



Dateline Federation

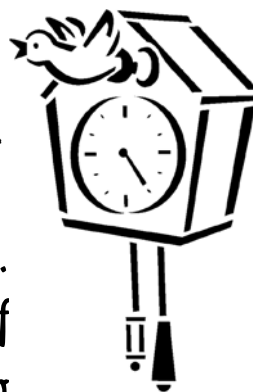
NEWSLETTER OF THE HEMOPHILIA FEDERATION OF AMERICA

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It's Time

By: Barbara Chang & Donald Akers, Jr



We have reached the New Year 2004. Everyone at the Hemophilia Federation of America is now focused on our next big event, the annual symposium. In March, we will be **CELEBRATING** our tenth year anniversary with a big splash in Las Vegas. As we have been reporting to you, the planning for this educational gathering has been going on for almost a year. So far, everything is on schedule and in place for a most exciting and rewarding time. All you have to do is consider your own situation. If you choose to get together with your blood brothers and sisters from around the country, then take the time now to register and make travel plans. We offer a program jam-packed with knowledge, camaraderie, exchange of ideas and love. Oh yes, and we also promise one more thing: **FUN**. You don't want to miss this one! If you'd like more information, please call the office 800-230-9797 or visit our updated web site www.hemophiliafed.org.

What's Your Excuse?

Born without arms, John Foppe's story has touched many hearts and his message has changed many lives. John will bring his inspirational message to the Hemophilia Federation of America at our 2004 Symposium in Las Vegas on Sunday, March 28. Born in 1970 with seven birth defects and not expected to live, Foppe not only beat the odds, but has gone on to lead a remarkable life: one that involves using his feet for everything from shaving to eating to driving a car. He travels around the world motivating others.

John has met a Pope, fired up a pro football team, skied in Austria, and climbed the steep steps of the Batu Cave, a Hindu Temple in Malaysia. He has written a book, earned a master's degree in social work, and been honored by the U.S. Jaycees as one of its Ten Outstanding Young Americans.

Foppe has spent the past 15 years as a professional speaker. Known for delivering high-impact presentations on overcoming adversity and fostering personal growth, he has spoken to businesses, schools, organizations and churches across the U. S. and internationally.

Foppe is the author of an inspirational and personal growth book, titled *What's Your Excuse? Making the Most of What You Have*, published by Thomas Nelson Publishers (\$19.99). His book will be available for purchase at Symposium.

Through sharing his heartwarming and humorous stories of overcoming adversity, John educates and encourages others. His basic message is: "Our only real handicaps are those mental and emotional ones that prevent us from participating fully in life." He says, "Most people think of a handicap as something physical like a lack of sight or mobility. Instead, I convince people that negative thoughts, cynical beliefs, and bitter emotions cripple our spirits. When you change your attitude, your life changes."

Foppe states, "I tell people my condition doesn't give me different problems. It just makes me experience the same problems everyone else has more deeply. Everybody struggles with liking themselves, getting along with others, and doing more with less. I simply tell people its OK and give them some ideas to help them cope along the way."

John doesn't allow his handicap to hold him back. His willingness to share his own struggles hits home for many audiences. "I acknowledge life is tough, and I still struggle. The tips I offer are grounded in my lived experiences of wrestling with my own problems." When people feel John's sincerity, they instinctively realize that "if John can do so much without arms, then I can do more with what I have" To hear John speak is an opportunity to be renewed and to move on with a new perspective on life. Be sure you don't miss John's inspiring message at Sunday morning's General Session. ♣

About This Publication

Dateline Federation is a publication of the Hemophilia Federation of America (HFA). It is published four times a year. The Material in Dateline is provided for your general information only. We do not give medical advice or engage in the practice of medicine. The HFA recommends that you consult your physician or local treatment center before beginning any form of treatment. Send all comments, suggestions, and article submissions to: Dateline Federation, 102-B Westmark Blvd, Lafayette, LA 70506.

Mission Statement

They Hemophilia Federation of America is a national nonprofit organization that assists and advocates for the blood clotting disorders community.

Vision Statement

The vision of the Hemophilia Federation of America is that the blood clotting disorders community has removed all barriers to both choice of treatment and quality of life.

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Lone Star Chapter of the NHF
Nebraska Chapter of the NHF
Northern Ohio Hemophilia Foundation
Oklahoma Hemophilia Foundation
Texas Central Hemophilia Foundation

Data Analyses Further Support Safety and Efficacy of Baxter's ADVATE for Hemophilia A
First and Only Human- and Animal Plasma Protein- and Albumin-Free
Recombinant Factor VIII Recognized as Next Generation Treatment
For Adults, Children with Hemophilia A

DEERFIELD, Ill., – December 2003 – Study results on Baxter Healthcare Corporation's ADVATE Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method (rAHF-PFM) were presented at the 45th Annual Meeting and Exposition of the American Society of Hematology (ASH). These results add to the growing body of data evaluating the therapy's safety and efficacy in patients with hemophilia A. This data is consistent with previously presented study results on ADVATE.

The studies in previously treated patients presented at the ASH included:

- The Pivotal Study, which evaluated safety and efficacy in patients at least 10 years of age
- The Continuation Study, which is evaluating longer-term safety and efficacy
- The Pediatric Study, which is evaluating the use of ADVATE in patients six years or younger
- The Surgery Study, evaluating bleed control in patients undergoing surgery or other invasive procedure

Testing for factor VIII inhibitors was performed in all studies. Only one low-titer, non-persistent inhibitor that was undetectable eight weeks later was reported in one patient during the pivotal study.

