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The Bloody Truth: Examining America's Blood Industry and its Tort Liability Through the Arkansas Prison Plasma Scandal

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THE BLOODY TRUTH: EXAMINING AMERICA'S BLOOD INDUSTRY AND ITS TORT LIABILITY THROUGH THE ARKANSAS PRISON PLASMA SCANDAL

ABSTRACT

Most of the time, blood transfusions are safe. Over the years, however, tragedies connected to tainted blood and blood products have ripped through communities on an international scale. Blood contaminated with hepatitis C, HIV, and hepatitis B has sickened and killed recipients, causing financial, political, and legal repercussions for those found responsible.

This Note seeks to explore one such tragedy: the Arkansas Prison Plasma Scandal. Occurring between 1982 and 1994 at the Cummins Prison in Grady, Arkansas, the scandal stemmed from the operation of a blood product center in which prisoners "bled" in exchange for $7 to $10 per donation. It is alleged that tainted blood products from the prison were distributed internationally, and that thousands of people became infected with hepatitis C as a result.

This Note will address: (1) the nature of the blood business in America, (2) the events at the Cummins prison plasma center and the ensuing scandal, (3) the response of the Canadian and British legal systems and governments to the tainted blood victims, and (4) the likely outcome of a negligence claim against the allegedly responsible parties if the victims had successfully filed suit.

With this analysis, this Note will show that even if all the alleged facts about the circumstances at the prison plasma center are true, injured parties suing in the United States would not be able to prevail in a negligence claim because of the impossibility of proving causation in American blood product litigation.

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INTRODUCTION

"[W]hy was it that we became the dumping ground for your poison?"
~Michael McCarthy, plaintiff (Canadian hemophiliac infected by tainted blood).[1]

Blood runs through every human vein,[2] pumping through the human heart[3] and powering human life.[4] Unlike other necessities such as water, oil, and even air, blood has no equivalent substitute.[5] Throughout the centuries, this precious, life-sustaining fluid has intrigued poets, philosophers, and doctors. In surgery, on the battlefield, and during childbirth, blood transfusions often make the difference between life and death.

Today, we still do not entirely understand blood and its unique and mysterious properties,[6] and that lack of understanding has sometimes led to tragedy.[7] Blood is easily contaminated and can become dangerous when it is tainted or misused.[8] Diseased blood turns into poison when transfused, causing illness or death for those who receive it.[9]

The importance of the U.S. blood supply cannot be overstated: according to the American Red Cross, "[e]very two seconds someone in the U.S. needs blood,"[10] and in the year 2001 alone, fourteen million blood transfu-

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[1] Nihal Kaneira, *Canadian Victims of Tainted Blood to Sue U.S., Clinton*, GLOBAL NEWS WIRE, Feb. 26, 1999.

[2] *See* LAURALEE SHERWOOD, HUMAN PHYSIOLOGY: FROM CELLS TO SYSTEMS 371 (Cengage Learning, 7th ed. 2010) ("[V]eins serve as a blood reservoir .... Under resting conditions, the veins contain more than 60% of the total blood volume.").

[3] *See id.* at 372.

[4] JUSTICE HORACE KREVER, COMMISSION OF INQUIRY ON THE BLOOD SYSTEM IN CANADA 11 (1997), *available at* http://epe.lac-bac.gc.ca/100/200/301/hcan-scan/commission_blood_final_rep-e/index.html [hereinafter KREVER COMMISSION REPORT].

[5] *See Blood Facts*, BLOODBOOK.COM, http://www.bloodbook.com/facts.html#GENERAL (last visited Mar. 4, 2012). *But see Blood Substitutes*, BROWN UNIV. DIV. OF BIOLOGY & MED. (2006), http://biomed.brown.edu/Courses/BI108/2006-108websites/group09artificialblood/Pages/history.htm. Scientists are working on developing blood alternatives: "Today, the two most promising red cell substitutes are perfluorocarbon-based oxygen carriers (PFBOCs) and hemoglobin-based oxygen carriers (HBOCs)." *Id.*

[6] *See* DOUGLAS STARR, BLOOD: AN EPIC HISTORY OF MEDICINE AND COMMERCE at x (1998).

[7] *See Blood Facts*, *supra* note 5. *But see Blood Substitutes*, *supra* note 5.

[8] *See Blood Facts*, *supra* note 5.

[9] *Id.*

[10] *Blood Facts and Statistics*, AM. RED CROSS (2012), http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics.

sions occurred.[11] At the same time, the demand for blood is rising at a rate that available donations and viable donors fail to match.[12]

This blood shortage means that the commodity is extremely expensive,[13] resulting in the development of a lucrative business surrounding its collection and distribution.[14] Indeed, the blood business has been growing both domestically and internationally[15] for decades, and today it is a multibillion dollar industry[16]—an industry that few people know much about.

Most of the time, especially in recent decades, blood transfusions are safe.[17] However, over the years, a few tragedies connected to tainted blood and blood products have ripped through communities on an international scale.[18] Blood contaminated with hepatitis C, HIV, and hepatitis B has sickened and killed recipients, causing financial, political, and legal repercussions for those found responsible.[19]

This Note seeks to explore one such tragedy, the Arkansas Prison Plasma Scandal, which occurred between 1982 and 1994, when the Cum-

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[11] *Id.*

[12] *See Blood Substitutes*, *supra* note 5 ("According to Doctor Bernadine Healy, former president of the American Red Cross, donations are increasing by about 2–3% annually in the United States, but demand is climbing by between 6–8%.").

[13] *See generally* STARR, *supra* note 6.

[14] *See* Lisa M. Korsten, Note, *The Global Market for Blood: A Proposal for Expansion and a Consistent System of International Regulation*, 11 B.U. INT'L. L.J. 227, 227 (1993) ("It is estimated that there is a $2.5 billion market for transfusion blood in the United States alone.").

[15] *See id.*

[16] *See id.*

[17] *See Knowing Your Options*, AM.'S BLOOD CTRS., http://www.americasblood.org/go.cfm?do=Page.View&pid=247 (last visited Mar. 13, 2012) ("The risk of contracting HIV from a blood transfusion is about one in 1.5 million. That is much less than the risk of dying from a lightning strike. Thanks to new blood testing procedures, the chance of getting HCV is about the same.").

[18] *See* James Harder, *More Bad Blood out of Arkansas*, INSIGHT ON THE NEWS, Mar. 12, 2001, at 18.

[19] *See* Linda M. Dorney, Comment, *Culpable Conduct with Impunity: The Blood Industry and the FDA's Responsibility for the Spread of AIDS Through Blood Products*, 3 J. PHARMACY & L. 129, 130 (1994). Even by 1994, blood transfusions had infected a reported 6,311 Americans with HIV, and plasma concentrates infected approximately 12,000 American hemophiliacs. *Id.*

mins Prison in Grady, Arkansas, operated a blood product[20] center in which prisoners "bled"[21] in exchange for $7 to $10 per donation.[22]

As of 1982, prison blood and plasma were no longer approved for use in America[23] or Canada,[24] because prisoners possess a significantly higher risk of infection than the general population.[25] The Arkansas Department of Corrections (ADC) managed to avoid Food and Drug Administration (FDA or Agency) warnings and recommendations by employing private organizations to run the prison blood and plasma program.[26] These organizations then sold the blood products to a Canadian blood broker,[27] who distributed them to countries around the world.[28] The ultimate buyers of the product were unaware that they were providing their populations with prisoners' blood.[29] It is alleged that this "blood laundering"[30] resulted in thousands of people becoming infected with hepatitis C (especially hemophiliacs, for reasons explained in greater depth below).[31]

Victims of this tainted blood launched class action lawsuits in most of the purchasing countries,[32] and the Canadian government ordered a criminal probe into the circumstances surrounding these transactions.[33] Howev-

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[20] For the purposes of this Note, the term "blood products" refers to platelets, whole blood, fresh frozen plasma, and blood coagulants.

[21] As will be explained in more detail below, the prisoners donated their plasma through a special process. *See* discussion *infra* Part II.A.2.

[22] Telephone Interview with Kelly Duda, Producer, Concrete Films (Jan. 18, 2011). This price started out in the early 1960s at $3 to $5 per donation, and increased in the 1980s from $7 to $10. Email Interview with Kelly Duda, Producer, Concrete Films (Nov. 16, 2011) [hereinafter *Duda Interview II*].

[23] *See* Harder, *supra* note 18.

[24] *See* Anthony DePalma, *Suit Says Canada Imported Tainted Blood from U.S. Inmates*, N.Y. TIMES, Jan. 29, 1999, at A4.

[25] *See* André Picard & Anne McIlroy, *Hemophiliacs Launch $1-Billion Suit over Use of U.S. Prisoners' Plasma*, THE GLOBE & MAIL (Canada), Jan. 28, 1999, at A7.

[26] Telephone Interview with Kelly Duda, *supra* note 22.

[27] *See* Harder, *supra* note 18.

[28] *Id.*

[29] FACTOR 8 (Concrete Films 2005).

[30] Telephone Interview with Kelly Duda, *supra* note 22.

[31] *See* Michael J. Miller, Note, *Strict Liability, Negligence and the Standard of Care for Transfusion-Transmitted Disease*, 36 ARIZ. L. REV. 473, 475 (1994); *see also* discussion *infra* Part I.A.1.

[32] *See* Tomoko Otake, *Blood Battle Is About the Past and Future*, JAPAN TIMES, Sept. 14, 2006. Plaintiffs have been reasonably successful in France and Japan, where responsible parties in tainted blood scandals have been sent to prison. *Id.*; *see also* Ian Birrell, *2,000 Dead and Still No Justice for the Victims of Britain's Blood Transfusion Scandal*, DAILY MAIL, Oct. 19, 2010 (Good Health Viewpoint) ("In Canada, the Red Cross was prosecuted for negligence.").

[33] *See* FACTOR 8, *supra* note 29.

er, as of March 2012, there are no available records of either a victim filing a similar lawsuit in the United States, or of any U.S. criminal investigation of the scandal occurring.[34]

This Note will address: (1) the nature of the blood business in America, (2) the events at the Cummins prison plasma center and the ensuing scandal, (3) the responses of the Canadian and British legal systems and governments to the tainted blood victims, and (4) the likely outcome of a negligence claim against the allegedly responsible parties if the victims *had* successfully filed suit. The time for such actions has now passed,[35] but this Note will contrast the events at Cummins with similar hepatitis and HIV transfusion litigation to explain the reasoning a court might follow.

With this analysis, this Note will show that even if *all* the alleged facts about the circumstances at the prison plasma center are true, injured parties suing in the United States would not be able to prevail in a negligence claim because of the impossibility of proving causation in American blood product litigation.

Because no direct American legal action regarding the information in this Note has occurred, it is impossible to be sure all the facts regarding the prison plasma program are true, though there are more than enough witness accounts, international lawsuits, newspaper articles, inquiries, documentaries, and reports to provide the evidence needed to state a claim.[36] The negligence suit discussed below is based on the assumption that all of the plaintiffs' allegations could be proven by a preponderance of the evidence.[37]

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[34] *But cf.* Barrie McKenna, *Canadian Hemophiliacs to Sue U.S. Government*, THE GLOBE & MAIL (Canada), Feb. 25, 1999, at A16. This proposed lawsuit never came to fruition. *See* discussion *infra* Part IV.A.1.

[35] The typical statute of limitations for negligence and products liability cases is approximately four years, and because most of these infections occurred in the 1980s and 1990s, the statute of limitations would preclude the case from being heard. *See, e.g.*, Lynnette S. Pisone, Case Note, Walls v. Armour*: Upholding the Principles of Liability*, 3 J. PHARMACY & L. 225, 228–29 (1994) (discussing Florida's four-year statute of limitations).

[36] WILLARD B. RIANO, FUNDAMENTALS OF CIVIL PROCEDURE 495 (Rex Printing Co., Inc. 2005) ("In considering the dismissal of a case for failure to state a cause of action, the inquiry is the sufficiency of the material allegations of the complaint and not the veracity of the allegations.").

[37] THOMAS BUCKLES, LAWS OF EVIDENCE 25–26 (Thomson 2003). A preponderance of the evidence is the standard of proof for a civil suit, and it means that the trier of fact must find that the plaintiff's claim is more likely true than not. *Id.*

I. BACKGROUND

A. Blood, Blood Products, and Tainted Blood

1. Blood and Blood Products

A healthy adult body contains four to five liters of whole blood.[38] Whole blood is rarely utilized in transfusions anymore: as science advanced, medical personnel learned how to transfer only the blood components required by the recipient.[39] The basic blood transfusion involves the simple transfer of red blood cells from one person to another, usually at a hospital during a surgery.[40]

In addition to this method, however, is the lesser-known and more profitable use of plasma,[41] which can be used to manufacture clotting products[42] for hemophiliacs.[43] The use of these clotting factors, beginning in the 1960s, has doubled the average hemophiliac's life expectancy.[44]

Under this process, after blood is collected, it is "spun off"[45] through plasmapheresis,[46] and its component parts are used for different purpos-

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[38] KREVER COMMISSION REPORT, *supra* note 4, at 15. Each whole blood cell is composed of three different components: plasma, red blood cells, and the "buffy coat" (a thin layer containing white blood cells and platelets). *Id.*

[39] *Id.* at 45.

[40] *Id.* at 3, 24.

[41] Walter Rugaber, *Prison Drug and Plasma Projects Leave Fatal Trail*, N.Y. TIMES, July 29, 1969, at 1. Plasma makes up about fifty-five percent of a unit of blood. Under the process of plasmapheresis, an entire unit of blood is taken from the donor, then the plasma is spun out and the remaining cells are re-injected. *Id.*

[42] *See* Dorney, *supra* note 19, at 133.

