Hemogram

Western Pennsylvania Chapter of the National Hemophilia Foundation

October 2012

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DESIGNATE UNITED WAY GIFTS TO THE CHAPTER!

If your company is participating in the United Way campaign, you may designate all or a portion of your gift to the Chapter.

WPCNHF Contributor Agency Code Number is: **83**

Carnival Night at Camp

There was lots of fun to be had during the annual Carnival Night at Camp Hot-to-Clot! The hot weather was perfect for starting the night off with a game of "sponge tag," which has become a camp tradition! The kids enjoyed many carnival themed games, basketball, an oversized Twister game and more. New this year, and definitely the biggest attraction, was a Dunk Tank. The campers eagerly lined up for a chance to dunk a camp counselor! The counselors were great sports and had as much fun as the campers.

The activities for the evening were planned by the Chapter and sponsored by many Industry Partners, who donated prizes and gave their time to help setup and work the games. We thank everyone who helped to make this night a memorable one!

2012 Hemophilia Walk & Run For Their Lives 5K

The 2012 Western Pennsylvania Hemophilia Walk was outstanding! We raised over $55,000 on a warm, sunny day at Harmar Grove in North Park. The weather was unbelievably beautiful! There were 38 registered teams representing families and businesses from all over Western Pennsylvania. Over 400 walkers joined us for the day's activities.

WPCNHF also hosted a 5K Race the same day. Run For Their Lives started with registration at 7:30 am and the race began at 8:30. The winners of the Run For Their Lives 5K were:

Men – Ron Romanoff with a time of 18.55 mins.
Women – Morgan Hoffman with a time of 22.56 mins.

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Letter from the Chapter Staff

Dear Chapter Members and Friends,

As many of you know by now, Jennifer Pegher has resigned from our organization to accept a position in government relations. We thank her for contributions during the past year and wish her well in her future endeavors.

Although we are in a state of transition, the pace at the Chapter has not slowed down at all! As we eagerly await the arrival of our new Executive Director, we are busy planning our Fall and Winter events and are working on our Calendar of Events for the coming year.

Speaking of our Calendar of Events, a lot of thought and planning goes into each event the Chapter offers for our members. In regards to program planning, we take feedback we receive from our members into serious consideration when identifying topics for educational events. In addition to the feedback we've received verbally and written (on our Family Weekend Evaluations) in the past year, you have another opportunity to provide input on our future events. Recently, a Chapter Evaluation & Needs Assessment was mailed to our members. We ask that you please take the time to fill out the form and send it back to the Chapter. Your feedback will help us to provide and improve high-quality programs and events that better serve you and your family. In addition, you will have the opportunity to provide feedback on the location of events, communication with the chapter, our newsletter, our fundraisers, and more! If you haven't already completed and returned the form, we ask that you please take the time to do so.

In November, the Chapter will be hosting the 3rd Annual Take A Bough, silent auction of decorated holiday items. A few weeks ago you should have received a postcard describing the theme of the Chapter tree for 2012 – black and gold. Look at the inserts with this newsletter to learn about more ways you can get involved with Take A Bough.

Sincerely,
WPCNHF Staff

Cash For Trash Fundraiser

Recycle your inkjet and toner cartridges

Cartridges can be brought from home, work, or local businesses. Be sure to ask your employer to sponsor us by saving their empty toner cartridges. We receive funds for the Chapter for empty laser, fax, and copier cartridges. Inkjet cartridges can earn money too! Recycling cartridges not only helps to alleviate America's landfills, it makes "cents" too! All money earned from this program will go to WPCNHF. Please drop empty cartridges at:

WPCNHF
20411 Route 19, Unit 14
Cranberry Twp., PA 16066

Letter from the President, Scott Miller

Dear Members, Friends, and Supporters,
This has certainly been a busy summer with the golf outing, camp, and the Walk. The staff has done a fantastic job preparing for our Fall events. If you look at the event calendar, you will see so many good programs and fundraisers planned. I hope that you take advantage of these opportunities.

In the near future, the staff will send you a chapter assessment. This is being sent in an effort to continually improve the chapter through not only the programs and services we provide, but where we provide those programs and services. Please be sure to complete this assessment when you receive it and return it as soon as possible.

Please remember that each event takes time (and money) to plan. When we have to cancel events, it affects the chapter negatively not only financially, but personally as the staff spends countless hours trying to make these successful for you. It is our goal to provide high level programming that best meets your needs, therefore, the Chapter Assessment will assist us in this endeavor.

I want to thank all of those who participated in the Walk. Given the current economic conditions, the push over the last two weeks was very impressive. The money raised will ensure that we can continue our efforts in meeting our mission and providing you with educational programing and other resources to improve the lives of our members. You will see information in this newsletter about Take A Bough, which has become one of our signature events. Please try to attend the event at Station Square and tell your friends! This event is not only a fundraiser for our chapter, but provides awareness to the Pittsburgh and surrounding community about bleeding disorders and the Chapter's services.

Thank you all for your efforts and assistance over the past month as we transition to a new Executive Director. The staff has, again, done a wonderful job ensuring the Chapter runs smoothly and I look forward to welcoming our new Executive Director to our team.

