

PEN



inside

- 3 As I See It: The Hemophilia Archive
- 4 Inhibitor Insights: Inhibitor Products
- 5 Transitions: Living Abroad with Peace of Mind
- 6 Richard's Review: Hemophilia and AIDS in Film

Bad Blood, Good Movie?

Laurie Kelley and Paul Clement

A Viewer's Guide: New Documentary about Hemophilia HIV History

A new film about hemophilia during the HIV crisis of the 1980s has energized our community. *Bad Blood* documents events that caused the mass contamination of factor products. Community advocates cheer the movie's release and hope it will bring more attention to the hemophilia community—for funds, for continued blood safety, and for preserving memories of our fallen heroes.

But will *Bad Blood* needlessly raise fears about plasma-derived products? Most Americans with hemophilia use recombinant products, and most don't fully understand the difference between product safety and purity. Many of us aren't aware of the complex production of products, or the fact that *all* US products are now considered safe.

Use of plasma-derived products is on the rise as a treatment for inhibitors—and parents are worried. Now, along comes a film that taps into a parent's deepest fear: what am I injecting into my child? Will this new documentary reinforce that fear, preventing parents from making good product choices?

Flashback

It was November 2008, the opening event of National Hemophilia Foundation's annual meeting in Denver. The audience of hemophilia families and hemophilia chapter representatives filed into a large, festive room decorated with red and blue balloons. Seating sections were marked with state names, just like a national political convention. An empty stage awaited Val Bias, new CEO of NHF.

With President Obama just elected, it seemed that NHF was ready to celebrate, too.



FOR 10,000 AMERICANS
A MIRACLE TREATMENT BECAME
THEIR DEATH SENTENCE.

THE WORST
MEDICAL DISASTER
IN U.S. HISTORY

Bad Blood

A CAUTIONARY TALE A FILM BY MARILYN NESS

A NECESSARY FILMS PRODUCTION EDITED BY MARIAN SEARS HUNTELL
CINEMATOGRAPHY BY DAVID FORD MUSIC BY JOEL GOODMAN & DAVID BRAMELTI
WRITTEN BY SHEILA CORRAN BERNARD & MARILYN NESS PRODUCED & DIRECTED BY MARILYN NESS

www.BadBloodDocumentary.com

welcome



Laurie Kelley

My company was founded in 1990, at the height of lawsuits and tension over the HIV contamination scandal, to serve primarily the non-HIV hemophilia community. I made no apologies for that in 1990: I represented the new generation of young parents who were being ignored by the community then. I did not live with HIV and hepatitis C, and I barely knew how to live with hemophilia, let alone coinfections. I was in the dark about how to care for my child with hemophilia, and I spent all my time trying to write my first book about hemophilia, to help other young families like mine.

And I was shocked by the backlash from the HIV-infected segment of our community. I clearly recall the 1992 NHF annual meeting in Atlanta: the anger and hostility threatened to tear our community in two. But at that meeting, I met for the first time people infected with HIV, heard their powerful stories, and got to know them as people. They were, and remain, my heroes. Thanks to them, my son Tommy, now 23, lives free from worry about viruses. He infuses at will, he is healthy, and he leads a normal life.

LA Kelley Communications still focuses primarily on the non-HIV community. But thanks to the new film *Bad Blood*,

I am grateful to be reminded of how lucky I am. Marilyn Ness's *Bad Blood* is a compelling documentary that chronicles the suffering when no factor existed, the relief and freedom when factor was developed, and the horror when factor became contaminated with deadly viruses. The film is a gut-wrenching rollercoaster ride that everyone in the community must see.

As with all important work, you should think critically—not just react emotionally. That's hard to do when suffering is involved, especially when you can only be thankful that your own child escaped the cruel fate of HIV. But for the future of blood safety, and to make the best treatment decisions for our children now, we all must think analytically while not forgetting the past. I hope PEN can help, with this special edition that offers a review and critique of the movie. What are the film's strengths? What does it get wrong? Overall, we give it a thumbs-up and applaud Ness for her concern for our special community, for documenting our tragic past, and for immortalizing our brave heroes. ☺

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inbox

Test Your Knowledge!

THE QUIZ [PEN, AUGUST 2001] WAS A GREAT IDEA. I FOUND out there are lots of things I didn't know about hemophilia. Because our son has mild hemophilia, he hasn't had to have as much treatment as those with a more severe type. In some ways, this makes it difficult because we are less knowledgeable as a result. I always enjoy reading PEN. Thanks for your efforts.

*Sandra Bolar
Arizona*

I LOVED THE QUIZ! I WAS CURIOUS TO LEARN WHAT MY 15-year-old knew about his bleeding disorder. I made him take the quiz and he did great!

*Sheryl Bennett
Pennsylvania*

I TRULY ENJOYED THE LAST ISSUE OF PEN, ESPECIALLY THE quiz. I must say, I did fairly well!

*Tracie Jordan
New York*

»» page 17

as i see it



Barry Haarde

Honoring Our Unique Past: The Hemophilia Archive

“Who was Ryan White?” “What is HFA?” “Who’s Corey Dubin?”

These are just a few of the questions I’ve heard recently from adult members of the bleeding disorder community. And parents of children newly diagnosed with hemophilia have asked, “Why are factor concentrates so expensive?” or “I’ve heard that many people contracted HIV and hepatitis from factor products and later died—are today’s medications safe?”

I’ve noticed a tendency in our community to insulate young people with hemophilia and their parents from the older generation—the HIV generation, like me. Perhaps this is because our experiences were so vastly different from those of the younger generation, many of whom have never experienced a joint bleed, an aspiration, or a joint replacement surgery.

This generation gap is often unintentionally widened by the painful and often divisive events that occurred in our community in the 1980s and 1990s, the details of which require sensitivity and discretion when we present them to new parents and young people. In fact, I believe that historical material relating to the AIDS era should never be presented to children until they become teenagers, as the events are too difficult and upsetting. And new parents need time to adjust to the realities of raising a child with hemophilia; they should not be immediately confronted with our community’s past: this can be too much to absorb and may increase new parents’ worries.

Still, I began to consider that we in the hemophilia community are not doing all we can to preserve our history and

pass it on to future generations. Enter the Hemophilia Archive.

My mother, Emily, was something of a packrat. She saved every bit of information our family ever received about hemophilia, dating back to 1960. This archive contains over 100 newspaper clippings relating to hemophilia, the advent of factor concentrates, research and patient profiles, and the AIDS era. Also in the archive are dozens of National Hemophilia Foundation (NHF) and local chapter mailings dating from the mid-1960s.

After leafing through Emily’s collection, which had been reposing undisturbed in a closet for more than 15 years, it occurred to me that this material provides a complete visual and written history of where we have been as a community, and what we have accomplished over the past 50 years. We have indeed come a long way: from research in the 1960s on peanuts and birth-control pills as hemophilia treatments, to recombinant factor concentrates made in a bioreactor. But though we have gained much, we have also lost much. We have mourned the loss of so many along the way to arrive where we are today.

So to preserve and pass on our history to future generations, I began distributing an informal e-newsletter containing scanned images of the archival documents accompanied by brief descriptions that provide useful historical context. As the project has grown, community members across the country have shipped archival items to me for the collection. I’m accepting this type of material from those who want to donate what they have.

» page 18



Inhibitor Products: When You Have No Choice

The new documentary *Bad Blood* graphically recounts what happened in the 1980s when no viral safety measures were in place to protect blood products for hemophilia: thousands of people died. The film may stir concerns about using blood-derived products even now. Though all products are declared safe by the US FDA, most Americans with hemophilia use recombinant factor. The exceptions? People with von Willebrand disease (VWD) or with inhibitors. And currently, patients with VWD have no choice: the only available products are plasma-derived.

Patients with high-responding inhibitors with acute bleeding have a choice—sort of. Two products are available to stop acute bleeds: NovoSeven®RT, a recombinant factor VIIa product made by Novo Nordisk, and FEIBA®VH, a plasma-derived product made by Baxter. Both are *bypassing agents*, designed to skip the need for—bypass—the missing clotting factor.

