; *French AIDS Scandal*, The Washington Post, Nov. 5, 1991, at Z7; *A Deadly 'Market Share'*, The Washington Post, Nov. 11, 1991, at A19. Yet government officials knowingly distributed the infected products until their existing stock ran out in October of 1985, without employing the heat-treatment technique that was available at that time and would have killed the AIDS virus present in the factors. *France's Ministers of Bad Blood*, U.S. News & World Report, Jan. 18, 1993 at 69; *Three Physicians Convicted*, *supra*. For additional information regarding these events, see also *France's Blood Scandal Draws Blood*, Nature, Oct. 29, 1992, at 759; *Verdict in French Blood Trial Shames Science*, Nature, Oct. 29, 1992 at 764; *AIDS Scandal Indicts French Government*, Nature, Sept. 19, 1991 at 197; *Catcalls Disrupt Trial in French AIDS Scandal*, The Washington Post, July 25, 1992, at A15; *Transfusion of Death*, The Washington Post, May 29, 1993, at D1. The French scandal does not have any real policy implications for this paper for the following reasons: 1) The French officials distributed blood that they *knew* was infected with the AIDS virus, while the U.S. government was simply trying to determine what safeguards to take to prevent or decrease the *possibility* that AIDS-infected blood would be distributed to members of the public, 2) The French scandal revolves around events that occurred in 1985, at a later point in the AIDS crisis than is the focus of this paper and indeed at a time of less uncertainty than was faced by the U.S. government between 1982 and early 1985, the time period this paper is designed to analyze, 3) The CNTS is a branch of government and has a monopoly on blood for transfusion in France, *French AIDS Scandal*, *supra*, and thus the French government is in a completely different position than is the U.S. government when evaluating how to react to a potential contamination of the blood supply; the government in France serves as the actual blood and health care provider, whereas the government in the U.S. serves as a regulator of providers; and 4) The French action was clearly inappropriate, as has been admitted by the French government (although all involved seem to blame the others) and is reflected by the convictions, whereas the actions taken or not taken by the U.S. government were more subtle and debatable.

³Dorney, *supra* note 1, at 29.

unnecessarily slow,⁴ and woefully inept.⁵ During the early 1980s, the AIDS virus was contaminating our nation's blood supply while the blood industry and the FDA refused to take appropriate steps to stop it—they, quite simply, failed us.⁶ This paper will focus on the time of uncertainty ó the time from when the first AIDS case was diagnosed to the time when AIDS testing became available and widespread. The failure of the FDA to protect the safety of the blood supply during these years will be examined in detail. The sequence of events during these years will be recounted and analyzed to determine exactly what happened, why this breakdown occurred, and what can be done to prevent such failures from occurring in the future.

II. Background

The blood industry is made up of two major components: 1) the blood banking industry which collects blood from unpaid volunteer donors to be used for transfusions, and 2) companies that manufacture blood products (primarily blood clotting factors for hemophiliacs⁷) made from plasma that is often collected from paid donors.⁸ Approximately one-half of the nation's blood

⁴*Blood Supply Safety: Hearings Before the Subcommittee on Oversight and Investigations of the House of Representatives Committee on Energy and Commerce* (Blood Supply Safety), 101st Cong., 2d Sess., at 15 (1990) (testimony of Dr. Ross Eckert, Professor at Claremont McKenna College); Report of the Presidential Committee on the Human Immunodeficiency Virus Epidemic (1988) at 78.

⁵Dorney, *supra* note 1, at 130. See also, Gilbert M. Gaul, *The Loose Way The FDA Regulates the Blood Industry*, Phila. Inquirer, Sept. 25, 1989, at A1 (The government's slowness in responding to the AIDS threat to the blood supply is evident, government regulators have dragged their feet), Blood Supply Safety, *supra* note 4, at 5 (statement of Congressman Wyden, segments of the blood industry dragged their feet on safety issues in the early 1980's).

⁶Blood Supply Safety, *supra* note 4, at 11 (testimony of Dr. Marcus Conant, Professor at the University of California Medical Center at San Francisco).

⁷Factor concentrate is the prevailing product in the treatment of hemophilia, a blood clotting disorder, for without such treatment the patient would eventually bleed to death. Lynnette S. Pisone, Case Note, *Walls v. Armour: Upholding the Principles of Liability*, 3 Ohio N.U.J. Pharmacy & L. 225, 226 (1991).

⁸Dorney, *supra* note 1, at 131-3.

is collected by the American Red Cross.⁹ The rest of the blood is collected by blood banks who are members of either the American Association of Blood Banks (AABB) or the Council of Community Blood Centers (CCBC).¹⁰

The entire blood industry is firmly under federal regulation through the FDA. Blood and blood products are biologics, and biological products are subject to FDA regulation under §351 of the Public Health Service Act (also known as the Biologics Act).¹¹ FDA authority under §351 includes licensing and inspection of relevant facilities.¹² Under §361 of the Public Health Service Act,¹³ the FDA is authorized to promulgate regulations to prevent the introduction, transmission, or spread of blood-related communicable disease from one state to another.¹⁴ In addition, all biological products are also drugs within the meaning of §201(g)(1) of the Federal Food, Drug, and Cosmetic Act, and are thus subject to regulation by the FDA as drugs as well.¹⁵ Thus the FDA has a clear duty to protect the safety of the blood supply in this country.

III. What Happened?: The Crisis of AIDS in the Blood Supply

The first case of AIDS was reported by the CDG in 1981.¹⁶ Dr. Donald Francis, an epidemiologist for the CDC at the time, and Dr. Max Essex, a retrovirology expert at the Harvard School of Public Health, immediately suspected that this new disease might be infectious.¹⁷ By July of 1982, 471

⁹Id. at 131.

¹⁰at 131-2.

¹¹42 U.S.C. §262.

¹²*Id*

¹³42 U.S.C. §264.

¹⁴40 Fed. Reg. 53040 (1975).

¹⁵38 Fed. Reg. 4319 (1973).

¹⁶*Post-transfusion AIDS Cases Require Special Strategies*, 5 BNA Civil Trial Manual no. 4 at 90, 92 (March 22, 1989); Dorney, *supra* note 1, at 139-40.

¹⁷*Frontline: AIDS, Blood, and Politics* (PBS television broadcast, Nov 30, 1993)(here-

cases of immune suppression, including 184 deaths, had been reported to the CDC, and the GDC was calling the outbreak an epidemic.¹⁸

On July 16, 1982, the CDC announced three cases of apparent AIDS in hemophiliacs that received blood clotting factors.¹⁹ Hemophiliacs tend to be the first group to become infected by a new infectious agent in the blood supply²⁰ because the factor concentrate they use is made from pooled plasma from thousands of donors.²¹ The three hemophiliacs that had contracted AIDS had no apparent risk factors except that they used large amounts of clotting factors.²² As a result of this development, the CDC called an emergency meeting to warn the blood industry and hemophiliacs that the clotting factors might be contaminated.²³ Representatives from the CDC, the FDA, the American Red Cross, the American Association of Blood Banks (AABB), the National Institutes of Health (NIH), the National Hemophilia Foundation and the National Gay Task Force were present at the meeting on July 27, 1982.²⁴ The CDC told the group that AIDS had characteristics which suggest an infectious etiology and that it might be transmitted through blood products.²⁵ The CDC recommended that donor deferral guidelines be put in place, namely that people who fit into the high-risk groups (gay men, Haitians, and intravenous drug users) should be asked not to donate blood.²⁶ However, their proposal was not

inafter *Frontline*).

¹⁸Randy Shilts, *And The Band Played On* 168 (1987).

¹⁹BNA, *supra* note 16, at 93; Dorney, *supra* note 1, at 140.

²⁰*Frontline*, *supra* note 17.

²¹Pisone, *supra* note 7, at 226.

²²Gaul, *supra* note 5.

²³*Frontline*, *supra* note 17.

²⁴BNA, *supra* note 16, at 93.

²⁵*Id.*

²⁶Shilts, *supra* note 18, at 170; Dorney, *supra* note 1, at 142.

well received. The gay representatives objected, claiming it was too soon to implement such guidelines and arguing that there would be civil rights implications.²⁷ The National Hemophilia Foundation did not want to believe that the disease was linked to their clotting factors and indeed made it very clear that this material was revolutionary—revolutionized their lives and it revolutionized their survival, and please do not take it away, even though it does have a risk.²⁸ The FDA was skeptical as well. Many people at the FDA were not convinced that the disease existed, and some FDA regulators apparently resented the COG for invading their territory, the blood industry.²⁹ In fact, in later private conversations with CDC officials, evidently some FDA officials admitted that they thought the COG had taken a bunch of unrelated illnesses and lumped them into some made-up phenomenon as a brazen ruse to get publicity and funding for their threatened agency.³⁰ In the end, no consensus could be reached as to any action to take³¹; instead it was agreed to wait and see what happened.³² The only thing that could be agreed on at this meeting was that the disease should be named Acquired Immune Deficiency Syndrome (AIDS).³³

On December 10, 1982, the first public announcement was made that AIDS might be in the general blood supply.³⁴ A baby had received platelets from a donor and both of them had developed AIDS.³⁵ The CDC issued an offi-

²⁷Shilts, *supra* note 1 8, at 1 70.