[43] Hemophilia is a genetic blood disorder that occurs primarily in males and causes spontaneous internal bleeding. Until scientific developments in the 1960s allowed hemophiliacs to inject themselves with plasma products, many of them died at a young age, and those with severe cases could not even engage in normal daily activities for fear of causing a deadly bleed. Eric A. Feldman, *Blood Justice: Courts, Conflict, and Compensation in Japan, France, and the United States*, 34 LAW & SOC'Y REV. 651, 664 (2000). Before the widespread use of the clotting products, the average hemophiliac died at age eleven; since these products have grown more commonplace, that age has risen to twenty-one. Moore v. Armour Pharm. Co., 88-392-CIV-T-15C, 1990 U.S. Dist. WL 369571, at *2 (M.D. Fla. Aug. 27, 1990).

[44] STARR, *supra* note 6, at xiv.

[45] The unit of blood is placed in a centrifuge which spins off the plasma, allowing the rest of the blood to be returned to the donor. *See* DePalma, *supra* note 24, at A4.

[46] This new method greatly increased the quantity of plasma available because it was no longer necessary to use whole blood (including red blood cells); thus, the donors did not become anemic. Also, red blood cells take several weeks to replenish, while plasma

es.[47] The plasma of thousands of donors is pooled[48] together[49] to create factor concentrates that form a blood product, known as Factor VIII,[50] used to medicate hemophiliacs.[51]

Depending on the severity of the disease, a hemophiliac might need to use Factor VIII several times a week.[52] This means, essentially, that people who are already ill with a life-threatening disease and a compromised immune system have no alternative but to inject themselves with plasma hundreds of times a year. If *one* of the plasma donors (out of many hundreds or thousands[53]) is infected with a blood-borne disease, the entire product will be tainted.[54] From this point, it is extremely likely that the hemophiliac, an innocent bystander,[55] will contract the disease as well, and might unknowingly pass it to another. Because of the factors dis-

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regenerates within days. Because of these improvements, donations could occur much more frequently and safely. STARR, *supra* note 6, at 207–08.

[47] SALLY V. RUDMANN, TEXTBOOK OF BLOOD BANKING AND TRANSFUSION MEDICINE 233 (Elsevier Saunders, 2d ed. 2005).

[48] At the same time the pool of donors for plasma products was growing, the federal government stopped using the same process entirely for whole blood because of the increased risk of hepatitis and the availability of safer alternatives. Unfortunately, no such safer alternatives existed for the clotting factors, so the general prohibition against pooling did not extend to them. STARR, *supra* note 6, at 225.

[49] *See* KREVER COMMISSION REPORT, *supra* note 4, at 22. The process can include anywhere from 1,000 to 60,000 donors. *Id.*

[50] Factor VIII and Factor IX are actually proteins in the blood that allow coagulation to occur. Hemophiliacs suffer from an insufficiency of these proteins. Wadleigh v. Rhone-Poulenc Rorer, Inc., 157 F.R.D. 410, 413 (N.D. Ill. 1994). The synthetic replacements that are created by donated plasma are also known as Factor VIII and Factor IX. *Id.* at 414. This Note is primarily concerned with Factor VIII.

[51] KREVER COMMISSION REPORT, *supra* note 4, at 3.

[52] *Id.*

[53] Feldman, *supra* note 43, at 665. In the words of documentary filmmaker Kelly Duda, "units of plasma are pooled into large vats in the making of Factor VIII (imagine some poison being stirred into a large pot of soup)." *Duda Interview II*, *supra* note 22.

[54] Gullone v. Bayer Corp. (*In re* Factor VIII or IX Concentrate Blood Prods. Litig.), 484 F.3d 951, 954 (7th Cir. 2007). To "cleanse" tainted blood of HIV and hepatitis C, the blood bank must utilize a heat treatment or other method of viral inactivation on the blood or blood product before it is distributed. *Id.* A government-sponsored 1995 report by the Institute of Medicine found that plasma product manufacturers proved especially slow to implement these safety measures because there were no competitive incentives, and the government failed to insist the system be revamped to comply with new standards. Donna Shaw, *Regulators Blamed in AIDS Deaths Lapses Led to Tainted Blood, Says New Report*, PHILA. INQUIRER, July 14, 1995, at A01.

[55] *See* Feldman, *supra* note 43, at 669 ("Hemophiliacs ... considered themselves the passive, 'innocent' victims of a 'drug-induced disaster' that was the fault of physicians, elected officials, government regulators, pharmaceutical companies, and blood banks ....").

cussed above, the chance of a recipient becoming infected by a blood product is much higher than the risk of infection from whole blood.[56]

The FDA is responsible for regulating the manufacture of Factor VIII products[57] under its authority from the Pure Food and Drug Act and the Public Health Service Act.[58] The Agency is charged with approving any changes to the manufacturing process or packaging of the clotting factor, and it licenses the producers and approves the concentrates before they are distributed.[59] In addition, the Agency inspects the blood plasma collection facilities producing Factor VIII, and these centers must comply with FDA rules.[60]

If these rules are violated, those responsible can be imprisoned or fined,[61] and licenses can be suspended (temporary) or revoked (permanent).[62] States are allowed to supplement FDA regulations[63] as long as any additional state laws do not conflict with the federal regulations.

2. Hepatitis C

There are three common viral forms of hepatitis: A, B, and C.[64] The basic definition of all three is: "[A]n inflammation of the liver caused by a hepatitis virus."[65] Hepatitis C is caused by contact with blood and bodily fluids of an already infected individual, and no vaccine currently exists to prevent the disease.[66] The risk of transmitting hepatitis A and B through blood has been known and guarded against for many years; hepatitis C, however, was not identified or detectable until 1988, after thousands of

[56] *Id.* at 665.

[57] Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 407 (Mo. Ct. App. 1999).

[58] Florence Shu-Acquaye & Leanne Innet, *Human Blood and Its Transfusion: The Twists and Turns of Legal Thinking*, 9 QUINNIPIAC HEALTH L.J. 33, 42–43 (2005).

[59] *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d at 407–08.

[60] Dorney, *supra* note 19, at 134–35.

[61] *Id.*

[62] *Duda Interview II*, *supra* note 22.

[63] Dorney, *supra* note 19, at 134–35.

[64] A.D.A.M., Inc., *Hepatitis Overview*, N.Y. TIMES (Sept. 29, 2010) http://health.nytimes.com/health/guides/disease/hepatitis/background.html. Other less common forms of hepatitis include hepatitis D, E, F, and G. *Id.*

[65] *Frequently Asked Questions*, HEPATITIS FOUND. INT'L, http://www.hepfi.org/living/liv_questions.html (last visited Mar. 13, 2012).

[66] *Id.*

people were already infected with the illness.[67] No test was available to check blood products for hepatitis C until 1992.[68]

Only ten percent of those infected with hepatitis C will escape developing chronic hepatitis.[69] Of the ninety percent with chronic hepatitis, twenty percent will develop cirrhosis of the liver, and one to five percent will develop liver cancer within twenty years.[70] According to the National Foundation for Infectious Diseases, 8,000 to 10,000 deaths result every year from hepatitis C infections, and half of the 4,000 liver transplants that occur annually are for victims of this disease.[71] The only treatments available are extremely time-consuming, complicated, and expensive, and they prove successful less than half of the time.[72] It is unlikely that a foolproof vaccine can be developed because the disease is extremely mutable.[73] Dartmouth Medical School estimates that, "[a]ssuming an estimated survival of 40 years, the annual health care costs for the affected U.S. population with chronic hepatitis C may be as high as $9 billion."[74]

B. The Blood Business

1. How Much Is the Blood Business Worth?

Blood is one of the most precious and expensive resources in the world, and it follows that the blood industry is extremely profitable.[75] In 1998, a barrel of crude oil was worth $13 per barrel; measured equally, whole blood was worth over $20,000.[76] If the blood were separated, or fractionated, into its derivative products,[77] the value of the same quantity

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[67] KREVER COMMISSION REPORT, *supra* note 4, at 4.

[68] Andres Rueda, *Rethinking Blood Shield Statutes in View of the Hepatitis C Pandemic and Other Emerging Threats to the Blood Supply*, 34 J. HEALTH L. 419, 423 (2001) ("Since 1992, a specific antibody assay (ELISA I) has been used to test blood products for hepatitis C ....").

[69] KREVER COMMISSION REPORT, *supra* note 4, at 3.

[70] *Hepatitis C*, NAT'L FOUND. FOR INFECTIOUS DISEASES, http://www.nfid.org/factsheets/hepc.shtml (on file with *William & Mary Business Law Review*).

[71] *Id.*

[72] Rueda, *supra* note 68, at 420.

[73] *Id.*

[74] *Hepatitis C: Associated Health Costs—United States*, THE C. EVERETT KOOP INST.—DARTMOUTH MED. SCH., http://www.epidemic.org/theFacts/theEpidemic/USHealthCareCosts/ (last visited Mar. 13, 2012).

[75] *See generally* Dorney, *supra* note 19.

[76] STARR, *supra* note 6, at x.

[77] For a discussion describing the fractionating process, see *supra* Part I.A.1.

in 1998 rises to more than $67,000, while the barrel of oil, including all of *its* derivatives, was worth $42.[78]

By 2001, a blood bank might "charge hospitals anywhere from $55 to $130 (with $80 being the national average) per unit of blood. Once a unit of blood is divided into red blood cells, plasma, platelets, and other specialized factors, it produces about $200 in revenues."[79] By 2006, a unit of blood cost the buyer approximately $200, and once storage and administrative costs were factored in, it is estimated that the actual cost was probably closer to $500.[80]

If one calculates the barrel of blood example from 1998 with the updated numbers from 2006, it is possible to estimate the rising value of the commodity between those eight years. Assuming the barrel from 1998 contained the same quantity of the liquid as a standard barrel of oil,[81] this can be estimated to be about 353.33 blood units per barrel.[82] If each unit of blood were worth $200, the total price of the same barrel would have risen from $67,000 to $70,666, and if each unit were worth $500, the total value would be $176,665 per barrel of blood. In contrast, as of March 2012 the value of a barrel of WTI Crude Oil was approximately $107, and the value of a barrel of Brent Crude Oil was approximately $125.[83]

2. How Did the System Evolve?

a. Poor Oversight and Commercialization

When the blood business first boomed in the 1960s and 1970s,[84] it suffered from poor oversight and regulation.[85] This led to cases of blood

[78] STARR, *supra* note 6, at x–xi.

[79] Rueda, *supra* note 68, at nn.84–85 (2001); *see also* Scott Hensley, *FDA Could OK Costly Blood Standards; An Expert Says That like Chicken Soup, Removal of White Cells from Blood Supply Can't Hurt*, MODERN HEALTHCARE, Nov. 29, 1999, at 8.

[80] *See Blood Substitutes*, *supra* note 5.

[81] A standard barrel of oil contains approximately 159 liters. CHRISTIAN NGÔ & JOSEPH B. NATOWITZ, OUR ENERGY FUTURE: RESOURCES, ALTERNATIVES, AND THE ENVIRONMENT 40 (2009).

[82] "A unit of whole blood is 450 milliliters, which is about 0.9510 U.S. pint. For components of blood, one unit is the amount of that substance that would normally be found in one unit of whole blood. The adult human body contains roughly 12 units of whole blood." Russ Rowlett, *How Many? A Dictionary of Units of Measurement*, UNIV. OF N.C. AT CHAPEL HILL (Oct. 5, 2004), http://www.unc.edu/~row lett/units/dictU.html.

[83] *See* OIL-PRICE.NET, http://www.oil-price.net/ (last visited Mar. 13, 2012) (charting daily crude oil and commodity prices).

[84] *See* STARR, *supra* note 6, at 207.

[85] *See* Shaw, *supra* note 54, at A01.

harvesting from individuals who should never have been permitted to donate.[86] Because the industry offered to pay for donations, it attracted exactly the wrong populations: indigents, drug addicts, and prisoner groups who faced a high risk of diseased blood because they tended to have a higher number of sexual partners and engaged more often in drug use through needles.[87] The danger of acquiring contaminated product skyrockets as soon as blood is collected from paid, rather than volunteer, donors.[88]

Despite the FDA's supposed authority over the industry, the blood product distributors viewed it mainly as a puppet supervisor from the 1980s through the mid-1990s; a perception caused by the FDA's lack of direct policymaking power and its domination at the hands of the blood industry.[89] This weakness in regulation allowed the blood business to operate with limited oversight, affording protection for the sellers rather than the recipients of the blood products.[90]

Additionally, blood shield laws became increasingly common for both the profit and non-profit industry, exempting suppliers of blood and blood products from strict liability.[91] This meant that, despite providing an incredibly risky product, the business did not need to worry about the possibility of many expensive lawsuits.[92] The large donor population, the lax supervision, and the diminished threat of litigation resulted in the United States becoming the premier producer of blood and plasma products.[93]

b. Volunteer Versus Paid Donors

In 1974, the Secretary of Health, Education, and Welfare published the National Blood Policy, recommending that blood donations should be

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[86] STARR, *supra* note 6, at 208–10.

[87] *See id.* at 210.

[88] Pamela T. Westfall, *Hepatitis, AIDS and the Blood Product Exemption from Strict Products Liability in California: A Reassessment*, 37 HASTINGS L.J. 1101, 1116 (1986).

[89] Feldman, *supra* note 43, at 672; *see also* Salmaan Keshavjee, Sheri Weiser & Arthur Kleinman, *Medicine Betrayed: Hemophilia Patients and HIV in the US*, 53 SOC. SCI. & MED. 1081, 1086 (2001) (describing hemophiliacs' feelings of betrayal by the government for failing to provide adequate oversight, in part because of the "revolving door of employment" that they believe existed between the FDA employees and the blood industry).

[90] Feldman, *supra* note 43, at 672.

[91] *See* Dorney, *supra* note 19, at 169 (discussing the problems associated with blood shield laws).