Sincerely,
Scott E. Miller, CPA, Esq.
WPCNHF Board President

Calendar of Upcoming Events

Thursday, November 15, 2012
Mixer with Shakers
Moon Township, PA

November 8-10, 2012
NHF Annual Meeting
Orlando, FL

November 16-19, 2012
Take A Bough Holiday Tree Auction
Pittsburgh, PA

Saturday, December 1, 2012
Winter Family Program
Pittsburgh, PA

Meet the HCWP Staff

Anna Dracar is the newest clinical nurse at HCWP. She started working at the Center on July 2, 2012. She previously worked for three years as a nursing assistant in the Alzheimer and Dementia Unit at Worthington and Adams Nursing Facility. After she received her nursing diploma from Ohio Valley General Hospital, she worked in their Medical-Surgical Unit for seven years. She plans to continue her education and obtain a bachelor's degree in nursing and eventually an advanced degree as a nurse practitioner.

New Board Member

Dear Community,

It is a privilege to introduce myself as the new member of the Board for the WPCNHF. I'm looking forward to this new role and the chance to make a difference in our bleeding disorders community. I have a passion to support causes that have an impact on the well-being of individuals and their families.

A little information about me; I earned my Bachelor of Science from the University of Pittsburgh. My professional background is primarily in sales and business. My husband and I have been together since we were teenagers and we currently live in Pittsburgh with our son.

I am honored for the opportunity to be a part of this exceptional organization. The Board and staff have been nothing short of warm and welcoming. I am humbly impressed by these professional, caring and committed individuals and I look forward to the many opportunities to meet and work alongside all of the members of our community.

Sincerely,

Jennifer Smith

Ask us about sponsorship opportunites and how you can help!

Prophylaxis with ADVATE delivers 44 to 1[1]

ADVATE IS THE **ONLY** RECOMBINANT FACTOR VIII (EIGHT) THAT IS FDA APPROVED FOR PROPHYLAXIS IN BOTH **ADULTS & CHILDREN (0-16 YEARS)**[1-3]

PROPHYLAXIS WITH ADVATE

THE POWER TO REDUCE YOUR ANNUAL BLEED RATE (ABR)

ADVATE
[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]
There's more to life.
advate.com | 888.4.ADVATE

Significant reduction in ABR[1]

After switching from 6 months of on-demand treatment to 12 months of prophylaxis with ADVATE in 53 previously treated patients with severe or moderately severe hemophilia A:

- **Median ABR of 1** while on either prophylaxis regimen[1]
  - prophylaxis every second day (20-40 IU/kg)
  - prophylaxis every third day (20-80 IU/kg, targeted to maintain FVIII trough levels ≥1%)
- **42% of patients experienced zero bleeds** during 1 year on prophylaxis[1]
- **No subject developed factor VIII inhibitors** or withdrew due to an adverse event (AE)[1]

Indication for ADVATE

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is a medicine used to replace clotting factor VIII that is missing in people with hemophilia A (also called "classic" hemophilia). ADVATE is used to prevent and control bleeding in people with hemophilia A. Your healthcare provider may give you ADVATE when you have surgery.

ADVATE is not used to treat von Willebrand Disease.

Detailed Important Risk Information for ADVATE

You should not use ADVATE if you are allergic to mice or hamsters or any ingredients in ADVATE.

You should tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines and dietary supplements, have any allergies, including allergies to mice or hamsters, are nursing, are pregnant, or have been told that you have inhibitors to factor VIII.

You can have an allergic reaction to ADVATE. Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea, or fainting.

Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Side effects that have been reported with ADVATE include: cough, sore throat, unusual taste, abdominal pain, diarrhea, nausea/vomiting, headache, fever, dizziness, hot flashes, chills, sweating, joint swelling/aching, itching, hematoma, swelling of legs, runny nose/congestion, and rash.

Call your healthcare provider right away about any side effects that bother you or if your bleeding does not stop after taking ADVATE.

Please see Brief Summary of ADVATE Prescribing Information on the adjacent page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References: 1. ADVATE prescribing information. Westlake Village, CA: Baxter Healthcare Corporation; December 2011. **2.** Helixate FS prescribing information. Kankakee, IL: CSL Behring LLC; August 2009. **3.** Kogenate FS prescribing information. Tarrytown, NY: Bayer Healthcare LLC; March 2011. **4.** Valentino LA, Mamonov V, Hellmann A, et al. A randomized comparison of two prophylaxis regimens and a paired comparison of on-demand and prophylaxis treatments in hemophilia A management. *J Thromb Haemost.* 2012;10(3):359-367.

TALK TO YOUR HEALTHCARE PROVIDER TO SEE IF PROPHYLAXIS WITH ADVATE CAN HELP REDUCE YOUR ANNUAL BLEED RATE (ABR)

ADVATE

[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]

Brief Summary of Prescribing Information. Please see package insert for full prescribing information.

INDICATIONS AND USAGE

Control and Prevention of Bleeding Episodes

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is an Antihemophilic Factor (Recombinant) indicated for control and prevention of bleeding episodes in adults and children (0-16 years) with Hemophilia A.

Perioperative Management

ADVATE is indicated in the perioperative management in adults and children (0-16 years) with Hemophilia A.

Routine Prophylaxis

ADVATE is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children (0-16 years) with Hemophilia A.

ADVATE is not indicated for the treatment of von Willebrand disease.

