Hemogram

Western Pennsylvania Chapter of the National Hemophilia Foundation

Fall 2014

Inside this issue

Congratulations

WPCNHF Scholarship Winner

Nikole Scappe

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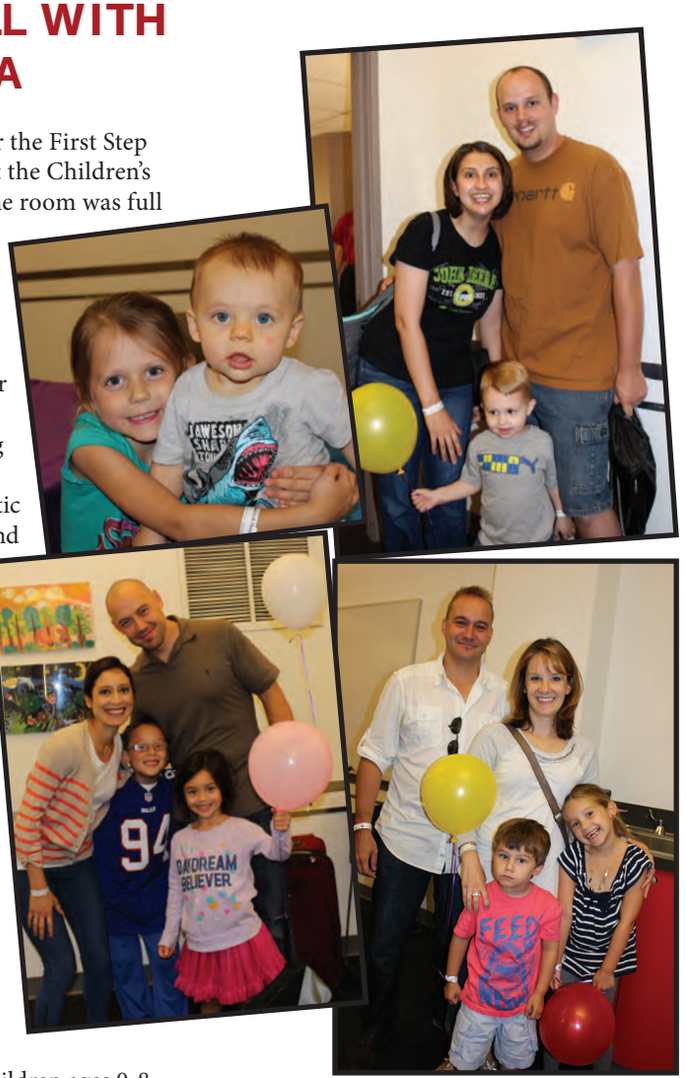
DESIGNATE UNITED WAY GIFTS TO THE CHAPTER

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**

LIVING WELL WITH HEMOPHILIA



We had a great turnout for the First Step program held in August at the Children's Museum in Pittsburgh! The room was full to capacity with families with young children who wanted to learn more about hemophilia.

Cathy Tiggs, a social worker at University Hospital in Cleveland, presented Living Well with Hemophilia. Her presentation included genetic information, recognizing and addressing different types of bleeds, and staying healthy to avoid potential complications. Cathy engaged the audience and had participation from people of all ages. We were very impressed with how much some of the children already knew about their bleeding disorders! This wonderful program was sponsored by Novo Nordisk.

First Step programs are offered for families with children ages 0-8 who have a bleeding disorder. In addition to educational programs, families can be matched up with an experienced mentor family. If you are interested in being matched with a mentor or would like to make a suggestion for a future program, please contact Janet Barone, Member Services Manager, at the Chapter office or Kathaleen Schnur, Social Worker, at the Hemophilia Center of Western PA.

WALK AND RUN FOR THEIR LIVES 5K

A Great Success!