If most non-inhibitor hemophilia patients use recombinant factor, why haven't most inhibitor patients switched to NovoSeven? Because neither FEIBA nor NovoSeven works for all patients, or even all the time for the same patient—an interesting and perplexing challenge for physicians who treat inhibitor patients.

Product Profiles

Let's look at the characteristics of each product.

FEIBA

FEIBA is usually used for patients with factor VIII deficiency who have developed an inhibitor to factor VIII (although some patients with inhibitors to factor IX also use it). FEIBA contains

activated clotting factors II (prothrombin), VII, IX, and X and factor VIII antigen. It carries two main risks:

Anamnesis is the immune system's memory of foreign substances it has previously encountered. This memory allows the immune system to respond rapidly if exposed to the foreign substance again. With high-responding inhibitors, the factor VIII antigen in FEIBA can cause anamnesis, which raises the inhibitor titer. The factor IX in FEIBA can also cause anamnesis in hemophilia B patients. FEIBA produces anamnesis in about 20% of patients with hemophilia A and inhibitors, and in most hemophilia B patients with inhibitors.

Disseminated intravascular coagulation (DIC) is dangerous: unwanted clotting occurs throughout the body. The risk of DIC is tied to FEIBA's dosing, which must be closely monitored and should not exceed 100 units per kilogram of body weight (U/kg) at 12-hour intervals, or 200 U/kg per day. More frequent or higher dosing may increase the risk of DIC. Normally, the risk of DIC is very low but may increase with crush injuries or blunt trauma, or following surgery, blood infection, and severe liver disease.



NovoSeven RT

Because NovoSeven contains no clotting factors other than recombinant factor VIIa, there is no risk of an anamnestic response to factor VIII or IX. NovoSeven is the product of choice for people with factor IX inhibitors who have allergic reactions to factor IX. And because NovoSeven operates mainly at the site of the injury, it's thought to be even less likely than FEIBA to cause DIC.

But NovoSeven has a very short *half-life* (the time it takes for half of the infused clotting factor activity to be used up by the body) of just over two hours. The half-life of FEIBA is about 12 hours. If your child needs repeated infusions—and most do—this will probably disrupt daily routines.



FEIBA or NovoSeven?

The key concern with inhibitors is to stop a bleed, and to use whichever product works. Though both NovoSeven and FEIBA effectively stop bleeds for most people, patients may have individual reasons for choosing one product over another:

Potential reactions. If a patient has hemophilia A and experiences anamnesis when exposed to the factor VIII antigen in FEIBA, or if he has hemophilia B and experiences anamnesis or suffers severe allergic reactions when exposed to the factor IX in FEIBA, he will need to use NovoSeven.



Kevin Correa

Living Abroad with Peace of Mind

Many young adults jump at the opportunity to live or study abroad. But making a seamless transition from home to overseas requires advance planning.

Preparing to move abroad with hemophilia isn't much different—it just takes a bit more leg work. You'll face the same questions you'd have to answer if you were moving to a new town: Where's the nearest hospital? Where am I going to get my factor?

Not in Kansas Anymore

One of your first steps in planning to live outside the US: find out if there is a hemophilia treatment center (HTC) where you'll be living. The World Federation of Hemophilia (WFH) maintains a database of contact information on its website for hemophilia organizations and HTCs in 118 countries.

If your destination has an HTC, contact it. The staff can tell you whether factor is widely available in the country, if prophylaxis is offered, and where to seek emergency treatment if you'll be far from the HTC.

If there isn't an HTC where you will be living, the US Department of State is a good place to start your research: the website www.state.gov lists contact information for US embassies and consulates, which can provide information on local hospitals and physicians. Also visit the Centers for Disease Control and Prevention website at www.cdc.gov. There you will find pertinent information, including required and recommended vaccinations for the country you'll be visiting.

Before leaving, learn as much as possible about treatment options where

you're headed. Telephone the US consulate or embassy and ask lots of questions: Is there a hematologist? A 24-hour hospital? Is the local facility an outpatient clinic or a trauma center?

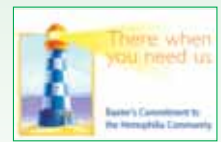
Getting answers will take time, and locating adequate treatment facilities is just the beginning. Equally important is ensuring that you have factor available when you need it.

Red Tape

Figuring out how to obtain factor overseas can be complicated. If you won't have access to factor through a local HTC in your host country, you'll need to make other arrangements. Patrick Sullivan, who has hemophilia, spent three years in Grenada while earning a veterinary degree. "I wasn't able to have factor shipped directly to me," he says. "So the factor was shipped to my mother, who then shipped it to me."

As Patrick learned, this method wasn't always perfect: "When my mother expedited the shipping, the factor got to Grenada quickly, but sometimes it sat in a customs' warehouse for several days." Having factor available is essential, so familiarize yourself with local drug regulations by contacting the US embassy or consulate. A travel letter from your doctor, written in the local language, describing your medical condition and medications required for treatment is a must, and can help mitigate customs delays.

As another option, Patrick also brought factor back to Grenada with him after visiting home. "I brought a three months' supply of factor," he says. "Even with fees for additional baggage, it was still cheaper than the shipping costs."



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Worst-Case Scenario

In Grenada, Patrick had access to local hospitals, but he wisely made contingency plans in case he needed treatment for a serious incident like a head injury: "If something went wrong, I planned to fly to Barbados or Puerto Rico, where I could seek treatment at more advanced medical facilities."

Though most clinics can adequately treat you for common ailments like the flu or dehydration, you should be ready for more serious circumstances. If not at an HTC, where will you seek treatment, and how will you get there? And just as significant: How will you pay for your transportation and treatment in an emergency?

The State Department's website advises, "Obtaining medical treatment and hospital care abroad can be expensive, and medical evacuation to the U.S. can cost more than \$50,000." Though you may not require transport back to the States, you could still face exorbitant bills for emergency treatment.

Review your medical insurance coverage to determine if it's valid in your host country—many won't be, or will require additional riders. If your current policy won't cover you, several companies offer insurance coverage for overseas emergency services including medical evacuation. But many will not cover pre-existing conditions such as hemophilia. Visit the State Department's website for a partial list.

Another crucial question: How will I let people know I have hemophilia if I'm

»» page 19

richard's review

Richard J. Atwood



Hemophilia and AIDS in Film

A short review cannot begin to describe the emotional impact of these movies about hemophilia and AIDS. Every viewer will need a full box of tissues. Gut-wrenching, based on real people, each film reinforces the need for our vigilance over blood-borne diseases.

The Doe Boy

2001, Wellspring
87 minutes, not rated

Filed in Tahlequah, Oklahoma, this coming-of-age movie is based on the experience of the film's writer/director. In 1984 Oklahoma, half-Cherokee teen Hunter Kirk has hemophilia. His father is frustrated by the financial burdens and the hunting limitations imposed by Hunter's disorder. Hunter's Cherokee mother, a nurse, is both caring and overprotective. Because hemophilia is considered a "white man's disease," Hunter is an outsider in a culture obsessed with blood identity. He must seek his own path to freedom and independence, apart from his parents, while discovering love and friendship.

Writer/director: Randy Redroad

Cast: James Duval, Kevin Anderson, Jeri Arredondo, Judy Herrera

Awards: Sundance/NHK International Filmmaker's Award; American Indian Film Festival Best Film, Best Director, Best Actor (James Duval), Best Actress (Jeri Arredondo), Best Supporting Actress (Judy Herrera)



Forever and Ever (Dei gau tin cheung)

2001, Universe
(Cantonese with English subtitles)
96 minutes, not rated

This reality-based drama, set in Hong Kong, portrays a mother's love and support for her young adult son, Xiao Fu, who has hemophilia and wants to be a writer. Xiao Fu contracts HIV from a contaminated blood transfusion, and must come to terms with his own death from AIDS. Xiao Fu overcomes challenges to find inspiration for the greatest work of his brief career, and his mother continues his mission after his death.