[92] *See* Yi-Chen Su, *Revisiting Factor VIII Cases: Is It Time for an Agency Adjudication System?*, 63 FOOD & DRUG L.J. 943, 947–48 (2008).

[93] *See* STARR, *supra* note 6, at 208–10.

collected only from volunteer donors.[94] The plasma industry disregarded this warning and continued to offer payment for plasma,[95] creating an incentive for people—even those who knew themselves to be at risk—to continue selling.[96] These products were utilized both domestically and overseas.[97]

One scathing analysis of the blood business came from Richard Titmuss, a respected scholar who studied the burgeoning trade of the new commodity from the late 1960s through the 1970s.[98] He believed that monetary compensation for donations provided the wrong incentives: it encouraged donors to hide their medical history, rather than revealing it.[99] Titmuss' conclusion on the system left little to commend the blood business:

> [T]he commercialisation [sic] of blood and donor relationships represses the expression of altruism, erodes the sense of community, lowers scientific standards, limits both personal and professional freedoms, sanctions the making of profits in hospitals and clinical laboratories, legalises [sic] hostility between doctor and patient, subjects critical areas of medicine to the laws of the marketplace, places immense social costs on those least able to bear them—the poor, the sick and the inept—increases the danger of unethical behaviour [sic] in various sectors of medical science and practice, and results in situations in which proportionally more and more blood is supplied by the poor, the unskilled, the unemployed ... and other low income groups and categories of exploited human populations of high blood yielders. Redistribution ... of blood and blood products from the poor to the rich appears to be one of the dominant effects of the American blood-banking systems.[100]

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[94] *See* National Blood Policy, 39 Fed. Reg. 9326, 9326–30 (Mar. 8, 1974).

[95] Because plasmapheresis was a fairly uncomfortable procedure at the time, plasma centers believed the additional incentive of payment was necessary to ensure adequate supply. STARR, *supra* note 6, at 255.

[96] *See generally* Harvey Sapolsky, *AIDS, Blood Banking, and the Bonds of Community*, 118 DAEDALUS 145, 145–63 (1989).

[97] *See, e.g.*, Kaneira, *supra* note 1; Shaw, *supra* note 54, at A01. For example, Canada was unable to domestically process enough plasma to fulfill the country's needs, so it was forced to buy, and trust, American plasma products. *See* KREVER COMMISSION REPORT, *supra* note 4, at 22.

[98] *See* CATHERINE WALDBY & ROBERT MITCHELL, TISSUE ECONOMIES: BLOOD, ORGANS, AND CELL LINES IN LATE CAPITALISM 10 (2006).

[99] *See generally* RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY 314 (Ann Oakley & John Ashton eds., The New Press 1997). *But see* Korsten, *supra* note 14, at 233–36 (providing a discussion of weaknesses in a volunteer-only donation system).

[100] TITMUSS, *supra* note 99, at 314.

This study produced such an impact that Richard Nixon created the National Blood Policy, which promoted voluntary blood donations.[101]

By 1979, the risks of using paid donors were so well-known that victims of tainted blood already began bringing negligence lawsuits against blood banks for failing to use a voluntary-donor system.[102]

c. Prisoners' Blood and Plasma

Prisoners proved a perfect target for paid donations because the inmates desperately needed money, and plasma donations often brought minimal compensation.[103] More importantly for the industry, the prisoners offered a stable, constant blood source that provided a steady stream of product.[104] In addition, prison plasma collection centers were automatically exempt from any real oversight, because plasma was considered a "vital resource."[105] This classification meant that, under special short-supply provisions governing such resources, drug companies were permitted to "buy certain materials from unlicensed, uninspected vendors,"[106] thus providing no incentive for prisons to improve the health and safety conditions of their plasma programs.

As early as 1970, the dangers of using prisoners' blood became public knowledge. A 2009 British inquiry into contaminated blood states that: "On 29 July 1969 the New York Times carried an article by Walter Rugaber, entitled 'Prison Drug and Plasma Projects Leave Fatal Trail.' In 1970, the New York Times wrote of the 'transfusion roulette' played by the blood industry."[107] By 1982, the FDA informally asked U.S. fractionators[108] to stop purchasing blood donated by prison inmates[109] for domestic consumption because it was considered too risky. A disproportionate

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[101] Korsten, *supra* note 14, at 232.

[102] *See, e.g.*, Gilmore v. St. Anthony Hosp., 598 P.2d 1200, 1202 (1979) (holding that summary judgment was not appropriate when determining whether a blood bank acted negligently by utilizing paid donors).

[103] Telephone Interview with Kelly Duda, *supra* note 22.

[104] STARR, *supra* note 6, at 210.

[105] *Id.*

[106] *Id.*

[107] INDEPENDENT PUBLIC INQUIRY REPORT ON NHS SUPPLIED CONTAMINATED BLOOD AND BLOOD PRODUCTS 18 (2009), *available at* http://www.archercbbp.com/report.php [hereinafter ARCHER INQUIRY].

[108] KREVER COMMISSION REPORT, *supra* note 4, at 377 ("Although the Food and Drug Administration used the language of requests and recommendations, its guidelines were treated as mandatory.").

[109] *Id.* at 372.

number of prisoners were infected with hepatitis C and HIV[110] compared to the free population,[111] and prisoners proved more likely to engage in high-risk sex and drug use, perpetuating the spread of these diseases.[112] All of the fractionators complied with the FDA's request.[113]

However, the FDA continued to license a few prison plasma centers that were *exporting* the product, a practice that was still permitted.[114] A 1984 information bulletin about prison plasma centers lists ongoing programs in Arizona, Arkansas, Louisiana,[115] Tennessee, Nevada, and Missouri.[116] Although in *practice* domestic prison sales ended in 1983,[117] the system has never been officially prohibited in the United States.[118]

d. The AIDS Comparison

Although hepatitis C does not inevitably result in death, as AIDS does,[119] there are certainly parallels between the victims of blood contaminated with AIDS and blood contaminated with hepatitis C. As with hepatitis C, scientists at first were not sure that AIDS passed through blood.[120] It was not until 1982 that an FDA memorandum to manufacturers of blood

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[110] Whitney Hinkle, *Giving Until It Hurts: Prisoners Are Not the Answer to the National Organ Shortage*, 35 IND. L. REV. 593, 605–06 (2002) ("A study conducted by the National Institute of Justice showed that the incidence rate of AIDS cases for the general public was 14.65 cases per 100,000 people compared to 202 cases per 100,000 in federal and state correctional facilities."); *see also* Rueda, *supra* note 68, at 419 ("40% of our country's prisoners ... are afflicted by [hepatitis C].").

[111] *See* Hinkle, *supra* note 110, at 606.

[112] *See* Picard & McIlroy, *supra* note 25, at A7.

[113] KREVER COMMISSION REPORT, *supra* note 4, at 372.

[114] Dennis Bueckert, *Prisoners Donated Blood as Part of Rehabilitation*, THE GLOBE & MAIL (Canada), Feb. 12, 1999, at A6.

[115] Prisoners at the Louisiana Department of Corrections at Angola actually brought suit against the company running their plasma center in 1981, contending they were paid below minimum wage in violation of the Fair Labor Standards Act. The plasma company, Sara, Inc. established the program in 1976 and paid the prisoners $3 per day and no overtime. The court found that the prisoners were not employees of Sara, Inc., but rather inmates who were not entitled to minimum wage. Alexander v. Sara, Inc., 559 F. Supp. 42, 44 (M.D. La. 1983), *aff'd*, 721 F.2d 149 (5th Cir. 1983); *see also* Lavigne v. Sara, Inc., 424 So. 2d 273, 274 (La. Ct. App. 1982).

[116] Suzi Parker, *Dumping Scandal: The Export of Bad Blood*, SALON.COM (Feb. 25, 1999), http://www.salon.com/1999/02/25/news_185/.

[117] KREVER COMMISSION REPORT, *supra* note 4, at 377. They also stopped using plasma from other identified problem areas, including New York, San Francisco, and the Hollywood area of Los Angeles. *Id.*

[118] *Id.* at 618.

[119] *See* Dorney, *supra* note 19, at 138.

[120] *See id.* at 140–41.

products warned that: "Although the cause of the outbreak is unknown, the information suggest[s] that a transmissible agent might be involved and concern about transmission through blood and blood products has been raised."[121]

Two years later, the Center for Disease Control (CDC) informed those in the business that blood transfusions "appear responsible for AIDS among hemophilia patients,"[122] and provided some preliminary measures to reduce the spread of the disease.[123] Unfortunately, as occurred later with hepatitis C, a significant number of those in charge of blood banks took little notice of these warnings and persisted in selling the blood without implementing the recommended improvements.[124] Many companies continued to export the unchecked blood overseas for more than a year after the government finally established safety processes for domestic blood.[125]

As a result of the blood bankers' inaction, more than 10,000 hemophiliacs and thousands of other blood transfusion recipients became infected with the deadly HIV virus during the 1980s.[126] The lawsuits resulting from the AIDS scandal provide a relevant precedent for victims who contracted hepatitis C, as many allegedly did following the Arkansas prison scandal.

II. THE ARKANSAS PRISON SCANDAL

A. What Happened? A History of the Prison

1. History

In 1970, the Arkansas District Court declared that certain practices at the Cummins Prison in Grady, Arkansas, amounted to cruel and unusual

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[121] Deborah Tedford, *Hemophiliacs Clash with Drug Companies; Suit: Firms Lax with AIDS Tests in '80s*, HOUS. CHRON., Dec. 5, 1994, at 1.

[122] *See* Walt Bogdanich & Eric Koli, *2 Paths of Bayer Drug in 80's: Riskier One Steered Overseas*, N.Y. TIMES, May 22, 2003, at A1.

[123] INST. OF MED., HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 101–06 (Lauren B. Leveton, Harold C. Sox, Jr. & Michael A. Stoto eds., 1995).

[124] *See* Robert Steinbuch, *The Executive-Internalization Approach to High-Risk Corporate Behavior: Establishing Individual Criminal Liability for the Intentional or Reckless Introduction of Excessively Dangerous Products or Services into the Stream of Commerce*, 10 N.Y.U. J. LEGIS. & PUB. POL'Y 321, 324 (2006–2007).

[125] *See id.* at 325.

[126] *See, e.g.*, Harder, *supra* note 18; *see also* Michael McLeod, *Bad Blood: Every Day, a Hemophiliac Dies of AIDS*; *It Didn't Have to Happen*, ORLANDO SENTINEL, Dec. 19, 1993, at 10.

punishment in violation of the Eighth and Fourteenth Amendments.[127] A 1969 description of the prisoners at Cummins by the court stated that:

> Many of the inmates are psychopathic and sociopathic; some of them are aggressive homosexuals. Many of the inmates are hardened criminals and some of them are extremely dangerous to society in general, to their keepers, and to fellow inmates. Many of them are malingerers and will go to any lengths to avoid work. Many are prone to destroy State property, even items designed for their welfare and comfort.[128]

The court in *Holt v. Sarver* discussed the problems the prison administration faced, including its difficulties in keeping the inmates disciplined and the administration's lack of funding.[129] Because Arkansas is one of the rare states that refuses to pay its prisoners for their labor,[130] the court noted: "The only legitimate way in which a convict at Cummins can earn money is to sell blood to the prison blood bank."[131]

By the time of the Arkansas blood scandal in the 1980s through the 1990s, the blood system was not the only problem plaguing the penitentiary.[132] Accusations and investigations of murder, rape, bribery, embezzlement, and poor medical care were ongoing, and the state government was working to end a system of bloated bonuses for the prison officials.[133] Arkansas newspapers described the prison system as a "fiefdom" or a "cartel" run by three prominent politicians: state Senator Knox Nelson of Pine Bluff, state Representative William F. "Bill" Foster of England, and Arkansas Department of Corrections Director A.L. "Art" Lockhart.[134]

All these internal problems meant that, as one former member of the Arkansas Department of Corrections admitted: "We weren't focused on plasma."[135]

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[127] *See generally* Holt v. Sarver, 309 F. Supp. 362 (E.D. Ark. 1970) [hereinafter *Holt II*], *aff'd*, 442 F.2d 304 (8th Cir. 1971).

[128] Holt v. Sarver, 300 F. Supp. 825, 829–30 (E.D. Ark. 1969) [hereinafter *Holt I*].

[129] *See id.* at 830.

[130] *See* Mara Leveritt, *Bloody Awful: How Money and Politics Contaminated Arkansas's Prison Plasma Program*, ARK. TIMES, Aug. 16, 2007 (Top Stories), *available at* http://www.arktimes.com/arkansas/bloody-awful/Content?oid=863387.

[131] *Holt I*, 300 F. Supp. at 829.

[132] *See* Leveritt, *supra* note 130.

[133] *Id.*

[134] *Id.* At the time, there were claims that those in charge, and their friends, were illegally profiting from the prison. *Id.*

[135] *Id.*

2. The Prison Plasma System

The Arkansas Prison Blood and Plasma Center existed at the Cummins Unit Infirmary at the Cummins prison in Grady, Arkansas, from 1963 through 1994.[136] Authorities decided to allow prisoners to donate blood and plasma to rehabilitate themselves and for business purposes; this method provided an assured group of donors who would donate on a regular basis and whose blood product could be picked up from one central location.[137] Prisoners were paid $7 per donation[138]—"like 'little cows,'" one government official commented later[139]—and the prison system sold this same unit for more than $100.[140]

Official estimates state that the Arkansas prisons produced from 300 to 500 units of blood every weekend.[141] A large portion of the plasma collected from the blood was utilized to create Factor VIII.[142] When the units were being collected during the 1980s, no test for hepatitis C or HIV/AIDS existed.[143]

B. Where Did the Tainted Blood Go?

In 1978, Health Management Associates (HMA), a private company, was given authority to run both the medical and plasma programs at Cummins Prison.[144] Cutter Laboratories, one of the major American blood product manufacturers, bought plasma from the Arkansas prisons from the 1960s to 1982—the year U.S. companies stopped purchasing prison blood.[145] An internal memo from Cutter Laboratories illustrates the attitude towards the risks of prison blood at the time:

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[136] FACTOR 8, *supra* note 29.
[137] *See* Bueckert, *supra* note 114, at A6.
[138] James B. Bienvenu, Letter to the Editor, *Documentary Shocking*, ARK. DEMOCRAT-GAZETTE (Little Rock), Aug. 2, 2007.
[139] Birrell, *supra* note 32.
[140] Bienvenu, *supra* note 138.
[141] *See* Bueckert, *supra* note 114, at A6.
[142] Philip Martin, *On Film: Non-fiction Debut Needs Big Release*, ARK. DEMOCRAT-GAZETTE (Little Rock), Apr. 21, 2006 (Moviestyle).
[143] *See* DePalma, *supra* note 24, at A4.
[144] *See* Harder, *supra* note 18.
[145] *See* Parker, *supra* note 116.