Despite another year of rain, the 2014 Western Pennsylvania Hemophilia Walk and Run For Their Lives 5K were a huge success! Over 400 walkers and 115 runners successfully raised over $60,000 to help those affected by bleeding disorders. Walk day activities included a moon bounce obstacle course, Velcro wall, face paint artist, and balloon artist. The gift baskets included goodies for the entire family! Money raised

(Continued on page 15)

National Hemophilia Foundation and Western Pennsylvania Chapter of NHF Present

HEMOPHILIA walk '14

Every step makes a difference

National Presenting Sponsor

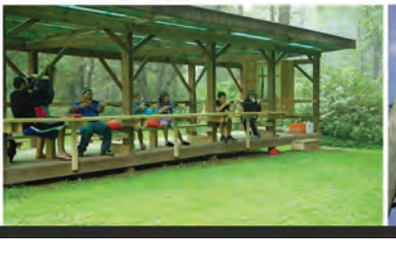
Baxter

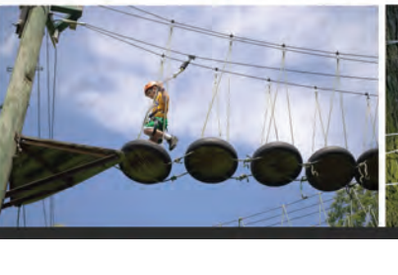
RUN FOR THEIR LIVES

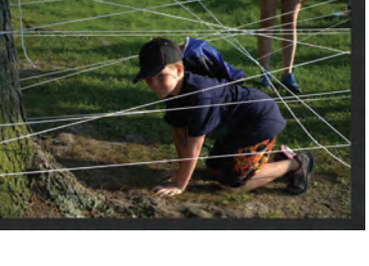
Bleeding disorders can't stop us.

CAMPERS VS WILD

CAMP HOT-TO-CLOT 2014







Camp Hot-to-Clot 2014 – Campers Vs. Wild

By Kathaleen Schnur

Camp-Hot-to-Clot 2014 welcomed the campers to challenge the wild and ended with our campers triumphantly, albeit exhausted, conquering the wild. During this sun up to sun down, fast paced, fun, and educational week, our campers learned about playing it safe while participating in different activities. On Monday, the campers learned about being resourceful in the wild to address medical or emergency situations, build fires, and construct a shelter. Tuesday the campers participated in service projects which were later shared with local groups. A special treat on Tuesday evening included the Wild World of Animals show which educated campers on various wild animals including a Red Tailed Hawk, a Snow Linx, and even a Boa Constrictor! After the wild animal show, the campers made a survival bracelet that in an emergency can be taken apart and used for tying things together or even fishing. Wednesday the campers spent much time (and bravery) on the high ropes, low ropes, zip lines, and climbing walls. In Camp Hot-to-Clot tradition, Wednesday night was carnival night! Many games, much laughter, a dunk tank, "photo booth," water balloons, and even a flavored shaved ice truck tired everyone out!

Amidst all the above excitement, the campers participated in the traditional camp activities such as boating, swimming, archery, fishing, creek stomping, gaga pit, crafts, and bon fires with s'mores. Every evening brought the reward of pizza to the group of campers with the cleanest cabin. Thursday and Friday were full of camaraderie as many of the campers attempted and successfully learned to infuse themselves. There was much "Sticking Together" happening as well for those campers who don't infuse with Factor, but learned the process of self-infusion to stand in solidarity with their siblings and friends.
Thursday evening the campers learned survival skills were put to the test in a camp wide challenge. Each group was given 30 minutes at each station where they had to build a functional raft, build a fire that burned hot enough and high

(Continued on page 15)

Camp Service Project

The following thank you note was received from Chris Sondej, Social Worker, Lutheran SeniorLife.

I just wanted to thank you and the campers from Camp Hot-to-Clot for the wonderful cards they designed and made for our residents at the Harbor Light Nursing Neighborhood at Passavant Retirement Center. The Residents are always very pleased to know that someone is thinking of them—they enjoyed the creative designs and loving messages—many are on display in their rooms!

Please thank all for their hard work and caring messages. God Bless you all!

Letter From The President, Scott Miller

Dear Members, Friends, and Supporters,

This has certainly been a busy start to the 2014-15 year! Our Annual Meeting, Camp Hot-to-Clot, the Walk and 5k Run for Their Lives, as well as NHF's Annual Meeting in Washington, DC. The staff has done a fantastic job preparing for our Fall events. If you look at the event calendar, you will see so many excellent programs scheduled. I hope that you take advantage of some these opportunities.