CONTRAINDICATIONS

Known anaphylaxis to mouse or hamster protein or other constituents of the product.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions

Allergic-type hypersensitivity reactions, including anaphylaxis, are possible and have been reported with ADVATE. Symptoms have manifested as dizziness, paresthesias, rash, flushing, face swelling, urticaria, dyspnea, and pruritus. [See Patient Counseling Information (17) in full prescribing information]

ADVATE contains trace amounts of mouse immunoglobulin G (MuIgG): maximum of 0.1 ng/IU ADVATE and hamster proteins: maximum of 1.5 ng/IU ADVATE. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Neutralizing Antibodies

Carefully monitor patients treated with AHF products for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures Factor VIII inhibitor concentration. [See Warnings and Precautions, Monitoring Laboratory Tests]

Monitoring Laboratory Tests

The clinical response to ADVATE may vary. If bleeding is not controlled with the recommended dose, determine the plasma level of Factor VIII and administer a sufficient dose of ADVATE to achieve a satisfactory clinical response. If the patient's plasma Factor VIII level fails to increase as expected or if bleeding is not controlled after the expected dose, suspect the presence of an inhibitor (neutralizing antibodies) and perform appropriate tests as follows:

- Monitor plasma Factor VIII activity levels by the one-stage clotting assay to confirm the adequate Factor VIII levels have been achieved and maintained when clinically indicated. [See Dosage and Administration (2) in full prescribing information]
- Perform the Bethesda assay to determine if Factor VIII inhibitor is present. If expected Factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADVATE, use Bethesda Units (BU) to titer inhibitors.
  - If the inhibitor titer is less than 10 BU per mL, the administration of additional Antihemophilic Factor concentrate may neutralize the inhibitor and may permit an appropriate hemostatic response.
  - If the inhibitor titer is above 10 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may rise following ADVATE infusion as a result of an anamnestic response to Factor VIII. The treatment or prevention of bleeding in such patients requires the use of alternative therapeutic approaches and agents.

ADVERSE REACTIONS

The serious adverse drug reactions (ADRs) seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to Factor VIII.

The most common ADRs observed in clinical trials (frequency ≥ 10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

ADVATE has been evaluated in five completed studies in previously treated patients (PTPs) and one ongoing study in previously untreated patients (PUPs) with severe to moderately severe Hemophilia A (Factor VIII ≤ 2% of normal). A total of 234 subjects have been treated with ADVATE as of March 2006. Total exposure to ADVATE was 44,926 infusions. The median duration of participation per subject was 370.5 (range: 1 to 1,256) days and the median number of exposure days to ADVATE per subject was 128.0 (range: 1 to 598).[1]

The summary of adverse reactions (ADRs) with a frequency ≥ 5% (defined as adverse events occurring within 24 hours of infusion or any event causally related occurring within study period) is shown in Table 1.

No subject was withdrawn from a study due to an ADR. There were no deaths in any of the clinical studies.

IMMUNOGENICITY

The development of Factor VIII inhibitors with the use of ADVATE was evaluated in clinical studies with pediatric PTPs (< 6 years of age with > 50 Factor VIII exposures) and PTPs (≥ 10 years of age with > 150 Factor VIII exposures). Of 198 subjects who were treated for at least 10 exposure days or on study for a minimum of 120 days, 1 adult developed a low-titer inhibitor (2.0 [BU] in the Bethesda assay) after 26 exposure days. Eight weeks later, the inhibitor was no longer detectable, and *in vivo* recovery was normal at 1 and 3 hours after infusion of another marketed recombinant Factor VIII concentrate. This single event results in a Factor VIII inhibitor frequency in PTPs of 0.51% (95% CI of 0.03 and 2.91% for the risk of any Factor VIII inhibitor development).[1,2] No Factor VIII inhibitors were detected in the 53 treated pediatric PTPs in clinical studies that enrolled previously untreated subjects (defined as having had up to 3 exposures to a Factor VIII product at the time of enrollment). 5 (20%) of 25 subjects who received ADVATE developed inhibitors to Factor VIII.[1] Four patients developed high titer (> 5 BU) and one patient developed low-titer inhibitors. Inhibitors were detected at a median of 11 exposure days (range 7 to 13 exposure days) to investigational product.

Immunogenicity also was evaluated by measuring the development of antibodies to heterologous proteins. 192 treated subjects were assessed for anti-Chinese hamster ovary (CHO) cell protein antibodies. Of these patients, 3 showed an upward trend in antibody titer over time and 4 showed repeated but transient elevations of antibodies. 182 treated subjects were assessed for muIgG protein antibodies. Of these, 10 showed an upward trend in anti-muIgG antibody titer over time and 2 showed repeated but transient elevations of antibodies. Four subjects who demonstrated antibody elevations reported isolated events of urticaria, pruritus, rash, and slightly elevated eosinophil counts. All of these subjects had numerous repeat exposures to the study product without recurrence of the events and a causal relationship between the antibody findings and these clinical events has not been established.

Of the 181 subjects who were treated and assessed for the presence of anti-human von Willebrand Factor (VWF) antibodies, none displayed laboratory evidence indicative of a positive serologic response.

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of ADVATE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Among patients treated with ADVATE, cases of serious allergic/hypersensitivity reactions including anaphylaxis have been reported and Factor VIII inhibitor formation (observed predominantly in PUPs). Table 2 represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Terms.