The U.S. Food and Drug Administration licensed ADVATE on July 25, 2003. It is the first and only recombinant factor VIII made without any added human or animal plasma proteins and albumin in the cell culture process, purification and final formulation, thereby eliminating the risk of infections caused by viruses that could be carried in these proteins.

NEXT GENERATION

In November, NHF's MASAC revised its formal treatment recommendations (MASAC Document #151) to recognize ADVATE as a "third-generation" recombinant therapy for hemophilia A. The guidelines define third-generation recombinant factor concentrate as follows: "No animal or human

plasma protein-derived is used in the cell culture medium or in the final formulation. The product is stabilized with a sugar such as sucrose or trehalose. Examples include ADVATE."

As the first third-generation recombinant therapy for hemophilia A, ADVATE is also the first hemophilia A therapy to comply with MASAC recommendations that state, "All efforts should be made to remove human albumin from recombinant factor VIII products" and "Increased efforts should be made to eliminate human and bovine proteins from the manufacturing process of recombinant products."

Side effects with the use of ADVATE are uncommon, with no serious adverse events related to treatment with ADVATE reported to date. Non-serious, mild or moderate adverse events related to ADVATE include: a strange taste, itching at the infusion site, dizziness, headaches, catheter-related infections, chills, hot flashes, diarrhea, lower limb edema, sweating, nausea, pain in the upper abdomen or lower chest, prolonged bleeding after post-operative drain removal, decreased red blood cell count, joint swelling and shortness of breath. Non-serious but severe related adverse events include: fever, headache and decreased coagulation factor VIII levels.

ABOUT ADVATE

The therapy is convenient to use because it is available in super-high potency (1500 IU/vial) with a smaller infusion volume (5mL diluent), which means shorter infusion times for patients. ADVATE comes packaged with a 10mL syringe, butterfly needle bandage, alcohol swab and a patient-friendly package insert.

ADVATE is processed by Baxter in its state-of-the-art, recombinant-protein, biotechnology facility in Neuchâtel, Switzerland. This facility has the capacity to help ensure sufficient supplies of this therapy based on current and anticipated patient needs. ♀

Celebrating With HFA Kids

By: Joyce Donlan & Judy Igelman

We hope you're all making plans to come to HFA's Symposium in Las Vegas in March. Again, your children are a big part of our plans. Last year in Houston, Yellow Ducky (aka Judy Igelman) and Granny GoodFood (aka Joyce Donlan) guided the children through a wide variety of arts and crafts, fun food projects and relaxing social activities, as well as a fun packed field trip for the older group of children.



This year Judy and Joyce are working on another wonderful spectrum of projects for the HFA Kids Program. There will be some special guests helping us to make it a fun-filled few days. This includes a magical troubadour with fascinating old world tales, musical instruments, and games. Also expect to see Dr. Zoolittle and work with an artist to create small

books. It is our hope to treat the kids to an experience of massage and yoga again this year. Of course we will have some fun food activities also.

But our real goal for the "kids" is for them to get to know each other and make special friends they won't forget. We want them to learn more about living healthy, positive lives and to feel confident about moving forward when a blood clotting disorder affects their lives, either directly or indirectly.

We are calling HFA Kids 2004's program CELEBRATION STATION. It will be a big birthday party to help HFA celebrate its 10th year. Be there to share the fun with us. We look forward to seeing many of you again and meeting lots of new families too. ♣

Attention all teens: HFA wants you in Vegas!

Our new teen Committee, spearheaded by HFA's young energetic Committee Chair, Zuiho "Z" Taniguchi, has been busy planning a fun-filled weekend for our teenaged audience. Brian and Kelly Craft of Comedy Lifeline International have created a dynamic agenda that will educate you on self-advocacy, communication and leadership skills, and will assist the group in developing an identity. As a professional comedian and actress who have take their program to hemophilia camps across the country, Brian and Kelly will have you on your feet and rolling in the isles in hysterical laughter. Our newly-formed Big Blood Brothers, a group of young adults mentoring teens, will also be there to share their time and talents with the next generation of HFA's leaders.

The teen program will begin Friday afternoon after the opening session with time for introducing the weekend's events and getting to know one another through fun activities. Saturday morning, Disabled Adventure Outfitters will tell us about their programs and then we'll dive right into learning more about ourselves and our group's strengths and talents. We'll discuss self-advocacy, peer pressure, relationships, and other issues today's teens face. We'll learn to use creative problem-solving techniques to develop the Teen Program's goals, future projects and activities that our teens decide they want to focus their efforts on. As a reward for working so hard, the group will journey to the Adventuredome, a 5-acre indoor theme park, on Saturday afternoon so they can put their new skills into practice, let off steam and have some fun!

Bring your ideas and a positive attitude with you to Las Vegas. Get ready for a great weekend! ♣

Disabled Adventure Outfitters

HFA is pleased to have Disabled Adventure Outfitters' present at the popular 'Sports in Hemophilia' Saturday Break-out session. The concept of such an organization originated in the 1980's when the Hemophilia Foundation of Northern California's Summer Camp added a teen overnight camping to its program offerings. Over time, this weekend trip evolved into the hemophilia adventure camp, a multi-day whitewater adventure. The leaders in the Northern California hemophilia community and the outdoor/whitewater community of the Six Rivers National Forest experienced the dramatic effect the camping trip had on people with hemophilia and, realizing the limited outdoor recreation opportunities available for disabled persons in general, decided to create an organization dedicated to providing outdoor experiences to the disabled. In 1998, Disabled Adventure Outfitters (DAO) was founded as a 501(c)(3) non-profit organization.