I want to thank all of those who participated in the Walk and Run for Their Lives. 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 – including taking TEN families to the NHF Annual Meeting in Washington, DC! Due to its relatively close location, we were able to extend additional scholarships to this meeting this year and we had a great showing from Western Pennsylvania! You will also see information in this newsletter about Take A Bough, one of our signature events. This year, the event is moving to One Oxford Centre, one of the largest office buildings in downtown Pittsburgh, which is an amazing opportunity. 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. Having the event at one Oxford Centre will increase awareness among the business community in Pittsburgh and be great exposure for our Chapter.

I look forward to seeing you and your family at our upcoming events. As always, please don't hesitate to contact me, or the Chapter staff, if you have any questions or concerns.

Sincerely,

Scott E. Miller, CPA, J.D., DBA
WPCNHF Board President

Letter From The Executive Director, Alison Yazer

Greetings!

I can't believe how quickly time has flown by as I start my third year with the Chapter!

We always strive to provide a variety of interesting, informative educational sessions – each of which also has a social aspect to it. Whether it's going to the movies after the Annual Meeting or attending a baseball game after Men's and Women's groups, we understand how important the friendships you build with other members are, so we do everything we can to help build networking opportunities into each and every event.

Please check the calendar for upcoming events – there are lots of them! They include educational events in Erie, Pittsburgh, Greensburg and more! The fifth annual Take A Bough will be November 19th – 22nd and this year it's moving to One Oxford Centre downtown. I hope you and your family will join us for one or more of these great events!

As always, please contact the Chapter with any questions or concerns. Thank you for all that you do on behalf of WPCNHF.

Sincerely,

Alison Yazer
Executive Director

WPCNHF Scholarship Winner

Congratulations to Nikole Scappe winner of the 2014-2015 WPCNHF Scholarship! Nikole is a student at LaRoche College, where she has a double major in Marketing and Management.

Calendar of Upcoming Events

Wednesday, October 15
Women's Group - Communications with Your Health Care Provider
Wexford, PA

Tuesday, October 28
Backyard Advocacy
Erie, PA

Wednesday, October 29
Backyard Advocacy
Greensburg, PA

Wednesday, November 12
Emotional Well-being in the Hemophilia Community
Indiana, PA

Thursday, November 13
Emotional Well-being in the Hemophilia Community
Robinson Township, PA

Wednesday, November 19 – Saturday, November 22
Take A Bough
Oxford Centre, Pittsburgh, PA

Winterfest: TBA

CFC® Combined Federal Campaign

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

Ask us about sponsorship opportunities and how you can help!

Researchers Report Advances in Plant-Based Hemophilia A Therapy

A team of researchers from the University of Florida, Gainesville (UF-G) and University of Pennsylvania (U-Penn) is developing a novel approach to tackling inhibitors in hemophilia A that uses genetically engineered plant cells. In a recent article published in the journal Blood, the authors reported making progress with the experimental therapy in mice with hemophilia A. The lead investigator of the study was Henry Daniell, PhD, Department of Biochemistry and Department of Pathology, School of Dental Medicine at U-Penn in Philadelphia.

Using genetically engineered plants, Daniell and his colleagues are developing therapeutic factor proteins that decrease unwanted treatment reactions such as anaphylaxis (a life-threatening allergic reaction) and inhibitor (antibody) responses by the immune system. The technique involves encapsulating a "tolerance-inducing protein" within plant cell walls so that when it is ingested it safely travels through the stomach before being released into the small intestines.

In this study, investigators synthesized tobacco plants and factor VIII-coded genetic material, which were fed to mice with hemophilia A. The therapy triggered an average of seven times fewer inhibitor responses. "This is a major step forward," said study co-author Roland W. Herzog, PhD, College of Medicine, UF-G. In the future, the goal is to replace tobacco plants with lettuce plants for human use.

Researchers have been developing this novel therapeutic approach for several years to create potential vaccines against malaria and cholera, and genetically engineered insulin to help prevent diabetes. In previous studies led by Daniell, factor IX-bioencapsulated plant cells were successfully delivered to mice with hemophilia B. The therapy prevented both anaphylaxis and inhibitors.

