NECESSARY FILMS

Presents

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BAD BLOOD
A Cautionary Tale

Short Synopsis

What if your life-saving medicine contained deadly viruses – and the drug manufacturers, the government, and your own doctors knew but failed to warn you?

Through the eyes of survivors and family members, BAD BLOOD chronicles how a "miracle" treatment for hemophilia became an agent of death for 10,000 Americans. Faced with evidence that pharmaceutical companies and government regulators knew the product was contaminated with deadly viruses from the 1960s through the early 1990s, they launched a powerful and inspiring fight to right the system that failed them and to make it safer for all.

Longer Synopsis

Hemophilia is a rare genetic blood clotting disorder, most often passed from mother to son, resulting in severe crippling and often death. But in the 1960s, Factor concentrates, a revolutionary new treatment derived from human blood, was processed, bottled, and offered for sale by drug companies, to be injected by the patient's themselves at home. The medicine transformed hemophilia from a fatal disease to a chronic condition and the patients were now able to lead nearly normal lives. This "miracle" product was considered so beneficial that it was approved by the FDA despite known risks of viral contamination, including the near-certainty of infection with hepatitis -- and despite the fact that the process by which it was made, the pooling of blood from thousands of donors, was otherwise outlawed. Because of its manufacturing process, each dose of Factor concentrate was made by pooling 60,000 individual blood donations, opening these vulnerable patients to an enormous contamination risk. At the time, pharmaceutical companies, government regulators, and even doctors considered hepatitis an "acceptable risk" for these patients. The patients themselves were rarely warned.

In the early 1980s, a deadly, unknown virus began to affect homosexual, urban men – and quickly spread to the hemophilia community, raising concern that the virus was in the nation's blood supply. Yet even as HIV was identified, hemophiliacs dependent on multiple doses of Factor concentrate were advised by their doctors and advocacy group to keep using them. By the time the medication was pulled from the market in 1985, 10,000 hemophiliacs had been infected with HIV, and 15,000 with hepatitis C; causing the worst medical disaster in U.S. history.

In the aftermath, dire questions remained. How could this have happened? What would prevent something like this from happening again – both for hemophilia medications or for any FDA-approved medication?

As the hemophilia community realized the extent to which the government had been lax in overseeing pharmaceutical companies, and the extent to which the safety of patients figured last in the equation of costs, benefits, and profits, they began to fight back. Patients and families demanded more stringent regulation of industry by the government and spurred government reform over the safety of the U.S. blood supply. Today this small community stands as the guardians of the nation's blood supply.

BAD BLOOD, a feature-length documentary film, recounts this cautionary tale from the perspective of six families affected by this tragedy and the doctors, nurses, and scientists who cared for them. Challenging viewers to their own vigilance, BAD BLOOD humanizes this under-reported medical disaster, stimulating further and much-needed public debate about the government's role and effectiveness in regulating the pharmaceutical industry today.

Marilyn Ness
Director/Producer/Writer

Marilyn Ness is a two-time Emmy Award-winning documentary producer. She founded Necessary Films in 2005, directing short films for non-profits and developing documentaries including *Bad Blood* and *GENOME: The Future Is Now.* Prior to that, Ness spent four years as a producer for director Ric Burns, collaborating on four award-winning PBS films: *Ansel Adams; The Center of the World*; *Andy Warhol*; and *Eugene O'Neil*. Ness's other credits include films for TLC, Court TV, and National Geographic, as well as films for the PBS series *American Experience* and the theatrical feature *The Life and Times of Hank Greenberg*. She lives in New York City with her husband and two sons.

# # #

Director's Statement

In 1999, Matthew Kleiner, a childhood friend, suggested that I make a film about how he and 70% of the hemophiliacs in the U.S. had been infected with HIV, and 100% with hepatitis, from the FDA-approved medication on which they were dependent.

As I spoke with Matt I came to understand what he had long understood. This was not just the story of the greatest medical disaster in U.S. history – one that would cost 10,000 lives – but a cautionary tale that has continued to play out in news stories about Vioxx and more recently, Avandia, drugs whose dangers come to light long after they've been marketed to consumers.

And so began a ten-year journey to craft a film that sought to alert people to the ongoing issues this crisis raised: Was the FDA too closely aligned to the pharmaceutical industry to effectively regulate medicines? Was the argument that pharmaceutical companies needed to be profitable in order to research and develop new treatments sufficient to justify the ways in which they made (and continue to make) cost-cutting decisions affecting patient safety – particularly when patients have no alternative treatment?