²⁸*Frontline*, *supra* note 1 7.

²⁹Shilts, *supra* note 18, at 170-1.

³⁰*Id.*, at 170.

³¹BNA, *supra* note 16, at 93; Dorney, *supra* note 1, at 142.

³²Shilts, *supra* note 18 at 1 70-1.

³³*Frontline*, *supra* note 1 7. Previously the disease had been referred to as GRID, or Gay-Related Immune Deficiency. *Id.*

³⁴Shilts, *supra* note 1 8, at 206-7.

³⁵*Frontline*, *supra* note 1 7.

cial report entitled *Possible Transfusion-Associated AIDS – California* claiming a possible relationship between AIDS and blood transfusions, and stating that [t]his report and continuing reports of AIDS among persons with hemophilia raise serious questions about the possible transmission of AIDS through blood and blood products.³⁶ Following the release of this information, Dr. Joseph Bove, Director of the blood bank at Yale University Medical Center, an officer of the AABB, and chairman of the FDA’s Blood Products Advisory Committee³⁷, went on network television to state that there was simply no evidence that transfusions spread AIDS.³⁸

On December 13, 1982, the second case of possible transfusion-related AIDS was reported.³⁹ The CDC met with the FDA’s Blood Products Advisory Committee in December to discuss this new information; however, Committee members insisted that more proof was needed to show that AIDS could be transmitted through transfusions.⁴⁰ The FDA’s Advisory Committee, headed by Dr. Bove, still refused to take action or recommend that high-risk individuals be encouraged to refrain from donating blood.⁴¹ Dr. Bove stated that there’s not enough evidence to finger any population or subset of individuals and say ‘This group should not be allowed to donate blood.’⁴² According to Dr. Francis of the COG, they never listened... we put [sic] the problem and we

³⁶Centers for Disease Control, *Possible Transfusion-Associated Acquired Immune Deficiency Syndrome (AIDS) - California*, 31 Morbidity and Mortality Wkly. Rep. 3 65-7 (1982).

³⁷The Blood Products Advisory Committee reviews and evaluates data on the safety, effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of diseases and then advises the FDA accordingly. 48 Fed. Reg. 54285 (1983).

³⁸Shilts, *supra* note 1 8, at 207; BNA, *supra* note 1 6, at 93.

³⁹BNA, *supra* note 1 6, at 93.

⁴⁰Shilts, *supra* note 1 8, at 206.

⁴¹*Frontline*, *supra* note 17.

⁴²*Id*

gave them the solution and they chose to ignore it.⁴³

The CDC then called another emergency meeting (which this time was open to the public) for January 4, 1983 to discuss what measures should be taken to protect the safety of the nation's blood supply.⁴⁴ The meeting would later be referred to by participants as that horrible meeting.⁴⁵ The meeting served as clear notice to the entire blood industry that AIDS could be transmitted by blood and blood products.⁴⁶ All interested groups were in attendance: The American Red Cross, the AABB, the National Hemophilia Foundation, the National Gay Task Force, the Pharmaceutical Manufacturers Association (representing the commercial blood-product manufacturers), the NIH, and the FDA.⁴⁷ Unfortunately, it was clear that each group had come with its own agenda⁴⁸ –the gay representatives did not want gays to be stigmatized, the hemophiliacs did not want the cost of blood products to skyrocket or the supply to be threatened, and the blood industry did not want to have to start doing any costly tests.⁴⁹ Dr. Marcus Conant, Professor at the University of California Medical Center at San Francisco and AIDS researcher, would later note that unfortunately, there was no one present at the meeting to represent the public who would actually be receiving the blood in question.⁵⁰ It seems, however, that representing the public is in fact the responsibility and role of the FDA.

⁴³Id.

⁴⁴Dorney, *supra* note 1, at 142; Donald C. Drake, *The Disease Detectives Puzzle Over Methods of Control*, Phila. Inquirer, Jan. 9, 1983 at A1; *Frontline*, *supra* note 17.

⁴⁵Shilts, *supra* note 18, at 221.

⁴⁶Dorney, *supra* note 1, at 143.

⁴⁷Shilts, *supra* note 18, at 220.

⁴⁸*Id*

⁴⁹Drake, *supra* note 11.

⁵⁰Blood Supply Safety, *supra* note 4, at 9 (testimony of Dr. Marcus Conant).

At the meeting, it was announced that there had now been 881 cases of AIDS in the United States, including eight hemophiliacs that had died from AIDS.⁵¹ AIDS was now the second leading cause of death for hemophiliacs.⁵² Dr. James Curran, leader of the CDC's task force on AIDS, described two options that could be taken to help stop the spread of this disease through the blood supply: 1) stop accepting blood donations from high-risk individuals or 2) start testing the actual blood to try to identify likely AIDS carriers.⁵³ The CDC favored using both approaches.⁵⁴ Dr. Thomas Spira, a COC virologist, presented evidence that although there was no test for AIDS, surrogate testing could be done and could be effective.⁵⁵ He claimed that virtually everyone in the high-risk groups had suffered from hepatitis B at some point in their lives, and that he had run studies and found that 88% of the blood from gay AIDS patients contained hepatitis core antibodies.⁵⁶ A hepatitis B core antibody test, then, could be used to identify and eliminate donors with hepatitis, thus serving as a surrogate test for AIDS by identifying likely high-risk donors. This should greatly reduce, although not eliminate, the incidence of transmission of AIDS through blood.

The blood banking industry was hesitant to even accept that AIDS was spread through blood, much less accept CDC's suggestions for precautionary measures. Dr. Aaron Kellner of the New York Blood Center immediately raised

⁵¹Id.at 2-3.

⁵²Id. at 3.

⁵³Shilts, *supra* note 18, at 221; Drake, *supra* note 44.

⁵⁴Shilts, *supra* note 18, at 221; Dorney, *supra* note 1, at 143.

⁵⁵Shilts, *supra* note 18, at 221.

⁵⁶*Id*

the issue of cost and stated We must be careful not to overreact. The evidence is tenuous.⁵⁷ Dr. Bove stated We are contemplating all these wide-ranging measures because one baby got AIDS after transfusion from a person who later came down with AIDS and there may be a few other cases.⁵⁸ The CDC was not happy with the response, and Assistant CDC director Jeffrey Koplan said: To bury our heads in the sand and say, 'Let's wait for more cases' is not an adequate public health measure.⁵⁹ Dr. Francis was furious, and asked the blood bankers How many deaths do you need? Give us the threshold of death that you need in order to believe that this is happening, and we'll meet at that time and we can start doing something.⁶⁰

It was eventually agreed that members of high risk groups should somehow be excluded from donating blood, but no consensus could be reached as to how that should be accomplished.⁶¹ The representatives of the gay groups felt that screening out gay donors would be discriminatory and ineffective (because many gay men would not admit to being homosexual), but did agree that hepatitis core testing should be done⁶². The blood bankers questioned the value of a surrogate test that was really only an indirect indication of whether the blood carried AIDS, and they also worried about the cost.⁶³ In addition, the blood bankers did not want to exclude gay donors or ask donors explicit questions for fear of a drastic drop in donations.⁶⁴ Some of the commercial blood

⁵⁷Drake, *supra* note 44.

⁵⁸Shilts, *supra* note 18, at 221.

⁵⁹*Id.*

⁶⁰at 220.

⁶¹BNA, *supra* note 16, at 93-4; Dorney, *supra* note 1, at 143.

⁶²Drake, *supra* note 44; Shilts, *supra* note 18, at 222; *Front/line*, *supra* note 17.

⁶³Drake, *supra* note 44.

⁶⁴Dorney, *supra* note 1, at 143-4.

product companies appeared more willing to take precautions, with in particular a representative of one of the main companies announcing that his firm had begun screening donors and excluding high-risk donors, including all gays.⁶⁵ The FDA appeared wary of the CDC in general.⁶⁶ In the end, no consensus was reached, and there was no agreed upon course of action.⁶⁷ The CDC stood alone and lost.⁶⁸

Two days later, all the major blood banking organizations and the National Gay Task Force met.⁶⁹ They issued a joint statement opposed to donor screening, stating that [d]irect or indirect questions about a donor's sexual preference are inappropriate.⁷⁰ At the meeting, the blood banking industry decided that surrogate testing was inadvisable because of the high cost, the inadequacy of the tests, and the unconvincing evidence that AIDS was spread through blood transfusions.⁷¹

Then, on January 13, 1983, the American Red Cross, the AABB, and the CCBB issued another joint statement calling the hypothesis that AIDS was transmitted by blood inconclusive and still unproven.⁷² The statement called for screening of donors for symptoms of AIDS, but did not recommend any laboratory screening test or donor screening on the basis of sexual preference.⁷³ However, although Dr. Bove was publicly denying that AIDS had been shown

⁶⁵Drake, *supra* note 44. *See also* Shilts, *supra* note 1 8, at 223.