The authors see a tremendous upside if this oral tolerance therapy were to become a viable option for humans. "Our technique, which uses plant-based capsules, has the potential to be a cost-effective and safe alternative," said Daniell.

The article, "Suppression of Inhibitor Formation Against FVIII in a Murine Model of Hemophilia A by Oral Delivery of Antigens Bioencapsulated in Plant Cells," was published in the September 4, 2014, issue of Blood.

Source: newKerala.com, September 4, 2014

If You Have Hemophilia, Your Female Relatives May Need Your Help!

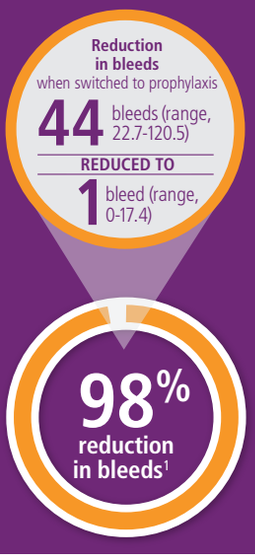
If you have hemophilia, some of your female relatives may be carriers of hemophilia. Being a carrier can impact a female's own health and management. It can also provide valuable information for that female's children and other family members.

Ultimately, this piece of information can lead to fewer health complications for carriers of hemophilia and their children. Even if your female relatives know that they have a chance to be a carrier, they may not know who to ask for more information or where to go to find out if they are a carrier or not. They may need your help!

The Hemophilia Center of Western Pennsylvania (HCWP) is here to support our patients and their families. Our staff is uniquely positioned to help your female relatives understand their chance to be a carrier and to help them figure out their carrier status, if interested. Please share this information with your female relatives. It could drastically impact their lives.

If you are a female relative of someone with hemophilia or are interested in more information, please contact Michelle Alabek, HCWP genetic counselor, at 412-209-7292.

ADVATE
[Antihemophilic Factor (Recombinant)]
There's more to life.



ADVATE PROPHYLAXIS MAY HELP YOU PREVENT OR REDUCE THE FREQUENCY OF BLEEDS[1]

SIGNIFICANT REDUCTION IN MEDIAN ANNUAL BLEED RATE (ABR) WITH PROPHYLACTIC TREATMENT COMPARED WITH ON-DEMAND TREATMENT[1]

- **42% of patients experienced 0 bleeds during 1 year on prophylaxis[1]**
- **98% reduction in median ABR from 44 to 1 when switched from on-demand to prophylaxis[1]**

In a clinical study, after switching from 6 months of on-demand treatment to 12 months of prophylaxis with ADVATE in 53 previously treated patients (PTPs) with severe or moderately severe hemophilia A.

A clinical study that evaluated treatment efficacy (the ability to control and reduce bleeds) of 2 prophylaxis regimens—Every-Second-Day (standard) prophylaxis dosed at 20 to 40 IU/kg every 48 hours and Every-Third-Day (pharmacokinetic-driven) prophylaxis dosed at 20 to 80 IU/kg every 72 hours, targeted to maintain factor VIII trough levels ≥1%.

INDICATIONS

ADVATE 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 adults and children (0-16 years) with hemophilia A. Your healthcare provider may give you ADVATE when you have surgery. ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand Disease.

DETAILED IMPORTANT RISK INFORMATION

You should not use ADVATE if you:

- Are allergic to mice or hamsters.
- Are allergic to any ingredients in ADVATE.

Tell your healthcare provider if you are pregnant or breastfeeding because ADVATE may not be right for you.

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

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.

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.

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

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

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.

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

Reference: 1. ADVATE Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; April 2014.

Baxter

ADVATE [Antihemophilic Factor (Recombinant)]

Lyophilized Powder for Reconstitution for Intravenous Injection

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

INDICATIONS AND USAGE

ADVATE [Antihemophilic Factor (Recombinant)] is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for:

- Control and prevention of bleeding episodes.
- Perioperative management.
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

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

CONTRAINDICATIONS

ADVATE is contraindicated in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product (mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80, and/or glutathione).