Writer/director: Raymond To

Cast: Sylvia Chang, Chris Lee Pui Shing, Josie Ho

Awards: Hong Kong Film Award for Best Actress (Sylvia Chang); Golden Bauhinia for Best Actress (Sylvia Chang), Best Supporting Actress (Josie Ho)



The Ryan White Story

1989, Landsburg Company
105 minutes, not rated

This television drama is the true story of young Ryan White, with hemophilia, who was diagnosed with AIDS at age 13. In his struggles to stay enrolled in school in Indiana, Ryan became a public figure—a role he did not want, but one that he used to increase AIDS awareness. His friends included celebrities such as Elton John and Michael Jackson. First televised a year before Ryan's death, this film is currently unavailable. Based on the book *Ryan White: My Own Story* by Ryan White and Ann Marie Cunningham (Dial Books, 1991).

Writers: Phil Penningroth and John Herzfeld

Director: John Herzfeld

Cast: Lukas Haas, Judith Light, Sarah Jessica Parker; Ryan White plays a supporting role as a friend with hemophilia and AIDS



Go Toward the Light

1988, Crown Media
93 minutes, not rated

Based on a real family in California, this made-for-TV drama focuses on the struggles of dealing with an overwhelming medical condition. In 1984, eight-year-old Ben Madison, eldest of three brothers with hemophilia, was diagnosed with AIDS. He was denied enrollment in public school, and suffered prolonged hospital stays. His parents endured long separations, health problems, staggering medical bills, and depression. Realizing that he was dying, Ben followed the bright light. Ben's mother speaks her inner feelings in voiceover throughout the film. Based on the book *Go Toward the Light* by Chris Oylar with Laurie Beckland and Beth Polson (Harper & Row, 1988).

Writers: Susan Nanus and Beth Polson

Director: Mike Robe

Cast: Richard Thomas, Linda Hamilton, Piper Laurie

Awards: Emmy award nomination



Bad Blood, Good Movie? ... from cover

But then, without warning, the lights went out. People hushed. Two screens on either side of the stage lit up, and a movie trailer was unveiled.

The music was somber, haunting. The scenes were disturbing: Technicians poured gallons of plasma into vats. Scruffy-looking men donated plasma. Young children were tethered to bleak hospital beds by IVs dripping cryoprecipitate. People with hemophilia unknowingly injected themselves with contaminated factor.

The festive mood of the opening ceremony vaporized.

The six-minute trailer caused a huge stir. A small group of older patients enthusiastically applauded. But other attendees were perplexed, and some pharmaceutical reps were angered. What was the point of showing the dramatic film trailer? Wasn't the community past all this by now? Some worried: Had something new happened to the blood supply? Or would the documentary promoted by the trailer shed new light on this devastating tragedy?

The feature-length documentary *Bad Blood* premiered on July 28, 2010, in New York City for a select group of people in the hemophilia community. Now, NHF is encouraging chapters to show the film to its members. But is this documentary appropriate and educational? Or is it the shocker that the trailer led us to expect? Should you see it?

In short, yes. You should see *Bad Blood*. It's a powerful and remarkable movie. More than just documenting the human immunodeficiency virus (HIV) contamination of the 1980s, the film also portrays the birth of advocacy in the hemophilia community. But before you watch the film, read our analysis. We hope to prepare you with a balanced look at the documentary, and present some key points to help you better understand the history of factor product development and blood safety today.

From A Friendship, A Promise

The origins of *Bad Blood* are personal. This film wasn't made because of a sudden, new threat to the nation's blood supply. Nor because of new evidence



Promise to a friend: *Bad Blood* director Marilyn Ness

about contamination during the late 1970s and early 1980s. Originally, this was a documentary by award-winning filmmaker Marilyn Ness, who wanted to tell the story of a friend who contracted HIV. But Ness's film eventually developed into much, much more.

"The project started in 1999," Ness recalls. "when my friend Matthew Kleiner, who had hemophilia, told me how he became HIV positive. It blew me away. He told me how [HIV-infected factor products] had happened, and we both knew, the full scope had not yet been understood."

But, explains Ness, "in 2000 many people couldn't speak to me, as litigation was still ongoing. I had to stop the project."

A class action lawsuit had been filed against pharmaceutical manufacturers on behalf of the estimated 10,000 patients with hemophilia infected by contaminated factor concentrates. Following the lawsuit's settlement, the film's scope grew. "People were desperate to talk to me," Marilyn reveals. "I picked up the project again later in 2006. I knew this story was relevant even beyond the bleeding disorder community—there was a lot to learn about FDA [US Food and Drug Administration] reform; how do you weigh safety against profit?"

Guide to the Players and Plot

Bad Blood portrays one of the most extraordinary stories in medical history.

Strange symptoms afflicting primarily gay men in the early 1980s led researchers to discover a new virus that slowly destroys the body's immune system, allowing opportunistic infections to flourish. The virus was also noted in certain other populations: drug users; Haitians living in the US; and people with hemophilia.

Why people with hemophilia? By the late 1970s, factor was being made from increasingly larger pools of plasma, each containing 10,000 to 60,000 donations. It took only one donation of plasma containing HIV to contaminate the entire pool, consequently contaminating each "lot" of factor concentrate produced from that pool. As a result of infusing this contaminated factor, about half of the estimated 20,000 people with hemophilia in the US became infected with HIV, and even more with hepatitis C.

The epidemic exposed deadly flaws in the US plasma collection system. As Americans began to realize that this virus had contaminated the nation's blood supply, government reaction was tragically slow, despite urgent warnings from the US Centers for Disease Control (CDC). Many believe that because the victims were members of the "4-H club"—heroin users, homosexuals, hemophiliacs and Haitians—they commanded little attention and sympathy from the media and the government. And even NHF recommended that patients continue using factor concentrates.

Matt Kleiner is the unfortunate star of *Bad Blood*. The cast also features the FDA and CDC, and the four manufacturers of clotting factor concentrates in the early 1980s: Bayer (Miles/Cutter Laboratories), Baxter (Hyland Laboratories), Armour Pharmaceuticals, and Alpha Therapeutic. Also appearing are national hemophilia organizations like NHF and Committee of Ten Thousand (COTT). And the supporting cast? The blood donors and the people with hemophilia.

The film attempts to capture the perspectives of all these players. "This was a cautionary tale for *all* drug companies, patients, and FDA interactions," Ness stresses. "It's an emotional and impactful story. It's about how all these people felt betrayed—by science, by technology, by those they trusted—all

the way around. There hadn't really been a film about this tragic story that put into context the lives they lived before AIDS emerged, especially now with twenty years' hindsight."

How to portray an era in which blame dominated, lawsuits were launched, and thousands of young men died? Could a filmmaker touch on so many sensitive subjects fairly, given that her close friend had died, and not leave an audience of new families with hemophilia scared to use their factor products? Jan Bult, president of Plasma Protein Therapeutic Association (PPTA), which represents manufacturers of plasma protein therapies, viewed the trailer at the 2008 meeting and wondered what the full-length film would be like. He recalls, "I feared *Bad Blood* wouldn't be balanced, and that it would create a fear factor for young parents who depend on these life therapies."

For Mature Audiences Only

The trailer set the tone for the documentary's release, provoking concerns that the film would not be balanced. Some worried that Ness would use docudrama techniques like those used by director Michael Moore in *Fahrenheit 9/11*, which might scare patients away from plasma-derived products. The trailer had the plasma products industry on pins and needles.

"I think people were unprepared for the powerful images and narrative presented in the initial trailer," remarks Chris Healey, vice president, Government and Public Affairs at Grifols, a manufacturer of plasma-derived factor. "The 2008 NHF annual meeting in Denver was an exciting time, full of hope and energy. When the film trailer was shown at the opening session with little warning or context for the audience, it seemed as though that energy and excitement left the room."

And Ness stresses, "The trailer was never intended for this [NHF] forum." She explains, "I'm usually present, someone from Blood Safety¹ is usually present; it's carefully handled. Showing it to

an auditorium full of people without the Q&A following was not intended. When the response was negative in some quarters, I was disappointed. It was scary for some. But people did respond to it and it helped me raise money for the film."