Matt's story also offers a new and important lens through which to view the HIV/AIDS crisis. Entirely dependent on medicine derived from donated human blood, hemophiliacs are the canaries in our public health system: their safety is our safety. Failure to adequately patrol the collection and processing of blood had dire consequences in the 1980s and 1990s. The blood supply is today free of both HIV and hepatitis, but how prepared are we to identify and stop the next source of infection?

In the course of making the film I built relationships within the hemophilia community, gaining access to new investigative findings, rarely seen footage and photographs, and eventually, secured the participation of government regulators and pharmaceutical companies. Some of them are speaking publicly for the first time because they, too, see BAD BLOOD as the seminal documentary covering this crisis.

The film builds on my experience in both social issue and historical documentary film. I made a conscious choice to use the historical record including news footage, actual memos, and personal photographs – not recreations – so the facts speak for themselves and reminds audiences that tragedy of this magnitude can unknowingly unfold right before our eyes. Emerging from tragedy, I hope, is a story of caution and inspiration, as victims of medical disaster fight to change the systems that failed them.

FACT SHEET

Hemophilia & Bleeding Disorders

- Hemophilia occurs in 1 in 5,000 live male births**.** There are approximately 20,000 hemophiliacs in the U.S. and more than 400,000 worldwide. (source: National Hemophilia Foundation)
- In the 1980s, nearly 90% of Americans with severe hemophilia were infected with HIV from contaminated blood products; more than 50% have since died. It is estimated nearly 70% of the total hemophilia population was infected with HIV. (source: National Hemophilia Foundation; Centers for Disease Control, MMWR, 1987b)
- It is estimated 90% of hemophiliacs infected with HIV were also infected with hepatitis C (HCV). It is further estimated that as of 1999, 75% of individuals with bleeding disorders over the age of 12 had chronic HCV infection. (source: National Hemophilia Foundation)

HIV & Hepatitis C Prevalence in the General Population

- The CDC estimates there were approximately 12,000 blood transfusion-associated HIV cases between 1978 and 1984. (source: Centers for Disease Control, MMWR, 1987a)
- The latest estimates indicate HIV prevalence— the total number of persons with HIV in the United States — is roughly 1 million persons. Approximately one in five people living with HIV are unaware of their infections. (source: Centers for Disease Control & Prevention website)
- An estimated 3.2 million persons in the United States have chronic hepatitis C virus (HCV). Infection with blood transfusion accounts for 10 percent of those cases. With the introduction of testing in 1992, risk of HCV transmission from blood transfusion has become negligible. Most people do not know they are infected because they do not look or feel sick. (source: Centers for Disease Control & Prevention; National Hemophilia Foundation)

Blood & Plasma Usage Today

- It is estimated more than 30 million blood components are transfused each year in the United States. (American Assn of Blood Banks).
- Plasma products ($12 billion industry) are used to treat a wide range of disorders and conditions, including: hemophilia and von Willebrand disease; alpha-1 antitrypsin deficiency, a genetic disorder affecting 1 in 2,500 Americans that causes life-threatening lung and/or liver disease; autoimmune diseases, such as Guillain-Barre syndrome, myasthenia gravis and Graves' disease; multiple sclerosis; shock; severe burns; organ transplants, particularly bone, kidney and liver transplants; immune deficiencies, either inherited or those that result from long-term chemotherapy, such as leukemia and other cancers; and during surgery. (Plasma Protein Therapeutic Association)

  Intravenous immune globulin (IVIG) is another blood component used to treat an estimated 35,000 Americans with immune deficiencies. It can also help restore movement to some people with paralyzing neurological conditions and is being tested for the treatment of Alzheimer's disease. ("Is Money Tainting the Plasma Supply?" *New York Times.* December 5, 2009.)
- To satisfy demand for plasma-based medicines, the industry has increased the number of donor paid collection centers to 408, from 299 in 2005. (Plasma Protein Therapeutics Association, the industry trade group.) Paid donations in the United States rose to 18.8 million in 2008 from 10.4

million in 2005. For the plasma industry, growth has averaged 8 percent a year over the last two decades. ("Is Money Tainting the Plasma Supply?" *New York Times*. December 5, 2009.)