With a mission of "providing access to fun, adventure, and personal growth", DAO's goal is to provide the disabled, through a variety of programs from day trips to weeklong camps, with outdoor recreation opportunities in a safe, professional environment. Such activities are fun and life affirming while building self-esteem and self-confidence. Unfortunately, disabled persons do not participate in such activities because of limited financial resources, access, or awareness. DAO seeks to overcome these obstacles by providing specialized programs for various disabled groups at little or no cost to the individual by working cooperatively with the organizations representing them and by seeking funding from external sources. The hemophilia chapters within California work with DAO to coordinate transportation for youths attending camp.

DAO Adventure Programs enrich the lives of participants via guided, challenging activities which build self-esteem, self-confidence, and positive self-image. Each Hemophilia Adventure Camp for adolescents and adults with bleeding disorders, is a week-long outdoor program for up to twelve affected participants. Campers are placed in unfamiliar and challenging situations that involve problem-solving and teamworking skills. Participants are provided with daily networking opportunities in both structured and unstructured settings. Program leaders insure all campers a comfortable environment stressing safety and good judgment.

DAO's Teen Adventure Camp is designed for boys and girls from ages 13 to 18 and tends to be a little more active than the adult programs. Campers spend the first two days camping at the coast, rock climbing and ocean fishing, then move up to the Trinity River for three days of whitewater rafting and inflatable kayaking. All DAO programs follow the philosophy of "challenge by choice", encouraging participants

to push themselves to the extent they wish, but also supporting them if they decide "that's enough for now." Such an atmosphere is quite contagious and, by the end of the week, campers usually form a cohesive, mutually supportive group.

DAO can be reached via email at daoinfo@mindspring.com, by phone at (707)822-1101, by snail mail at PO Box 152, Arcata, CA 95518, or on the web at www.specialadventures.org.



Available Educational Scholarships

Factor Support Network Pharmacy is awarding ten \$1000 scholarships through the Mike Hylton and Ron



Niederman Memorial Scholarship Program to be used for post secondary education at an accredited college, university, trade or technical school. Applicants must be individuals with bleeding disorders or members of their immediate family. Scholarship deadline is April 30, 2004. Applications may be obtained from Linda Leigh Sulser, 900 Avenida Acaso, Suite A, Camarillo, CA 93012. For more information, call toll free (877)376-4968/ Fax 805-482-6324 or log on to www.FactorSupport.com.

Positudes, Inc. is accepting applications for the Lawrence Madeiros Memorial Scholarship to graduating high school seniors living with a bleeding or other chronic disorder for continuing education at an accredited college or university. Each award is with a \$500 minimum. Applications will be accepted until June 16, 2004. For an application or more information, call 518 863-2668 or email lampsintacular@aol.com. 🧑

CSL Limited & Aventis-Behring Sign Agreement

In a letter from Joseph N. Pugliese, Vice President and General Manager of Aventis-Behring on December 8, 2003 we learned that Aventis and CSL Limited have signed a definitive agreement. CSL will acquire Aventis Behring and will combine this business with their ZLB Bioplasma operations to create ZLB Behring, a leader in the global plasma products industry. The business will be managed from its head office in King of Prussia, Pennsylvania. Peter Turner, the current head of the ZLB Group business, will run the combined business.

This business combination is the best possible option for Aventis-Behring patients and customers at this time. The industry is currently faced with challenges and must make some significant changes to remain viable. The new company will have the resources and long-term commitment from CSL to meet these challenges and develop an organization with a sustainable future that will continue to provide life-saving therapeutic protein products.

The pipeline and respective product offerings of both companies are highly complementary with Aventis Behring's hemophilia and specialty products businesses and ZLB's immunoglobulins products. The new company would also retain Aventis Behring's

distribution agreement with Bayer and would have long-term access to the leading recombinant FVIII, Helixate® FS/NexGen. The new company will also continue to have direct access to high-quality plasma through its plasma collection and testing organization, which is critically important to this business. Finally, the combined company will support patient activities at responsible levels in a manner that benefits the patient communities most.

Both companies will file with the appropriate regulatory authorities to seek approval for the transaction, which is expected to close during the first half of 2004. Until then, both organizations will operate independently and Aventis Behring will remain dedicated to meeting the needs of our patients and customers by continuing to provide all of the products and services currently relied upon.

Questions about how this business transaction may affect your relationship and interaction with Aventis Behring may be addressed to Joseph Pugliese. Please feel free to call Joseph Pugliese at 610-878-4141 and he will provide answers as they become available.



Do you have Hemophilia A and use any Recombinant factorVIII product?

Are you:

- ❖ Between the ages of 18 & 75?
- ❖ Willing to meet with a research staff who will ask questions about your treatment?

If so, you may be eligible to join our study.


You will be paid \$150 for your time.

For more information call: 866-733-5308 or e-mail us at BKF.LP@quintiles.com

A member of our team will contact you shortly.