Two people who responded were Shari and Stephen Bender of New York, whose daughter Rose has hemophilia. "Stephen and I were moved by the trailer," recalls Shari. "It was so powerful that we both decided to help fundraise to make [the movie] happen. The tragedy of the HIV crisis fortunately did not affect us—but we need to remember the past, remain vigilant, and demand a safer blood system." She notes, "Many HIV remembrance events are not well attended. As president of the New York City Hemophilia Chapter, I think many new parents are forgetting the past, and they need to know."

Kendra Baker is a young mother of two sons with hemophilia. Both Wyatt and Gavin were born many years after the HIV contamination. Despite her sons' good health, Baker lost five relatives with hemophilia to HIV. The question of blood product safety weighs on her now: Wyatt has an inhibitor, and recently her HTC suggested trying a plasma-derived product for Immune Tolerance Induction (ITI), to lower the inhibitor. "I'm concerned about switching to plasma products, because I know my family's history," says Baker. "I know that plasma products are safer

now; other people say they use them every day and they work. But I asked my hematologist, who I love and trust, 'Can you guarantee me five years from now we will not have problems?' She said that while we know more now than then, she still can't guarantee anything," Baker notes, "That's the same story we heard back then. I just am not comfortable using plasma-derived."

Baker would gain no comfort from the first 47 seconds of *Bad Blood*, which aims for shock value, as the audience hears or sees these words: *hemophilia holocaust, lawsuit, lawyers, tainted blood, pharmaceutical industry*. The film begins with a lawyer—who specializes in suing pharmaceutical companies—blaming pharma for putting profits above safety. With an opening like this, community members, especially those new to hemophilia, need some guidance. Ideally, viewers could avoid unnecessary fears when they see *Bad Blood* if informed and experienced blood industry experts are available. "I don't think families living with a bleeding disorder who are unaware of this history are prepared to see this [film] without some conversation beforehand," says Mark Zatyorka, who contracted HIV and hepatitis C from a transfusion to treat his hemophilia, and who is a founder of the Connecticut Hemophilia Society. "It's important that some discussion happen before showing the film, and it's important to have follow-up afterwards. You can expect there will be lots of questions."

Shari Bender, president of New York City Hemophilia Chapter, with daughter Rose, who has hemophilia: "We need to remember the past, remain vigilant, and demand a safer blood system"



Bender family

1. The Advisory Committee on Blood Safety and Availability of the US Department of Health and Human Services (HHS).



Chris Healey, Grifols: "My respect for the survivors and victims has only grown as a result of the film"

In any case, before you see *Bad Blood*, you should know what the film gets right, and what it omits.

What the Film Got Right

Bad Blood is a powerful testimony to the suffering of people with hemophilia. Rare archival footage accurately portrays life for them in the 1950s and 1960s, before factor concentrates: patients receiving plasma or cryoprecipitate; hemophilic children walking in their backyards or being admitted to the hospital. Parents of young children today will be emotionally touched by the scenes of suffering and frequent hospital stays of children with hemophilia. This glimpse into history paves the way for us to understand the intense gratitude of families and physicians for the advent of clotting factor concentrates, which ended much pain, reduced long hospital stays, and made life more normal.

Ness gives us an excellent overview of hemophilia: what it is, how it's transmitted, how untreated bleeding eventually cripples. Accurate diagrams and animated graphics enhance the information. *Bad Blood* also reviews the history of treatment: from nothing at all to whole blood, from fresh frozen plasma to cryo, and eventually to factor concen-

trates. The outstanding historical review is complete with photos and testimonials from patients today who recall the pain they endured as a result of ineffective treatments.

We learn how factor products were made in the 1970s: how blood plasma was collected, pooled and processed. At first, factor seems a miracle product, but the film exposes the reality. By today's standards, this early era of blood processing can look grim and even unsanitary. Images of impoverished or sickly-looking people donating plasma remind us of government and industry's low standards for plasma collection thirty years ago.

Bad Blood accurately portrays how poor oversight of the plasma collection industry set the stage for widespread viral contamination. The medical community and government already knew that hepatitis was in clotting factor. But everyone—government, physicians, patients, industry—tolerated it, because they considered these viral infections largely benign, and they believed that a greatly increased quality of life outweighed the risk of viral infection. The stage was set for disaster.

Overall, the film is a detailed timeline of one of the worst medical disasters in history. It's told through photos, and through the narratives of several people involved: physicians Dr. Shelby Dietrich and Dr. Bruce Evatt; patients Bob Massie, Matt Kleiner, and Glenn Pierce; journalist Donna Shaw; lawyer Eric Weinberg; and a single pharmaceutical representative, David Castaldi, president of Baxter/Hyland from 1977 to 1987. Ness adeptly weaves the timeline with many personal stories and perspectives. *Bad Blood* is heart-wrenching, sad, impressive, and educational.

And it's backed by a plethora of documents, collected from the pharmaceutical companies, FDA and NHF, chronicling the impending disaster. These documents reveal that some companies engaged in cover-ups and scandalous practices—including one that shipped product overseas, knowing it was likely contaminated, when the company could no longer sell it in the US.

Ness considers her film a balanced portrayal of viewpoints. "It was a challenge," she says. "My goal was to let each person tell the story from their perspective. We struggled hard and long



Once the mainstay of US hemophilia treatment, cryo and fresh frozen plasma risked transmitting blood-borne disease



Never again: Hemophilia community supports the Ricky Ray Act in 1993

with who to include... But I believe having someone from the drug companies, and the caregivers, and the FDA, and the families allows people a firsthand glimpse into how a crisis unfolds. I think we fairly portrayed everyone's point of view."

What the Film Missed

Ness believes she did her homework well, noting, "We needed three sources for every statement of fact in the film." Renowned physician Dr. Bruce Evatt of the CDC, who was one of the first to sound the alarm that HIV was spreading through the blood supply, reviewed the film for accuracy.

But the film is not without bias and several omissions. The AIDS epidemic is presented mostly from the viewpoint of people with hemophilia who have HIV or who lost loved ones, and not from the viewpoint of pharmaceutical companies, scientists, or the FDA. The context in which decisions were made regarding hepatitis, HIV, and product treatments is incomplete. For example, the film offers no explanation of the

difficulties of developing a heat-treatment viral inactivation process for factor concentrates, and later, a solvent-detergent treatment. And when these topics are mentioned, around 50 minutes into the film, the FDA is cast as inept, and the drug companies as profit-driven, heartless villains.

Ness admits that no pharmaceutical company representative would consent to be interviewed, save Castaldi. Yet Bult, who represents the plasma product producers, was interviewed—and then cut from the film. Bult described various measures in place today that provide greater product safety—film footage that could allay

fears of new parents. But Ness laments that in an 82-minute film, she had to choose "only the most salient issues for the lay audience to comprehend."

Given its length, *Bad Blood* is a stunning compilation of the history of hemophilia treatment and the unfolding of the HIV crisis. Yet it interprets 30-year-old, complex events in 20/20 hindsight, creating a black-and-white, simplistic story.

We've identified three key areas where viewers need a deeper understanding to supplement what is shown in the film:

1. How the American political climate impacted the FDA and other federal health agencies at the beginning of the AIDS crisis.
2. Basic science about viruses and viral inactivation methods, and the timeline of events, including efforts by pharmaceutical companies.
3. Advances in the safety of plasma-derived products since the 1980s.

1. How Politics Impacted the US and FDA

First, let's look at the political climate surrounding the AIDS era. In 1981, newly elected President Ronald Reagan vowed to reduce the size of government and decrease government oversight of private industry. Subsequent cuts resulted in the loss of almost 10% of the FDA's workforce of 7,500 employees in 1981. The day after Reagan took office, the FDA commissioner was fired. Over the next few years, the directors of the CDC and National Institutes of Health (NIH), and the Assistant Secretary for Health and Human Services (HHS) all changed, often with substantial intervals before a new appointee.