Hemophilia Therapy Manufacturers

- During the period chronicled in BAD BLOOD there were four U.S. companies producing Factor concentrate: **Hyland / Baxter**, **Cutter Laboratories, Armour Pharmaceuticals,** and **Alpha Therapeutics**. Virtually all of these companies were acquired and no longer retain the same name.

- Plasma products companies have been consolidating and since 1990 have reduced the number of independent companies worldwide from 13 to 5. They include: **Baxter International** (also currently manufactures H1N1 vaccine); **CSL Behring** (acquired Armour from Revlon); **Talecris Biotherapeutics***; **Grifols** (acquired certain assets from Alpha); and **Octapharma**.

  ***Cerberus**, a private equity firm, acquired what is now **Talecris**, from **Bayer** in 2005, taking over just the plasma portion of the Bayer business. An initial public stock offering in 2009 raised $1.1 billion for Talecris and Cerberus.

- Technological advances in the treatment of hemophilia resulted in the development of recombinant products. Recombinant DNA technology uses virtually no human plasma in its production of Factor therapies. The companies producing non-plasma based therapies today include: **Bayer** (during the period chronicled in BAD BLOOD the plasma therapeutics division of Bayer was called Cutter)**, Pfizer** (recently acquired **Wyeth**), and **NovoNordisk**.

# # #

Brief Timeline of Events

1818: First known successful human to human blood transfusion

1940: Dr. Charles Drew determines how to separate plasma from whole blood. It is used as an alternative to whole blood transfusion

1941: Dr. Edwin J. Cohn separates or fractionates plasma into its component proteins

1965: Dr. Judith Graham Pool discovers cryoprecipitate, a residue that remains after blood plasma has been frozen and thawed. With a high-concentration of blood clotting proteins, it is offered to hemophilia patients as a more effective therapy than plasma.

1966: The first commercially produced Factor VIII concentrate, derived from cryoprecipitate, is approved by the FDA and available for patient use.

1981: First AIDS case is documented. CDC investigation into a new infectious disease commences.

1982: AIDS reported in three hemophiliacs. The CDC theorizes AIDS is being transmitted through blood.

1983: Hyland Baxter obtains FDA approval for the first heat-treated Factor concentrate.

1984: The human immune deficiency virus, or HIV, is identified as the cause of AIDS.

1985: AIDS test is commercially available.

1985: The FDA contacts the U.S. Factor manufacturers and tells them to voluntarily withdraw all non-heated Factor products remaining on the market. Some companies export remaining products overseas. "2 Paths of Bayer Drug in 80's: Riskier One Steered Overseas" *New York Times*, May 22, 2003.

1985: Ryan White, a hemophiliac who contracted HIV from tainted Factor, is banned from attending school and quickly becomes the national poster child for AIDS.

1987: The Ray boys return to school having been banned for their HIV-infection contracted from hemophilia medications. A week later the Ray home is burned by arsonists.

1989: The hepatitis C virus identified. (Previously known as non-A non-B hepatitis.)

1992: A hepatitis C test is routinely used to test for HCV in blood and blood products virtually eliminating hepatitis C from blood and blood products.

1993: The first class action lawsuit is filed on behalf of hemophiliacs against the manufacturers of Factor concentrate. The class is eventually de-certified and families must pursue individual litigation against the companies.

1993: In response to concerns voiced by the hemophilia community, Senators Kennedy, Graham, and Goss request Secretary of Health and Human Services, Donna Shalala, open an investigation into the events leading to the contamination of the U.S. blood supply and hemophilia blood products with HIV. Secretary Shalala requests the Institute of Medicine convene a committee to study the transmission of HIV through the blood supply.

1993: The FDA took court action against the American Red Cross in response to safety violations. The Justice Department consent decree allows the FDA to administer fines for non-compliance.

1995: The Institute of Medicine issues its report stating, "The problems the Committee found indicated a failure of leadership and inadequate institutional decision-making processes."

1995: The Ricky Ray Relief Act offering compensation to each affected hemophiliac passes Congress but remains unfunded.

1997: The four U.S. Factor manufacturers agree to settle and pay each infected hemophiliac $100,000.

1998: Ricky Ray Hemophilia Relief Fund Act of 1998 is funded and each infected hemophiliac is paid an additional $100,000 by the U.S. government.