> Take no extraordinary actions. There are no data to support the emotional arguments that prison plasma collected from adequately screened prisoners is 'bad.' To exclude such plasma from manufacturer of our coagulation product would only be a sop or gratuity to the Gay Rights ... and would presage further pressure to exclude plasma collected from the Mexican border and the paid donor.[146]

Because of the warnings against the use of prison blood in transfusions within the U.S. after 1982,[147] the prison system decided to ship the blood abroad instead.[148] The blood was sold to a Montreal company, Continental Pharma Cryno[149] (the biggest blood broker in Canada), which then sold to Switzerland, Spain, Japan, Italy, and Toronto-based Connaught Laboratories,[150] who subsequently distributed it to the Canadian Red Cross. In at least one case, the blood was sent back to the United States.[151]

After HMA was cited in 1983 for health and safety violations, it created a subsidiary called Arkansas Blood Components Inc. (ABC Plasma),[152] under which it continued to sell the blood.[153] ABC Plasma remained on Connaught's list of approved suppliers in March of 1984.[154]

In 1986, for reasons explained further below, HMA's contract ended, but the plasma center continued operation under two different organizations (which followed HMA's distribution patterns),[155] until the program ended in 1994.[156]

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[146] *Id.*

[147] *See* discussion *infra* Part II.C.

[148] Martin, *supra* note 142.

[149] Cryno already had a reputation for buying risky blood products; the company had previously been accused of purchasing blood from Russian corpses (which they allegedly relabeled to hide the source) and from Haitian slums. *See* Birrell, *supra* note 32.

[150] *See* Harder, *supra* note 18. At the time, Canada Development Corporation (CDC), a Canadian government-owned corporation, controlled Connaught. *See* Dennis Bueckert, *Finance Staff Slammed for Withholding Files: Blood-Scandal Documents Linked Martin*, CALGARY HERALD, Mar. 26, 2002, at A8.

[151] *Tainted Blood: Poison from the Prisons*, THE ECONOMIST, Mar. 11, 1999, at 36, *available at* http://www.economist.com/node/319249.

[152] *See* Tim Harper, *Tainted Blood Linked to Theft, Arson*, THE TORONTO STAR, May 21, 1999 (News).

[153] *See* Canadian Press, *Tainted Blood Kept Flowing, Film Suggests*, THE RECORD (Kitchener-Waterloo), Nov. 21, 2003, at D15.

[154] *See* Mark Kennedy, *Opposition to Question Martin Tainted-Blood Link*, OTTAWA CITIZEN, May 25, 1999, at A3.

[155] *See* Suzi Parker, *Blood Money*, SALON.COM (Dec. 24, 1998), http://www.salon.com/1998/12/24/cov_23news/.

[156] *See* Harder, *supra* note 18.

C. What Were the Conditions of the Plasma Program?

Inmates interviewed for a documentary on the prison-blood scandal, *Factor 8*,[157] claimed that the prisoners themselves ran the plasma program, resulting in overbleeding,[158] bleeding disqualified donors,[159] unsafe conditions for the donations generally,[160] and the destruction and falsification of records and evidence.[161] Multiple witnesses to the events claimed that the plasma center accepted some donations from prisoners *known* to fail the required qualifications.[162] A previous inmate, Lewis Sorrells, described the conditions at the prison: "You had prisoners bribing prisoners, prisoners bribing officials, officials offering certain deals for them to bleed for extra money or drugs."[163] Sorrells himself passed away from hepatitis C shortly after the interview; he became infected with the disease during his time at Cummins prison.[164]

The Canadian Hemophilia Society claims that the plasma administrators allowed some inmates to bleed even after being diagnosed with hepatitis C, and permitted some to donate as often as sixty times per year.[165] During FDA investigations, officials documented numerous violations, including the use of dirty needles (which resulted in inmates infecting each other), and a hepatitis B testing laboratory out of commission for two

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[157] FACTOR 8, *supra* note 29.

[158] The overbleeding occurred when the donating prisoners bribed the supervising prisoners to be allowed to bleed more often, thus enabling them to receive additional payments. *See* DePalma, *supra* note 24, at A4 (showing bribery); Bill Dunphy, *Canadians to Sue Clinton in Tainted Blood Scandal: US Prison Blood Infected 1,000*, HAMILTON SPECTATOR (Canada), Feb. 25, 1999, at A1 (highlighting overbleeding).

[159] Dunphy, *supra* note 158, at A1.

[160] These unsafe conditions included reports of problems such as spoiled plasma being refrozen and then sold, and dirty needles being used by multiple prisoners to take their blood. FACTOR 8, *supra* note 29.

[161] Dunphy, *supra* note 158.

[162] *See* Dennis Bueckert, *Health Department Memo Says Use of US Prison Blood Products Continued in Canada After Being Halted in the United States Because US Authorities Did Not Tell a Canadian Broker the Products Were Unsafe*, CANADIAN BUS. & CURRENT AFFAIRS, Feb. 23, 2000. For example, bled prisoners included those known to be ill with hepatitis B, which is considered an indicator for AIDS. DePalma, *supra* note 24, at A4; *see also* FACTOR 8, *supra* note 29 (showing interviews of prisoners claiming that even when donors were known to be homosexuals or drug users, the administrators at the plasma center allowed them to bleed).

[163] Dennis Bueckert, *"Bleeding" for Smokes a Grave Mistake: Ex-Con Talks of Prison Blood Sent to Canada*, HAMILTON SPECTATOR (Canada), Mar. 15, 1999, at A1.

[164] *Id.*

[165] *See* Kaneira, *supra* note 1.

months while blood collection continued.[166] The prison plasma system was shut down three times because of safety violations, but it was allowed to reopen each time.[167]

1. The Recalls

The largest crisis at the plasma center occurred in 1983, when the FDA recalled thirty-eight blood units after it found that twelve inmates,[168] ineligible and likely infected with hepatitis, had donated.[169] Unfortunately, the recall came too late to retrieve all of the tainted blood[170]—almost 4,000 vials had already been exported.[171]

It was during this emergency that Canada first learned that it was importing inmate plasma.[172] Before this time, there were no obvious indications that the plasma came from a prison; the labels on the product simply noted the source as "ADC Plasma Center, Grady, Arkansas."[173] An FDA inspection report in Connaught's possession stated the plasma's true source, but no one at Connaught ever bothered to read the information.[174]

A second recall occurred one month after the first, causing the Canadian Red Cross to cancel its contract with Connaught.[175] In the letter of termination, the assistant national director of blood transfusion stated that recent crises left the Canadian Red Cross "with no confidence in the quality and safety of the material."[176]

After these incidents, the FDA shut down the prison center for over a year[177] and revoked its license[178] in February 1984.[179] The violations

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[166] *See Tainted Blood: Poison from the Prisons*, *supra* note 151.

[167] *See* Harder, *supra* note 18.

[167] Parker, *supra* note 155.

[169] Leveritt, *supra* note 130; KREVER COMMISSION REPORT, *supra* note 4, at 391.

[170] *See* KREVER COMMISSION REPORT, *supra* note 4, at 391–93. Though HMA informed Continental Pharma within days of the issue, Continental Pharma decided that the risk of contamination was relatively small because the current test results of the donors were negative for infection. However, two months after the problem became known, HMA decided to initiate a voluntary recall, and Continental finally informed Connaught. This delay in communication resulted in hundreds fewer units being successfully returned. *Id.*

[171] Leveritt, *supra* note 130.

[172] *See* KREVER COMMISSION REPORT, *supra* note 4, at 392.

[173] *See id.*

[174] *Id.*

[175] *Id.* at 393.

[176] *Id.*

[177] *See* Dave Komer, *Clinton's Arkansas Blood Deals Yield Horrific Results*, THE SOUTH END, Feb. 2, 1999.

found by the FDA included allowing disqualified donors to continue donating, altering records, and improperly storing the collected plasma.[180] HMA was sued over the first recall, and paid $250,000 to settle its share of the liability.[181]

2. Response

Perhaps in part because of these events, the FDA issued a national warning that inmates have a higher chance of being infected with HIV than the general population[182]—a caution to which the National Correctional Association responded quickly.[183] Those responsible for running the Cummins Plasma Program chose to disregard these communications and succeeded in reopening the program.[184] Their intentional blindness persisted even as HMA's insurance agency refused to continue its coverage.[185]

Responding to the FDA's warnings, the Arkansas Department of Corrections requested a report of HMA's program by the Institute for Law and Policy Planning of Berkeley, California (ILPP).[186] The response proved scathing: the ILPP identified forty areas where HMA completely failed to meet the requirements of its contract with the ADC.[187] Even worse, HMA also violated general professional standards, as it "hired a large number of unlicensed, uncertified or legally unqualified medical staff" who were not properly supervised.[188] The final analysis concluded that: "For HMA, all this must be viewed as profit-motivated business decision making, at best.

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[178] Parker, *supra* note 155.

[179] *See* Leveritt, *supra* note 130.

[180] Joe Stumpe, *Question Remains: Did Prisoner Blood Spread Ills?*, ARK. DEMOCRAT-GAZETTE (Little Rock), Oct. 18, 1998, at A1. *See supra* notes 165–67 and accompanying text.

[181] *See* Stumpe, *supra* note 180, at A1.

[182] Leveritt, *supra* note 130.

[183] *See id.* Shortly after the FDA's announcement, the National Correctional Association wrote an informational bulletin for prisons around the nation to reinforce the message, stating that there were concerns about the quality of plasma gathered from a population where many were "illicit drug abusers before their incarceration" and "because of the close living conditions of large groups of inmates, a high incidence of homosexual activity is found." The two actions combined were enough for the majority of prison plasma centers: nearly all shut down in the wake of this outcry. *Id.*

[184] *Id.*

[185] *Id.*

[186] *Id.*

[187] Parker, *supra* note 155.

[188] *Id.*

At worst, it calls for further inquiry."[189] ILPP's sharp words finally penetrated the ADC, and in 1986, HMA lost its contract with Cummins prison.[190]

3. After HMA

However, the plasma center did not end with HMA; Pine Bluff Biologicals (PBBP) took over and expanded it.[191] The new oversight provided little improvement, however, as an FDA inspector soon found that the center possessed inadequate screening measures and recordkeeping.[192] In addition, those in charge of the program were accused of using security officers to "recruit" inmates to donate plasma.[193] The prison medical director, John Byus, explained the business plan to a local reporter, stating: "We plan to stick with [the plasma program] to the last day .... [t]o the last drop we're able to sell."[194]

A New York group took over the plasma center in 1991, and it continued to produce and distribute prison plasma until 1994.[195] In 1999, Dina Tyler, the spokeswoman for Arkansas prisons, admitted that, "some inmates were allowed to take part in the program who should not have been."[196] She claimed a single clerk caused the errors, and that he charged inmates a fee to recertify them for donations.[197]

D. How Much Was the Arkansas Plasma Center Worth?

It was well known in Arkansas that the ADC profited from the plasma program;[198] the question is, by how much?

The total profits will probably never be accurately known, because before the tainted blood scandal occurred, the Arkansas legislature passed a

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[189] Leveritt, *supra* note 130.

[190] Parker, *supra* note 155.

[191] Two additional plasma clinics were opened at this time, including one in the prison hospital. *Id.*

[192] *Id.*

[193] *Id.*

[194] *Blood Money*, ARK. TIMES, Sep. 23, 2004, http://www.arktimes.com/arkansas/1991-blood-money/Content?oid=964677 [hereinafter *Blood Money*].

[195] Leveritt, *supra* note 130; *see also Blood Money*, *supra* note 194 ("The last drop came in 1994 ...."); Parker, *supra* note 155.

[196] Deborah Orin, *Bad Blood Between Clinton Pal and Canada*, N.Y. POST, Feb. 23, 1999, at 12.

[197] *See id.*

[198] The contract between HMA and the ADC supposedly guaranteed ADC about fifty percent of the total profit. Leveritt, *supra* note 130.

law declaring that the blood plasma program did not need to report its earnings to the Arkansas legislature.[199] According to vague records from the Department of Finance and Administration, from 1982 to 1986 the ADC earned $31,721 to $167,259 per year from the plasma program.[200]

Records recovered from 1986 provide slightly more insight into the potential income of the ADC and the organization running the program: by then, Pine Bluff Biological ran the clinic, and it reported collecting about 960 units of plasma every week.[201] At the time, a unit of plasma was worth at least $50 to an international blood broker.[202]

Based on these numbers, a conservative estimate of PBBP's gross sales for that fiscal year would come out to $2.5 million.[203] PBBP's contract promised the ADC $5 per unit of plasma collected.[204] The resulting breakdown may have occurred: "Of PBBP's $2.5 million in annual gross sales, $350,000 went to pay inmates their $7-per-unit fees.[205] The state of Arkansas collected $249,600 for prison operations. PBBP had gross revenues of $1,896,969."[206] Calculating for inflation, that profit would translate to approximately $3,923,143 in March 2012.[207]

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[199] ARK. CODE ANN. § 19-4-803 (West 2010). The exemption is still included in the law today, and allowed the prison program to avoid the requirements of Arkansas Code section 19-4-802: "State agencies ... shall be required to post all financial transactions of cash funds in the [S]tate's financial management system ...." *Id.* at § 19-4-802.