Table 1
Summary of Adverse Reactions (ADRs)[a] with a Frequency ≥ 5% in 234 Treated Subjects[b]

MedDRA[c] System Organ Class	MedDRA Preferred Term	Number of ADRs	Number of Subjects	Percent of Subjects
General disorders and administration site conditions	Pyrexia	78	50	21
Nervous system disorders	Headache	108	49	21
Respiratory, thoracic and mediastinal disorders	Cough	75	44	19
Infections and infestations	Nasopharyngitis	61	40	17
Gastrointestinal disorders	Vomiting	76	27	12
Musculoskeletal and connective tissue disorders	Arthralgia	44	27	12
Injury, poisoning and procedural complications	Limb injury	35	24	10
Infections and infestations	Upper respiratory tract infection	24	20	9
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal pain	20	20	9
Respiratory, thoracic and mediastinal disorders	Nasal congestion	24	19	8
Gastrointestinal disorders	Diarrhea	24	18	8
Gastrointestinal disorders	Nausea	21	17	8
General disorders and administration site conditions	Pain	19	17	8
Skin and subcutaneous tissue disorders	Rash	16	13	6
Infections and infestations	Ear infection	16	12	5
Injury, poisoning and procedural complications	Procedural pain	16	12	5
Respiratory, thoracic and mediastinal disorders	Rhinorrhea	15	12	5

[a] ADRs are defined as any Adverse Event that occurred within 24 hours after being infused with investigational product OR (b) Adverse Events assessed treated or possibly related to investigational product OR Adverse Events for which the investigator's or sponsor's opinion of causality was missing or indeterminate.

[b] The ADVATE clinical program included 234 treated subjects from 5 completed studies in PTPs and 1 ongoing study in PUPs as of 27 March 2006.

[c] MedDRA version 9.1 was used.

Table 2
Post-Marketing Experience

Organ System [MedDRA Primary SOC]	Preferred Term
Immune system disorders	Anaphylactic reaction* Hypersensitivity*
Blood and lymphatic system disorders	Factor VIII inhibition
General disorders and administration site conditions	Injection site reaction Chills Fatigue/Malaise Chest discomfort/pain Less-than-expected therapeutic effect

* These reactions have been manifested by dizziness, paresthesias, rash, flushing, face swelling, urticaria, dyspnea, and pruritus.

References: 1. Shapiro A, Gruppo R, Pabinger I et al. Integrated analysis of safety and efficacy of a plasma- and albumin-free recombinant factor VIII (rAHF-PFM) from six clinical studies in patients with hemophilia A. Expert Opin Biol Ther 2009;9:273-283. **2.** Tarantino MD, Collins PW, Hay PW et al. Clinical evaluation of an advanced category antihaemophilic factor prepared using a plasma/albumin-free method: pharmacokinetics, efficacy, and safety in previously treated patients with haemophilia A. Haemophilia 2004;10:428-437.

To enroll in the confidential, industry-wide Patient Notification System, call 1-888-873-2838.

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Baxter

How Save One Life Began

Courtesy of Saveonelife.net

Save One Life was founded in 2000 by Laureen A. Kelley, a mother of a child with hemophilia who has witnessed first-hand the devastating and crippling effects of hemophilia in young children in developing countries. Laurie is the author of numerous parenting and children's books on bleeding disorders, and president of LA Kelley Communications, Inc.

During her many trips to developing countries from 1996-2000 while educating patients about hemophilia, Laurie realized that more immediate help was needed. Her company began donating medicine to stop bleeds, and soon was donating millions of dollars worth. But she saw that patients also required funds for basic necessities: food, vitamins, school fees and transportation to clinics. Most patients Laurie encountered lived in households earning about $1 a day. Laurie believed that families with hemophilia in wealthier countries, with vast resources and adequate healthcare, would be willing to help once they understood the suffering of people with hemophilia in developing countries. Her idea was modeled after other child sponsorship agencies, in which sponsors would donate $20 per month to support an individual. But Save One Life went one step further than most organizations: 100% of donations goes directly to the sponsored child and his local chapter and not to overhead.

Save One Life now donates funds to over 550 families in nine countries. Save One Life works in partnership with the hemophilia foundations in the host country, whose members volunteer their care, time and resources to improve the lives of impoverished people with bleeding disorders. Save One Life is a nonprofit organization that offers sponsorships directly to individual children or adults with a bleeding disorder in developing countries. Unlike many other child sponsorship programs where sponsor funds are pooled, Save One Life beneficiaries receive money directly from their sponsors, with only a small percentage given to the national or local hemophilia nonprofit organization that registers and cares for them.

More than just charity, Save One Life is also a development tool that helps promote long term care and NGO capacity-building by training, monitoring for progress, and rigid accountability.

Update on Arjun Limbu

Thank you for helping Arjun go to school and pay for transportation to the clinic this past year!

WPCNHF has been sponsoring Arjun Limbu, through Save One Life, since 2009. Arjun Limbu is now 19 years old and is in college. He is doing well in his studies and he enjoys singing. Arjun had six bleeding episodes last year and visited the clinic six times. He received six infusions of either cryoprecipitate or factor concentrate.

Arjun continues to be supported by his parents and they live in the same home. He participated in his local hemophilia camp and attended the society's annual general assembly.

Please consider making a donation to the Chapter towards this sponsorship. A donation of just $20 is the equivalent of a one month sponsorship. If you'd like to help the Chapter sponsor Arjun, please send the Chapter a check made payable to WPCNHF, and put Save One Life in the memo.

2012 Hemophilia Walk & Run For Their Lives 5K

Continued from page 1

Congratulations to all who participated in the race! Thank you to all who contributed as sponsors of the Run For Their Lives 5K. Generous sponsorships were given by Trib Total Media, Dick's Sporting Goods, Hemophilia Center of Western Pennsylvania, Mike and Karen Covert Family and Up N' Running Specialty Running Store. The Chapter looks forward to an even bigger race in 2013!