2003: Litigation filed on behalf of all hepatitis C (HCV) infected individuals within the U.S. and all HIV/HCV infected individuals worldwide. This class action lawsuit is still pending as of this time.

2003: The Justice Department consent decree against the American Red Cross was renewed. In 2008 $1.7 million in fines were levied against the Red Cross. The consent decree remains in effect as of this time.

2010: At the encouragement of 17 U.S. Senators and Gay Men's Health Crisis, the FDA is currently reviewing the policy that prohibits men having sex with men from donating blood indefinitely.

# # #

Current Relevant Issues

- The **U.S. Food and Drug Administration** (FDA) has 10,000 employees to regulate a full 25% of America's gross national product. Their total funding amounts to $8 per American per year. **Alliance for a Stronger FDA** has issued a statement in response to the recommended 2010 federal budget proposal for the FDA seeking an increase for the agency. The group lists seven former FDA commissioners and many of the largest and most influential consumer, food, and pharmaceutical trade groups among its 180 members.
  Zajac, Andrew. "FDA Budget Draws Cries of 'Not Enough'." Los Angeles Times. February 11, 2010.

- In 2006 **Avandia**, the type-2 Diabetes drug, was one of the biggest-selling drugs in the world. Then a 2007 cardiology study showed Avandia might cause increase risk of heart attack and heart failure and sales of the drug plummeted. A panel of independent experts recommended the drug remain on the market and in response, the FDA voted to accept that advice. A 2009 Congressional inquiry criticized GlaxoSmithKline, the drug's maker, for failing to warn patients Avandia was potentially deadly. Most recently an internal FDA report written in 2008 surfaced in which two FDA officials recommended Avandia be withdrawn from market because of the increased risk of heart events and the availability of a safer alternative drug. The report claims about 500 heart attacks and 300 cases of heart failure would be averted each month if Avandia was no longer prescribed. 304 deaths were linked to Avandia in the third quarter of 2009 alone. The FDA has convened another independent panel to review the evidence in the summer of 2010. As of March, 2010 Avandia remains on the market. Harris, Gardiner. "Research Ties Diabetes Drug to Heart Woes." *New York Times. February 19, 2010*.

  In 2010, 17 Senators and Gay Men's Health Crisis approached FDA Commissioner Hamburg about re-evaluating the lifetime ban of men who have sex with men from donating blood. The bleeding disorders community is encouraging the FDA to "consult the science" as they determine how to proceed. Decisions are expected to be handed down in Summer, 2010 and both the GMHC and bleeding disorders groups are actively participating in discussions. UPI: Ban on gay men's blood donations reviewed. April 5, 2010.

- Concerns continue to be raised about the **purchase of plasma** from towns on the U.S. Mexican border. In 2007, Octapharma, which does not collect on the border, threatened to quit the plasma trade association, saying in a letter to the association that the border collections "compromised the fundamental ethics of our business." But the other companies defended the practice and the matter was dropped. Pollack Andrew. "Is Money Tainting the Plasma Supply?" *New York Times.* December 5, 2009.

- For 15 years, the **American Red Cross** has been under a federal court order to improve the way it collects and processes blood. Yet, despite $21 million in fines since 2003, and repeated promises to follow procedures intended to ensure the safety of the nation's blood supply, the Red Cross continues to fall short. This situation prompted a first-ever visit in 2008 from the FDA commissioner warning the Red Cross it could face criminal charges for non-compliance. Strom, Stephanie. "Problems Persist With Red Cross Blood Services." *New York Times*. July 17, 2008. As of 2010, the Red Cross remained under the Justice Department consent decree for non-compliance.

- **Litigation** is still pending for United States blood product users infected with hepatitis C before 1992 though not co-infected with HIV. (People who received HIV settlements in the 1990s were precluded from suing for Hepatitis C infection). In addition, the international HIV/hepatitis C infection cases are still pending. (http://www.hemophilia-litigation.com/)

- The number of plasma product companies has declined from 13 in 1990 to 5 today. The industry "operates as a tight oligopoly, with a high level of information sharing," the **Federal Trade Commission** said in a 2009 lawsuit that broke up a planned $3.1 billion acquisition of Talecris by CSL. The FTC dropped its suit when the deal was abandoned in June but a dozen hospitals have filed class-action suits charging that industry collusion has driven up prices of plasma products. Pollack Andrew. "Is Money Tainting the Plasma Supply?" *New York Times.* December 5, 2009.