⁶⁶Shilts, *supra* note 1 8, at 222.

⁶⁷*Id.*, at 223.

⁶⁸*Id.*

⁶⁹*Id.*, at 224; Drake, *supra* note 44.

⁷⁰Shilts, *supra* note 1 8, at 224; Drake, *supra* note 44.

⁷¹Drake, *supra* note 44.

⁷²BNA, *supra* note 1 6, at 94; Dorney, *supra* note 1, at 1 45.

⁷³BNA, *supra* note 1 6, at 94.

to be transmitted through blood, he was privately acknowledging the risk. Dr. Bove was the Chairman of the Committee on Transfusion Transmitted Diseases for the AABB, and in a confidential report to the AABB's Board dated January 24, 1983, he wrote: While I believe our report reacts appropriately to the data at hand, I believe that the most we can do in this situation is buy time. There is little doubt in my mind that additional transfusion related cases and additional cases in patients with hemophilia will surface... We do not want anything 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.⁷⁴ It appears that the blood industry was telling the public something other than what it actually believed. However, Dr. Bove's report insisted that [w]e need to do whatever is medically correct and that [w]e... will continue to react responsibility [sic] to whatever scientific and medical information we have.⁷⁵ He also acknowledged that it might eventually become necessary to screen out donor populations who are at high risk of AIDS, which [for practical purposes... means gay males.⁷⁶

Meanwhile, the FDA was doing absolutely nothing to protect the nation's blood supply from this new virus. In February of 1983, researchers at the University of California Medical Center at San Francisco publicly called on the blood bankers to begin surrogate testing procedures.⁷⁷ However, it appeared that no one in the blood banking industry or at the FDA listened.

On March 4, 1983, the U.S. Public Health Service finally issued

⁷⁴Joseph Bove, *Report to the Board Committee on Transfusion Transmitted Diseases*, January 24, 1983 (reprinted in *Blood Supply Safety*, *supra* note 4, at 73-4).

⁷⁵*Id.*

⁷⁶*Id.*

⁷⁷*Blood Supply Safety*, *supra* note 4, at 9 (testimony of Dr. Marcus Conant).

a statement of the CDC, the FDA, and the NIH, that laid out the first set of guidelines for protecting the blood supply from the AIDS virus. The vague recommendations suggested that members of high-risk groups refrain from donating blood, studies should be done to evaluate screening procedures for effectiveness, and work should continue towards developing safer blood products.⁷⁸ This recommendation was a broad compromise between the COC and the FDA – the CDC wanted vigorous donor screening and blood testing, while the FDA favored the moderate restrictions proposed by the blood bankers.⁷⁹

At the end of March, the FDA issued recommendations to centers that collected blood and plasma. However, these recommendations were viewed by some as simply watered-down recommendations from the blood banking industry itself.⁸⁰ In addition, the guidance was purely in memorandum form and was thus not binding. On March 21 and 24, 1983, Dr. John Petricciani, Director of the Office of Biologics, sent memorandums indicating that centers should institute educational programs to inform persons who are at an increased risk of AIDS that they should not donate blood, re-educate personnel responsible for donor screening to more readily identify the symptoms of AIDS, examine donors for lymphadenopathy, keep track of donor's weight, and establish standard procedures for handling and disposing of plasma or blood that is believed to be infected with the AIDS virus.⁸¹ However, notably missing from the guidelines

⁷⁸Centers for Disease Control, *Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations*, 32 Morbidity and Mortality Wkly. Rep. 101(1983).

⁷⁹Shilts, *supra* note 18, at 242.

⁸⁰Blood Supply Safety, *supra* note 4, at 11 (testimony of Dr. Marcus Conant).

⁸¹from John C. Petricciani, Director, Office of Biologics, to All Establishments Collecting Source Plasma, *Recommendations to Decrease the Risk of Transmitting Acquired Immune*

was any mention of surrogate testing or donor screening of high-risk groups, and thus the CDC's suggestions had clearly been rejected. The FDA had considered these possibilities but decided against them, evidently rejecting surrogate testing because the value of such testing was unknown at that time.⁸² In May of 1983, the Stanford University Blood Center became the first major blood bank to begin surrogate testing for evidence of AIDS.⁸³ Dr. Edgar Engleman, the medical director of the blood bank, believed it was important for the safety of patients in the Stanford University Hospital, and now estimates that 50-100 cases of AIDS were prevented in their medical center alone by implementing this testing.⁸⁴ However, blood bankers criticized him and the press suggested that testing was being done as a publicity stunt and a ploy to try to lure patients from other hospitals.⁸⁵

On July 7, 1983, the FDA issued a final rule stating that licensed blood banks would only be inspected once every two years, replacing the previous rule that they would be inspected once every year.⁸⁶ Blood center inspections were thus being cut back at the very time that AIDS was apparently contaminating the blood supply. The yearly inspection policy was apparently

Deficiency Syndrome (AIDS) from Plasma Donors, reprinted in BNA, *supra* note 4, at 100-1 (note there are two versions of this memo); BNA, *supra* note 4, at 94; *Alert on AIDS*, 17 FDA Consumer 2 (June 1983).

⁸²*Blood Supply Safety: Hearings Before the Subcommittee on Oversight and Investigations of the House of Representatives Committee on Energy and Commerce* (Blood Supply Safety II), 102nd Cong., 1st Sess., at 49 (1991) (statement of Dr. Gerald Quinnan, Jr., Acting Director, FDA's Center for Biologics Evaluation and Research in 1991).

⁸³Shilts, *supra* note 18, at 308. Note that the Stanford University Blood Center implemented a surrogate test that used the ratio of helper to suppressor lymphocytes instead of utilizing the hepatitis core antibody testing. *Id*

⁸⁴*Frontline*, *supra* note 17.

⁸⁵Shilts, *supra* note 18, at 410; *Blood Safety Supply*, *supra* note 4, at 96 (testimony of Dr. Edgar Engleman).

⁸⁶48 Fed. Reg. 26313 (1983).

changed as part of the Reagan administration's sweeping deregulation efforts of the early 1980s, when the FDA's workforce was actually being cut.⁸⁷ Apparently, the blood industry also supported the cutback.⁸⁸ A document was found in which blood banks mentioned how they had successfully lobbied the FDA to reduce the number of inspections to once every two years.⁸⁹ The FDA claimed that less frequent inspections will have no adverse effect in the manufacture of safe, pure, and potent blood products.⁹⁰ However, when the FDA changed the inspection rate back to once every year in 1988, FDA officials indicated that the increase in inspections would be an effective way to detect problems. Dr. Gerald Quinnan, Jr., Acting Director for the FDA's Center for Biologics Evaluation and Research in 1991, pointed out that enhancing surveillance also results in our observing increased numbers of problems in blood banks⁹¹, while Frank Young, Commissioner of the FDA in 1988, suggested that the inspections were increased to be sure that a safe blood supply is made even safer.⁹² Thus, it appears that the FDA consciously reduced surveillance in 1983 with the consequence that more problems would likely go undetected at a most critical time.

On June 22, 1983, the AABB, CCBC, and the American Red Cross issued another joint statement that again downplayed the risk of transfusion-associated AIDS and in fact stated that there was only one AIDS case per

⁸⁷Gaul, *supra* note 5.

⁸⁸*Id*

⁸⁹*Frontline*, *supra* note 17.

⁹⁰48 Fed. Reg. 26313 (1983).

⁹¹Blood Supply Safety II, *supra* note 82, at 47 (statement of Dr. Gerald Quinnan, Jr.).

⁹²Gaul, *supra* note 5.

one million patients transfused.⁹³ Although it was discovered that the one in a million figure was grossly inaccurate, it was never corrected.⁹⁴ Meanwhile, FDA Commissioner Dr. Arthur Hull Hayes, Jr. said: I think the nation's blood supply is safe, but there's no question that we have a new and growing problem with AIDS.⁹⁵ In August, Dr. Bove, still chairman of both the FDA's Blood Products Advisory Committee and the Committee on Transfusion Transmitted Diseases for the AABB, continued to publicly deny that there was any conclusive proof that the blood supply was contaminated with the AIDS virus, again referring to the one in a million figure.⁹⁶

During December of 1983, Dr. Dennis Donohue, the Director of the FDA's blood and blood products laboratory, began advocating that the industry adopt the hepatitis core antibody test.⁹⁷ On December 15 of 1983, the FDA's Blood Products Advisory Committee met to debate the issue of surrogate testing. The FDA had now recognized that there was a substantial problem of AIDS in the blood supply, and thus they invited people from all over the country to come to the meeting and present views and share their experiences with any surrogate tests.⁹⁸ Not surprisingly, the blood industry continued to vigorously object to the use of these tests on the grounds that the testing was costly, was not specific for AIDS, its use would result in the exclusion of some safe donors, and its use could seriously threaten local blood

⁹³Shilts, *supra* note 18, at 333; Dorney, *supra* note 1, at 146.

⁹⁴Dorney, *supra* note 1, at 147.

⁹⁵*As AIDS Scare Hits Nation's Blood Supply*, U.S. News & World Report, July 25, 1983, at 71.