[200] Stumpe, *supra* note 180, at A1.

[201] Leveritt, *supra* note 130.

[202] *See* Stumpe, *supra* note 180, at A1.

[203] *See* Leveritt, *supra* note 130. PBBP's actual profits have never been released and are considered proprietary. *Id.*

[204] *Id.*

[205] It is important to note here that these $7 fees were not cash fees, but merely "script" noted in the prisoner's book—meaning money that could only be used at the prison commissary to pay for products such as cigarettes at inflated commissary prices. With this system, PBBP gave prisoners the equivalent of monopoly money, useful only in one place. Thus, this estimated number is probably too high. *Duda Interview II*, *supra* note 22.

[206] *Id.* (footnote added).

[207] *CPI Inflation Calculator*, BUREAU OF LABOR STATISTICS, http://www.bls.gov/data/inflation_calculator.htm (last visited Mar. 13, 2012).

III. INTERNATIONAL RESPONSE

A. Canada

1. What Happened to the Tainted Blood in Canada?

Canada stopped using plasma from its own prison inmates in 1971,[208] based on the recommendation of the Red Cross, because of hepatitis concerns.[209] In 1982, however, when HMA was searching for a new, foreign buyer, Canada represented one of the few countries in the world that continued to allow the *import* of prisoner's blood and plasma.[210]

The consequences of that practice proved dire. It is estimated that over 1,000 Canadian hemophiliacs were provided with tainted plasma from the Cummins prison.[211] At least 42,000 Canadians have been infected with hepatitis C, and thousands more with the HIV virus, due to tainted plasma, some imported from the Cummins prison.[212] It is estimated that more than 7,000 Canadians will die from the contaminated blood.[213]

As a result of this scandal, the Canadian Red Cross declared bankruptcy and was removed from the direct collection of blood.[214] Further, Canadian authorities launched the Krever Commission (the Commission) in 1995 to trace the trail of the tainted blood.[215] The Commission was the first to publicize the likelihood that the Canadian blood supply was contaminated by blood donated by U.S. prisoners.[216]

The Commission report found that the distribution of the tainted blood could have been avoided if better management and oversight had been in place.[217] The report noted that Connaught Laboratories bought exported plasma only because the domestic supply was so small that importing blood and plasma became necessary.[218] In addition, the report implied that Connaught was negligent; it determined that "Connaught decided it was

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[208] KREVER COMMISSION REPORT, *supra* note 4, at 372.

[209] *See* DePalma, *supra* note 24, at A4.

[210] *See* Michele Mandel, *Bad Blood: A New Novel Probes Bill Clinton's Possible Role in Canada's Red Cross Scandal*, THE TORONTO SUN, Oct. 4, 1998, at 30.

[211] *See* Bueckert, *supra* note 162.

[212] *See* Parker, *supra* note 155.

[213] *See id.*

[214] DePalma, *supra* note 24, at A4.

[215] *Tainted Blood: Poison from the Prisons*, *supra* note 151.

[216] *See* McKenna, *supra* note 34, at A16.

[217] *See* Anne McIlroy, *U.S. Prisoners' Blood Fed Hep-C Infections: Ottawa Documents Show for the First Time That Government Knew About Risk of Supply*, THE GLOBE & MAIL (Canada), June 30, 1999, at A1.

[218] *See id.*

'impracticable' to inspect all the plasma-collection sites itself, and decided to rely instead on FDA reports which it did not, in fact, review."[219] The Bureau of Biologics (the Bureau), Canada's counterpart to the FDA, only required that the FDA license the plasma centers.[220] Connaught provided the Bureau with their list of FDA-approved collection sites, and neither party inquired further.[221] One Connaught official stated it best during a hearing for the Krever Commission when he commented: "Obviously the system broke down."[222]

A 1998 Canadian Health Department memo explains that the use of the prison blood continued in Canada because the Canadian broker (Continental-Pharma) was never informed that the blood had a "high probability" of being infected with HIV and hepatitis C.[223] The memo stated that:

> The use of these blood products in Canada can be attributed to a failure by U.S. blood and regulatory authorities to inform a Canadian blood broker that blood collected at prisons was no longer safe and as a result was no longer being used in the U.S. ....
> ... At the time, these blood centres [sic] were still licensed by the U.S. Food and Drugs [sic] Administration ... but blood coming from them for the most part was exported.[224]

Unfortunately, it was not illegal to sell prison blood in the U.S., although in practice it no longer occurred.[225] Therefore, when Connaught inquired about the matter in 1983, it was told only that no regulations on the matter existed, not that the U.S. fractionators, in consultation with the FDA, ended the practice[226] the year before.[227]

In 1999, *The Globe and Mail*, under access-to-information legislation, obtained a briefing note written by Health Minister Allan Rock that suggested the Arkansas prison blood was responsible for at least some Canadians becoming infected with hepatitis C. The document explained: "Plasma from such high-risk populations may indeed have contributed to the transmission of blood diseases such as AIDS and hepatitis C."[228]

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[219] *Tainted Blood: Poison from the Prisons*, *supra* note 151.
[220] KREVER COMMISSION REPORT, *supra* note 4, at 391.
[221] *Id.*
[222] *Id.*
[223] Bueckert, *supra* note 162.
[224] *Id.*
[225] *See* KREVER COMMISSION REPORT, *supra* note 4, at 377.
[226] *Id.* at 398.
[227] *See supra* note 108 and accompanying text.
[228] McIlroy, *supra* note 217, at A1.

In 2001, documents from Health Canada, the company responsible for running the country's health system, proved that the Canadian Red Cross did distribute plasma from U.S. prison inmates.[229] The documents admitted that "risky" blood from the Arkansas prison was used and that "a significant amount of the product made from the potentially HIV-infected blood was not retrieved and it was learned that it had already been used."[230] Evidence brought to light in 2003 showed that the Arkansas prison continued to sell—and Canada continued to receive—the inmates' blood long after the prison had been cited for multiple safety and health violations, including approving donors who were infected with HIV and hepatitis C.[231]

The Canadian government settled a class action lawsuit brought by Canadian hemophiliacs for $1.118 billion in 1999.[232] This settlement only covered those infected between 1986 and 1990.[233] The group, led by plaintiff Michael McCarthy, vice president of the Canadian Hemophilia Society, also filed a suit against Continental Pharma.[234]

In 1999, a group of Canadian hemophiliacs declared their intent to sue the responsible parties in America for $5 billion.[235] In 2001, the Canadian Hemophilia Society announced further plans: they hoped to sue Arkansas, Louisiana, the businesses that participated in the sale and export of prison plasma, and the FDA.[236] The two companies they planned to name in the lawsuit were Health Management Associates in Arkansas and Community Plasma Center in Louisiana.[237]

Despite the announcement, the lawsuit was never filed.[238] McCarthy, also piloting this effort, reported that "numerous obstacles ... delayed the filing—including the inability to get legal help from respected blood litigators south of the [U.S.-Canadian] border."[239]

As of 2006, the Royal Canadian Mounted Police (RCMP) had been investigating the blood scandal for five years, and despite supposedly con-

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[229] *See* Harder, *supra* note 18.
[230] *See id.*
[231] *See* Canadian Press, *supra* note 153, at D15; *see also* discussion *supra* Part II.B.
[232] *See Canada Proposes $1.1 Billion Settlement in HCV Lawsuit*, REUTERS HEALTH MEDICAL NEWS, June 18, 1999 (Legal) [hereinafter *Canada Proposes $1.1 Billion Settlement*].
[233] *See id.*
[234] *See id.*
[235] Dunphy, *supra* note 158, at A1.
[236] *See* Harder, *supra* note 18.
[237] *See Canada Proposes $1.1 Billion Settlement*, *supra* note 232.
[238] *See* Harder, *supra* note 18.
[239] *Id.*

templating charging those in the United States with criminal negligence,[240] the only charges filed thus far have been against the Red Cross and the Federal Bureau of Biologics.[241] One of the factors the probe is focused on is "the importation of tainted blood from prisoners in Arkansas, brought into Canada by a Montreal-based blood broker and used by Canadian hemophiliacs. The same tainted blood product was exported around the world by the Canadian broker."[242]

2. Canadian Response

In 2006, the Canadian government finally compensated victims of Canada's tainted blood scandal who contracted hepatitis C and were not included in previous settlements, including those claiming to have been infected by plasma from Cummins prison.[243] More than 5,000 victims who were given contaminated blood and blood products before 1986 and after 1990 will receive compensation under the plan.[244] The previous settlement in 1998 only included those infected between 1986 and 1990, because the government claimed it could not have prevented contamination before 1986; however, evidence of screening techniques introduced prior to 1986 weakened the government's position.[245]

Under the new agreement, the government set aside nearly $1 billion to provide compensation, thus matching the compensation for those infected between 1986 and 1990.[246] Further, those who contracted the disease through tainted blood before 1986 and after 1990 will now receive between $1,000 and $300,000.[247]

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[240] Dunphy, *supra* note 158, at A1.

[241] *See* Laura Cudworth, *Stuff Movies Are Made of: Tainted Blood Scandal to Be Turned into Film*, STRATFORD BEACON-HERALD (Ontario), Jan. 18, 2006, at 1.

[242] Tim Harper, *Criminal Charges Likely End to Tainted Blood Probe*, HAMILTON SPECTATOR (Ontario), Nov. 15, 1999, at C14.

[243] *See* Op-Ed., *Long Time Coming*, THE SIMCOE REFORMER (Ontario), Aug. 2, 2006, at 4.

[244] *See id.*

[245] *See id.*

[246] *See id.*

[247] *See id.*

B. Britain

1. What Happened to the Tainted Blood in Britain?

Britain outlawed paid donations of blood earlier than the United States because the British government believed that paying would attract the wrong type of donor.[248] Britain also did not permit collection of prisoners' blood, both because the government considered it exploitive and because it recognized earlier than the United States that such blood was more likely to be contaminated.[249] However, Britain, like Canada, continued to *purchase* blood from international vendors, like the United States, [250] and this allowed tainted blood to poison thousands of British citizens.[251] Tainted blood that was sold to Britain in the 1980s—including blood products from the Arkansas prisons—resulted in what Lord Robert Winston called "the worst treatment disaster in the history of the NHS."[252] Most of the victims believed the blood and clotting factors they were using came from British donors; the possibility the blood might have been imported did not even occur to them, much less the prospect that it might not meet British health standards.[253]

This disaster left 4,670 British hemophiliacs infected with hepatitis C, and 1,243 of those were also infected with HIV.[254] Nearly 2,000 have died, and many more need treatment.[255] The diseases have continued to spread to partners and children.[256] The outcry surrounding this tragedy resulted in a two-year private report, the Archer Inquiry (the Inquiry),[257] released in February 2009. The Inquiry found that "Britain was slow to

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[248] *See* Birrell, *supra* note 32.

[249] *See* Leveritt, *supra* note 130.

[250] *See* ARCHER INQUIRY, *supra* note 107, at 24 (describing the negotiations between British pharmacists and commercial suppliers—primarily American suppliers).

[251] *See* Birrell, *supra* note 32.

[252] *Id.*

[253] *See* Leveritt, *supra* note 130.

[254] *See* Birrell, *supra* note 32.

[255] *See* ARCHER INQUIRY, *supra* note 107, at 5.

[256] *See* Birrell, *supra* note 32.

[257] The Independent Public Inquiry on NHS Supplied Contaminated Blood and Blood Products. This independent inquiry was not financed in any way by the English government. ARCHER INQUIRY, *supra* note 107, at 6–7. Its mission statement is: "To investigate the circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia [sic] community and others afflicted; and suggest further steps to address both their problems and needs and those of bereaved families." *Id.* at 7.

react to the problems as they emerged[,] and said commercial interests were put ahead of safety."[258] It ultimately determined that:

> [A] significant burden of responsibility [for tainted blood provided to British hemophiliacs] rests on American suppliers of Factor VIII concentrate. Long after alarms had been sounded about the risks of obtaining paid-for blood donations from communities with an increased incidence of relevant infections, such as prison inmates, this practice continued. It is difficult to avoid the conclusion that commercial interests took precedence over public health concerns.[259]

Unfortunately, it is difficult to determine *exactly* where all the blood came from, and how much of it might have come from the United States or the Arkansas prison. A significant part of this uncertainty stems from the fact that during the 1990s many of the records keeping track of the imports and sales of blood were shredded.[260] The British Haemophilia Society has sought an inquiry into the plasma transactions, specifically for the Factor VIII sent from the Arkansas prisons, but their requests have yet to be addressed.[261] According to the Communications Manager of the Hemophiliac Society, "[w]e know of three UK cases of HIV that can be directly traced back to Arkansas prison blood."[262] By October 2010, an estimated 1,800 out of the 4,800 British hemophiliacs poisoned by tainted blood products had died,[263] and this number certainly increased over the past two years.

2. English Response

The English government has been struggling to come to a settlement for the sufferers of contaminated blood and blood products. In October 2010, however, the government decided that, given spending costs and the current financial crisis, it would be too expensive to offer a compensation package similar to that of Ireland, where those infected with hepatitis C were each given £750,000 after a similar inquiry in 1991.[264] Instead, it

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[258] Birrell, *supra* note 32.

[259] ARCHER INQUIRY, *supra* note 107, at 105.

[260] The British Department of Health ordered an inquiry into the destruction of the documents in 2000, but failed to publish its findings. When reporters from the BBC requested the findings in 2007, they were informed that the Prime Minister ordered them withheld. *See* Leveritt, *supra* note 130.