# # #

CREW BIOS

Marian Sears Hunter
Editor

Marian Sears Hunter has been editing films for theatrical, festival, and broadcast release for over thirty years. Her body of work includes the Academy Award nominated film *Promises to Keep;* the theatrically-released *The Life and Times of Hank Greenberg* which garnered 21 film critic awards; and a number of films for the Emmy-award winning PBS series *American Masters* and *Great Performances*. Other credits include *Slavery and the Making of America, School, Harlem in Montmarte,* and *Zora Neale Hurston*, among many others.

Sheila Curran Bernard
Writer

Sheila Curran Bernard is an Emmy and Peabody Award-winning filmmaker and the author of the best-selling *Documentary Storytelling* (Focal Press). She has written or consulted on numerous documentary projects, including the PBS series *I'll Make Me a World,* the Imax film *Wired to Win,* and programs for HBO and Lifetime. A former fellow at the MacDowell Colony and the Virginia Center for the Creative Arts, Bernard is on the faculty of the University at Albany, SUNY, where she is Associate Director of the Documentary Studies Program and a Media Fellow at the New York State Writers Institute.

David Ford
Director of Photography

David Ford is an accomplished Director of Photography whose work on documentary films, narrative features, and commercials has appeared on PBS, HBO, national cable outlets, and film festivals nationwide. His credits include Emmy Award winning documentaries by director Ric Burns (Eugene O'Neill; New York: A Documentary Film) and Florentine Films' Divided Highways. In addition David recently became a partner in Gotham Creative & Gotham Digital directing & producing multi-camera HD shoots. He is a successful signed Producer/Director with Image Bank, the largest stock footage supplier in the world.

Joel Goodman
Composer

Acclaimed by The Hollywood Reporter as an "Indie Composer to Watch," Joel Goodman is a multi-talented, award-winning composer and co-founder of MusicBox. His original composition credits include work on Oscar and Emmy Award winning films, including "Sister Rose's Passion" (2005 Academy Award Nomination); "The Collector of Bedford Street" (2004 Academy Award Nomination) and "Children Underground" (2002 Academy Award Nomination) for such producers as HBO, Disney, GreeneStreet Films, Good Machine, Anonymous Content, TriggerStreet Films, Double A Films, Maysles Films, PBS, Hybrid Films, Working Pictures and Cypress Films.

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CAST BIOS

Characters Available for Comment

Bruce Evatt, MD
Bruce Evatt, MD began his career as a hematologist treating patients with hemophilia. In 1976 he transferred to the Hematology Division of the Centers for Disease Control. He received the first call to the CDC reporting a patient with hemophilia had died of pneumocystis carinii pneumonia – the rare syndrome affecting, until that point, only gay men -- and understood almost immediately the repercussions for the hemophilia community. From that point forward, Bruce Evatt was on the frontlines trying to slow the spread of AIDS among hemophiliacs. He spearheaded the experiments to prove heat would kill HIV in Factor concentrates that ultimately ended the AIDS epidemic among hemophiliacs. Now retired, Evatt continues to lecture around the country warning, "This will happen again."

Jenny Kleiner
Jenny Kleiner is the wife of Mathew Kleiner (see below). Widowed in 2003, she is raising their triplets, Samuel, Megan and Abigail, now seven years old, in Westport, CT. She has been profiled in *Parents Magazine* for her courage following the tragic loss of her husband. In the article she is quoted, "My 31-year old husband died just eight weeks after becoming a father but he gave our family enough love to last a lifetime."

Dana Kuhn, PhD
Dana Kuhn, PhD is a minister and holds a PhD in clinical psychology. Suffering from mild hemophilia he was not diagnosed with the disease until he was 17 years old. In March, 1983 he suffered a broken ankle during a basketball game and received his first-ever infusion of Factor concentrate which was contaminated with hepatitis C and HIV. Dana unknowingly passed HIV onto his wife Patty and within three years she died of AIDS-related pneumonia leaving Dana to care for their two young children. By the 1990s Dana became a leading activist in the hemophilia community seeking restitution for the community's injuries and reforming the system that failed them. He was the first patient advocate to serve on the Health and Human Services Blood Safety Advisory Committee. Today he is the Founder and President of Patient Services, Inc., a non-profit organization that helps patients with catastrophic chronic illness find and finance adequate health coverage. Kuhn underwent grueling interferon treatment to clear his hepatitis C by 1996. He is still living with HIV/AIDS. He resides in Virginia with his second wife, Jan, and his twin "HIV-free" babies.