The Walk started with registration at 9:00 am. The Pittsburgh Pirates Parrot and Chik-Fil-A Cow mascots entertained the crowd between the Run and the Walk. The Walk officially began at 10:00 am.

Following the Walk, the festivities continued with some music from DJ Dave from First Class Entertainment. Other activities included a giant inflatable slide, balloon art, face painting, a photo booth, an inflatable skee ball game and lots of food. Prizes were awarded to a variety of teams and individuals, Chinese Auction baskets were won by 25 walkers and the 50/50 raffle winner donated her winnings back to the Chapter. Congratulations to all of the winners!

Congratulations to the winner of our t-shirt contest – Gavinators Army raised the most money through coin voting – their t-shirt received $124.49. Gavinators's Army t-shirt will be on display at the Hemophilia Center of Western Pennsylvania throughout the year until a new winner is crowned at the 2013 Walk. Congratulations Katy Legreco and the Gavinator's Army team!

The winner of the Jeff Rizzo Memorial Award was Sydney Evans, she was the highest adult fundraiser by raising $2,075. The winner of the "Awesome" John Eyrolles Award was Devin Smith, he was the highest youth fundraiser by raising $1,550. Congratulations to both winners!

Planning has already begun for the 2013 Western PA Hemophilia Walk and Run For Their Lives 5K. Save the date of September 21, 2013, for another fabulous day in North Park!

Spotlight on the Member: Meet the Herndon family

It is our pleasure to introduce the Herndon family! Joe, Christen, their daughter Sophia, age 5, and their 2-year-old son, William, reside in Gibsonia, PA. The Herndons are an active family and enjoy many activities together such as swimming, vacations at the beach, trips to the zoo, museum visits, and Pitt football games! They are also active members within our Chapter. They particularly enjoy being involved with the Walk and the Take a Bough Fundraisers. For the second year, Christen has been a captain of a Walk team in honor of her son. This year, her team "Will Power-We will not be Inhibited" raised over $2,500! To help raise money for the Walk, Joe and his band, the All Star Little Big Band, held a charity band concert and accepted donations. And that wasn't the first time Joe and his band helped support the Chapter—Last November, Joe's brass trios volunteered their services and performed during the donor reception for the Take A Bough fundraiser. They were fantastic! We are so appreciative of all that this family does for the Chapter.

The Herndon's have been active members of the Chapter since their son was diagnosed at birth with Severe Hemophilia A. William was tested at birth because there was a family history of hemophilia. William's grandfather (Christen's father) had Severe Hemophilia A with an inhibitor. Sadly, he passed away from liver disease, two months before William was born. At 8 months old, William was diagnosed with an inhibitor, too. The family opted to do immune tolerance, and William had a Mediport surgically implanted. Unfortunately, the Mediport became infected and needed to be removed after just 2 weeks. After using PICC lines for a while, they opted for another Mediport. The second port was a success! During this time period, they spent many weeks at Children's Hospital and experienced many ups and downs. The Herndon's say that the support they received from the Hemophilia Center of Western PA was amazing and they couldn't have done this without them. Although they still have a ways to go, they are happy to report that William's current inhibitor level is zero!

Christen had watched her father suffer with limitations due to an inhibitor and is very grateful for the advancements of immune tolerance. She says, together as a community, we can work toward further advancements for all bleeding disorders—no more limitations!

Christen advises others faced with a bleeding disorder to learn as much as you can about the diagnosis, so that you can be prepared to handle the situations that may arise. She recommends that you talk with as many people as possible. Talk with both healthcare providers and other families who have bleeding disorders, and know that you are not alone. For her, knowledge has given her the power to take control!

Medical News

The Carrier Barrier Jul 19, 2012
Article courtesy of HemAware
copyright 2012.

They experience similar bleeds and bruises as men with mild hemophilia, yet they're called "symptomatic carriers." For women, that label is confining and confounding. It also places their health at risk.

"Using the term 'symptomatic carrier' doesn't validate us," says Tammy Davenport, 38, of Kingwood, Texas, a regional coordinator for Matrix Health. "We have very different issues than men, but they're no less severe." Davenport's father had hemophilia A and had her tested for it when she was 5. Her factor VIII (FVIII) assay was 23%. The doctor told her parents, "She has mild hemophilia. If she ever has any surgeries or accidents, she may need factor."

However, that news did no good when Davenport went into labor with her son in 1994. "I went into the hospital explaining that I had hemophilia, and they needed to be aware of that," she says. The doctors told her, "That's impossible. Women can't have it." Consequently, they ordered no factor product. Davenport developed a large hematoma with a golf ball-sized knot on her spine from the epidural. It took a year to heal.

The burden for women whose concerns are discounted is both physical and emotional. When their bleeding symptoms are undertreated, they experience health complications. When their concerns are brushed aside, they feel frustrated and angry, losing confidence in the medical community.

But women are finding ways to get around the carrier barrier. Through advocacy and education, patients and providers are pushing for recognition of mild hemophilia.