⁹⁶Shilts, *supra* note 18, at 361.

⁹⁷*Id.*, at 411.

⁹⁸*Frontline*, *supra* note 17.

supplies.⁹⁹ The cost would include not only the cost of testing, but also the cost of recruiting additional donors to replace those screened out by the testing.¹⁰⁰ Michael Rodell, a representative of the plasma industry, suggested that a task force be formed to further consider the use of surrogate testing for AIDS, and the Advisory Committee unanimously agreed.¹⁰¹ The task force agreed to meet in three months.¹⁰² Thus, nearly one year after the CDC had recommended blood testing and donor screening, the FDA was still stalling.

It appears that the task force idea was one that the plasma industry had come up with collectively. The evening before the December 15th Advisory Committee meeting, officials from the four major clotting factor manufacturers had held a private meeting in a hotel room in Washington D.C., at which they agreed to propose a task force to study the question of surrogate testing as a way to delay the process.¹⁰³ This was explained in a memorandum from an official of Cutter Biologicals, the largest U.S.-based plasma manufacturer: This proposal was one that had been agreed upon by all the fractionators the previous evening. The general thrust of the task force is to provide a delaying tactic. It was generally agreed that core testing would eventually become a requirement.¹⁰⁴ In addition, the Cutter official also wrote in private correspondence that the anti-core testing would add a further measure of confidence in product safety at a relatively low cost for the products involved, and in fact Cutter

⁹⁹Gaul, *supra* note 5.

¹⁰⁰*Id.*

¹⁰¹*Id.*

¹⁰²Shilts, *supra* note 18, at 411; Gaul, *supra* note 5.

¹⁰³*Frontline*, *supra* note 17.

¹⁰⁴Gaul, *supra* note 5.

was already implementing the test at its collection sites.¹⁰⁵ An internal memo stated: We recommend that the implementation of core testing be accelerated to the maximum degree possible to obtain a competitive advantage in the marketplace. We made no mention of our plans to the others.¹⁰⁶ Thus, once again, blood industry members were expressing privately much different opinions than they were expressing publicly.

In January of 1984, conclusive proof of transfusion-associated AIDS was first published in the *New England Journal of Medicine*.¹⁰⁷ However, Dr. Bove wrote a separate essay in the same issue of the *New England Journal of Medicine* claiming that whether the disease is caused by a transfusion-transmitted infectious agent is still unknown... patients should be reassured that blood banks are taking all possible steps to provide for safe blood transfusions.¹⁰⁸

In March of 1984, other San Francisco blood banks followed Stanford University Blood Center by announcing that they were going to begin surrogate testing.¹⁰⁹ However, many cited competitive pressure from other blood banks as the reason for instituting testing instead of safety concerns, and the blood banks immediately came under fire from others in the blood banking industry.¹¹⁰ Dr. David DeJongh, the Director of the blood bank at Charity Hospital in New Orleans claims that his center did not begin surrogate testing

¹⁰⁵Id

¹⁰⁶Id

¹⁰⁷Dorney, *supra* note 1, at 141.

¹⁰⁸Shilts, *supra* note 18, at 410.

¹⁰⁹Id., at 433.

¹¹⁰Id.

because of intensive pressure from the blood industry, including the American Red Cross.¹¹¹ It appeared that the industry was trying to hang together to avoid having to use surrogate testing.¹¹²

The AIDS task force of the FDA Blood Products Advisory Committee met in March of 1984 to study Dr. Donahue's suggestion that hepatitis core antibody testing be implemented by the blood industry.¹¹³ The task force voted not to require or recommend surrogate testing.¹¹⁴ In May of 1984, the task force's findings were issued in a formal report, which included a majority report (joined by eight members) opposing surrogate testing and a minority report (joined by three members, including Dr. Donahue) recommending hepatitis B core testing.¹¹⁵ The task force was industry dominated; it had only 2 non-industry members (one of whom was Dr. Donahue), with the remainder of the task force consisting of six plasma industry members and three blood bank members.¹¹⁶ The full FDA Advisory Committee adopted the conclusion of the task force majority and did not recommend the hepatitis core antibody testing.¹¹⁷

Interestingly, Dr. Thomas Asher, Chairman of the Board of Hemo-Care (a manufacturer of blood products) and a member of the Board of Directors of the American Blood Resources Association, later testified in court that: By 1984, blood which was not tested by one of the following three tests: T4/T8 cell

¹¹¹Blood Supply Safety, *supra* note 4, at 94 (affidavit of Dr. David Dejongh).

¹¹²*Id.*

¹¹³Shilts, *supra* note 18, at 434.

¹¹⁴*Id.*, Gaul, *supra* note 5.

¹¹⁵Gaul, *supra* note 5; *Frontline*, *supra* note 17.

¹¹⁶Gaul, *supra* note 5.

¹¹⁷*Id.*

test, lymphocyte count or hepatitis B core-antibody was unreasonably dangerous. A reasonable blood bank would have at the very least performed one of the above tests. To not test blood by any of the above three tests was unreasonable and negligent.¹¹⁸ At this time, the FDA did not even recommend, much less require, the use of surrogate testing.

On April 23, 1984, Margaret Heckler, Secretary of Health and Human Services, announced the discovery of the AIDS virus, and also claimed that a blood test would be available within six months.¹¹⁹ Also in April of 1984, the FDA released a statement that: on the basis of the information available to date, it is possible that screening tests other than anti-core may ultimately prove to be more predictive and generally useful in improving the safety of blood and blood products. It would therefore be unwise to adopt anti-core testing to the exclusion of other screening tests.¹²⁰ It appeared, therefore, that the FDA was simply waiting for an AIDS test.

By September of 1984, the CDC had counted 80 cases of transfusion AIDS and no one even debated whether AIDS was spread through the blood supply anymore.¹²¹ Dr. Bove had even shifted his views and now argued that the FDA should require hepatitis B core antibody testing.¹²² Nonetheless, when hepatitis testing had been discussed again by the FDA's Blood Advisory Committee during the summer of 1984 the Committee again voted not to require

¹¹⁸Blood Supply Safety, *supra* note 4, at 85 (affidavit of Dr. Thomas Asher).

¹¹⁹Shilts, *supra* note 18, at 450-1.

¹²⁰Gaul, *supra* note 5.

¹²¹Shilts, *supra* note 18, at 478.

¹²²*Id*

the testing over Dr. Bove's objections.¹²³

In December of 1984, the FDA revised its recommendations for protection of the blood supply. The revisions broadened the class of donors who should refrain from donating blood or plasma, outlined specific questions that donors should be asked regarding symptoms of AIDS, listed additional requirements for donors of plasma, and identified various procedures for voluntary self-exclusion of donors.¹²⁴ However, the FDA still did not recommend donor screening for high-risk groups or any type of surrogate testing.

Finally, on March 2, 1985, Secretary Margaret Heckler announced the licensing of the first AIDS test, produced by Abbott Laboratories.¹²⁵ The test was an antibody blood test known as the ELISA (enzyme-linked immunosorbent) assay which detects antibodies to HTLV-III, the AIDS virus.¹²⁶ The test was approved for commercial use in blood banks, plasma centers, and public health clinics.¹²⁷ However, the AIDS test could not detect all carriers of the virus because not everyone who is infected will have antibodies to the virus when they donate blood.¹²⁸

The FDA recommended that the blood industry utilize the new ELISA test. Most blood banks were using the ELISA test by July of 1985,

¹²³*Id.*

¹²⁴BNA, *supra* note 16, at 95. See Memorandum from Elaine C. Esber, M.D., Acting Director, Office of Biologics Research and Review, to All Establishments Collecting Blood, Blood Components or Source Plasma and all Licensed Manufacturers of Plasma Derivatives, *Revised Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood and Plasma Donors* (reprinted in BNA, *supra* note 16, at 102).

¹²⁵Shilts, *supra* note 18, at 539.

¹²⁶Faye Peterson, *Screening Blood Donations For AIDS*, 19 FDA Consumer 5, at 5-6 (May 1985).

¹²⁷*Id.* at 5.

¹²⁸*Id.* at 9.

even though the FDA did not actually require the test to be used.¹²⁹ However, since the test was not required, many blood banks did not ever test the inventory of blood they had on hand at the time that the AIDS test came out.¹³⁰ Dr. Art Silvergled of the AABB, has said that it was a mistake not to test the current inventory, but has also said that he believes it was an honest mistake.¹³¹ In addition, there were some blood banks that did not begin using the still-voluntary test so quickly.¹³²

The FDA did not move towards actually requiring the use of the ELISA test until 1986, and a regulation was proposed on February 21, 1986 that would require every unit of human blood to be tested for the presence of antibodies to HTLV-III.¹³³ The FDA stated that it believed that most blood establishments will begin routine tests of blood and blood components for antibody to HTLV-III before any final rule based on this proposal is published in the Federal Register.¹³⁴ The FDA was apparently content to rely on the industry to take voluntary precautionary steps, because the final regulation requiring AIDS testing did not become effective until February 4, 1988.¹³⁵ Thus, testing was actually voluntary for three years after the test became available. By the time the AIDS test was required by the FDA, 60% of America's 20,000 hemophiliacs had been infected with the AIDS virus through contaminated clotting factors.¹³⁶

Today all blood is screened for AIDS, hepatitis B, and hepatitis C

¹²⁹Dorney, *supra* note 1, at 141 fn92.