Welcome HFA's Newest Intern



The Hemophilia Federation of America is excited to welcome its newest intern Kaissy Hammer, RN. Kaissy holds a Bachelor of Science Degree in Nursing from the University of Louisiana at Lafayette. Kaissy is presently a Gates Millennium Scholar currently working on her Master of Education with a concentration in Health Promotion and Wellness. Kaissy at this time works as a registered nurse at Women's and Children's Hospital in Lafayette, LA. At HFA, Kaissy is assisting in organizing and planning the Symposium in Las Vegas. After graduation, Kaissy wants to be an advocate for the healthcare community. 

Knowing the Factor:

One nurse/mother/sister gives so much to those with bleeding disorders

By Teresa A. Andrasik, BS, RN



Linda Eleanora Wyman Collins, BSN, RN, C, is known by the nickname “Lew” in the NICU of George Washington University Hospital (GWUH), Washington, DC, where she has worked as a full-time nurse for 20 years.

A single mother of three and active in her church, Lew is moving through her life quietly, while making a big difference. She is a member of the board of directors of the Hemophilia Foundation of Maryland (HFM) and a volunteer at the local chapter. In addition, she has worked for the Hemophilia Association of the Capitol Area (HACA) for 12 years. She is the HFM’s representation on the board of directors of the Hemophiliac Federation of America (HFA), a non-profit national advocacy group for people with coagulation disorders. For the past 3 years on the HFA board Lew has continued her work as an advocate, volunteer and lobbyist.

Family History of Bleeding Disorders

Lew, my friend and co-worker, was diagnosed with von Willebrand’s disease (VWD) 11 years ago. She is also a carrier for hemophilia A. “Looking back, I always had a lot of bruises growing up, ulcerative colitis, bleeding with dental work, even undiagnosed joint bleeds,” she remembers. “Beginning in the teenage years I had heavy periods, yet so did my mom, grandmother and aunts. My brothers were born premature and did not live long. My theory is they died of pulmonary hemorrhage or intraventricular hemorrhage. Because of the technology back then, the listed cause of death was hyaline membrane disease. It was not pursued any further. Also, doctors were baffled by my sister’s death; she passed away after a minor closed head injury in a motor vehicle accident.”

The journey toward diagnosis for this family was long and eventful:

In 1981, Lew’s 21-year-old sister mysteriously died the vehicle accident.

Also in 1981, Lew’s firstborn son was circumcised and promptly hemorrhaged. Later, at 17 months old, he woke up from a nap and couldn’t walk. After numerous misdiagnoses, a savvy resident from GWUH discovered abnormal coagulation studies. Further testing revealed the toddler was a severe hemophiliac, type A

In 1984, a second son was born (he was not circumcised!). He was tested and is also a severe type A hemophiliac.

In 1988, Lew’s daughter was diagnosed as a carrier for hemophilia A.

In 1996, a nephew was found to have hemophilia A

In 1997, a niece was diagnosed to be a true hemophiliac. She has factor VIII (hemophilia A) and factor XI deficiency (hemophilia C).

Inherited Bleeding Disorders

Von Willebrand’s (vWD) disease is an inherited disorder that affects 2-3 percent of the population. It is caused by a deficiency or defect in a protein, called von Willebrand’s factor, which promotes blood coagulation.

In fact, vWD is just one of many bleeding disorders. This collection of hereditary bleeding disorders is each associated by a lack of one of the factors needed to coagulate blood. The two most common hereditary bleeding disorders are hemophilia A and hemophilia B.

Hemophilia A, the classic type of hemophilia, is handed down as an X-linked recessive trait and has a lack of coagulation factor VIII. More than 80 percent of patients have type A hemophilia.

Hemophilia B is handed down as an X-linked recessive trait and has a lack of coagulation factor IX. About 15 percent of patients have type B. (A less common disorder is hemophilia C. This bleeding disorder is caused by an X-linked recessive trait and a deficiency of factor XI.)

Approximately 60 percent of patients with hemophilia A and B are severe cases and can have spontaneous bleeding without any precipitating event. Routine problems experienced by those with bleeding diathesis include: significant loss of blood when having simple dental procedures; epistaxis (nosebleed), a common problem with children; and excessive fatigue from chronic anemia. Another complication is that a simple hematoma can become a continuous bleed.

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Hemarthrosis (bleeding into a joint) requires extravasation of the blood and can result in scarring of the joint as well as joint disease and permanent disability. Vision can be lost from bleeding into the eye. Women experience abnormal menstrual bleeding that often results in unnecessary hysterectomies. The leading causes of death for those in the hemophilia community at this time are intracranial bleeding or complications of AIDS, transmitted by contaminated plasma concentrates which were being used as treatment for hemophilia in the early 1980s, prior to advanced screening tests for the presence of HIV in the blood.

Coagulation factors in the blood are responsible for the process of blood clotting. There are as many as 20 different plasma proteins or clotting factors that interact in human blood. Factor replacement therapy is lifesaving for those with bleeding diathesis. Some have been duplicated for use in the chronic bleeding community.

Treatment

Difficulties can also arise with the treatment for hemophilia. The top three complications of factor infusion and blood replacement are the potential for the transmission of the HIV virus and hepatitis B and C. (It's the transmission of hepatitis B and C that is the complication. The term "liver disease" is too general and, in fact, not correct. Many other substances such as alcohol, drugs and toxins can also cause "liver disease"). All persons who receive blood products should be immunized against hepatitis B.