[261] *See id.*

[262] *Id.*

[263] 14 Oct. 2010, PARL. DEB., H.C. (2010) 555 (U.K.).

[264] *See generally id.* at 521.

offered only to provide a "rapid, but limited, review into the cases of those infected with hepatitis C."[265]

3. Scottish Response

In Glasgow, hemophiliacs who believe they were infected by the Arkansas prison plasma have repeatedly asked for a public inquiry into the matter.[266] The hemophiliacs believe that the inmates were allowed to continue donating even though authorities knew they were infected with hepatitis C and HIV. They have even threatened to call former President Bill Clinton, Governor of Arkansas at the time of the scandal, to the witness stand.[267]

According to the Public Health Minister, victims have received compensation of up to £45,000, and therefore a public inquiry would not provide "any real benefit."[268] The hemophiliacs have already taken legal action against the Lord Advocate and the Health Minister.[269]

IV. THE LAWSUIT

A. Why Did the Victims Fail to File Suit Against the Responsible American Parties?

1. In General

No clear answer exists as to why the victims of the Arkansas prison plasma scandal failed to sue the allegedly responsible parties, especially because the Canadian Hemophilia Society planned to do so as early as 1999.[270] As of that date, the Canadian victims also stated their desire to "seek a full investigation by the U.S. [J]ustice [D]epartment to determine

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[265] Birrell, *supra* note 32.

[266] *See* Matt Dickinson, *Infected Blood Victims Protest at Clinton Visit; Transfusions Came from Former President's Home State*, EXPRESS NEWSPAPERS (Scotland), May 11, 2006, at 13.

[267] *Clinton's Scottish Court Warning*, DAILY RECORD (Scotland), Oct. 31, 2005, at 21.

[268] Dickinson, *supra* note 266, at 13.

[269] *See Clinton's Scottish Court Warning*, *supra* note 267.

[270] Tim Harper, *Tainted Blood Victims Seek U.S. Retribution*, THE TORONTO STAR, Feb. 22, 1999 (News) ("The Canadian hemophiliacs ... plan to seek American retribution for the tainted blood collected from U.S. prisoners and exported to [Canada]. They will launch a lawsuit against the U.S. Food and Drug Administration (FDA), the state of Arkansas, and possibly Clinton, the Arkansas governor while Health Management Associates collected plasma from inmates of Cummins Prison."). *Id.* The RCMP supposedly began talks with the FBI and the U.S. Justice Department. *Id.*

how inmates ... continued to give dirty blood which was exported to Canada and then to other countries."[271]

Victims in Britain felt angry enough to search through the records on their own until they determined that they did receive plasma from the Cummins prison.[272] In Canada, victims threatened to subpoena prominent government officials to explain their actions.[273]

So why did such a suit never materialize? The unfortunate truth is probably because the United States courts have demonstrated a general distaste for finding liability for contaminated blood defendants, and often dismiss the cases on summary judgment.[274] Courts have been especially reluctant to find liability in cases where hepatitis C was the transmitted disease for two major reasons: "(1) the judicial fear that to impose such liability would severely restrict the availability of blood, and (2) the absence of any reliable way to detect hepatitis-carrying blood."[275]

In addition to this initial reluctance, the plaintiffs would face basic procedural limitations.[276] Precedent cases show that it has been historically difficult to procure a class action certification approved for groups of hemophiliacs suing the blood industry.[277] Moreover, forty-eight out of

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[271] *Id.* The victims also believed they had the legal standing to do so. As the foreign affairs spokesperson announced: "Canadians are free to pursue alleged wrongs perpetrated by foreign governments." *Id.*

[272] *See* Leveritt, *supra* note 130.

[273] *Tainted Blood: Poison from the Prisons*, *supra* note 151.

[274] *See, e.g.*, Kozup v. Georgetown Univ., 851 F.2d 437, 438–39 (D.C. Cir. 1988); Smythe v. Am. Red Cross Blood Serv., 797 F. Supp. 147, 147 (N.D.N.Y. 1992); Howell v. Spokane & Inland Blood Bank, 785 P.2d 815, 824 (Wash. 1990).

[275] 37 AM. JUR. 2D *Proof of Facts* § 1 (1984).

[276] Such as the relevant statute of limitations passing. *See, e.g.*, *In re* Factor VIII or IX Concentrate Blood Prods. Litig., No. Civ. A. 94-0382, 2000 WL 282787, at *7 (E.D. La. Mar. 14, 2000).

[277] *See, e.g.*, *In re* Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1298 (7th Cir. 1995) (holding that class certification was inappropriate because such actions might bankrupt the industry, or force them into blackmail settlements). This has also been true to a lesser extent in Canada; a class action suit filed against the Canadian Red Cross and the Canadian Government by about 1,000 hemophiliacs infected with HIV was thrown out because the judge determined that, "lawsuits involving contaminated blood should be filed individually." *Canada Drops Blood Suit*, N.Y. TIMES, Feb. 20, 1994, at 3. However, some courts have allowed consolidation and centralization of claims under 28 U.S.C. § 1407 (meaning that claims with similar bases in fact can be tried at a central location for convenience and efficiency purposes, though the defendants are not actually being tried together). *See, e.g.*, *In re* "Factor VIII or IX Concentrate Blood Prods." Prods. Liab. Litig., 303 F. Supp. 2d 1377, 1379 (J.P.M.L. 2004); *In re* "Factor VIII or IX Concentrate Blood Prods." Prod. Liab. Litig., 853 F. Supp. 454, 455–56 (J.P.M.L. 1993).

fifty states[278] have passed blood shield laws,[279] limiting the available causes of action against those in the industry.[280]

B. Hypothetical Negligence Case

1. The Hypothetical

If the Canadian Hemophilia Society *had* brought suit against HMA and Pine Bluff Biologicals,[281] like most of the plaintiffs in the tainted blood litigation thus far in the United States, the victims of the Arkansas blood scandal probably would not have prevailed,[282] even if all the facts alleged were true,[283] and even though the distributed blood products were not "unavoidably unsafe."[284]

This is the unfortunate reality even when considering the horrific conditions purported to exist at the prison plasma center. At any plasma center during this period, it is possible that a few cases of blood tainted with hepatitis C were inevitable, especially given the fact that the causative agent of the disease was not known at the time,[285] and that no accurate test to identify it existed.[286] But the situation at the Cummins plasma center was *not* inevitable. The fact that the disease infecting the recipients was

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[278] Including Arkansas. McKenna, *supra* note 34, at A16.

[279] Dunphy, *supra* note 158, at A1.

[280] *Id.* ("An American group seeking compensation for contracting HIV and hepatitis C from tainted blood has had no success in seven years of court action.").

[281] Assuming the relevant statute of limitations had not run and that venue, jurisdiction, class certification, et cetera were correct.

[282] Assuming the evidence proved the poor conditions at the prison and the knowledge of the prison administration, as explored *supra* notes 274–75 and accompanying text.

[283] *See* Mandel, *supra* note 210, at 30. The Krever Commission Report at least confirms that the basic facts of the Cummins Plasma Program and the distribution of the blood products to Canada are correct. *Id.*

[284] *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). The concept of "unavoidably unsafe" is addressed in § 402A comment k, which provides an exception to strict liability for products deemed to meet the standard of "products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* The blood products here were not "avoidably unsafe" because, under the state of human knowledge at the time, it was well known that the use of prisoners' blood and the unsanitary conditions at Cummins prison made contamination more likely, but the plasma was distributed anyway.

[285] *See* 37 AM. JUR. 2D *Proof of Facts* § 2 (1984) (identifying hepatitis C only as "non-A, non-B").

[286] Dorney, *supra* note 19, at 169 (noting that even the best hepatitis C tests were only twenty-five to thirty percent effective).

unknown and unpreventable at the time[287] does not change the truth: those in charge of monitoring the program either knew or should have known that the conditions at the prison provided a breeding ground for diseased product. They were aware of the warnings from the FDA against using prisoners' blood and of an established industry custom against using plasma from paid donors, but they disregarded these red flags and distributed it anyway,[288] causing the spread of needless disease and death in order to secure a profit.[289]

Despite this apparent negligence, despite the findings of the Krever Commission, and despite the responses of the Canadian and British governments showing that it is likely that this tainted plasma was distributed to and sickened their populations, a legal remedy for victims in this matter could not be easily obtained. Due to the extreme difficulty of proving causation in a tainted blood product case,[290] unless the plaintiffs could prove that a vial of tainted blood from Cummins prison directly caused their hepatitis C, a negligence suit against the responsible parties would fail,[291] given the current state of litigation against the blood industry in America.[292]

2. Why Negligence?

Why bring a negligence suit then, if it is likely to fail? The explanation is that plaintiffs have a slightly higher chance of prevailing in a negligence action against a blood product supplier than they do in winning a strict liability[293] or breach of implied warranty[294] action.[295] Negligence is effec-

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[287] *But see* Westfall, *supra* note 88, at 1123 (arguing that the risk of blood products should not have been inevitable because it could have been reduced by decreasing the pooling and ending the use of high-risk donors).

[288] *See* discussion *supra* Part II.C.

[289] *See* discussion *supra* Part II.D.

[290] *See* Miller, *supra* note 31, at 473.

[291] *See* George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1094 (2000) ("Negligence claims for blood products ... were practically impossible for plaintiffs to win.").

[292] *See* Rueda, *supra* note 68, at 424 (explaining that plaintiffs in tainted blood litigation have a very small chance of prevailing).

[293] Strict liability is a tort theory that allows a plaintiff to recover for damages caused by a defective product, even if the seller of the product took all reasonable precautions in manufacturing the product. This cause of action is codified in § 402A of the Restatement (Second) of Torts. *See* Miller, *supra* note 31, at 482–83. Very few cases have allowed strict liability in blood-supply cases, and then only when the court determined that the blood created an unreasonable risk of harm to others. *See, e.g.*, DeBattista v. Argonaut-Southwest Ins. Co., 403 So. 2d 26, 32 (La. 1981).

tively the only possible cause of action against blood product producers because of the enactment of blood shield laws across the United States.[296] As one author described the current legal climate:

> Today, the provider of a virally contaminated unit of whole blood, blood component, or blood derivative bears virtually no liability to the injured recipient of the transfusion. First, the transfusion of blood products is not the sale of goods; therefore, the implied warranties of Article 2 of the Uniform Commercial Code (UCC) do not attach. Second, barring negligence, blood products that are virally contaminated are not legally defective and unreasonably dangerous, thereby avoiding any provider liability under a theory of strict liability in tort. This unique legal protection of blood products and providers arises by operation of law as stated in each state's blood shield statute.[297]

Blood shield laws in the United States codify the rule that blood and blood derivatives are not considered "products" under strict products liability[298] and implied warranty, mainly out of concern that the risks cannot be completely eradicated when there are so many possibilities for contamination.[299] Thus, rather than simply asserting a strict liability or breach of implied warranty cause of action,[300] a tainted blood or plasma victim must face the higher burden of proving the elements of a negligence claim to

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[294] Implied warranty is a contract theory defined and controlled by the Uniform Commercial Code, Article 2. *See* Miller, *supra* note 31, at 482. Though causes of action for breach of implied warranty generally fail, they have occasionally been successful if the state's blood shield statute provided an exception. *See, e.g.*, IDAHO CODE ANN. § 39-3702 (West 2011) (restrictions on liability do not apply to suppliers who use paid donors or who profit); WASH. REV. CODE ANN. § 70.54.120 (West 2011) (restrictions on liability do not apply if the donor was paid); MONT. CODE ANN. § 50-33-102 (West 2009) (restrictions on liability do not apply to a hospital if blood came from a source in which the hospital held a financial interest).

[295] *See* Conk, *supra* note 291, at 1094.

[296] *See, e.g.*, Miles Labs. v. Doe, 556 A.2d 1107, 1125 (Md. 1989) (effectively holding that only a negligence cause of action could be brought against the defendant blood bank).

[297] Shu-Acquaye & Innet, *supra* note 58, at 33 (footnotes omitted).

[298] *See* Poole v. Alpha Therapeutic Corp., 698 F. Supp. 1367 (N.D. Ill. 1988) (holding that the legislature's enactment of a blood shield statute demonstrated their intent to end strict liability for the blood industry).

[299] *See* DEBORAH R. HENSLER ET AL., CLASS ACTION DILEMMAS: PURSUING PUBLIC GOALS FOR PRIVATE GAIN 295 (2000).

[300] *See id.* ("To establish negligence, plaintiffs must show that the defendants either knew or should have known of the risk of transmitting a deadly virus through the sale of factor concentrate.").

prevail, because legislatures and courts have both decided to prohibit or strongly limit the application of no-fault liability in these situations.[301]

Under the burden of negligence, the plaintiffs would need to show that the injury they suffered resulted because HMA and Pine Bluff Biologicals failed to use reasonable care in their collection and distribution of the blood products, *and that this failure caused the victims to contract the disease*.[302]

3. Arkansas' Blood Shield Law

Arkansas' blood shield law is codified in section 20-9-802 of the Arkansas Code. It only permits negligence and willful misconduct causes of action against those involved in the manufacture, sale and transfer of blood or blood products,[303] stating:

> No physician, surgeon, hospital, blood bank, tissue bank, or other person or entity who donates, obtains, prepares, transplants, injects, transfuses, or otherwise transfers or who assists or participates in obtaining, preparing, transplanting, injecting, transfusing, or transferring any tissue, organ, blood, or component thereof from one (1) or more human beings, living or dead, to another human being, shall be liable as the result of the activity, except that each such person or entity shall remain liable for negligence or willful misconduct only.[304]

Section 20-9-801 clarifies the public policy reasons behind the blood shield statute, explaining that this shield is necessary to ensure the availability of scientific knowledge and that, by preventing strict liability causes of action (which might inhibit such development), the State is better able to promote the health and welfare of its citizens.[305] In addition, Arkansas law precludes actions under Article 2 of the Uniform Commercial Code for breach of warranty in cases of blood services.[306]

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[301] *See* Andrew R. Klein, *A Legislative Alternative to "No Cause" Liability in Blood Products Litigation*, 12 YALE J. ON REG. 107, 117 (1995).