¹³⁰*Id.*, *Frontline*, *supra* note 17.

¹³¹*Frontline*, *supra* note 17.

¹³²Gaul, *supra* note 5.

¹³³51 Fed. Reg. 6362 (1986).

¹³⁴*Id.*

¹³⁵53 Fed. Reg. 111 (1988).

¹³⁶Gaul, *supra* note 5.

and this has not created the blood shortage feared by the blood industry.¹³⁷ Many lawsuits have been brought by victims who were infected with AIDS through transfusion or blood products against various members of the blood industry, but most plaintiffs have not been successful.¹³⁸ A class action lawsuit was filed in September 1993 against the five blood product companies and the National Hemophilia Foundation on behalf of 1 0,000 hemophiliacs who were infected with the AIDS virus through contaminated blood products.¹³⁹ However, it is generally very difficult to win a case against members of the blood industry because: 1) the industry is shielded from strict liability and contract claims in nearly every state by blood shield laws and 2) most courts have held that the professional standard of care will apply on a negligence claim, thus allowing the inadequate response of the entire industry to the AIDS crisis to serve as a defense for an individual defendant.¹⁴⁰

IV. Why?: The Reasons for the FDA's Failure to Protect the Nation's Blood Supply

Dr. Conant told a Congressional subcommittee that: It is my view that between 1 2-22,000 Americans were infected with [the AIDS virus] as a direct result of blood transfusion, because of the failure of blood banks to screen out high risk donors, the failure of the blood industry to try to accurately disseminate information to their member blood banks, the failure of the regulatory

¹³⁷Blood Safety Supply, *supra* note 4, at 1 (statement of Congressman Dingell).

¹³⁸Dorney, *supra* note 1, at 30.

¹³⁹*Frontline*, *supra* note 17; Dorney, *supra* note 1, at 150fn 151.

¹⁴⁰Michael J. Miller, *Strict Liability, Negligence and the Standard of Care for Transfusion-Transmitted Disease*, 36 Arizona Law Rev. 471 (Summer 1994); Blood Supply Safety, *supra* note 4, at 1 5 (testimony of Dr. Ross Eckert).

Agency, namely the division of Biologicals of the Food and Drug Administration (FDA), to demand minimum standards of donor evaluation and products screening, and a failure of the Centers for Disease Control (CDC) to demand accountability of the blood industry and the blood regulators.¹⁴¹

Most people seem to agree that the blood industry and the FDA failed to properly safeguard the nation's blood supply in the early 1980s. Since the blood industry is firmly under the regulatory control of the FDA, it would have been easy for the government to step in and remedy the poor response of the blood industry to this crisis, but it did not. The CDC could only offer advice, it did not have the regulatory power to require donor screening or blood testing.¹⁴² Only the FDA had that power, and they chose not to use it – they never required aggressive donor screening or surrogate testing and in fact the weak guidance they did provide was not even in the form of binding regulation. In all fairness, however, it must be remembered that this was a time of uncertainty and no one really knew how deadly AIDS would turn out to be. Had the consequences that resulted been known, undoubtedly more aggressive action would have been taken. However, even though the extent of the danger was unknown, it was clear that there was some danger to the blood supply and thus uncertainty cannot provide an easy excuse for inaction. Congressman Dingell called the FDA's regulatory policy of that time kinder and gentler, and indeed commented that it was a far too kind and far too gentle version of the now-discredited FDA-wide 'honor system' of the 1980s.¹⁴³ Indeed, current

¹⁴¹Blood Supply Safety, *supra* note 4, at 12 (statement of Dr. Marcus Conant).

¹⁴²Gaul, *supra* note 5.

¹⁴³*Blood Supply Safety: Hearings Before the Subcommittee on Oversight and Investigation*

FDA Commissioner David Kessler said in 1993 that the 1980s represented a collegial approach to regulated industry and that the blood industry has generally not assumed adequate responsibility for putting in place and following the basic quality assurance programs and standard operating procedures required to assure the safety of the blood supply.¹⁴⁴ He called for a change in the culture and practices of the blood industry and of FDA as well.¹⁴⁵

Dr. Francis of the CDC summarizes his view of what happened during this period and why: '83 and '84 were the lost years and they were lost on the first year because of the Joe Bove-AABB-Red Cross bury your head in the sand approach to AIDS. The first year, they just kind of ignored it. And then came the second year, starting in January of-or December of '83, going onwards, where the Blood Product Advisory Committee said, 'Okay, now we really do need to recommend hepatitis B testing, at least,' and then they all voted, 'Well, we need a task force to evaluate it.' And by the time the task force got to evaluate it, then Margaret Heckler and Bob Gallo stood up and said, 'Now we're going to have a test,' and so a whole other year goes by and they still did nothing. And so this combination of the first year of sticking your head in the sand and the second year of having your expectations come that we have an HIV test around the corner, when you knew it was going to take a long time, just combined to kill tens of thousands of Americans.¹⁴⁶ This explanation seems fairly reasonable, even if oversimplified. It is generally agreed that the

of the House of Representatives Committee on Energy and Commerce (Blood Supply Safety III), 103rd Cong., 1st Sess., at 1 (1993)(statement of Congressman Dingell).

¹⁴⁴*Id.*, at 21 (testimony of Dr. David Kessler).

¹⁴⁵*Id.*, at 20 (testimony of Dr. David Kessler).

¹⁴⁶*Frontline*, *supra* note 17.

FDA relied on the industry for guidance and in fact the FDA clearly followed the desires of industry over the recommendations of the COC during this entire time period. In addition, there was some indication that the FDA was waiting for an AIDS test when it issued its April 1 1984 statement that hepatitis B testing should not be used exclusively because other tests might later prove to be better. Undoubtedly the promise of a test for the AIDS virus had some influence on the inaction of the blood industry and the FDA during 1984.

The central reason why the FDA never proposed any strong recommendations or regulations during this period appears to be their reliance on the desires of the blood industry. The FDA apparently blindly followed the advice of the Blood Products Advisory Committee during this period, and that committee consisted almost exclusively of members of the blood industry at that time.

So why was the blood industry so strongly opposed to taking safeguards to protect the nation's blood supply in the early 1980s? When a Congressional Subcommittee met to hold hearings regarding the safety of the blood supply in 1990, Congressman Bliley asked: Was the decision not to test made for purely economic reasons, at cost of countless lives and of thousands or perhaps tens of thousands of blood-transfusion recipients now testing positive for the AIDS virus?¹⁴⁷ The decisions made in the early 1980s by the blood industry were surely not made on solely an economic basis. This really was a time of uncertainty – the AIDS virus had not been isolated and there was thus obviously

¹⁴⁷Blood Safety Supply, *supra* note 4, at 4 (statement of Congressman Bliley).

no way to test for it directly. There were, at least at the beginning, real doubts on the part of some people whether this disease really existed. Thus it appears that this was a situation where it was easy to slip into a state of denial and to pretend there was not a major problem, that it was something more trivial than it was. Dr. Engleman stated at a Congressional hearing: In my view, they were acting in good faith and they were doing the best they could, but they were blinded. They did not objectively analyze the data that was available.¹⁴⁸

Although this tragic situation was undoubtedly not solely caused by cost factors, they certainly played a very large role. At the meeting of the AIDS Task Force of the FDA's Blood Products Advisory Committee, the blood bankers argued that hepatitis core antibody testing would be too expensive, stating that testing could add \$1.2 to the cost of a unit of blood and that it would also be costly to recruit new donors to replace the 6% of donors whose blood would test positive for hepatitis core antibodies.¹⁴⁹ They had similarly argued cost at the January 4, 1983 meeting with the CDC. Dr. Aaron Kellner of the New York Blood Center had stated at that it would cost New York City over \$5 million to implement surrogate testing, including the cost of the tests, the cost of the paper work, and the value of the blood discarded in the estimated 5% of samples where a healthy donor would be ruled out by surrogate testing.¹⁵⁰ He claimed that the cost would be \$1.00 million a year nationally, and thus he

¹⁴⁸Id. at 96 (testimony of Dr. Edgar Engleman).

¹⁴⁹Shilts, *supra* note 18, at 434.

¹⁵⁰Drake, *supra* note 44.

opposed widespread testing.¹⁵¹ It is not clear that the additional cost would have really been unreasonable, however. Dr. Asher, Chairman of the Board of HemoCare, claimed that his own company was doing surrogate testing during this period and the price of his platelet concentrates were still significantly lower than those of a competing blood center nearby that did not do the testing.¹⁵² In addition, it seems reasonable to believe that additional costs of testing could be passed along to consumers in the price of the blood or blood product. These products are a matter of life and death – the American attitude has generally been that price is no object when it comes to health care, and thus it seems unlikely that a rise in the price of blood would not make people decide to stop purchasing needed blood or blood products.