Routine lab tests for those suffering an injury or possible spontaneous episode include a CBC and a factor level. Treatment with clotting factors is a percentage correction — treat higher for an injury involving the head or abdominal area. For example, a 40 percent correction will treat a joint bleed. A member of the bleeding community must keep 100 percent correction on hand at all times.

RICE — rest, ice, compression and elevation — is the treatment often prescribed for bleeding injury. An air-filled cooling cuff is an ingenious device that encompasses all the RICE points. It is made of three components, a cuff, a tube and a cooler, which applies pressure to the affected area as well as cooling water to keep swelling down. By lowering the cooler as the body warms the water from the tube, the water is rechilled, making this a convenient method to keep pressure and coolness applied.

An important nursing role is to teach self-infusion to the chronic bleeding patient.

Accessing a vein or existing central line should be done with sterile technique. These skills can become routine for the patient who is properly prepared.

A nurse working with the chronic bleeding patient should teach patients how to articulate and identify their episodes. Is the bleed in a muscle, joint, mucous membrane or soft tissue? The sensation of blood entering a confined space such as a joint results in a dripping feeling. As a bleed progresses it will feel warm to the touch. Treatment should begin before swelling occurs if possible. Patients are taught to take a skin pen and mark the borders of a tissue bleed. The breeching of the border will be a visible sign of continued bleeding or under-treatment

Parents should be conscious of a child who favors an extremity or who refuses to put weight on both extremities. All members of the bleeding community should be encouraged to keep a bleeding log. They will be given guidelines on how to treat injuries in advance, how much factor or desmopressin acetate (DDAVP or Stimate) to infuse depending on the type of injury. By following the prescribed guidelines of their physician, chronic bleeding patients will have more independence.

Finally, patients should be taught to wear medical alert bracelets, carry wallet cards with their diagnosis and keep a letter from their treating physician explaining their personal treatment program. All those with the diagnosis of chronic bleeding should carry a case with their 100 percent factor dose and self-infusing IV supplies when traveling.

Twenty-five years ago the life expectancy of a severe hemophiliac was 40 years; now, with advanced medical treatment available in HTC's, safer factor products and home infusion, the CDC estimates a life expectancy of 64 years. These extra years are necessary if hemophiliacs are to live a healthy life and raise their children.

Community Resources, Treatment Centers

Hemophilia is a rare bleeding disorder, which affects approximately 20,000 people. Speed of treatment is of the utmost priority in saving lives. Specialists who have factor products and DDAVP on hand are needed on standby to support this community. The National Hemophilia Foundation (NHF) was established in 1940 to meet the needs of the chronic bleeding community. Its mission is education, research and advocacy on behalf of people with bleeding disorders.

According to the NHF, more than 70 percent of the hemophilia community participates in one of the 150 centers or hemophiliac treatment centers (HTCs) that comprise this network.

HTCs grew out of concern over dangerous delays in getting coagulation treatment for the chronic bleeding community. Michael Soucie, PhD, at the CDC, who conducted a study to determine if there is any real benefit to the HTCs, said, "Persons who received care in the HTCs were 40 percent less likely to die than those who had not."

HTCs have a hematologist available 24 hours a day, 365 days a year. They are also staffed with physical therapists, orthopedists, social workers, dentists and RN coordinators. HTCs are equipped with CT scans and MRIs, and keep factor products in stock. "Due to the high cost of factor products many emergency departments and hospitals do not stock them. Factor costs per year can be as much as \$250,000-\$500,000. My sons use 2,500-3,000 units per dose of factor, at a cost of \$1.20 per unit," Lew reveals. "Yet all patients in the bleeding community are not insured for access to an HTC. This is a serious health issue that needs to be addressed. Many insurance companies have a \$1 million lifetime cap."

Becoming Politically Active

As a young adult, Lew did not imagine herself in the political arena. Yet living and raising children with a bleeding disorder has opened the door to a serious need for advocacy. As a nurse advocate with intimate knowledge of bleeding disorders, Lew has been influencing change and improving conditions for this population.

She helped gain support lobbying for the Ricky Ray Act, a bill that gave compensation to people infected with the AIDS virus from the blood supply, during a time when the government was aware the virus existed and did not take proper precautions. Lew also lobbied tirelessly to prevent Blue Cross/Blue Shield Care first from converting to a for-profit company that would have caused many HTCs to close.

Lew has also worked to access specialty care and recombinant products, and to identify women in the community with undiagnosed bleeding disorders. When asked what she is currently focused on, Lew immediately answers, "Some insurance companies will not cover the cost of an HTC visit, it is important that a patient bill of rights is implemented to ensure that those in need can see specialists."

In addition to her efforts on Capitol Hill, Lew has applied herself at the grassroots level. She has taught

many families how to be advocates for their own health care. She has educated physicians and school personnel about bleeding disorders. "Education and patient advocacy are important for our quality of life," she states.

Educating Children Too

Not all of Lew's efforts are focused in the adult arena; she makes time to volunteer at Camp Young Blood in Virginia, a place dedicated to helping children deal with a chronic bleeding diagnosis. "At summer camp we teach the children to self-infuse. I have had 5 and 6 year olds successfully self-infuse with good sterile technique," she says. "They are very proud of themselves and are thrilled with the independence they gain from being able to infuse and not be homebound."