By cutting budgets and personnel, the Reagan administration crippled the enforcement power of the FDA and other health agencies. Many FDA initiatives to inform consumers about the ingredients and side effects of drugs were stopped cold. FDA regulatory inspections dropped by 88%. At the beginning of the AIDS epidemic around 1982, the FDA was short-handed, demoralized, and in disarray, which greatly compromised its ability to react to the emerging health crisis.

At the same time, the religious right and newly minted "moral majority," both significant constituents of Reagan's electorate, used HIV infection to rally against homosexuals. AIDS conspiracy theories abounded, and AIDS hysteria engulfed the country. *Bad Blood* skillfully portrays the discrimination and hatred experienced by the families of Ricky Ray and Ryan White.

2. Heat Treatment: Not So Simple

Bad Blood might make you wonder, why didn't companies implement plasma safety procedures earlier? But the science isn't so simple. The film implies that a heat treatment to kill hepatitis could have been implemented as early as 1980. In hindsight, this could have saved lives by preventing infection with yet-to-be discovered HIV. But companies didn't implement this safety method for many reasons



Mark Zatyryka, person with hemophilia:
 “You can expect there will be
 lots of questions”

beyond just profit margin concerns.

Since the 1940s, medical science has known that blood products can transmit hepatitis, a liver disease. By the 1970s, two types of hepatitis had been identified: hepatitis A (HAV) and hepatitis B (HBV). Mandatory testing was initiated in 1971 to screen plasma donors for HBV. A test for HAV became available in 1978. By the late 1970s, it was apparent that factor concentrates were also infected with another, yet unknown virus, then called non-A, non-B hepatitis; it slowly attacked the liver, often with no early symptoms. The virus was finally identified in 1989 and named hepatitis C (HCV).

Heat treatment had been used for decades to inactivate hepatitis viruses in blood products such as albumin. But early experiments with heat treating factor concentrates in the mid-1970s

were disappointing—the factor was destroyed along with the viruses. In *Bad Blood*, Dr. Evatt remarks that heat treatment was “simple in the end.” But the development of a heat-treatment process for factor VIII was far from simple. In fact, it would become a difficult challenge: the large, very fragile factor VIII protein is easily destroyed by heat. Time-consuming, expensive research involved testing dozens of variables, one at a time, and injecting the product into chimpanzees to see if they developed signs of liver disease.

Research into heat treatment of factor concentrates was a low priority in the late 1970s. Infection with hepatitis rarely resulted in serious disease. Patients and hematologists believed that treating people with hemophilia rapidly and more effectively at home, which improved quality of life, more than offset the risk of hepatitis. And at the time, no one knew that HCV was in the factor—and would eventually become a killer. Hematologists also argued that heat treatment could cause an immune response in patients, resulting in higher incidence of inhibitors, which did occur with two European products a decade later.

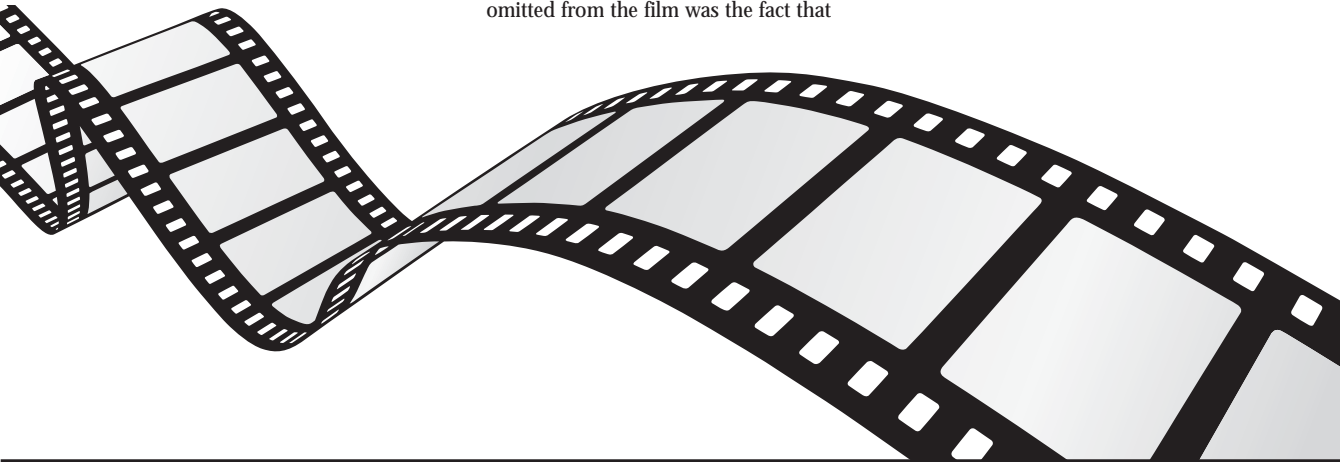
Research picked up pace in 1980 after scientists working for the small German company Behringwerke published a report suggesting that their heat treatment removed the risk of HBV. Contrary to statements in *Bad Blood*, the Behringwerke report did *not* prove previous US and European drug company experiments wrong. Nor was the German product hepatitis free—it still transmitted HAV and HCV. Also omitted from the film was the fact that

the Behringwerke process resulted in a loss of 75% to over 90% of the factor, and the product cost ten times as much as unheated product.

Perhaps the key point overlooked in *Bad Blood* is that implementing any heat-treatment process in 1980 would have required doubling the size of the plasma collection industry, retooling production facilities, and relicensing products—impossible in a short time. If these changes had been implemented, perhaps as many as 90% of people with hemophilia would have been unable to purchase clotting factor concentrate or cryoprecipitate, leaving them with no treatment at all.

By 1980, cryo was no longer available as a backup for the vast majority of people with hemophilia. In *Bad Blood*, Dr. Dietrich notes that trying to return to cryo would have been impossible: the American Red Cross had lost the workforce and infrastructure needed to process large volumes of cryo, and blood centers were unwilling or unable to process the huge amount of plasma needed.

Unlike the film’s portrayal of hematologists at the January 1983 CDC meeting, most hematologists did “get it.” They knew that people with hemophilia were between a rock and a hard place. The film also never mentions that the FDA was expediting approval of virally inactivated clotting factor concentrates: the Baxter heat-treated product was approved in just eight months instead of the typical three to six years, and debuted in March 1983.



3. Where the Film Left Off: Improved Blood Safety

Viewers of *Bad Blood* will be less fearful if they know what has happened since the 1980s to improve blood safety. Ness addressed this after the movie premiere on July 28, with a panel discussion that included NHF CEO Val Bias, PPTA's Jan Bult, and the president of Gay Men's Health Crisis. "Someone asked what's changed and what's different now," recalls Mark Zatyorka, "and Jan made clear how industry has changed and what additional safeguards exist now. It was very courageous for him to be there."

Bult says, "Matt Kleiner's family was at the premiere. After the movie, Matt's father came to me and said, 'Thank you for coming; it made us feel good to see what changes have been made.'"

Bult continues, "*Bad Blood* accurately depicts the tragic events that occurred in the hemophilia community in the 1980s." But, he adds, "Not noted in the film is the safety record of current therapies; there have been no viral transmissions for decades. The movie provides no information on the number of safety and quality initiatives that have been put in place since that time."

And what initiatives have been taken since that time? Hemophilia patients became activists, and forever changed the way blood and blood products are processed and approved in this country—for all citizens. Patient activists like Glenn Pierce, Dana Kuhn, Corey Dubin, and Val Bias were directly responsible for the restructuring of FDA's Blood Products Advisory Committee² and the establishment of a consumer position as one of the committee's 17 voting members. The hemophilia community was also instrumental in establishing the Advisory Committee on Blood Safety and Availability (ACBSA) in 1997, part of HHS. The committee has 20 members, including at least one consumer member—usually from the hemophilia community.