"Carrier" Confusion

In genetics, a carrier is typically defined as a person who has a genetic mutation for a disease that can be passed on to a child, but who doesn't have symptoms. But for hemophilia, the label "symptomatic carrier" describes a woman who not only has the mutation but also has symptoms. "I want to clarify this terminology because people get this confused all the time," says Marion A. Koerper, MD, medical adviser of the National Hemophilia Foundation (NHF). She is also director emerita of the HTC at the University of California, San Francisco, where she practices pediatric hematology. "Being a carrier is a genetic designation, not a diagnosis. It says nothing about how you are clinically."

Clinical information is partially provided by measuring the factor level. "Regardless of whether you're male or female, if your factor FVIII (FVIII) or factor IX (FIX) level is below 49%, you can have bleeding symptoms," Koerper says. "You have mild hemophilia."

The hemophilia diagnosis can be confirmed by genetic studies. "As genetic testing is becoming more available, particularly gene mutation analysis, it's becoming increasingly helpful," says Steven W. Pipe, MD, medical director of the Pediatric Hemophilia and Coagulation Disorders Program at the University of Michigan, Ann Arbor. For a woman with no family history of hemophilia, the lab can analyze her DNA for the most common FVIII mutation, the intron 22 inversion, a reversal of a section of DNA. It accounts for 40% –50% of cases of severe hemophilia A. "We've identified some women from that secondstep testing," Pipe says.

The concept that women can't have hemophilia needs to be corrected. "That's a misconception that we probably have to devote some more attention to for education and outreach purposes," Pipe says. "If they have bleeding symptoms that can be managed with the interventions we have available, then they should be considered as having a mild bleeding disorder."

According to NHF, the normal plasma levels of FVIII range from 50% to 150%. Mild hemophilia is defined as having a FVIII level of 6%–49%. Because women have two X chromosomes, the level of FVIII they produce depends on the balance between the normal X chromosome and the abnormal one carrying the hemophilia gene. If the balance is equal, the FVIII level would not typically be lower than 50%.

"If the greater proportion of their FVIII level is dependent on the mutant FVIII gene, their factor levels can clearly be in the low range," Pipe says. Additionally, some carrier women with FVIII levels as high as 50%–60% may still experience bleeds.

Symptoms: Missed and Dismissed

Mild hemophilia's trademark symptoms—bruising, nosebleeds,

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heavy menstrual periods (menorrhagia), and prolonged bleeding after trauma or dental or surgical procedures—can be missed or dismissed in girls and women. Danielle and Heather Schwager, 25, twins from Strongsville, Ohio, had symptoms during childhood. "We were kids who grew up playing outside all the time, and we were always bruised," says Danielle. The twins' mother, Vickie, a neonatal nurse practitioner, periodically questioned the pediatrician, wondering if her daughters had hemophilia B, like her father. "He kept telling me, 'No, females don't have hemophilia,' " Vickie says.

Five years later, Danielle bled for 10 days after having four teeth pulled. Her oral surgeon and orthodontist sensed something amiss and referred the family to the hemophilia treatment center (HTC) in Cleveland. Factor level testing confirmed Vickie's hunch. "My factor level was about 8% or 9% when I was diagnosed with mild hemophilia B," says Danielle. Heather's was about 40%. Those diagnoses took more than a decade.

During NHF's Annual Meeting in Chicago in November 2011, Koerper and Vickie conducted an educational session for women with mild hemophilia. Many women recounted similar experiences. "These women know they're bleeding too much," Koerper says. But their doctors disregarded their concerns, saying: "You got a big bruise because you banged your leg." Problems result when a surgery is performed without a treatment plan. "They'll have their gallbladder out, and then they have bleeding complications," says Koerper.

Davenport warned her new hematologist, who was inexperienced in treating women with bleeding disorders, that her factor level might soar from the stress she was feeling before a hysterectomy, but then would plummet afterward. Because her factor level skyrocketed to 80%, the hematologist took no precautions. Davenport woke up in the recovery room hearing her doctor tell the staff, "I don't know what's causing her bleeding. She doesn't have hemophilia."

"When they call you a 'symptomatic carrier,' and that's your label, you tend not to be treated seriously," Davenport says. For her, that resulted in post-op bleeding. For others, it might mean joint damage and arthritis from untreated bleeds or serious complications following childbirth.

Emotional and Behavioral Toll

The emotional and behavioral consequences for women with mild hemophilia who perceived errors in their medical care were documented in a 2011 study in Haemophilia by Nisa Renault and researchers at Dalhousie University in Halifax, Nova Scotia, Canada. The 11 women interviewed cited 264 negative emotional responses, including anger, doubt and mistrust.

A doctor's disbelief can lead to a patient's disillusionment. "It is frustrating to try to explain this to physicians who I would expect to know something about bleeding disorders," says Vickie.

Davenport was devastated when her doctor denied that she had hemophilia after her hysterectomy. "It was very hard on me to doubt the fact that maybe I believed this for 35 years, and it just wasn't right," she says. The pain went deep, as Davenport lost a comforting family connection. "That took away my identity—all I had of my dad."

Perceived mistreatment by healthcare providers also produced negative behavioral responses

Combined Federal Campaign

WPCNHF is an approved charitable organization for the Combined Federal Campaign (CFC). If you participate in the CFC, please consider designating all or a portion of your donation to the Chapter.

WPCNHF CFC Number is: **81343**

Continued from page 10

in the Canadian study subjects. Some women minimized the importance of their symptoms. Others avoided conflict by finding a new doctor or treatment center. Some were so desperate that they treated themselves with factor product they borrowed from a family member. However, this practice is not recommended and may even be dangerous. The borrowed medication may be the wrong dosage or wrong medication entirely from what your physician would have prescribed, says Pipe.