In addition, Lew volunteers at a teen retreat in Maryland for adolescents with bleeding disorders. "The retreat makes it possible for young adults to spend time together, relax and share in a comfortable environment. We do activities like a rope course, wall climbing, swimming, archery, horseback riding or just watching movies. It is so healing for them to be with others who have the same or similar diagnosis."

Lew's volunteering is not limited to the land. She volunteered on an overnight outing aboard the U.S. Coast Guard cutter, Taney. This educational trip, which also gives the diagnosed young men and women a chance to be together, just as importantly gives the parents a break from the care of their unique children.

The word hemophilia is of Greek origin, "haima" meaning blood, and "philos" meaning beloved or dear. This is a true definition for Lew Collin's mission. Though she is one person, one nurse, she is making an enormous impact on the lives of others.

Resources

Anderson, K.N., & Anderson, L.E. (1998). *Mosby's pocket dictionary of medicine, nursing and allied health* (3rd ed). Chicago: R.R. Donnelley and Sons Co.

Hemophilia Federation of America: www.hemophiliefed.org; 800-230-9797.

CDC: www.cdc.gov/ncidod. Click on search, then use keyword "hemophilia."

Hemophilia Foundation of Maryland Inc.: www.hemophilia.org; 800-964-3131. (For resource materials call 1-800-42-HANDI)

Hemophilia Association of the Capitol Area: www.hacacares.org. (E-mail address: hacacares@aol.com)

Teresa A. Andrasik is a NICU nurse for George Washington University Hospital, Washington, DC, and a coordinator of the Special Diet Support Group of St. Mary's Hospital, Leonardtown, MD. This article was reprinted from ADVANCE, vol. 5, Issue 20, with permission from the author. ♀

HFA in Action

By: Jan Hamilton, Executive Director



The week of January 26, 2004 was a very busy one for HFA. While most of the staff was busy in our Lafayette office with the whirlwind of activities surrounding preparations for our March 26-28 symposium in Las Vegas, a few of us were scurrying around Washington, D.C. and environs to speak up for members of the blood clotting disorders community.

HFA Executive Committee member Donnie Akers accompanied me to D.C.. On Monday, we made a round of visits with key legislators thanking them for their assistance in 2003 and alerting them to our concerns for 2004. The weather was not very welcoming, as we were greeted with high winds and snow for the entire week. It would have been interesting to have a camera crew follow us and then present it to Washington's powers that be to let them see how difficult it is for a person with a handicap to traverse D.C. in any kind of weather, but especially in snow and ice. (That's another whole story.)

Tuesday found Donnie and I at the regular meeting of the Advisory Committee for the Patient Notification System and it was great to learn that registrations are up. There are many expansions of this service that we would like to accomplish, but they cost a lot of money. One thing that would free up budget, for instance, to provide a Spanish translation for the service would be if current subscribers who have opted to receive notification by overnight mail would change to opting for e-mail notification. Always keep in mind that, if the initial form of notification fails, you will receive a standard letter in the mail. Please consider this change.

On Tuesday afternoon, we attended a Stakeholders meeting that also included

representation from COTT, NHF, Immune Deficiency Foundation, Alpha One Foundation, World Federation of Hemophilia, Guillian-Barre Foundation along with representatives from PPTA (Plasma Protein Therapeutics Association.) The purpose of these sessions is to share thoughts and ideas on items such as reimbursement and access that affect each of our communities.

On Wednesday and Thursday, we were joined by board members Lew Collins, RN, Ray Dattoli, and Don Han as we attended the regular session of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability. While this meeting is frequently a very lively one, it dealt for the most part with whether we need to revise the 30 year old National Blood Policy. One of the bigger points of interest is that it doesn't really pertain to plasma products in its current format.

In addition to this session, we also met with Judy Hagopian of HRSA's Maternal and Child Health Bureau on Wednesday noon and ventured out to the National Institute of Health campus on Thursday afternoon to meet with the new director of the National Heart Lung and Blood Institute, Barbara Alving, MD and three of her staff from the blood division. It was a great exchange of information.

Throughout the week, we were accompanied by Jim Romano and Dale Dirks of Health and Medicine Counsel of Washington. Jim and Dale are wonderful eyes and ears for HFA in the D.C. arena and help to keep us informed of items of importance where action is needed. ♣



Bayer AG Seeks Divestiture of Its Plasma Business

Kogenate® Product Line Not Included in Initiative

Bayer AG announced recently it is initiating a process to divest its plasma business which is part of the Bayer Biological Products (BP) division. The recombinant factor VIII blood coagulation business — comprising the Kogenate® product line — is not included as part of this Bayer AG initiative.

As this initiative is being pursued, Bayer BP will continue its long-standing commitment to the bleeding disorders community.

“Our technology expertise, exciting product line, demonstrated safety expertise, and product pipeline will allow us to continue to provide reliable, high-quality products and services to extend and improve patients’ lives,” said Dr. Gunnar Riemann, president, Bayer Biological Products. “Specifically, our work on key hemophilia projects and programs designed to advance patient care and promote research and education is continuing as planned.” These key areas of focus include:

- Developing BIO-SET®, a needleless reconstitution device for Kogenate® FS and KOGENATE® Bayer
- Pursuing a next-generation recombinant factor VIII product designed to require less frequent dosing for prophylaxis
- Partnering with Avigen to develop the Coagulin-B® gene therapy product for hemophilia B
- Advancing clinical research programs related to quality of life issues and prophylaxis
- Supporting research in the field of hemophilia through the Bayer Hemophilia Awards program and other grants
- Continued development of our hand-held electronic patient diary that more accurately and conveniently captures bleeding and treatment information

Bayer Biological Products to Introduce Enhanced Tamper-Evident Packaging Features

Shrink-Banding Marks Latest Phase in Initiative to Enhance Safety of Biological Products

Bayer Biological Products (BP) announced plans to introduce shrink-banding as an enhanced tamper-evident packaging innovation for all liquid products in vials produced at its Clayton, N.C., production facility.