Robert Massie, Jr.
Rev. Robert Massie, Jr., author, Episcopal priest, political candidate, and former anti-apartheid activist, was born with hemophilia in 1956. In the process of learning to deal with his disease, his parents, both writers, began to study its history, including the information on the most famous hemophiliac, the Tsarevich Alexis, son of Nicholas II, the last tsar of Russia. Their experience led to Robert Massie Sr.'s book *Nicholas and Alexandra*. The Massie's also documented their son's early trials in their jointly-written book *Journey.* Though he was infected with HIV by Factor concentrates, Massie did not develop any symptoms of HIV or AIDS and has been the subject of various studies of asymptomatic carriers of HIV. He ran for the post of Lt. Governor of Massachusetts in 1994, becoming the first HIV-positive Democratic candidate by winning a statewide primary. He had to step down from his position as Executive Director of Ceres, a non-profit concerned with global climate change, due to health problems stemming from his contraction of hepatitis C years earlier. In July, 2009 he had a successful liver transplant in a rare "domino procedure". (A woman with an enzyme disorder received a new liver and then donated her liver to Massie, who could produce the enzyme in his other organs.) He is now cured of hemophilia. He currently resides in Boston with his wife Ann and three children.

Terry MacNeill
Terry MacNeill is the mother of Brian and Shawn, both severe hemophiliacs. Brian spent 300 days in the hospital before his third birthday due to the complications of hemophilia. Both boys were infected with HIV during the 1980s AIDS crisis. Shawn passed away from AIDS-related illness in 1996. Brian is married and currently lives in Boston with his wife and son. In 1998 Terry MacNeill became the Co-Vice President of COTT, the Committee of Ten Thousand, named for the number of men believed to be infected with HIV by Factor. She was active in the passage of the Ricky Ray legislation that awarded $100,000 to each HIV-infected hemophiliac. She currently resides in the Boston area with her husband, her son Brian, his wife, and their child.

Mary Lou Murphy
Mary Lou Murphy is the mother of Matt and Leo Murphy, lost just one year apart to AIDS-related illness. Her son Matt was an early founding member of COTT; her other son Leo, was the co-founder of COTTWEST. Murphy is the longest serving COTT board member and active in the passage of the Ricky Ray legislation that awarded $100,000 to each HIV-infected hemophiliac. Both her daughter and granddaughter are hemophilia carriers. Murphy currently resides in the Boston area.

Glenn Pierce, MD
Glenn Pierce, MD PhD has seen the HIV/hemophilia tragedy from every perspective. Born with hemophilia in 1955 he spent the first years of his life enduring the crippling disability and prolonged hospitalizations of hemophilia. With the arrival of Factor concentrate in the 1960s he was able to shed his wheelchair for crutches, his crutches for braces, and ultimately walk on his own. He was infected with HIV in 1982 while earning his medical degree and went on to earn his PhD researching coagulation disorders. Always active in the National Hemophilia Foundation at the local chapter level, in 1992 he became President of the organization during a tumultuous period, just as the full scope of the HIV tragedy was coming to light. He assumed a second term as President in 2000 and helped restore trust in the national organization. Throughout the 1990s he served on the Health and Human Services Blood Safety Advisory Committee. He served as Scientific Head of U.S. Research for Bayer Pharmaceuticals (Bayer had acquired Cutter, one of the early manufacturers of Factor concentrate) working in their hemophilia division. In 2009 he left Bayer and is making boardroom decisions developing new hemophilia therapies as Chief Medical Officer and Vice President of the Hemophilia business at Biogen. In 2002, suffering from the ill-effects of hepatitis C, he received a liver transplant curing him of hemophilia. He commutes between Boston and San Diego where he lives with his wife Bea.