Industry also took initiatives. Pharmaceutical manufacturers listened to

consumers and developed recombinant products, which most US hemophilia patients now use, eliminating the use of blood plasma. Pharmaceutical manufacturers also implemented extensive safety measures in collecting and producing plasma products. Gone are the days when plasma was collected from prisoners or people with high-risk behaviors. All donors today are carefully screened, and all plasma-derived products are virally inactivated. Some products even use a double-viral-inactivation procedure.

Changes in the plasma collection business implemented since the mid-1980s center on three equally important measures: (1) donor selection, (2) testing for pathogens, and (3) inactivation and removal of pathogens. Industry standards now include

- *Qualified Donor Standard.* At plasma collection centers, each donor has a physical exam and regular follow-up exams to create a comprehensive health history. The donor must return for a second donation and pass all health and blood tests again before his or her plasma can be used.
- *60-Day Inventory Hold Standard.* Source plasma is frozen and held in inventory for a minimum of 60 days. This allows any suspect donations to be retrieved and discarded before being considered for use in fractionated blood products.
- *Implementation of more sensitive viral blood tests.* One example is the Nucleic Acid Tests (NAT). Since the late 1990s, NAT has allowed contaminated donations to be detected earlier and removed from the plasma pool.

The best news of all? There has been no known transmission of HIV since 1986, and of HCV since 1989. But despite these advances, fear lingers. Baker says, "My HTC told me there hasn't been a viral transmission in over twenty years using plasma-derived...yet my heart sinks when I hear they might put Wyatt on human product.

TO *Learn* MORE

Movies & DVDs

And the Band Played On

1993, HBO, made-for-TV

Go Toward the Light

1988, made-for-TV

Plasma Safety: A Firsthand Look at our Donor Centers (DVD)

888-GRIFOLS (888-474-3657)

ps@grifols.com

Thicker than Water

2009, independent documentary

Bradley Rappa director/producer

www.thickerthanwater-movie.com

To learn more about *Bad Blood* or to purchase a copy:

www.badblooddocumentary.com

Publications & Websites

The Source

Quarterly magazine of Protein Plasma Therapeutic Association (PPTA)

COTT News

www.cott1.org

HIV and the Blood Supply: An Analysis Of Crisis Decisionmaking.

Lauren B. Leveton, Harold C. Sox, Michael A. Stoto, Institute of Medicine. Committee to Study HIV Transmission Through Blood and Blood Products.

www.nap.edu/openbook.php?record_id=4989&page=R1

The AIDS Research Program of the National Institutes of Health

www.nap.edu/catalog.php?record_id=1769

PEN February 2010

PEN August 2009

www.hemaware.org/story/plasma-derived-factor-safer-ever

2. The Blood Products Advisory Committee (BPAC) reviews and evaluates data concerning the safety, effectiveness, and appropriate use of blood, and of products derived from blood and serum or from biotechnology.



Time bomb: Blood collected at a blood bank in the 1980s

But I think if I watched the movie *Bad Blood*, I'd want to learn more about what happened. I'm not sure how I would feel about using plasma products after seeing a movie like that."

And what if Baker's hematologist orders plasma-derived products, declaring the risk of inhibitors to be greater than the risk of using plasma-derived? "In the end, I probably would use them," admits Baker. "I trust my hematologist. And I'm open to learning more about plasma products."

Today, plasma products are seen in a new light. They are a mainstay in developing countries where recombinant products are too expensive, and they're used to treat von Willebrand disease. Plasma products are also being researched as a treatment for patients with inhibitors, and even for early treatment in infants and children as a way to avoid inhibitors.

What to Take Away?

Families with hemophilia who see *Bad Blood* will take away some positive messages. Ness hopes patients will realize that they must remain active. "They cannot resume passivity," she warns. "A lot of people currently in the community's leadership were affected by HIV and hepatitis C, and were active because their lives were at stake. But who will fill their leadership role when they are gone? My hope is that people will walk away from this film and say, *'What can I do now?'*"

But the takeaways aren't all positive. One group hasn't warmed up to *Bad Blood*. "The medical community has not yet embraced the film," admits Ness. "We are telling them the community wants the film; the patient advocacy groups are saying they want the film. Medical staff want to move past this, but I hope that patients will say, 'Okay, this happened, and now I

want to talk with my doctor about what's different today.'" Ness contends, "The film is an opportunity for open and honest communication."

Zatyrka walked away with a better sense of history—and closure. "I always heard bits and pieces of the hemophilia community's history, but never saw it all put together, especially chronologically. I think the older families will appreciate the film, especially those who have lost somebody. It kind of gives closure. It's probably shocking to some newer families, but I think it's good for them to be made aware of happened."

He adds, "And I like to think that the blood in the country is safer as a result of what happened. Something positive can come out of something negative, but if the story is not told and kept alive, it could happen again."

Bult declares, "Everyone should see it. But I do believe when it is seen, it should be done where experts are available to answer questions."

Shari Bender agrees. "Absolutely, new parents should see it. Some parents will be afraid when they see the film. It might make people skeptical about their product, but it should spur them to get more information, and they will learn that the current plasma-derived products are safe. They will ask themselves, what am I giving my child? Is it safe? How can I take a more active role in my child's care?"

Bad Blood is the powerful story of a horrific medical catastrophe that should stand as a warning to anyone in government or medicine. It's also an enduring monument to the hemophilia community's heroes and victims: people like Dana Kuhn, Val Bias, and Corey Dubin, who are alive today and who have dedicated their lives to keeping millions of Americans safe. Healey affirms, "My respect, admiration, and empathy for the survivors and victims has only grown as a result of the film."

Ness herself learned a lot while making this movie. "I learned about the power of advocacy: that a tiny community, though sick and dying, could make a difference in the way this country regulates blood products. And I hope this community will once again have an impact as we consider the way this country regulates drugs. The community's spirit is inspiring." ☺

headlines

manufacturer

New Vial Size for NovoSeven® RT

The US Food and Drug Administration (FDA) has approved NovoSeven RT in an 8 mg vial size. The treatment for people with hemophilia A or B and inhibitors is now available in 1 mg, 2 mg, 5 mg, and 8 mg vials. FDA has also approved the extension of shelf-life for all vial sizes from 24 months to 36 months at room temperature (at or below 77° F). **Why this matters:** A larger dosing size offers easier dosing for heavier patients.

For info: contact your HTC

New HeliTrax

CSL Behring has launched a new version of HeliTrax, now available on an iPhone device, with superior graphics. This system is an excellent way to record bleeds and factor treatment information, allowing patients to send directly to their HTC. Available via Web interface or handheld device; fully compatible with all HTC Lab Tracker and Web Tracker databases. **Why this matters:** An easier way to log in factor usage means a better way to manage healthcare.

For info: contact your local CSL Behring sales rep or HeliTrax hotline: 800-598-6445



Tracking Bleeds with FactorTrack™

Bayer HealthCare Pharmaceuticals launched FactorTrack, the first free, customizable application (app) for iPhone, iPod touch, or iPad to help track and record factor VIII infusions. Available to the entire community, the app allows patients to customize infusion schedules, track infusions and doses, add notes, and email the information to their healthcare team. Bayer does not collect personal information from FactorTrack. **Why this matters:** This is an easier way to track vital medical and consumer information, regardless of product.

For info: www.livingwithhemophilia.com/FactorTrack



New DVD from Grifols

Plasma Safety: A Firsthand Look at our Donor Centers

To order: contact your local Grifols sales representative or 888-GRIFOLS (888-474-3657) or email Professional Services at ps@grifols.com

Fast-Acting Factor VIIa

Novo Nordisk's ultra fast-acting recombinant factor VIIa is progressing to a phase III trial after the successful completion of a phase II safety, pharmacokinetics, and efficacy trial.

Why this matters: A faster-acting NovoSeven® RT means fewer injections.

For info: www.novonordisk-us.com

Long-Acting Factor VIII in Progress

B-LONG is a recombinant factor IX:Fc fusion protein (rFIXFc) currently in clinical studies. According to findings presented by Swedish Orphan Biovitrum and Biogen Idec, B-LONG was well tolerated and demonstrated an approximately 300% increase in half-life, compared to historical half-life data available for existing factor IX products. Current prophylactic regimens for hemophilia B require twice-weekly intravenous injections, but results show that rFIXFc may reduce infusions to once weekly or less. **Why this matters:** Longer-acting factor IX means fewer infusions, good news for those on prophylaxis.