Additionally, Bayer BP is actively pursuing alternative packaging safety innovations for other Bayer BP products in a manner responsive to product differences and the unique needs of various geographic regions. Current plans to introduce tamper-evident packaging to Kogenate® FS and KOGENATE® Bayer feature a customized overseal with a Bayer logo.

The shrink-band, which will be used on vials of liquid products, is designed as a clear plastic wrap, covering the neck and lid of the bottle with the imprinted Bayer BP logo. The shrink-band comes with a pull-tab for easy removal. If tampering has occurred, the shrink-band will be broken or loosened, and the disruption will be obvious to the naked eye. Additionally, the shrink-band contains the Bayer BP logo, making it difficult to duplicate.

Last year, Bayer BP became the first company in the biological products industry to introduce enhanced packaging safety innovations. The introduction of shrink-band packaging marks the latest phase in this product safety initiative to prevent the tampering of products after they leave Bayer BP’s control, including packaging and distribution innovations, patient and treater education, and inter-industry collaboration. 📌

RESEARCH ON HEMOPHILIA

We are conducting interviews during the upcoming Hemophilia Federation of America March 26,27 conference to learn more about preferences for hemophilia treatment reconstitution methods. We are looking for the following 3 types of participants:

- ❖ **Adults** ages 18 to 35 who have been diagnosed with hemophilia and infuse themselves.
- ❖ **Parents/Caregivers** of a child with hemophilia who infuse their child with product.
- ❖ **Nurses** who treat hemophilia patients.

If you are one the persons described above you may be eligible to participate in an interview about hemophilia treatment methods.

Patients and Caregivers will be reimbursed \$150 for their time.

Nurses will be reimbursed \$200 for their time.

For more information about this study, please contact:

MEDTAP International, Inc. at 1-877-954-4252

The A.C.C.E.S.S.® Program

Timing is Everything

For more than a decade, Hemophilia Health Services' A.C.C.E.S.S.® (Advocating for Chronic Conditions, Entitlements and Social Services) Program has been helping the bleeding disorders community navigate the often complex maze of state and federal entitlement programs. We also help you understand your rights to continuation of group health coverage based on federal laws and your eligibility for health insurance through state high-risk pools and other alternatives. We represent people in the community with Social Security Disability and Supplemental Security Income claims without regard to choice of provider and free of charge.

It is critical that you recognize those times and situations where your access to health and disability benefits may be affected. Based on our many years of experience, we identified a list of key events where you should consider your options and ask questions about your healthcare.

Times to call A.C.C.E.S.S.®:

I quit my job.

I lost my job.

Most of us get our health insurance through our employer. If you change your employment for any reason, COBRA (Consolidated Budget Reconciliation Act) can help you maintain insurance until you are eligible for a new group policy under your new employer's health insurance plan. In addition, HIPAA (Health Insurance Portability and Accountability Act) may allow you to further continue your health benefits if your new employer does not offer health insurance benefits.

When you quit or lose your job due to your medical condition, disability may be an issue. This is the time to consider applying for Social Security Disability (SSD) or Supplemental Security Income (SSI).

I got a new job.

A new job may or may not offer group medical coverage or a new employer's medical benefit package may not provide the same coverage as your previous provider. COBRA can extend your existing insurance from your previous employer's policy to continue coverage until your new employer's policy takes effect. HIPAA may help by insuring that you do not have to undergo a new pre-existing condition waiting period under your new coverage.

I'm looking for work.

Looking for work is often a stressful time, made more stressful when you are concerned about maintaining continuous health insurance. COBRA and HIPAA may help keep you insured regardless of the time period between jobs. COBRA can provide a vital bridge between employer policies when you have a gap of no more than 18 months between jobs. Even if you are unemployed beyond the 18 months of standard COBRA coverage, HIPAA may help by ensuring the availability of an individual policy.

I am no longer able to work.

Deciding that you are no longer able to work full-time due to health concerns is a very difficult decision to make. Before you leave your job, you should explore if you are entitled to federal disability program benefits. You will also need to think ahead about how to secure access to healthcare for yourself and your family when you are not employed.

I'm about to lose my health insurance.

I'm about to use up my health insurance.

I just lost my health insurance.

There are many different circumstances that may cause someone to lose their health insurance, from losing a job to reaching your lifetime maximum. COBRA and HIPAA may protect your rights to an insurance policy, or you may be eligible for a high risk insurance pool or for other entitlement programs. It is always best to investigate your options *before* you lose your insurance to assure continuous coverage.

I can't get health insurance.

It is often difficult to obtain a new insurance policy if you have a pre-existing medical condition and are unable to work. When you qualify for federal disability entitlement programs, such as SSD and SSI, you frequently gain access to health coverage from Medicare or Medicaid. When you cannot get health insurance because your employer does not offer healthcare benefits, state programs, as well as COBRA and HIPAA, may be available to you.