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, and pruritus.

ADVATE contains trace amounts of mouse immunoglobulin G (MuIgG) ≤0.1 ng/IU ADVATE, and hamster proteins ≤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

Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. 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

- 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*]
- 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 reactions seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions 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 clinical trials in previously treated patients (PTPs) and one ongoing trial 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 (range: 1 to 598).[3]

The summary of adverse reactions with a frequency ≥5% (defined as adverse events occurring within 24 hours of infusion or any adverse event causally related occurring within the trial period) is shown in Table 3.

No subject was withdrawn from a clinical trial due to an adverse reaction. There were no deaths in any of the clinical trials.

Table 3
Summary of Adverse Reactions[a] with a Frequency ≥5% (N = 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	104	49	21
Respiratory, thoracic, and mediastinal disorders	Cough	75	44	19
Infections and infestations	Nasopharyngitis	61	40	17
Gastrointestinal disorders	Vomiting	35	27	12
Musculoskeletal and connective tissue disorders	Arthralgia	44	27	12
Injury, poisoning, and procedural complications	Limb injury	55	24	10
Infections and infestations	Upper respiratory tract infection	24	20	9
Respiratory, thoracic, and mediastinal disorders	Pharyngolaryngeal pain	23	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] Adverse reactions are defined as all adverse events that occurred (a) within 24 hours after being infused with investigational product, or (b) all adverse events assessed related or possibly related to investigational product, or (c) 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 trial in PUPs as of 27 March 2006.

[c] MedDRA version 8.1 was used.

Immunogenicity

The development of factor VIII inhibitors with the use of ADVATE was evaluated in clinical trials 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 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).[3,4] No factor VIII inhibitors were detected in the 53 treated pediatric PTPs.

In clinical trials 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.[3] Four subjects 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. 182 treated subjects were assessed for anti-Chinese hamster ovary (CHO) cell protein antibodies. Of these subjects, 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 mulgG protein antibodies. Of these, 10 showed an upward trend in anti-mulgG 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.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ADVATE with the incidence of antibodies to other products may be misleading.

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 4 represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Terms.

Table 4
Post-Marketing Experience

Organ System [MedDRA Primary SOC]	Preferred Term
Immune system disorders	Anaphylactic reaction[a] Hypersensitivity[a]
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

[a] These reactions have been manifested by dizziness, paresthesias, rash, flushing, face swelling, urticaria, and/or pruritus.

Patented: see www.baxter.com/productpatents/

Baxter Healthcare Corporation, Westlake Village, CA 91362 USA

U.S. License No. 140 Issued 04/2014

USBS/34/14-0104

Baxter

Spotlight on the Member: Brendon Simpson

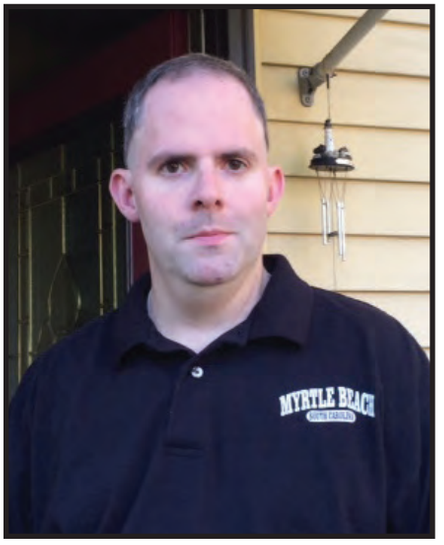
Hemophilia has been in Brendon Simpson's family for at least three generations. The first family member to be diagnosed was Brendon's grandfather. His grandfather was born in the 1910's. Growing up, his grandfather had a number of issues with bleeds, but no one knew what the cause was. He was able to manage his bleeds until he had a tooth extracted sometime in the mid 1940's. He was hospitalized and bled for days. Although many people were willing to donate blood, he had a rare blood type. A few days into his hospital stay, a doctor spotted his grandmother crying in the waiting room and stopped to talk with her. When he heard her story, he donated blood and his blood type was a match! Although he still didn't have a diagnosis, his grandfather's bleeding stopped after he received the blood transfusion. It wouldn't be until many years later that he would receive a diagnosis.