In addition to explicit cost concerns, the blood industry was concerned about the lack of adequate donors. They were afraid that a requirement of donor screening or blood testing would cause a blood shortage. As for donor screening, they were afraid that too many donors would be eliminated and also that the simple fact that personal questions about high risk behaviors were asked would cause some people to become unwilling to donate blood voluntarily.¹⁵³ As for surrogate testing, estimates at that time were that 3-6% of blood would be rejected as a result of implementing hepatitis core.¹⁵⁴ The blood bankers were concerned about the amount of safe blood that would be rejected by these surrogate tests since the tests were obviously not specific for the AIDS virus.¹⁵⁵

¹⁵¹ *Id.*

¹⁵² Blood Supply Safety, *supra* note 4, at 86 (affidavit of Dr. Thomas Asher).

¹⁵³ *Id.*, at 10 (testimony of Dr. Marcus Conant).

¹⁵⁴ *Id.* at 78 (testimony of Dr. Ross Eckert), 94 (affidavit of Dr. David Dejongh).

¹⁵⁵ *Id.*, at 27 (statement of Dr. Ross Eckert), 77 (testimony of Dr. Edgar Engleman).

There is some disagreement as to the blood industry's actual concerns in regard to the potential blood shortage. Dr. Oscar Ratnoff, a hematologist at Case Western Reserve University, believes that it was the fear of losing donors that motivated the inertia about surrogate testing, fear that they would not have the blood supply that was needed for the care of patients rather than a primary concern about cost.¹⁵⁶ However, Dr. Ross Eckert, Professor of Economics and Legal Organization at Claremont McKenna College and member of the FDA's Blood Products Advisory Committee from 1987 to 1991, argues that these supply concerns are in the end really arguments about operating costs because the industry was deeply concerned about the cost and effort of replacing the rejected donors that would be necessary to keep the supply high if surrogate testing were implemented.¹⁵⁷ Also, perhaps this was all tied into the fact that if donors do not come to blood centers there will be no product to sell to hospitals and patients and thus new measures might threaten the financial viability of the blood banks.¹⁵⁸ In reality, all of these concerns were probably in the minds of blood bankers around the country.

Another reason the blood industry did not want to require donor screening was that screening out male homosexuals would be intrusive, unethical, and institutionalize a stigma on groups already prone to prejudice and persecution.¹⁵⁹ The blood industry allied themselves with the gay groups on this issue, meeting with the National Gay Task Force in January of 1983 and

¹⁵⁶ *Id.*, at 77 (testimony of Dr. Oscar Ratnoff).

¹⁵⁷ *Id.*, at 27 (statement of Dr. Ross Eckert), 76 (testimony of Dr. Ross Eckert).

¹⁵⁸ *Id.*, at 10 (statement of Dr. Marcus Conant).

¹⁵⁹ BNA, *supra* note 16, at 94.

together devising a statement asserting that donor screening was inappropriate.¹⁶⁰ Dr. Herb Perkins, the medical director of the Irwin Memorial Blood Bank in San Francisco, used gay rights arguments to argue against hepatitis core antibody testing, claiming that the hepatitis testing would mark gay men with a biological pink triangle.¹⁶¹ Although there may be valid civil rights arguments for the proposition that donor screening of male homosexuals is inappropriate, it seems a stretch to use gay rights rhetoric to argue against blood testing. Clearly a positive result on a hepatitis core antibody screening would be kept confidential and there is no discriminatory aspect to doing the same test on all blood samples. This type of argument begins to make one wonder whether the asserted civil rights concerns may have been used at least partially to cover up the blood banker's fundamental desire to keep costs down and maintain the status quo.

There was not any real pressure on the blood banks to take extra precautions. According to Dr. Eckert, [i]n most communities, blood banks are monopolies or cartels, so patients lack competitive market processes for protection.¹⁶² Patients are generally unaware of what precautions need to be taken, and in any case are not in a position to take the time to obtain information when emergencies or illnesses requiring blood arise.¹⁶³ In addition, the public may rely on the FDA to protect them.¹⁶⁴ Thus, the general public cannot effectively produce competitive pressure on blood banks. It seems that the

¹⁶⁰Shilts, *supra* note 18, at 224, 226.

¹⁶¹*Id.* at 226. Pink triangles were worn by gays in Hitler's death camps. *Id.*

¹⁶²Blood Supply Safety, *supra* note 4, at 1 5 (testimony of Dr. Ross Eckert).

¹⁶³*Id.*, at 21 (statement of Dr. Ross Eckert).

¹⁶⁴*Id.* at 1 5 (testimony of Dr. Ross Eckert).

hospitals that purchase the blood could have exerted pressure on the blood banks, but they apparently did not do so. Consumers of blood products such as clotting factors, however, can in fact exert pressure on manufacturers, and this may explain the fact that clotting factor manufacturers were more willing to take precautions than blood bankers (although even they fought formal requirements even though many manufacturers took precautions individually).

In addition to the lack of competitive pressure at the time, the blood bankers and blood product manufacturers lacked incentive to take new safety measures because they generally did not fear future liability the way other industries might. As mentioned above, the blood industry is shielded from strict liability and contract claims by state blood shield laws and industry custom will generally serve as a defense in a negligence action. This explains the desire for the industry to hang together so that the standard of care for the industry would be low. The immense criticism by the industry of those blood banks that did institute new safety measures and the pressure on other blood banks around the country to avoid beginning any new donor screening or blood testing are consistent with the desire to make sure the industry custom did not include donor screening or surrogate testing in an effort to avoid potential liability later. Dr. David Dejongh, Director of the Blood Bank at Charity Hospital in New Orleans during 1983 and 1984 has testified that his blood bank was under heavy pressure not to begin surrogate testing and that the blood banking industry feared that the institution of the Core test by some blood banks would create a standard of care by which other blood banks would

be required to abide.¹⁶⁵ The industry apparently felt that they would not be held accountable if they all insisted together that nothing needed to be done. So, overall it appears that without sufficient competition, liability or regulation, the incentives of blood bankers to provide the service quality that consumers want are relatively weak.¹⁶⁶

So the question then becomes: Why did the FDA listen to the blood industry instead of the CDC? It appears that from the beginning the FDA may have been skeptical of the CDC. In general, different federal agencies have different turfs, and each one is eager to protect its own territory.¹⁶⁷ The FDA may have become defensive early on, feeling that the COG was trying to infringe on the FDA's authority to regulate the blood industry by so openly recommending that the industry take specific precautions. At the first meeting in July 1 1982, it has been reported that the FDA was keenly aware of maneuvers for control of turf. Some FDA regulators resented the CDC's brash invasion of what was plainly their territory, the blood industry.¹⁶⁸ It appears that at least at this first meeting, some FDA representatives simply did not believe that this so-called disease existed.¹⁶⁹ At the January 4, 1983 meeting, again the FDA representatives seemed wary of the CDC and.. slightly irritated that the FDA's turf had been so brazenly invaded..¹⁷⁰ If these reports of FDA's reaction are accurate, the actions of the COG may have contributed to the FDA's lax

¹⁶⁵ *Id.*, at 94 (affidavit of Dr. David Dejongh).

¹⁶⁶ *Id.*, at 15 (testimony of Dr. Ross Eckert).

¹⁶⁷ Conversation with Peter Hutt, January 23, 1995.

¹⁶⁸ Shilts, *supra* note 18, at 170.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* at 222.

response and unwillingness to follow the CDC's recommendations.

The more central issue, however, involves the FDA's alliance with the blood industry. Congressman Bliley asked in 1990: Was there a conspiracy of silence by the blood industry and its regulators to hide the problem of transfusion AIDS?¹⁷¹ In reality, it appears that a conspiracy was not necessary because the FDA's decisions were virtually being made by the blood industry itself, through the Blood Products Advisory Committee. According to Dr. Conant, the FDA never attempted to bring into the review process individuals without ties to the blood bank industry who were expert in evaluation and treatment of patients with AIDS, or representatives from the hospital industry, American medicine or indeed the general public who would be receiving the blood that was drawn from infected donors.¹⁷² The FDA apparently did not even give much if any weight to the suggestions of its own researchers, rejecting the suggestion by Dr. Dennis Donohue, director for the blood and blood-products lab of the FDA, that the FDA should require hepatitis core antibody testing. Indeed, Dr. Donohue, stated that given the task force membership, all efforts at initiating testing were doomed. Members were either in the blood industry or allied with blood interests... Both the task force and the blood advisory committee were clubbish groups devoted to little more than protecting the interests of blood banks.¹⁷³ The 1988 Presidential Commission on the I-IIV Epidemic cited as an obstacle to progress the FDA's heavy reliance on the blood industry for advice

¹⁷¹Blood Supply Safety, *supra* note 4, at 4 (statement of Congressman Bliley). at 11 (testimony of Dr. Marcus Conant).