Donna Shaw
Donna Shaw was a business reporter for the *Philadelphia Inquirer* from 1993 through 1999. She worked the Business beat focusing on the pharmaceutical industry in particular. In 1993 she came across a small story on the AP wire describing a lawsuit that had been brought by hemophiliacs against the blood products industry. She spent the next four years covering the story for the paper. Her research took her back more than a half-century delving through medical journals, army archives from WWI, WWII, and the Korean war to try to piece together what led up to the largest medically-induced disaster of the 20th Century. She continued to cover the tech/pharma beat writing a series on the diet drug Fen Phen that was ultimately pulled off the market due to health risks. Today Donna Shaw teaches journalism at The College of New Jersey including a course about how business and politics impact science. She is currently writing a book about the HIV/hemophilia tragedy.

Eric Weinberg
Eric Weinberg, JD was approached in 1991 by a woman whose hemophilic husband had died of AIDS and unknowingly infected her with HIV. Weinberg had some experience handling FDA-licensed products that had injured people and agreed to investigate whether she had a case against the companies whose products infected her husband with HIV. Upon filing the first lawsuit more hemophiliacs became aware of the potential to litigate and Weinberg was referred other clients throughout the tri-state area, including Mathew Kleiner. Cases nationwide joined in a class action suit

and Weinberg developed the case around the companies' failure to implement viral inactivation. Inspired by their courage in the face of HIV infection Weinberg explains, "I felt like this was what I went to law school for, this was the case. So for better or worse, you know, I took it on and just kept going." It took ten years before the litigation settled. "What we've learned in these several years, in hundreds of depositions, in millions of pages of documents, proves the case without question. But it took too long." He has since gone on to litigate the Vioxx and Baycol injury cases. He resides in Hyland Park, NJ with his wife and two sons.

ADDITIONAL CHARACTERS IN THE FILM

Regina Butler, RN
Regina Butler, RN has been nursing families with hemophilia since 1973. Given the intensity of treatment required for hemophilia, the relationship between families and medical caregivers quickly grew intimate. Her hemophilia clinic located at the Children's Hospital of Philadelphia was one of the few to offer families an alternative to the contaminated Factor medication in the midst of the AIDS crisis. As a result, her clinic had a 20% rate of HIV infection rather than the 70% experienced nationwide. Still, her heartbreak is palpable when she explains, "We went to funeral after funeral after funeral of children who we knew for their whole lives. Who we cared about tremendously. And who we felt so helpless to protect from their ultimate demise. It was very very very painful."

David Castaldi
David Castaldi was the President of Hyland/Baxter from 1977 through 1987. During his administration a German company developed a safer, virus-free medication for hemophilia. Within three years, Hyland Baxter released a comparably safe product in the U.S. despite two decades of insistence it was not technologically feasible. It was that technology that ultimately ended the AIDS epidemic among hemophiliacs. Castaldi left the plasma industry in 1987 well before litigation revealed the troubling manufacturing practices and business decisions that resulted in the infection of 10,000 hemophiliacs with HIV and 15,000 with hepatitis.

Shelby Dietrich, MD
Shelby Dietrich, MD began her career as a pediatrician transferring to hemophilia care in 1957. She remembers those early years were not a happy time "marked by death, bleeding, terrible catastrophic problems, overwhelming blood loss, and occasionally screaming children." One of the few women in her field, she pioneered the use of physical therapy and counseling revolutionizing modern hemophilia treatment. As AIDS decimated her patient community she stuck by her patients becoming an expert in both hemophilia and AIDS management. Now in her 80s and retired, Shelby reflects on the enormous burden she carries having lost far too many of her boys. "I suppose the only lesson I can think of is that we should really be honest…even communicating one's unknowns and fears is better than not communicating at all."

John Finlayson, PhD
John Finlayson, PhD is a 50-year veteran in the regulation of biologics, specifically blood products. He began in 1958 when his division was housed at the National Institutes of Health and then moved under the auspices of the FDA in 1972. While Dr. Finlayson's regulatory responsibilities included oversight of blood products not used in the treatment of hemophilia, Dr. Finlayson worked cheek by jowl with Dr. David Aronson, lead regulator for Factors 8 and 9, since their start together in 1958.