By the time Brendon was born, his older brother had been diagnosed with Hemophilia after experiencing a number of bleeding episodes. So Brendon was tested at birth and was diagnosed with severe hemophilia A. Brendon recalls long days at the blood bank being treated with cryoprecipitate, when he was a child.

Although Brendon and his brother had the same diagnosis, Brendon's bleeds did not occur as frequently nor did they stay active as long as his brother's bleeds. His brother had frequent, heavy nose bleeds, and fortunately, Brendon did not. As with many people with bleeding disorders, though, he would occasionally have a mouth bleed which were always a challenge to control. Fortunately, he did not get them often, either.

Brendon's parents were cautious with their children; however, they did their best not to hold them back from having many of the same experiences as children without bleeding disorders. Although Brendon didn't participate in team sports, he did play catch, tag football, and street hockey with his friends and over time, he learned his limits. Today he enjoys bowling, spending time on the driving range hitting golf balls, and playing deck hockey.

Brendon has been a long time member of the Chapter and he particularly enjoys participating in the Hemophilia Walk. He



says it's a great way to get a little exercise and some fresh air and he likes that it brings people together for a great purpose! As long as his ankles are feeling good, he makes it a point to attend the Walk.

Brendon has also served on the Consumer Advocacy Committee for the Hemophilia Center of Western PA for the past seven years. He takes his role seriously. He feels that he represents adults with hemophilia and he offers opinions and raises concerns on their

(Continued on page 15)

ALPROLIX™
[Coagulation Factor IX (Recombinant), Fc Fusion Protein]

Now Available

A new treatment for hemophilia B

ALPROLIX provides protection* from bleeds starting with at least a week between prophylaxis infusions.

Dosing regimen can be adjusted based on individual response.

*Protection is the prevention of bleeding episodes using a prophylaxis regimen.

To learn more, contact CoRe Manager **Christine Rowe**

E: christine.rowe@biogenidec.com T: 267.249.8372

Indications and Important Safety Information

Indications

ALPROLIX, Coagulation Factor IX (Recombinant), Fc Fusion Protein, is a recombinant DNA derived, coagulation factor IX concentrate indicated in adults and children with hemophilia B for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

ALPROLIX is not indicated for induction of immune tolerance in patients with hemophilia B.

Important Safety Information

Do not use ALPROLIX if you are allergic to ALPROLIX or any of the other ingredients in ALPROLIX.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies and all your medical conditions, including if you are pregnant or planning to become pregnant, are breastfeeding, or have been told you have inhibitors (antibodies) to factor IX.

Allergic reactions may occur with ALPROLIX. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called “inhibitors” against ALPROLIX, which may stop ALPROLIX from working properly.

ALPROLIX may increase the risk of formation of abnormal blood clots in your body, especially if you have risk factors for developing clots.

Common side effects of ALPROLIX include headache and abnormal sensation of the mouth. These are not all the possible side effects of ALPROLIX. Talk to your healthcare provider right away about any side effect that bothers you or does not go away, and if bleeding is not controlled using ALPROLIX.

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.

Please see Brief Summary of full Prescribing Information on the next page. This information is not intended to replace discussions with your healthcare provider.

biogen idec®

ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein], Lyophilized Powder for Solution For Intravenous Injection.

FDA Approved Patient Information

ALPROLIX™ /all' prō liks/
[Coagulation Factor IX (Recombinant), Fc Fusion Protein]

Please read this Patient Information carefully before using ALPROLIX™ and each time you get a refill, as there may be new information. This Patient Information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is ALPROLIX™?

ALPROLIX™ is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital Factor IX deficiency.

Your healthcare provider may give you ALPROLIX™ when you have surgery.

Who should not use ALPROLIX™?

You should not use ALPROLIX™ if you are allergic to ALPROLIX™ or any of the other ingredients in ALPROLIX™. Tell your healthcare provider if you have had an allergic reaction to any Factor IX product prior to using ALPROLIX™.

What should I tell my healthcare provider before using ALPROLIX™?