Advocacy in Action

A positive behavior that emerged among women in the Canadian study was to advocate for themselves or others. Some insisted on in-depth testing or better treatment, or seeking another opinion.

When Davenport needed emergency gallbladder surgery, she chose a smaller hospital closer to home. There she found an understanding hematologist. "He said, 'Okay, you seem to know what you're talking about,' " says Davenport. "He went with my history, not my labs." She brought in factor and saw the hematologist three times before the procedure. "I was on prophylaxis for a week out," Davenport says. "I had zero bleeding problems."

Vickie and Danielle are involved in local advocacy through the Northern Ohio Hemophilia Foundation in Cleveland. "Our local task force set up a program for dental professionals to make sure that they were educated on women's bleeding disorders," says Vickie. Further, the chapter has invited gynecologists and obstetricians to evening meetings to educate them. Danielle put together a brochure for the chapter to raise awareness about women's bleeding disorders. Both are on NHF's Women's Task Force, broadening their advocacy reach.

Critical Role of the HTC

Building a relationship with your HTC is critical for women with bleeding disorders. "Primary care physicians don't always understand the nuances of the testing," says Koerper. They may order the standard screening tests, see that the partial thromboplastin time [PTT, a measure of clotting time] is within normal range, and tell women they're fine, she says. "They don't understand that they have to order the actual FVIII or FIX activity test." The HTC can also order further tests to pinpoint the mutation. A 2011 study in Haemophilia showed that a woman's mutation, not factor level per se, was a better predictor of bleeding. (See "Test Takers," HemAware Fall 2011; "What's Your Genotype?" HemAware Spring 2010.)

Once you receive a mild hemophilia diagnosis from your HTC, you can get the benefits of comprehensive care. "We can offer them the same things we do for men with mild hemophilia, guidance around procedures and hemostatic support if necessary," Pipe says. "We can help them with their family planning."

Prior to surgery or dental procedures, your HTC can create a treatment plan to prevent or stop bleeding, which the dentist or surgeon can follow. "They were very aggressive with my treatment when I had dental work," says Davenport of the staff at her son's HTC. "I was on prophy, and everything was taken care of."

Treatment centers can also help untangle insurance hassles. Their experience with medical coding can make all the difference. "They have to use the appropriate code on every single encounter with you and for any treatment you need, such as factor, so that the insurance company will pay for it," Koerper says.

Without the diagnosis, the "carrier" label may be interpreted to mean you are asymptomatic. "A genetic designation does not equal a diagnosis," says Koerper. "To an insurance company, it means nothing." The Schwagers discovered that the hard way. "With the 'symptomatic carrier' label, we run into a lot of insurance issues. They see my birth control pills as contraception and an optional medication," Danielle says. At times, the insurer has denied her coverage.

Mild Hemophilia: Not for Men Only

Mild hemophilia should no longer be a "for men only" diagnosis, says Davenport. "If you have the symptoms of a disease or disorder and you have the labs to prove it, then you have it. It doesn't matter what your gender is." Danielle has fully accepted her diagnosis and identity. "When I identify myself, I say, 'I am a woman with mild hemophilia. I am a woman with hemophilia B.' "

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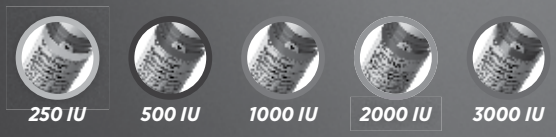

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What Is XYNTHA?

Xyntha® Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease.

Important Safety Information for XYNTHA

- Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction: wheezing, trouble breathing, chest tightness, turning blue (look at lips and gums), fast heartbeat, swelling of the face, faintness, rash, or hives. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your healthcare provider if you have had an allergic reaction to hamster protein.
- Call your healthcare provider right away if bleeding is not controlled after using XYNTHA; this may be a sign of an inhibitor, an antibody that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests to monitor for inhibitors.
- The most common adverse reaction in the safety and efficacy study is headache (24% of subjects) and in the surgery study is fever (43% of subjects). Other common side effects of XYNTHA include nausea, vomiting, diarrhea, or weakness.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. You may experience local irritation when infusing XYNTHA after reconstitution in XYNTHA® SOLOFUSE®.

Please see brief summary of full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Brief Summary

See package insert for full Prescribing Information, including patient labeling. For further product information and current patient labeling, please visit XYNTHA.com or call Wyeth Pharmaceuticals toll-free at 1-800-934-5556.

Please read this Patient Information carefully before using XYNTHA and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical problems or your treatment.

What is XYNTHA?

XYNTHA is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia A. Hemophilia A is also called classic hemophilia.

XYNTHA is not used to treat von Willebrand's disease.

What should I tell my healthcare provider before using XYNTHA?

Tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if XYNTHA may harm your unborn baby.
- are breastfeeding. It is not known if XYNTHA passes into your milk and if it can harm your baby.

Tell your healthcare provider and pharmacist about all of the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies.

XYNTHA contains trace amounts of hamster proteins. You should not use XYNTHA if you are allergic to hamster protein.

How should I infuse XYNTHA?

Step-by-step instructions for infusing with XYNTHA are provided at the end of the complete Patient Information leaflet. The steps listed below are general guidelines for using XYNTHA. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedures, please call your healthcare provider before using.