For info: www.biogenidec.com

New Resource for von Willebrand Disease Patients

Von U is a community of care committed to sharing with and caring for those touched by VWD through outreach, education, and research efforts that bring together individuals, families, and healthcare providers. The program helps encourage communication of possible symptoms to health-care providers, provides information about optimal treatment for specific VWD types, and promotes awareness of VWD and treatment options.

Why this matters: The prevalence of VWD is estimated at 1% to 2% of the US population, and most who suffer from the disorder currently remain undiagnosed.

For info: CSL Behring Consumer Affairs 888-508-6978 or consumeraffairs@cslbehring.com



manufacturer

New Delivery System for Xyntha

The US FDA approved a prefilled dual-chamber syringe for Pfizer's Xyntha recombinant factor VIII product. The syringe provides 3,000 IU of Xyntha in a total volume of 4 mL. Other dosages will be available in the dual-chamber syringe format in 2011. **Why this matters:** This new reconstitution system eliminates the transfer step previously required to mix the saline diluent and freeze-dried powder, making infusions faster.

For info: contact your HTC

New FEIBA

The US FDA has approved a next-generation version of Baxter Healthcare's FEIBA, called FEIBA NF (nanofiltered and vapor-heated). It replaces FEIBA VH (vapor-heated), which does not include the nanofiltration pathogen reduction step in its manufacturing process. **Why this matters:** A viral reduction and viral inactivation process (nanofiltration removes some viruses, and vapor-heating inactivates some viruses) reduces the risk of viral contamination.

For info: www.thereforyou.com

New Blood-Type-Free Plasma Product

Octapharma has completed clinical development of Uniplas, a new blood-group-independent, solvent-detergent-treated human pooled plasma for infusion. The product has been filed for registration in Europe and will be submitted for marketing approval in the US. **Why this matters:** Uniplas can be administered to all patients regardless of blood group, eliminating the serious consequences that can result from transfusing an incompatible plasma unit.

For info: www.octapharma.com

home care

Two Programs Put Fun into Hemophilia

Fun with Sports and Nutrition (FSN) seeks to improve the physical health of people with bleeding disorders and their families. Structured half-day, full-day, and weekend sessions focus on nutrition, introduce safe exercises, offer experiential learning, and provide take-home materials to maintain practice. Community-based mentors bolster the curriculum with personal insights, friendship development, and practical advice for everyday living.

Let the Bandana Games Begin! is an engaging and creative program for children who attend summer camp. A bandana is used as a prop for playing group games and building camaraderie.

Why these matter: Hemophilia can take a toll physically and mentally; programs like these are fun and educational.

For info: Factor Support Network
www.factorsupport.com



headlines

international

India: The Lucky Few

A survey of 3,953 people with hemophilia in India found that 99% are treated on demand with factor replacement therapy, while just 1% receive prophylaxis.

Why this matters: Patients in countries like the US are fortunate to have prophylaxis available.

Source: IBPN, August 2010

China: Lower Inhibitor Rates?

The prevalence of inhibitor antibodies in Chinese people with hemophilia A is reported to be 3.9%.

This figure is much lower than the 4.3% reported for other ethnic groups. Clinical information and blood samples from 1,435 patients were collected from six treatment centers. Of 56 patients with inhibitors, only 18 had high inhibitor titers. **Why this matters:** These results can shed light on why some people develop inhibitors and others do not.

Source: IBPN, August 2010





Unequal response. Patients may have varying responses to each product. Some need to use both products to effectively control a bleed, alternating doses between one product and the other. Alternating products in this manner should be done only under the supervision of your HTC.

Convenience. FEIBA is infused only once every 12 hours, and NovoSeven is infused every two to three hours. With FEIBA, the infusion time is 30 to 45 minutes, while NovoSeven can be infused in just a few minutes. If both products work for you, you may prefer the convenience of one over the other.

Lingering Fears?

Even when required to use a plasma-derived product, some inhibitor patients and their parents have lingering doubts about product safety. Elvira Brown is the mother of 18-year-old Miguel, who has factor X deficiency and inhibitors, and who uses a plasma-derived product now. "No one can guarantee that

plasma-derived is clean," she says, referring to the potential presence of blood-borne viruses. "I just try not to think about it."

Yet plasma-derived products are making a comeback: plasma-derived products (especially factor VIII products containing von Willebrand factor [VWF]) are being examined in clinical studies to see if their use in newly diagnosed infants can help prevent inhibitors from forming.

For people with low-responding inhibitors, hematologists can treat acute bleeds with high doses of recombinant or standard plasma-derived products to overwhelm the inhibitor. As the inhibitor tries to neutralize or inactivate the circulating factor, there just aren't enough antibodies to do the job. Only some of the factor is neutralized, while enough is left to participate in the clotting process. Factor VIII containing VWF is sometimes used for this: it's thought that the body might better "recognize" the factor VIII in its more natural form, compared to recombinant products, which contain

pure factor VIII. Some Immune Tolerance Induction (ITI) protocols also call for a plasma-derived product if the first trial using a recombinant product fails.

Despite reminders of a dark time when products were not treated to remove viruses, and regardless of which type of product you use and how you use it, work with your HTC team to control the inhibitor. The team will monitor for blood clots and DIC in the event of serious injuries, when using high FEIBA doses, or during prolonged use of FEIBA. And have a serious talk with your hematologist: share your concerns about product safety and even your frustration at lifestyle interruptions and drawn-out treatments. Having inhibitors is no picnic.

"I don't feel well informed about how our product is produced," admits Elvira. "It takes vast numbers of gallons of blood to extract the factor, and it goes through a cleaning process to remove impurities. But I don't even know where the plasma comes from."

Even with concerns about safety, it's unlikely that blood will be drawn for viral analysis when you visit your HTC. All FDA products, including plasma-derived, are considered safe. The most important thing now is that they effectively stop bleeds. "If our [plasma-derived] product is the only thing that keeps the inhibitor at bay," confirms Elvira, "then I'll use it." @

Correction

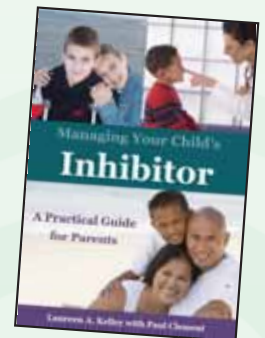
In the August issue of PEN, we inadvertently printed two incorrect letters in our answer key on page 17.

- The correct answer to question 3 is B (17,000).
- The correct answer to question 5 is B (12 hours).

In both cases, the text of the answer is correct; only the letter was incorrect. We have corrected the problem on the pdf of PEN available for download at www.kelleycom.com.

Adapted from
Managing Your Child's Inhibitor
by Lauren A. Kelley with Paul Clement.
Published by
LA Kelley
Communications, Inc.

Please see chapter 3 for more specific information on treatment with FEIBA and NovoSeven. To order *Managing Your Child's Inhibitor*, www.kelleycom.com



I GOT MOST OF THE ANSWERS CORRECT.

I did know both ibuprofen and aspirin extended clotting times, but had never heard the nuances of the differences in how these work on platelets, and how ibuprofen affects you for shorter time than aspirin. The quiz was very helpful, very detailed, and a good teaching tool for all, even those who have been through this for 30 years.

Our son is 29, with severe hemophilia. I know this is the most costly disorder, hence the need for strong advocacy on insurance issues nationally. I am embarrassed and angry to live in a nation without so much as a catastrophic health clause for those with special needs through no fault of their own, to say nothing of a nation that leaves 50 million people totally uninsured. In addition, one in seven people now live below the federal poverty line of \$22,000 for a family of four. I read every issue of PEN cover to cover. You are so comprehensive and thoughtful to all in the hemophilia community, leading us forward always without making us feel there are any stupid questions. Thanks for your teaching role. You're doing everything right through your most helpful newsletters.