¹⁷²*Id.*

¹⁷³Shilts, *supra* note 18, at 434.

on what standards to set – a relationship that presents a significant opportunity for conflicts of interest to arise.¹⁷⁴

The FDA has traditionally placed a great amount of confidence in the blood industry to regulate itself.¹⁷⁵ The FDA's Blood Products Advisory Committee was formed in 1980 to advise the Commissioner in discharging his responsibilities as they relate to assuring safe and effective biological products and related medical devices.¹⁷⁶ Although the Committee's charter only provides that it serve to give advice, in reality the Committee helps to shape FDA's policies, and FDA officials virtually always follow the decisions and advice of the Committee.¹⁷⁷ The members were largely from the industry, until more diversity emerged in the later 1980s. Dr. Asher stated that it's insular to a fault and it's very protective of its own self-interests, and [e]ven today, it remains what I call an Old Boys' Club.¹⁷⁸ Not only does the Advisory Committee consist mainly of allies of the industry, but Dr. Eckert, a former member of the Committee, stated that the information that the Committee receives in general is heavily skewed in favor of the blood banking industry over consumers.¹⁷⁹ He cites the fact that blood banks and their trade associations appear at Committee meetings consistently while consumers are virtually never represented.¹⁸⁰ Thus, Eckert claims that the Committee and the FDA as a whole simply cannot make balanced decisions because they do not receive balanced information

¹⁷⁴Presidential Report, *supra* note 4, at 78.

¹⁷⁵Gaul, *supra* note 5.

¹⁷⁶*Id.*

¹⁷⁷*Id.*

¹⁷⁸*Id.*

¹⁷⁹Blood Supply Safety, *supra* note 4, at 16 (testimony of Dr. Ross Eckert).

¹⁸⁰*Id.*

and advice.¹⁸¹

The FDA undoubtedly appoints members of the blood industry to the Advisory Committee because it feels that they are very knowledgeable about these issues and thus make good advisors. However, the FDA must remember that it does have its own researchers and that members of any industry are always at least somewhat self-interested. The blood industry is no different, and thus their expertise, while it certainly provides a valuable source of information and advice, is not sufficient to justify such extensive control as was allowed between 1982 and 1985.

It could be argued that part of the FDA's inadequate reaction to the crisis of AIDS in the blood supply was a consequence of its limited resources. Dr. Francis, a CDC epidemiologist who has been extremely critical of the FDA's response to this crisis, admitted that the federal government was very limited in its resources, including the FDA and CDC, and the responsibility... was turned over to the blood bankers and they were the only ones that could respond fast enough.¹⁸² Indeed, Frank Young, FDA Commissioner in 1988, said that the agency was forced to adopt a crisis-management style due to its limited cadre of inspectors and overall cutbacks at the agency dating to the Carter administration... As a result of this strategy, the FDA is forced sometimes to disregard problems.¹⁸³ FDA's staff was cut from 7,799 to 6,963 full-time employees (nearly 11%) between January 1981 and 1987. However, the limited resources of the FDA do not seem to provide a valid justification for its specific

¹⁸¹ *Id.*

¹⁸² *Frontline*, *supra* note 17.

¹⁸³ Gaul, *supra* note 5.

decisions not to recommend aggressive donor screening or surrogate testing since the costs of those measures would have been borne primarily by the industry and not the FDA. The FDA did in fact spend the money to bring the Advisory Committee together numerous times and to assemble an AIDS task force, and it seems that a recommendation to implement donor screening or surrogate testing would not have imposed significant additional costs on the FDA, at least if recommendations were issued instead of actual regulations (which would require enforcement resources). The FDA's untimely decision to decrease the frequency of inspections in June of 1983, however, may actually have been at least partially caused by the decrease in its resources, as the number of inspectors was decreased 22% between 1977 and 1984.¹⁸⁴ Nevertheless, even that reason seems inexcusable since the crisis of a dangerous new disease in the blood supply should have taken priority over other areas under FDA's jurisdiction when allocating scarce resources.

One additional concern that may have influenced FDA's decision not to recommend aggressive donor screening may have been the fear that they might be sued by gay or civil rights activists. The FDA and members of its Advisory Committee may have been worried that if they were to recommend or require donor screening that would eliminate gay donors they would be faced with a claim alleging discrimination against gays. Thus, they may have felt that it was inadvisable to risk a lawsuit when there was really no risk of the FDA being sued if they did *not* require donor screening.

¹⁸⁴Id.

Finally, it seems likely that, at least in part, the general course of action taken in this country regarding AIDS in the blood supply was affected by sheer politics and individual agendas. At the January 4, 1983 meeting, it was clear that each group had come with its own agenda, and on most lists, stopping the potential spread of AIDS was secondary.¹⁸⁵ A reporter who attended that meeting remarked that the meeting was an excellent example... of when vested interests come into conflict with the bigger good, and people chose to side with the vested interest.¹⁸⁶ Gays were concerned about civil rights, blood bankers were concerned about their own financial viability, and hemophiliacs were concerned about the cost of their clotting factors. It is very possible that the FDA was worried about trampling on the interests of any of these groups, since they are all organized groups with potentially powerful lobbies.

V. What can be done? Proposed solutions to prevent such failures in the future

It is clear that there are significant problems with the way the FDA responded to the problem of the AIDS virus contaminating the blood supply in the early 1980s. What is not so clear is what the strategy should be for the future when similar situations arise. Dr. Eckert noted that it is critical that the FDA and the blood banking industry have a plan to cope with the next lethal bloodborne virus or other agent when it arrives..., other than to primarily wait for better medical tests to be developed as they did in the case of hepatitis and AIDS.¹⁸⁷ The 1988 Presidential Commission on the HIV Epidemic

¹⁸⁵Shilts, *supra* note 18, at 220.

¹⁸⁶*Frontline*, *supra* note 17.

¹⁸⁷Blood Supply Safety, *supra* note 4, at 16-7 (testimony of Dr. Ross Eckert).

recommended that the FDA should define a mechanism that quickly identifies a new threat to the safety of the blood supply and implements procedures that will abrogate that threat in order to ensure that the nation's blood supply is never contaminated.¹⁸⁸ However, they did not make any specific suggestions as to how this should be done.

A. Changing the way the FDA obtains information and makes decisions

The one change that commentators tend to agree on is that the makeup of the FDA's Blood Advisory Committee must be changed. As of March 1984, when the AIDS task force of the FDA Blood Products Advisory Committee was formed, virtually all members of the Advisory Committee (including the chairman) were either from the blood industry or allied with blood interests, and there were no members whose role it was to represent consumer interests, according to Dr. Dennis Donahue, director for the blood products laboratory of the FDA at that time.¹⁸⁹ As of 1989, there were 11 voting members on the Committee, including one hematologist, one pathologist, one economist, five medical school faculty, and three blood bankers, with the chairman being from the blood banking industry.¹⁹⁰ In addition, there was one nonvoting consumer representative and one nonvoting plasma industry representative.¹⁹¹

The 1988 Presidential Commission on the HIV Epidemic recommended that the Advisory Committee be restructured so that it represents the

¹⁸⁸Presidential Report, *supra* note 4, at p. 79.

¹⁸⁹Shilts, *supra* note 18, at 434.

¹⁹⁰Blood Supply Safety, *supra* note 4, at 29 (statement of Dr. Ross Eckert).

¹⁹¹*Id*

entire blood products community, the plasma industry, the related academic community, and one or more public members.¹⁹² Dr. Eckert, an economist appointed to the FDA's Blood Advisory Committee in 1987, has proposed very specific changes in the Committee. He advocated elimination of the nonvoting industry representative, because [t]he committee gets adequate advice from blood products manufacturers from the floor each meeting.¹⁹³ In addition, Dr. Eckert believes that the consumer representative should be given a vote, as well as appointing additional voting members who are expected to represent consumers.¹⁹⁴ Physicians who specialize in relevant areas and primarily treat patients with diseases that use a lot of blood or blood products would be excellent choices to represent consumers while also serving as an early warning system of new problems in the blood supply.¹⁹⁵ Dr. Eckert also argues that only one member of the committee should be a blood banker, and that person should not be chairman of the committee. He believes that blood bankers are very well represented at every meeting and the committee thus gets plenty of their advice on almost every subject.¹⁹⁶ Finally, Dr. Eckert proposes that an economist should continue to sit on the Committee to provide a society-wide perspective... of the effects of blood safety.¹⁹⁷

The main point to remember is that the FDA exists to protect consumers, NOT the blood industry itself. Dr. Eckert has said that [t]he FDA has

¹⁹²Presidential Report, *supra* note 4, at 79.

¹⁹³Blood Supply Safety, *supra* note 4, at 30 (statement of Dr. Ross Eckert).

¹⁹⁴*Id.*, at 16 (testimony of Dr. Ross Eckert), 30-1 (statement of Dr. Ross Eckert).