[302] *See* Feldman, *supra* note 43, at 671. This is discussed in a preliminary version of the Restatement (Third) of Torts, which states: "A seller of human blood products or human tissue is subject to liability for harm to persons caused by product defects [only] if, at the time of sale, the seller failed to exercise reasonable care in obtaining, processing or selling the blood product or tissue." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4B (Preliminary Draft No. 2 1994).

[303] ARK. CODE ANN. § 20-9-802 (West 2010).

[304] *Id.*

[305] ARK. CODE ANN. § 20-9-801.

[306] *See* Kirkendall v. Harbor Ins. Co., 887 F.2d 857, 859 (8th Cir. 1989) ("The implied warranties of the Uniform Commercial Code therefore do not apply to blood ....").

4. Establishing the Elements

In order to prove negligence, the plaintiffs would need to show: (1) that they were owed a legal duty by the responsible parties, (2) that such duty was breached, (3) that the breach was the proximate cause of their injury, and (4) that they suffered damage.[307]

a. Duty

The first concern that the plaintiffs in such a case would need to prove is that those responsible for the conditions at the plasma center owed them a duty[308] of care.[309] The victims would have to address *who*, precisely, owed them a duty. Given HMA's dissolution in 1986, it would make the most sense for the plaintiffs to sue those in charge of HMA and Pine Bluff Biologicals[310] as individuals[311] if they hoped to achieve a monetary victory.[312]

The contract between PBBP and the ADC provided that, for the ADC's portion of the earnings, PBBP could use the plasma center and any utilities without cost, and could have access to inmates for donations and occasional staffing of the center.[313] In exchange, PBBP promised to "assume responsibility/liability for all plasma product(s) produced."[314] It is likely that a similar contract bound the ADC and HMA.[315]

Based on legal precedent, it is clearly true that blood product distributors owe a duty of care to the recipients of the blood product.[316] This duty,

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[307] Endres v. Endres, 968 A.2d 336, 340 (Vt. 2008).

[308] *See* W. KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53 (5th ed. 1984) ("'[D]uty' is ... an expression of the sum total of those considerations of policy which lead the law to say that the plaintiff is entitled to protection.").

[309] 37 AM. JUR. 2D *Proof of Facts* § 5 (1984).

[310] This is based on the assumption that these defendants are under the jurisdiction of the court. Constitutionally, the plaintiffs cannot sue the state of Arkansas or the Arkansas Board of Corrections without the state consenting, because "the Eleventh Amendment prohibits federal courts from entertaining suits by private parties against States and their agencies." Alabama v. Pugh, 438 U.S. 781 (1978) (holding that a federal court's injunction against the Alabama Board of Corrections was unconstitutional).

[311] For the purposes of this Note, these individuals will continue to be collectively referred to as HMA.

[312] Though it would probably be more of a moral victory than a monetary victory, as it is unlikely that individual defendants could provide much compensation.

[313] Leveritt, *supra* note 130.

[314] *Id.*

[315] No evidence was available to confirm or deny this, so for the purposes of the hypothetical, it will be assumed true.

[316] Dorney, *supra* note 19, at 157.

stated generally, is to collect the commodity in a non-negligent manner.[317] "Non-negligent manner" means that the defendant did not and should not have foreseen that his actions might harm another.[318] A major part of this determination is a court's inquiry into what was or should have been known by the scientific community and the blood industry at the time.[319]

Courts differ in the standard of care they believe the blood industry should adhere to: the ordinary standard or the professional standard.[320] On one side, industry proponents contend that blood and plasma centers are service providers selling an inherently dangerous product. They argue, therefore, that the producers should be held to a professional standard, out of concern that the industry will otherwise suffer, because no one will want to work in it and face such a high likelihood of liability. A New Jersey Court of Appeals, meanwhile, clearly explained the opposing side's position, stating:

> [I]f the blood bank industry is allowed to establish its own custom or practice of testing for the presence of an infectious disease, then no matter how unreasonable such standard might be by ordinary judgment, all members of the blood bank industry would be insulated from liability as long as they conformed their practice to the industry's self-established norm. This result is not tolerable in our system of justice.[321]

Even now, jurisdictions are greatly divided on this question.[322] For example, the court in *Doe v. American Red Cross Blood Services* found that, as

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[317] *Id.*

[318] RESTATEMENT (SECOND) OF TORTS § 289 cmt. b (1965).

[319] Dana J. Finberg, Note, *Blood Bank and Blood Products Manufacturer Liability in Transfusion-Related AIDS Cases*, 26 U. RICH. L. REV. 519, 534 (1992).

[320] If held to a professional standard of care, the plaintiffs in this case must prove that the conditions that HMA and PBBP allowed in the prison did not meet the contemporary industry-wide custom. *See, e.g.*, Osborn v. Irwin Mem'l Blood Bank, 7 Cal. Rptr. 2d 101, 120–21 (Ct. App. 1992). Professional standards in this context would include: "[S]tatutes, such as blood bank acts and communicable disease acts; regulations, such as those of the Food and Drug Administration; licensure examination requirements; internal rules, by-laws and regulations of organizations, such as the AABB; professional publications and learned treatises; conduct or standards of like organizations; and expert testimony." R. Jo Reser & Barbara A. Radnofsky, *New Wave of Tainted Blood Litigation: Hepatitis C Liability Issues*, 67 DEF. COUNS. J. 306, 309 (2000).

[321] Estate of Elkerson v. N.J. Blood Ctr., 776 A.2d 244, 250 (N.J. Super. Ct. App. Div. 2001).

[322] For a comprehensive discussion of industry versus a general standard of care and its implications for jury considerations, see generally Reser & Radnofsky, *supra* note 320, at 307–08 ("While compliance with industry standards has not allowed defendants an out in litigation, the failure to comply with such standards usually proves fatal.").

a service provider, the Red Cross should be held to a professional standard;[323] however, in an Arkansas case, *Kirkendall v. Harbor Insurance Company*, the court determined that complying with industry standards could be *evidence* of what ought to be done, but that it was not conclusive.[324] Similarly, the Colorado Supreme Court held that meeting industry standard was permitted as evidence of non-negligence, but found that the plaintiff must be given the opportunity to prove the standards of the *entire industry* negligent.[325]

Given the Eighth Circuit court's decision in *Kirkendall*, it is likely that the court would hold HMA and PBBP to the ordinary standard of care; however, as discussed below, the plasma center administrators' negligence was great enough to breach either standard. In conclusion, it is clear that HMA and PBBP owed the recipients of the plasma a duty of care, whether ordinary or professional.

b. Breach

In order to breach their duty, the defendants in this case would need to have failed to meet the required standard of care.[326]

Even if judged by the standards of the industry, HMA and PBBP behaved negligently in continuing the prison plasma center long after such programs were widely discontinued.[327] By the end of 1982, given the FDA recommendations, all of the major American fractionators had stopped collecting donations from paid donors, and it was well known *in the industry* that prison blood was significantly riskier than the blood of the majority of the population.[328]

Further, the hypothetical Arkansas case can be distinguished from a case such as *Fogo v. Cutter Laboratories*, an important California plasma transfusion case, in which the court determined that even though the de-

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[323] Doe v. Am. Red Cross Blood Serv., 377 S.E.2d 323, 326 (S.C. 1989) (holding that the plaintiff must prove that the Red Cross failed to meet industry standards).

[324] *See* Kirkendall v. Harbor Ins. Co., 887 F.2d 857, 860–61 (8th Cir. 1989). Though appealed to the Eighth Circuit, this case involved events that occurred in Arkansas, and was originally tried in the United States District Court for the Western District of Arkansas. *See id.* at 859.

[325] United Blood Servs. v. Quintana, 827 P.2d 509, 524–26 (Colo. 1992). *But see* Brown v. United Blood Servs., 858 P.2d 391, 396 (Nev. 1993) (rejecting *Quintana* as an outlier).

[326] *See* Miller, *supra* note 31, at 473.

[327] *See, e.g.*, Fuentes v. Vose, 53 F.3d 327 (1st Cir. 1995) (stating that the Rhode Island Adult Correctional Institutions ended their prison blood donation program in 1983).

[328] *See* discussion *supra* Part II.B.

fendant intentionally utilized and paid a slum population for their donations, such practice was not negligent because of an insufficiency of volunteer blood donors.[329] The major difference is that the defendant in *Fogo* possessed a different level of knowledge than the administrators at Cummins: the *Fogo* decision came down in 1977, five years before the FDA recommended ending the use of paid donors.[330] Moreover, though the defendants in *Fogo* permitted donations from persons who were "unclean, elderly, transients, alcoholics and otherwise debilitated,"[331] no evidence presented indicated the *conditions* at the plasma center themselves were dirty and corrupt.[332]

In contrast, HMA and PBBP did not meet industry standards given the supposed conditions of the plasma program. This was not a situation in which the plasma service providers simply failed to treat blood to prevent hepatitis,[333] or failed to screen one particular donor.[334] Instead, the prisoners allegedly ran the plasma center themselves, and there are eyewitness accounts and FDA documentation of over-bleeding, bleeding prisoners known to be disqualified donors, a filthy environment, and incidents when plasma was incorrectly stored but still distributed.[335] As one Nevada court held, a supplier of blood can be found liable if there is proof that measures taken by the supplier "to screen donors and eliminate contaminated blood fell below the standards promulgated and practiced by the industry."[336] This was certainly the case at the Cummins Plasma Center.

Finally, HMA and PBBP breached their duty of care by failing to follow the FDA's recommendations to end the use of blood from paid donors. Even though this was a "recommendation" rather than a regulation, a 1989 Arkansas circuit court decision found that an FDA recommendation that blood suppliers begin testing blood as soon as the required supplies became available imposed a *duty* on them to do so immediately.[337]

Negligence can be shown by evidence of the defendant's actual or constructive knowledge of the risk his behavior entails,[338] and HMA and PBBP were given repeated warnings over the conditions at the plasma

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[329] *See generally* Fogo v. Cutter Laboratories, Inc., 137 Cal. Rptr. 417 (Ct. App. 1977).
[330] *Id.*
[331] *Id.* at 426–27.
[332] *See* discussion *supra* Part II.C.
[333] *See Fogo*, 137 Cal. Rptr. at 420.
[334] *See, e.g.*, United Blood Servs. v. Quintana, 827 P.2d 509, 517 (Colo. 1992) (determining that the donor to the blood bank was a homosexual infected with HIV).
[335] *See* discussion *supra* Part II.C.
[336] Brown v. United Blood Servs., 858 P.2d 391, 396 (Nev. 1993).
[337] *See* Kirkendall v. Harbor Ins. Co., 887 F.2d 857, 861 (8th Cir. 1989).
[338] *See* Endres v. Endres, 968 A.2d 336, 341 (Vt. 2008).

center, including through the recall of their product, revocation of their license by the FDA, warnings about the risks of prison blood from the FDA and the National Correctional Association, and the end of the prison plasma collection system in virtually every other state.[339]

Based on the analysis above, HMA and PBBP breached their duty of care to those who received blood from the prison.

c. Causation

It is extremely challenging, if not impossible, to prove causation in blood and plasma liability cases.[340] This frustration occurs because of the difficulty in showing with absolute certainty the source of a contaminated blood product (especially when hemophiliacs inject themselves so frequently[341]) and in establishing that one particular vial resulted in the transmission of the disease.[342] To make matters more complicated, during the relevant years at issue for this hypothetical, Connaught purchased plasma not only from the Cummins prison, but also from San Francisco, where the blood bank confirmed several cases of AIDS[343] and from where the victims might easily have contracted hepatitis C.

In negligence cases, the plaintiff bears the burden of proving causation.[344] The defendant's breach of duty must be the proximate cause of the plaintiff's injury, meaning that the defendant's negligence must have caused the injury and that the law would require the defendant to be responsible for his conduct.[345] The plaintiff must be able to show by a preponderance of the evidence that one specific defendant caused the harm. Courts virtually never permit plaintiffs to use either market share liability[346] or alternative liability theory,[347] either of which would ease the chal-

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[339] *See* discussion *supra* Part II.C.

[340] Patricia Kussmann, Annotation, *Validity, Construction, and Application of Blood Shield Statutes*, 75 A.L.R. 5th 229 (2000).

[341] *In re* Factor VIII or IX Concentrate Blood Prods. Litig., 484 F.3d 951, 953 (7th Cir. 2007).

[342] *See, e.g.*, Dunphy, *supra* note 158, at A1.

[343] Stumpe, *supra* note 180, at A1.

[344] *In re* Factor VIII or IX Concentrate Blood Prods. Litig., No. Civ. A. 94-0382, 2000 WL 282787, at *10 (E.D. La. Mar. 14, 2000).

[345] *See* Palsgraf v. Long Island R.R., 248 N.Y. 339, 351–53 (N.Y. 1928) (discussing the limitations of proximate cause) ("The right to recover damages rests on additional considerations. The plaintiff's rights must be injured, and this injury must be caused by the negligence.").

[346] Market share liability is a theory of liability utilized by plaintiffs in cases where they were injured by a generic, fungible product that is inherently harmful, but they cannot conclusively determine which company in an industry caused their injury. In these

lenge of proving causation, because both allow the plaintiff to bring suit against multiple parties when it is clear that *one* of the defendants was negligent, but determining which one is impossible. For example, in the hypothetical discussed here, two different administrators—HMA and PBBP—both ran the prison plasma center. If a victim somehow managed to prove that they received tainted plasma from the ADC during the year when the two defendants overlapped, a court accepting the market share liability concept would hold both HMA and PBBP liable.[348] Precedents from the majority of tainted blood litigation in the United States,[349] however, suggest that unless the victim could decisively show *which administrator* distributed the contaminated blood product, the court would instead hold *neither* liable.