Mathew Kleiner
Born in 1971, Mathew Kleiner was diagnosed with hemophilia when he was three years old. Diligently taking his Factor concentrates to manage the bleeding episodes of hemophilia, at 10-years old he was infected with HIV and hepatitis C by those very medications. Mathew Kleiner became a vocal safe sex advocate appearing on MTV, HBO, and in the New York Times during the 1990s at a time when hostility towards people with HIV was pronounced. In 2003, Kleiner, husband to Jenny, recent father to

8-week old triplets, and an assistant district attorney in New York City, died from liver failure as a result of HIV and hepatitis C complications. Kleiner grew up in Brooklyn with director/producer Marilyn Ness and approached her in 1999 to make a film about hemophilia in the age of AIDS. This film is dedicated to the memory of Mathew Kleiner.

Sidney Kleiner
Father of Mathew Kleiner currently residing in Queens, NY with his wife Suzanne.

Suzanne Kleiner
Mother of Mathew Kleiner. While hemophilia, a sex-linked genetic disorder, can be caused by a spontaneous genetic mutation it is generally passed by a mother to one or more of her sons. In the case of the Kleiner's, Suzanne passed the disease onto her older son, Mathew, but not her younger son, Daniel. The Kleiner's were not aware hemophilia ran in their family until an older cousin was diagnosed and doctors recommended all related males be tested. Suzanne currently resides in Queens, NY with her husband Sidney.

Susan Resnik, DrPH
Susan Resnik, DrPH served as the Director of Education for the National Hemophilia Foundation from 1982 to 1983. She was sitting at her desk at the Foundation when Executive Director, Alan Brownstein, came out of his office to say Dr. Bruce Evatt of the CDC had called explaining three hemophiliacs had come down with AIDS. What began as her doctoral thesis was soon published as *Blood Saga: Hemophilia, AIDS, and the Survival of Community* (Univ. of California Press, 1999), which is recognized as the seminal book on the history of the American hemophilia community. Dr. Resnik taught doctor/patient communication at the University of California, San Diego Medical School and founded *Viewing Voices*, an oral history documentation company.

MINOR CHARACTERS

Ryan White
Ryan White was an American teenager from Kokomo, Indiana who became a national poster child for HIV/AIDS in the United States after being expelled from school because of his infection. A hemophiliac, he was infected with HIV by contaminated Factor products and, when diagnosed in 1984, was given six months to live. Though doctors said he posed no risk to other students, AIDS was poorly understood at the time, and when White tried to return to school, many parents and teachers in Kokomo rallied against his attendance. A lengthy legal battle with the school system ensued, and media coverage of the struggle made White into a national celebrity and spokesman for AIDS research and public education. Surprising his doctors, White lived five years longer than predicted and died in April 1990, shortly before he would have completed high school.

Ricky Ray

Ricky, Robert, and Randy Ray were three hemophiliac brothers who were diagnosed with HIV in 1986. They were the subject of a federal court battle against the De Soto County School Board to allow the children to attend public school despite their diagnosis. Although the Rays were victorious in their legal battle, the Ray home was burned down a week after the 1987 decision, forcing the family to leave Arcadia. Ricky Ray died in 1992 at age 15. Robert was 22 when AIDS claimed him in 2000. Randy Ray lives in Orlando, Florida, and manages his HIV through medication. In 1998, Congress passed the Ricky Ray Hemophilia Relief Fund Act, paying restitution to those hemophilia patients who contracted HIV from July 1, 1982 to December 31, 1987.

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NECESSARY FILMS

Marilyn Ness is a two-time Emmy Award winning documentary film producer with over fifteen years of experience. After years of producing films for high-profile, big-budget companies and less well-known, smaller budget productions, Marilyn opened her own production company, Necessary Films, in 2005. Necessary Films accepts commissions from non-profits, foundations, and educational institutions and develops original programming for television and theatrical release including *BAD BLOOD* and *GENOME: The Future Is Now* (currently in production).

Necessary Films' debut production, *Changing Lives*, explores the journey of two teens using writing to rise above the stigma of growing up in foster care. (Produced for Youth Communication.) Finding the delicate balance between protecting our national security and protecting our civil liberties in the midst of the war on terror is at the heart of *Stop the Abuse of Power* (produced for the ACLU). Shortly after we completed *Setting the Stage*, a fundraising film for the Kaufman Center, a non-profit music and theater arts community organization in New York City. *The Holleys: An American History* offers a rare look at five generations of Americans – from the earliest days of the American Revolution through the Steel Age in America – and the impact one family can have on the growth of a nation. She has been commissioned to complete a 50th Anniversary film for the World Federation of Hemophilia in 2012.