¹⁹⁵*Id.*

¹⁹⁶*Id.*

¹⁹⁷*Id.*

over-relied on blood bankers to set the minimum standards it has, and that has resulted in a trade-off between the health interests of consumers and the interests of the blood banks.¹⁹⁸ Such a trade-off is simply inappropriate since the FDA's mission is to protect the public health. It seems that there is a natural conflict of interest when blood bankers and those clearly allied with the blood industry are advising the agency that regulates them. Limiting the number of blood bankers to one, as suggested by Dr. Eckert, thus seems appropriate because of this conflict of interest. However, it seems unfair to have a representative of the blood banking industry while not allowing a representative of the blood products industry to serve on the Committee. Dr. Eckert's argument that manufacturers do not need to be represented by having a member on the Committee because the Committee already gets abundant advice from the blood products manufacturers does not provide a distinction from the blood bankers since he agrees that blood bankers also give plenty of advice to the Committee at each meeting. The perspectives of the two different segments of the blood industry may be different and thus both segments should be represented instead of just one, out of fairness and a desire to achieve the goal of getting information from all possible sources and perspectives. Blood industry representatives should not be eliminated from the Committee completely because they are very knowledgeable and may provide important insights regarding the reality of the industry.

However, it seems critical that an advisory committee should be

¹⁹⁸Gaul, *supra* note 5.

made up largely of people that will *not* be biased in favor of the blood industry. This would include professors, physicians, and independent researchers who have special expertise in the area of blood and blood products. The majority of the Committee should consist of neutral individuals who can evaluate data objectively and give informed opinions about the scientific information and the potential societal impact of FDA's action or inaction. Finally, the Committee should contain two informed public or consumer members who can serve as advocates for the consumer perspective and thus provide some balancing to offset the two blood industry members.

In addition, the advice of the Blood Advisory Committee must not be automatically followed over the advice from the members of FDA's own blood product laboratory. The recommendations of the Advisory Committee are nearly always accepted by the FDA.¹⁹⁹ The FDA took the Advisory Committee Task Force's recommendation over that of their own blood product laboratory in deciding not to require surrogate testing in 1984. The FDA has its own researchers for a purpose, and it seems appropriate to look to them for guidance *along with* the Advisory panel – in essence, a balance must be struck and no one should hold the proverbial trump card.

In addition to restructuring the FDA's system for obtaining advice from within its own agency, the FDA must try to work more closely with the CDC and seriously consider their recommendations. The CDC is the government agency that deals with epidemiology and has vast experience with blood-

¹⁹⁹Id.

borne diseases. The FDA should take advantage of that specialized knowledge and give great weight to CDC's suggestions instead of fighting them, as appears to have been the approach in the AIDS crisis. Perhaps it would be advantageous for the CDC and FDA to meet regularly in order to discuss potential blood borne diseases, in a setting where the blood industry representatives and other special interests groups are not present and the agencies can try to work together without playing the games that public turf battles entail. In the end, however, it seems that the FDA must simply learn to accept the fact that the CDC will usually learn of bloodborne diseases that pose a danger to the nation's blood supply first because of the focus of that agency. The FDA must take information from the CDC very seriously and work with them to identify appropriate safeguards.

As well as improving relations with the CDC specifically, the FDA needs to foster closer relationships with researchers and medical and epidemiological experts in general in order to receive all relevant information in a timely fashion. The 1988 Presidential Commission recommended that the FDA's Blood Advisory Committee closely monitor advances in research and development to determine what changes in policy and practice are needed to preserve the safety of the blood supply.²⁰⁰ Dr. Eckert also suggested that steps be taken to improve relationships between blood banks and medical research and teaching institutions so that new discoveries can be quickly applied by the blood banking community.²⁰¹ This closer relationship would be useful to the FDA as

²⁰⁰Presidential Report, *supra* note 4, at 79.

²⁰¹Blood Supply Safety, *supra* note 4, at 37 (statement of Dr. Ross Eckert).

well in providing quality regulation to protect the blood supply – an uninformed committee cannot provide up-to-date advice on what precautions are needed. Adding more researchers and physicians to the Advisory Board would be a step towards increasing the communication between the FDA and the medical research community.

B. Adopting a policy of better safe than sorry

Blood, obviously, is essential to life. The safety of the blood supply is of utmost importance – if blood is unsafe, people die. It's that simple. Considering this fact, it seems that blood is one area where it is clearly best to adopt a policy of better safe than sorry. In the face of uncertainty regarding the threat of AIDS to the blood supply and how it could best be controlled, the FDA chose to do virtually nothing and take no precautions. Instead, the FDA should have done *something*, even if it may not have been the perfect solution in hindsight, and taken extra precautions when faced with this uncertainty.

The FDA should have required surrogate testing as soon as it was recommended by the COC. It appears that key researchers at that time believed that surrogate testing should be done and would be partially effective in stopping the spread of the virus. The FDA should not have been swayed by the interested blood banking industry into saying the testing should not be done, but instead should have been listening to the more objective scientists, including the director of it's own blood products laboratory, who recommended the testing. When it comes to the safety of our blood supply, cost should basically be no object. The FDA's duty is not to weigh the overall costs and benefits of certain actions, it's

duty is to protect the safety of the blood supply. The cost of surrogate testing should not have been a consideration for the FDA when it was determining what to require of the blood industry. In the future, in situations where an infectious agent can be partially screened out with surrogate testing, that testing should be required by the FDA in the interests of keeping the blood supply as safe as possible, even though it cannot be kept completely safe with only a surrogate test. A partial solution is better than no solution at all. The FDA's policy of the early 1980s seems to have been If we can't fix it, why even try when it should have been OK, we can't fix it, but lets do the best we can and try to keep our losses to a minimum. It is inexcusable to sit around and wait until a definitive test is available, even if it is to be available in the near future – instead the alternative testing should be implemented and continued until the primary testing actually becomes a reality.

Surrogate testing could be ordered overnight without going through the lengthy notice and comment rulemaking procedure if the FDA for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are.., contrary to the public interest.²⁰² It seems that evidence of an epidemic that could be partially controlled would be sufficient to deem the delay caused by notice and comment procedures to be contrary to the public interest.

If the FDA does not wish to require surrogate testing, it may want to consider an alternative system for addressing the issue. In 1978, the FDA

²⁰²Administrative Procedure Act, § 5 53(b)(B).

issued a final regulation requiring that blood be labeled with whether the blood was drawn from a volunteer or paid donor.²⁰³ The new labeling requirement was believed to result in at most a minimal cost increase, while it significantly aids in reducing the incidence of posttransfusion hepatitis, and.., also promotes blood therapy safety and is therefore a valid, albeit partial, answer to the problem.

²⁰⁴A similar regulation could have been enacted in response to the

AIDS crisis – the FDA could have required the label of blood products to state whether or not surrogate testing had been done on the blood and what type of testing had in fact been done. In addition, an extensive educational effort could have been undertaken at the same time to inform consumers, but most importantly physicians and hospitals, of the importance of using blood that has been tested.

If the labeling requirement was used and physicians and hospitals were adequately informed, the forces of competition would be allowed to play out in the marketplace. Physicians and hospitals would learn to differentiate between the safety levels and quality of blood from different sources, and thus blood banks and blood product manufacturers would be forced to compete with each other on the basis of safety. A labeling requirement along with needed education to those people deciding which products to buy would increase competition among blood banks on a local and regional level, which would tend to force the industry to keep the safety levels high without the government having to actually require the surrogate testing. In addition, the concerns of the blood

²⁰³43 Fed. Reg. 2142 (1978).

²⁰⁴Id.

industry in the early 1980s that nationwide implementation of surrogate testing techniques would threaten the financial viability of some blood banks and possibly cause a blood shortage as well would be addressed because the more competitive market created by a labeling requirement would allow for untested (and thus less safe) blood to remain on the market if there was sufficient demand for it. This demand would be created if there was not enough safe blood available or if some people could not afford the higher priced blood that had been tested. This labeling scheme would probably not completely eliminate untested blood from the market, but it would go a long way towards it, and certainly goes much farther than doing nothing at all.

The FDA should also consider donor screening of high-risk donors as soon as high-risk groups can be identified when there is any concern over the safety of the blood supply. The FDA was hesitant to exclude the gay population from donating blood from the very beginning. Although it would be politically difficult, it seems that precautions such as this would be preferable to complete inaction. If there are specific areas, such as San Francisco in this case, where a large part of the blood supply comes from high-risk donors, then accommodations can be made to phase out those donors or to allow some of them to continue donating to preserve the blood supply in general. However, that should be the exception and not the rule. The FDA allowed such city-specific arguments to dictate the rule in the early 1980s, when a flexible but determined approach to do everything possible to stop the spread of this virus would have been much more appropriate.

It is important that the FDA provide stringent and strong regulation of the blood industry. Given that the blood industry is virtually immune from tort liability, the responsibility of protecting consumers lies with the federal agency. The FDA is the only deterrent on the blood industry's conduct.²⁰⁵ This means that the FDA must be aggressive in its rulemaking and enforcement in order to keep the industry in line and protect the nation's blood supply. Inspections should occur annually, and violations must be punished. Clear and vigorous binding regulations must be implemented instead of relying on voluntary compliance with vague recommendations. And most of all, the FDA must stop relying on the industry it regulates for advice and remember that FDA's decisions must be made with the sole motivation of preserving the safety of the nation's blood supply.

²⁰⁵Dorney, *supra* note 1, at 1 66.