The court in *In re Factor VIII or IX Concentrate Blood Products Litigation* addressed the problem of causation, agreeing with the plaintiffs that the correct test for causation was the "substantial factor" test, but finding that plaintiffs must prove that the defendant's negligence was the cause-in-fact of the diseases they contracted.[350] Even though the plaintiff in *In re*

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cases, the court has allowed any producer of the product to be liable for its portion of the market share at the relevant time, unless it can prove it was *not* the manufacturer of the product. Sindell v. Abbott Labs., 607 P.2d 924, 932, 936-37 (Cal. 1980). However, courts have generally been unwilling to extend market share liability to blood product litigation, because they believe Factor VIII is not a generic, identical, fungible, and inherently dangerous product that would meet the *Sindell* criteria. *See, e.g.*, King v. Cutter Labs., 685 So. 2d 1358, 1359 (Fla. Dist. Ct. App. 1996); Doe v. Cutter Biological, 852 F. Supp. 909, 913 (D. Idaho 1994).

[347] The courts have also proven unwilling to extend the theory of alternative liability to blood product litigation. Alternative liability arises when two defendants acted in a simultaneous or similarly tortious manner and caused harm, but the plaintiffs cannot identify the actual tortfeasor who caused their injury. In order to meet the requirements of alternative liability, *all possible tortfeasors* must be before the court. RESTATEMENT (SECOND) OF TORTS § 433B(3) cmt. f. (1965). *See, e.g.*, Spencer v. Baxter Int'l, Inc., 163 F. Supp. 2d 74, 79 (D. Mass. 2001); Doe *ex rel.* Doe v. Baxter Healthcare Corp., 178 F. Supp. 2d 1003, 1014 (S.D. Iowa 2001), *aff'd sub nom.* Doe v. Baxter Healthcare Corp., 380 F.3d 399 (8th Cir. 2004).

[348] *See, e.g.*, Conley v. Boyle Drug Co., 570 So. 2d 275, 281, 286 (Fla. 1990) (holding that a DES-plaintiff could recover from the defendants based on market share liability, because she could not determine which defendant caused the harm); McCormack v. Abbott Labs., 617 F. Supp. 1521, 1526 (D. Mass. 1985) ("[T]he magnitude of the physical and psychological injuries which are at issue in DES cases counsels toward permitting a remedy under some form of a market-share theory of liability.").

[349] Hawaii proves to be the exception: in one case the court permitted the plaintiffs in Factor VIII litigation to use market share liability. *See* Smith v. Cutter Biological, Inc., 823 P.2d 717, 729 (Haw. 1991).

[350] *In re* Factor VIII or IX Concentrate Blood Prods. Litig., No. Civ. A. 94-0382, 2000 WL 282787, at *10 (E.D. La. Mar. 14, 2000).

Factor VIII kept logs of his Factor VIII infusions (including the manufacturers' details), the court found this evidence insufficient to conclusively prove which batch caused his HIV infection.[351]

Often, a plaintiff involved in tainted blood litigation can prove only that it is *likely* that he contracted the disease from one provider,[352] but the general response has been that a strong likelihood of causation is not sufficient to *prove* causation.[353] The plaintiff is required to show by a preponderance of the evidence that the defendant's negligence *directly caused* his injury.[354]

Proving this element is so problematic that even the three plaintiffs in Britain who claimed they could trace their infection directly back to the Arkansas prison would face enormous difficulties in establishing causation.[355] Given the time it takes for HIV[356] and hepatitis C to manifest after infection,[357] it is nearly impossible to prove that one particular vial caused the disease for a hemophiliac plaintiff, because the time of infection cannot be confirmed.[358] In the case of *Doe v. Baxter Healthcare Corp.*, even though the named defendants held between 88 and 94.5% of the market share over the years when the plaintiff used Factor VIII,[359] and the date of the plaintiff's infection could be pinned down to within a range of a year,[360] the court found this insufficient to prove causation and approved summary judgment in favor of the defendants.[361] As the court stated, "Doe I became infected by the HIV virus on *one particular occasion* from *one particular product*,"[362] and he could even have been exposed to blood

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[351] *Id.* at *11.

[352] *See, e.g.*, *Spencer*, 163 F. Supp. 2d at 78 (granting defendants' motion for summary judgment because of plaintiff's inability to conclusively prove causation).

[353] *See Doe v. Baxter Healthcare Corp.*, 380 F.3d at 406.

[354] Moore v. Armour Pharm. Co., No. 88-392-CIV-T-15C, 1990 WL 369571, at *6 (M.D. Fla. Aug. 27, 1990).

[355] *See* discussion *supra* Part III.B.

[356] HIV infections may take at least two to six weeks to manifest after the date of infection. *See* Doe *ex rel.* Doe v. Baxter Healthcare Corp., 178 F. Supp. 2d 1003, 1008 (S.D. Iowa 2001), *aff'd sub nom.* Doe v. Baxter Healthcare Corp., 380 F.3d 399 (8th Cir. 2004). Additionally, a person can be exposed to AIDS and not become infected with the disease. *See id.*

[357] Hepatitis C has a six to eight-month incubation period. Mellis v. N.Y. State Dept. of Corr., 779 N.Y.S.2d 857, 858 (App. Div. 2004).

[358] *See Doe v. Baxter Healthcare Corp.*, 380 F.3d at 406 ("[T]here is no way to identify the moment of infection.").

[359] *Doe ex rel. Doe v. Baxter Healthcare Corp.*, 178 F. Supp. 2d at 1009.

[360] *See id.* at 1008.

[361] *See id.* at 1012.

[362] *Id.* at 1013 (emphasis added).

products containing HIV after the date of infection, which would not impact his diagnosis.[363]

However, in the same case for plaintiff Doe II, because the experts generally agreed on the date of infection, and because the named defendants owned one hundred percent of the market share of Factor IX at the time of infection, the court denied summary judgment for the defendants.[364] Yet Doe II had not even successfully proven causation: he had only managed to convince the court that a material question of fact existed, allowing the case to proceed to trial.[365]

Thus, the burden of proving causation is incredibly high, and this is only for the plaintiffs to pass summary judgment. *Doe v. Baxter Healthcare Corp.* is a fairly recent case, and it indicates that, to establish causation, a petitioner involved in blood product litigation must be able to determine the *exact* product, on the *exact* date, by the *exact* manufacturer. If the court applied this standard in the current hypothetical case, it would likely be hopeless for any significant number of the victims to ever overcome their burden of proof. The court's reasoning in *Baxter Healthcare* makes it virtually impossible for a victim of tainted blood product to ever successfully prove causation.

d. Injury

Finally, to obtain a favorable ruling, the plaintiffs must also show injury, which in this theoretical case should not be problematic. Generally, damages are self-evident when the plaintiff suffers from a potentially fatal disease contracted through contaminated blood products.[366] Examples of other injuries the plaintiffs might assert include medical expenses, loss of earnings, and mental and emotional distress.[367]

e. Outcome

Although the plaintiffs in a hypothetical negligence case against HMA and PBBP could establish that they were owed a duty of care, and that the defendants had breached that duty, the cause of action would ultimately

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[363] *Id.*

[364] *See id.* at 1009, 1017.

[365] *See Doe ex rel. Doe v. Baxter Healthcare Corp.*, 178 F. Supp. 2d at 1017.

[366] *See* Dorney, *supra* note 19, at 163.

[367] *See* David Polin, *Hepatitis from Blood Transfusion*, 37 AM. JUR. 2D *Proof of Facts* § 14 (1984).

fail because the plaintiffs would be unable to sufficiently prove that the defendants' negligent conduct caused their injury.

CONCLUSION

The blood business is a "uniquely favored industry,"[368] one of the most profitable and critical enterprises in the world, as it permits the sale, manufacturing, and transfusion of life-saving blood and blood products.[369] American methods have long been considered the gold standard of blood distribution,[370] and American blood and plasma companies dominate the majority of the world market.[371] Especially because most countries do not have the resources to gather as much blood and plasma as the U.S. does,[372] they depend on the American system to be safe, transparent, and progressive. However, as the hypothetical Arkansas prison lawsuit demonstrates, the system ultimately fails the victims.

Courts and legislatures face difficult decisions in dealing with the liability of blood and blood product suppliers because they must wrestle with the dueling desire of ensuring the safety of the product for the population and the responsibility of keeping the blood industry solvent and willing to continue selling such a risky commodity.[373] The industry almost always triumphs in this calculus.[374] Despite victims' repeated attempts to hold these producers accountable for tainted blood, the blood business remains effectively unscathed because so few lawsuits against it prove successful.[375]

As the Arkansas plasma center hypothetical illustrates, under the American legal system, it is virtually impossible for casualties of tainted blood products to conclusively determine causation.[376] Because of blood shield laws, negligence is a plaintiff's only realistic recourse against the blood industry; however, these negligence actions repeatedly fail because the plaintiffs cannot meet the high burden of proving causation, and courts

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[368] Conk, *supra* note 291, at 1089.
[369] *See* Miller, *supra* note 31, at 473.
[370] Telephone Interview with Kelly Duda, *supra* note 22.
[371] *See* Feldman, *supra* note 43, at 671–72.
[372] As with Canada and Britain. *See generally* 14 Oct. 2010, PARL. DEB., H.C. (2010) 534 (U.K.); KREVER COMMISSION REPORT, *supra* note 4, at 50.
[373] *See* Shu-Acquaye & Innet, *supra* note 58, at 33–34.
[374] *See* Feldman, *supra* note 43, at 671–72.
[375] *See id.*
[376] *See* Su, *supra* note 92, at 948.

generally refuse to ease this burden by permitting market share or alternative liability theories.[377]

In the hypothetical case discussed, even if viewed in the light most favorable to the plaintiffs, a negligence cause of action would fail, despite the mountain of allegations that the Cummins Plasma Center operated in a manner that clearly created a breeding ground for disease, and resulted in a substantial likelihood of tainted plasma products being distributed.

The outcome of such a hypothetical is extremely relevant to the global blood industry today, as foreign victims of contaminated blood sold from America continue to seek justice.[378] Emerging economies like China and Brazil are facing litigation from victims of their own for-profit plasma centers,[379] and they will likely look to United States' precedents for guidance. Another example is Iraq, whose previous government forcibly injected HIV-tainted plasma imported from France into a group of hemophiliacs.[380] This group now hopes to bring a civil suit against the French companies involved, which, thus far, have ignored calls for acknowledging accountability.[381] Considering the United States' position in helping establish the emerging Iraqi legal system,[382] the reaction of our own courts to similar cases influences the likelihood of this lawsuit ever being tried, and thus the chances of success for the sufferers.

The Arkansas Prison Plasma hypothetical illustrates one example of a system that provides blood and plasma providers with the wrong incen-

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[377] *See* Dorney, *supra* note 19, at 176–77.

[378] *See, e.g.*, *In re* Factor VIII or IX Concentrate Blood Prods. Liab. Litig., 595 F. Supp. 2d 855, 858 (N.D. Ill. 2009) (examining the foreign plaintiffs' allegations that after defendant blood product manufacturers stopped distributing untested products in the United States, they continued to sell them abroad); Conk, *supra* note 291, at 1100 (describing the development of the global plasma industry developed by U.S. producers); Feldman, *supra* note 43, at 665 (examining the devastating impact of tainted American plasma products that were collected in part from high-risk populations and were being sold to Japan).

[379] *See* Korsten, *supra* note 14, at 236–37 (explaining the paid-donor system developing in China and Brazil); *see also* Chi-Chi Zhang, *China Red Cross Calls for Urgent Blood Donations*, ASSOCIATED PRESS, Oct. 9, 2010, *available at* http://www.physorg.com/news/2010-10-china-red-urgent-blood-donations.html (discussing the consequences of the "blood-buying rings" in China in the 1990s and the current blood shortages China is facing).

[380] *See* Paul von Zielbauer, *Iraqis Infected by H.I.V.-Tainted Blood Try New Tool: A Lawsuit*, N.Y. TIMES, Sept. 4, 2006, at A8 (describing the plight of Iraqi hemophiliacs suffering from HIV and their efforts to bring a lawsuit against the French plasma producers).

[381] *See id.*

[382] *See id.*

tives.[383] Despite the inquiries and responses of the Canadian and British governments, which clearly show that the conditions at Cummins were unacceptable and that hemophiliacs suffered and died as a result of these conditions, the United States has failed to respond to calls for an investigation, or even to acknowledge the victims at all.[384]

The American system discourages this story from being told,[385] and even worse, it protects those who callously bled donors from high-risk populations and who, knowing the danger of infection to the recipients, distributed and sold the blood products anyway.

Most of the victims of tainted blood are looking for something much more important than money: they want recognition and retribution, and the United States has refused even to encourage the blood industry to supply this acknowledgement.[386] In the heartbreaking words of one hemophiliac attempting to join a class action suit: "I don't give a shit about the compensation. What are the chances of putting these criminals in jail? I'll give you everything I've got. I'll sell my house, I'll sell my business—just *get* those sonofabitches!"[387] Unfortunately, the bloody, dirty, sad truth is that this victim, like so many others, will probably never prevail.

Sophia Chase[*]

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[383] Conk, *supra* note 291, at 1090 ("[T]he freedom from liability ... retarded the research, development, and implementation of pasteurizing techniques for blood derivatives.").

[384] Telephone Interview with Kelly Duda, *supra* note 22.

[385] *See* Feldman, *supra* note 43, at 674–75 (2000) (discussing multiple failed attempts by the hemophiliac community to attract attention to their plight in the United States and the complete disinterest of the American media).

[386] *See id.* at 651. Compared to the French and Japanese governments, "the United States has been the least accepting of the plethora of demands for recompense." *Id.*

[387] *See* STARR, *supra* note 6, at 342.

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