Doug Anderson
New York

THANK YOU FOR THE QUIZ. HAVING

two toddlers with severe hemophilia A who recently got ports, I was a little disappointed at how much I *didn't* know! My husband and I learned a lot. About number 26: if it's true that small syringes can rupture the catheter or cause separation, why then are heparin lock syringes just 5 mL? Thanks so much for PEN. It's a great wealth of information and support for our young, growing family. We appreciate all that you do!

Becca Robbins
Arkansas

Science editor's note:

Becca, you bring up a good point. The pressure a syringe can generate with any given force depends on the *diameter* of the syringe and not on the volume, as we stated in the answer to number 26. The smaller the diameter, the greater the pressure the syringe will generate with any given force on the plunger. Small-

volume syringes also typically have a small diameter, and generate greater forces—enough to damage a catheter. But most heparin lock syringes are specially designed to reduce the force on the catheter: they are “fat,” with a diameter equal to that of a standard 10 mL syringe to reduce the risk of catheter damage. (Small-diameter heparin lock syringes are available, but are not recommended for flushing a port.)

MY SON FINN IS NINE MONTHS OLD AND

has hemophilia A, moderately severe. His diagnosis came as a shattering blow to our expectations as new parents. We live in a rural area where there are few other families who live with this disorder, and even fewer who have Internet connection or support of any kind. I rallied some of these families together and created a support group to help share practical information, concerns, and our stories of joy and grief. Another mom and I have teamed up to build a website where we can share our information and connections with more families in Maine. We have even convinced some local businesses to create red tags for their products that explain what hemophilia is, and that a dollar per sold product goes toward funding our efforts to open up our community to this disorder. Trying to constantly explain hemophilia to those who don't live with it can be exhausting emotionally, so it is a marvelous feat of community connection to have a place to normalize an otherwise crazy situation.

I share this with you because I was so happy to see the quiz in PEN. I photocopied and gave it to friends and family to help further their understanding of the disorder. This was a fantastic experience, as it opened up so many valuable conversations. I hope that you include more interactive educational pieces like this in the future.

Sarah Lou Peters
Maine

THANK YOU FOR AN EXCELLENT ISSUE

of PEN. Since I have four sons with hemophilia A, ranging in age from 32 to 11, I thought I would ace the quiz. I was surprised when I missed five! I won't miss those again!

Thanks also for the information regarding private factor donations. It was very enlightening as to the proper procedure for giving.

Kathleen George
Virginia

THE ARTICLE ON DONATING FACTOR WAS very informative and necessary for the community. As usual, you point out important topics, while others have ignored this issue as far as I know.

The test in PEN was a challenge. I didn't cheat and didn't get a very good score. Learned from it, though!

Tom Albright
Arkansas



Project SHARE



PREMROOF'S ORAL SURGERY WENT WELL, and he is healing very fast by God's grace and all your help. You have been in our thoughts and prayers. Thank you very much.

Sarojini Alva
India

TODAY WE INAUGURATED OUR FIRST comprehensive hemophilia care center with a workshop for the patients and their relatives. The need for hemophilia care is immense in this part of the country. We now have a special test laboratory under clinical hematology. The factor you sent has a large impact, and more and more patients are benefiting from it. Thank you once again for your continued support.

Joseph John, MD, DM
Clinical Hematology, Hemato-Oncology &
Bone Marrow Transplant Unit
Christian Medical College
Ludhiana, India

THANK YOU FOR THE FACTOR THAT YOU sent to me. I went out of the hospital last Wednesday and am still being infused with factor. Tomorrow morning I will have my EEG, and my third CT scan three days later. I hope that everything will be okay, with no more operations needed. Thank you very much for the help that you have given me. God bless.

*Patrick Miguelle N. Malijan
Philippines*

I FEEL MUCH BETTER NOW, AND MY joint bleeding is much lessened, compared to the past when it was almost spontaneous. With your help, I am more comfortable now physically, and even in my work. I am very glad that I found Project SHARE. We are grateful for your help.

*Marson Bocobo
Philippines*

THANK YOU VERY MUCH FOR THE HELP you provided us. Luis Carlos is recovering well, but is still having difficulty with his left elbow. We are giving him factor every week. Thank you for sending the medicine, and may God bless you.

*Gricelda González
Guatemala*



As I See It... from p. 3



Along with Hemophilia Federation of America's (HFA) *Voices* campaign and Committee of Ten Thousand's (COTT) national memorial effort, I hope the Hemophilia Archive can be used to educate and inspire our community to learn more about our unique, tragic, and unforgettable history. ☺

Barry Haarde is part of an AIDS ministry at Woodlands Church near Houston, Texas. Barry and his older brother John were born with hemophilia A, and both contracted the HIV virus from tainted blood in the 1980s. John lost his life to liver failure from hepatitis C in 2007. Barry's brother-in-law, Joseph "Pat" Grant, who also had hemophilia, died of AIDS in 1990. Barry is now overseeing development of a website that will eventually display the Hemophilia Archive for the community. To subscribe to Barry's e-newsletter, contact him at redsaleen97@yahoo.com and he'll add you to the distribution list, which is always sent blind copy to preserve the confidentiality of community members' email addresses.



Ryan White was an Indiana teenager with hemophilia who fought the school system that, because of his HIV status, sought to prohibit him from attending school. Media coverage brought celebrities like Elton John and Michel Jackson to his aid, and Ryan became a national celebrity and spokesperson for AIDS research and public awareness. See Richard's Review, page 6, for more on Ryan.



Corey Dubin is a founder of COTT, a national organization dedicated to protecting the nation's blood supply. Dubin has long been a champion of people with hemophilia and HIV, and helped obtain compensation from the pharmaceutical industry for those with HIV. He remains active today in COTT.

Our Three National Hemophilia Organizations



Committee of Ten Thousand (COTT)
www.cott1.org



Hemophilia Federation of America
www.hemophiliafed.org



National Hemophilia Foundation (NHF)
www.hemophilia.org



Become a Campaign 2011 Sponsor!

Help us celebrate our tenth anniversary by reaching 1,000 sponsorships in January 2011. We have just over 250 deserving children and adults with bleeding disorders waiting for your support. It costs only 65 cents a day!

Go to *Become a Sponsor* at www.saveonelifenet.net or call 978-352-7652.

We look forward to welcoming you to our Save One Life family. ☺

Imagine caring for your child with hemophilia—with no factor, refrigerator, running water, electricity, or transportation to a clinic.

This is the reality for thousands of families in developing countries.

For just \$20 a month, you can help an impoverished child with hemophilia.

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www.hemophiliavillage.com

Transitions... from p. 5

incapacitated? In 2009, a Norwegian student with hemophilia sought treatment for a head injury at a Danish hospital. Because of a language miscommunication, he was sent away without treatment. He died.

That's an extreme case, but it highlights the necessity of wearing medical identification tags or jewelry, and the importance of carrying an emergency information card at all times. On your card, at a minimum, include this information:

- Your name
- The fact that you have hemophilia and any other medical conditions
- Type of factor and any other medications you use
- Telephone number of your HTC
- Telephone number of a person to notify in an emergency

If you'll be living in an area where English isn't widely spoken, have this information translated into the local language.

Develop a Plan, Then Be Flexible

Well in advance of your departure, get a physical. Tell your hematologist about the kinds of activities you'll be doing abroad, and try to anticipate medical issues you might encounter. Is your ankle a target joint? Then your doctor should know if you'll be walking long distances daily.

During your visit with the HTC, ask the staff to help you develop your own checklist of items to have squared away before you leave. If you'll be studying abroad, the school can also help answer many of your questions.

It's rare for overseas trips to work out precisely as planned. Don't be surprised if a customs official requests an additional "fee" to release your factor. Don't panic if your train is two days late. Expect bumps along the road, and be ready to adapt. Living and traveling abroad can be challenging, but with sound preparation, your experience will be rewarding.

Patrick offers some final advice if you're considering living abroad: "Definitely do it! Don't let hemophilia be the deciding factor that keeps you from going." ☺

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