Call your healthcare provider right away if bleeding is not controlled after using XYNTHA. Your body can also make antibodies against XYNTHA (called "inhibitors") that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests from time to time to monitor for inhibitors.

Call your healthcare provider right away if you take more than the dose you should take.

Talk to your healthcare provider before traveling. Plan to bring enough XYNTHA for your treatment during this time.

What are the possible or reasonably likely side effects of XYNTHA?

Common side effects of XYNTHA are

- headache
- fever
- nausea
- vomiting
- diarrhea
- weakness

Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction:

- **wheezing**
- **difficulty breathing**
- **chest tightness**
- **turning blue (look at lips and gums)**
- **fast heartbeat**
- **swelling of the face**
- **faintness**
- **rash**
- **hives**

Talk to your healthcare provider about any side effect that bothers you or that does not go away. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XYNTHA?

Do not freeze.

Protect from light.

XYNTHA Vials

Store XYNTHA in the refrigerator at 36° to 46°F (2° to 8°C). Store the diluent syringe at 36° to 77°F (2° to 25°C).

XYNTHA can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA at room temperature, carefully write down the date you put XYNTHA at room temperature, so you will know when to either put it back in the refrigerator, use it immediately, or throw it away. There is a space on the carton for you to write the date.

If stored at room temperature, XYNTHA can be returned one time to the refrigerator until the expiration date. Do not store at room temperature and return it to the refrigerator more than once. Throw away any unused XYNTHA after the expiration date.

Infuse XYNTHA within 3 hours of reconstitution. You can keep the reconstituted solution at room temperature before infusion, but if you have not used it in 3 hours, throw it away.

Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

XYNTHA SOLOFUSE

Store in the refrigerator at 36° to 46°F (2° to 8°C).

XYNTHA SOLOFUSE can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA SOLOFUSE at room temperature, carefully write down the date you put XYNTHA SOLOFUSE at room temperature, so you will know when to throw it away. There is a space on the carton for you to write the date.

Throw away any unused XYNTHA SOLOFUSE after the expiration date.

Infuse within 3 hours after reconstitution or after removal of the grey rubber tip cap from the prefilled dual-chamber syringe. You can keep the reconstituted solution at room temperature before infusion, but if it is not used in 3 hours, throw it away.

Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

What else should I know about XYNTHA?

Medicines are sometimes prescribed for purposes other than those listed here. Talk to your healthcare provider if you have any concerns. You can ask your healthcare provider for information about XYNTHA that was written for healthcare professionals.

Do not share XYNTHA with other people, even if they have the same symptoms that you have.

This brief summary is based on the Xyntha® [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free] Prescribing Information LAB-0516-3.0, revised 06/12, and LAB-0500-7.0, revised 06/12.

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Printed in USA/June 2012

Please join us for the 3rd Annual Take A Bough Holiday Tree Auction. This 3-day festival will showcase decorated trees, wreaths and tabletop centerpieces that are available for bid.

3rd ANNUAL

TAKE A BOUGH

HOLIDAY TREE AUCTION TO BENEFIT WPCNHF

THE SHOPS AT STATION SQUARE

Friday, November 16
10:00am-9:00pm

Saturday, November 17
10:00am-9:00pm

Sunday, November 18
12:00pm-5:00pm

- Children's crafts will be available throughout the weekend.
- Vote for the People's Choice Award for a chance to win a prize.
- Enjoy the beautifully decorated trees, wreaths and other table top items.

www.takeabough.org

WPCNHF

SPONSORSHIP OPPORTUNITIES ARE STILL AVAILABLE!

For more information on this event and other programs offered by the Western Pennsylvania Chapter of the National Hemophilia Foundation visit www.westpennhemophilia.org.

All proceeds benefit The Western Pennsylvania Chapter of the National Hemophilia Foundation.

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Staff office hours are Monday through Friday from 9 a.m. until 4 p.m. Every attempt will be made to return calls received during regular office hours on the same day.

Our Mission:

The Western Pennsylvania Chapter of the National Hemophilia Foundation is leading the way in Western Pennsylvania in improving the quality of care and enriching the lives of those with bleeding disorders through education, advocacy, resource, and referral.

WPCNHF Wish List

The Chapter is always doing fundraisers to raise money for our educational programs and member support activities but sometimes we just need a few small things for the office. WPCNHF has a list of items needed in the office. If you, or anyone you know, is interested in donating any of the following please contact the office at info@westpennhemophilia.org or call us at 724-741-6160.

- White copy paper by the ream or by the case
- Colored copy paper by the ream for invitations and newsletter inserts
- Legal pads for note taking
- Forever U.S. Postage stamps
- 10 x 13 Ready-seal envelopes for newsletter mailings
- Paper towels
- Apartment-sized refrigerator
- Small microwave oven
- Conference table and chairs
- Waiting room chairs

Hemogram is published quarterly by the Western Pennsylvania Chapter of the National Hemophilia Foundation.

Mixers with Shakers

WPCNHF has been selected to participate at Mixer With Shakers, a fundraising opportunity for non-profits through the Pittsburgh Airport Area Chamber of Commerce.

Event Details

Thursday, November 15, 2012
5:00pm-8:00pm
Pittsburgh Airport Marriott

A Chapter member will be the bartender for the WPCNHF and everyone interested in attending and supporting the Chapter should send an e-mail to info@westpennhemophilia.org. Tickets are $20 and support WPCNHF. Please join us!

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