I just got married.

Both COBRA and HIPAA provide certain protections to newly married couples and their minor children. Under COBRA, marriage is considered a qualifying event that triggers certain rights. HIPAA also protects a new spouse and minor children under an employer's health insurance benefit package. Getting married may also impact your access to certain state and federal safety net programs, such as SSI and Medicaid. It is important to consider these issues before your benefits change in order to understand how you and your family may be affected.

I just had a child.

I just adopted a child.

Newborns and newly adopted children are specifically protected under both HIPAA and COBRA. Although you must be certain to meet specific deadlines to enroll them in your group health insurance policy, they are guaranteed coverage with no pre-existing condition exclusions. The criteria for children seeking Medicaid are often different than the criteria for adults seeking Medicaid. Medicaid may be available for a child in the household where it would not be available for an adult.

My child has lots of medical bills I can't pay.

Finding healthcare coverage for a child with high medical costs can be a daunting task. SSI and/or Medicaid may be a

solution. Many states also offer high-risk insurance pools for those who cannot obtain health insurance elsewhere. It is important to sort through the possible solutions to determine which one works best in your situation.

My child just turned 18.

My child is about to leave for college.

COBRA provides special protections for continuation of coverage under a parent's group healthcare policy when a covered minor child loses dependent status. Also, when a disabled child turns 18, their eligibility for SSI may change.

My spouse stopped working.

If you received your healthcare coverage through your spouse's employer, COBRA can help you maintain coverage until your spouse gets a new job with benefits or until you are considered eligible for the protections of HIPAA. If your spouse stopped working due to a medical condition, you may be able to keep your COBRA coverage for an extended period. If you are disabled but did not meet the financial guidelines for SSI while your spouse was working, benefits may be available to you if only for a limited time while your spouse is not working.

I'm getting a divorce.

Going through a divorce is often a very stressful time. Both COBRA and HIPAA have provisions to protect the health insurance rights of the persons getting divorced and any minor children in the family. Also, if your household income and assets are affected by the divorce, you or your disabled child may meet the financial guidelines for SSI or Medicaid.

I'm moving.

Any time you move – whether you are moving within the

same city or to another state – it is important to notify the appropriate agencies in order to insure uninterrupted continuation of your federal or state entitlement benefits. Moving may also impact your access to healthcare under your current insurance policy. COBRA and HIPAA may provide some protections. Before you move, look into how COBRA and HIPAA may be able to help you maintain continuous access to healthcare coverage.

ACCESS Can Help

Remember that the protections provided by federal law can only help you if you know what they are and how they work. ACCESS provides information and counseling to help you understand these issues.

We can outline federal disability programs, as well as how COBRA, HIPAA, Medicare, and Medicaid intertwine with the disability process. We can help you decide if filing for SSD or SSI is right for you. We offer representation to persons with bleeding disorders throughout the disability process. The ACCESS program can also explain what protections you may have under COBRA and HIPAA when moving from one health insurance policy to another.

We encourage you to call ACCESS toll-free at 888.700.7010 when you need help understanding how life changes may affect the availability of healthcare coverage or other important benefits for you and your family. Our professional staff will be happy to help you make the choice that is best for you.

The A.C.C.E.S.S.® Program is a service of Hemophilia Health Services.

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Wyeth Closes Plant in United States

Manufacturing Transition

As you may be aware, Wyeth recently announced that it is closing its St. Louis, Missouri manufacturing facility and consolidating [US: ReFacto® Antihemophilic Factor (Recombinant); EU: ReFacto® (moroctocog alfa, recombinant coagulation factor VIII)] drug substance production to the Stockholm, Sweden manufacturing facility. Manufacture of the company's investigational recombinant factor VIII drug also is transitioning to this facility in Sweden.

As a result, the company has withdrawn its marketing application for this investigational drug from the U.S. Food and Drug Administration (FDA) so that the application can be updated. Wyeth intends to update and resubmit its application after the manufacturing transfer to Stockholm is completed and

documents for the Stockholm facility are available for submission to the FDA.

Similarly, in Europe, the company plans to update its marketing application to reflect the change in manufacturing site prior to submitting the application to regulatory authorities.

Ongoing Clinical Trials

Clinical trials for our investigational drug remain ongoing. Patients and clinicians involved in these clinical trials can be assured that sufficient clinical supply is available to complete the current studies.

Wyeth remains committed to the development of this investigational drug, to providing safe and effective recombinant factor products with enhanced viral safety, and to supporting individualized tailored care for the hemophilia community. ♿

the
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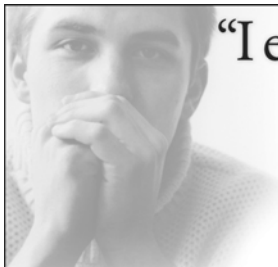
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Community Calendar 2003

March

NHF Washington Day will be March 10-12.

HFA's Annual Symposium will be held the weekend of March 26-28 at the Riviera Hotel in Las Vegas, Nevada and it is going to be a Federation Celebration.

April

Advisory Committee for Blood Safety and Availability will be April 6-8 at the Grand Hyatt Hotel in Washington, DC.

June

PPTA Plasma Form will be June 9-11 in Washington, DC.

Editorial Committee:

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Layout & Design**

**Carnell Chappelle
Jan Hamilton
Bob Marks
Mike Morse
Carl Weixler
Phill Blomquist
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