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

Tell your doctor about all of your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if ALPROLIX™ may harm your unborn baby.
- are breastfeeding. It is not known if ALPROLIX™ passes into breast milk or if it can harm your baby.
- have been told that you have inhibitors to Factor IX (because ALPROLIX™ may not work for you).

How should I use ALPROLIX™?

ALPROLIX™ should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider. Many people with hemophilia B learn to infuse their ALPROLIX™ by themselves or with the help of a family member.

See the **Instructions for Use** for directions on infusing ALPROLIX™. The steps in the **Instructions for Use** are general guidelines for using ALPROLIX™. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedure, please ask your healthcare provider. Do not use ALPROLIX™ as a continuous intravenous infusion.

Contact your healthcare provider immediately if bleeding is not controlled after using ALPROLIX™.

What are the possible side effects of ALPROLIX™?

Common side effects of ALPROLIX™ include headache and abnormal sensation in the mouth.

Allergic reactions may occur. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: hives, chest tightness, wheezing, difficulty breathing, or swelling of the face.

ALPROLIX™ may increase the risk of forming abnormal blood clots in your body, especially if you have risk factors for developing blood clots.

Your body can also make antibodies called, "inhibitors," against ALPROLIX™, which may stop ALPROLIX™ from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.

These are not all the possible side effects of ALPROLIX™.

Talk to your healthcare provider about any side effect that bothers you or that does not go away.

How should I store ALPROLIX™?

Store ALPROLIX™ vials at 2°C to 8°C (36°F to 46°F). Do not freeze.

ALPROLIX™ vials may also be stored at room temperature up to 30°C (86°F) for a single 6 month period.

If you choose to store ALPROLIX™ at room temperature:

- Note on the carton the date on which the product was removed from refrigeration.
- Use the product before the end of this 6 month period or discard it.
- Do not return the product to the refrigerator.

Do not use product or diluent after the expiration date printed on the carton, vial or syringe.

After Reconstitution:

- Use the reconstituted product as soon as possible; however, you may store the reconstituted product at room temperature up to 30°C (86°F) for up to 3 hours. Protect the reconstituted product from direct sunlight. Discard any product not used within 3 hours after reconstitution.
- Do not use ALPROLIX™ if the reconstituted solution is cloudy, contains particles or is not colorless.

What else should I know about ALPROLIX™?

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ALPROLIX™ for a condition for which it was not prescribed. Do not share ALPROLIX™ with other people, even if they have the same symptoms that you have.

Manufactured by
Biogen Idec Inc.
14 Cambridge Center
Cambridge, MA 02142
U.S. License #1697

Half the volume
Twice the factor*

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is now available in a **2000 IU FVIII vial** with a reconstitution volume of only **10 mL**.

*That's **TWICE** the amount of factor of the largest vial available for other FVIII/VWF products,[1-4] so patients may require:

- **Less volume**
- **Less time**
- **Fewer syringes**

Isn't it time you tried ALPHANATE?

Learn more at
alphanate.com

Alphanate®
Antihemophilic Factor/von Willebrand Factor Complex (Human)

Indications

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:

- Control and prevention of bleeding in patients with hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP®) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery

Important Safety Information

ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with ALPHANATE should be discontinued, and emergency treatment should be sought.

Development of activity-neutralizing antibodies has been detected in patients receiving FVIII containing products. Development of alloantibodies to VWF in Type 3 von Willebrand disease (VWD) patients has been occasionally reported in the literature.

Thromboembolic events may be associated with AHF/VWF Complex (Human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may be associated with infusion of massive doses of AHF/VWF Complex (Human).

Rapid administration of a FVIII concentrate may result in vasomotor reactions.

Plasma products carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

The most frequent adverse events reported with ALPHANATE in >5% of patients are respiratory distress, pruritus, rash, urticaria, face edema, paresthesia, pain, fever, chills, joint pain, and fatigue.

Please see brief summary of ALPHANATE full Prescribing Information on 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. ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) Prescribing Information. Grifols. **2.** CSL Behring. Humate P Package Insert. August 2013; **3.** Octapharma. Wilate Package Insert. January 2012; **4.** Kedrion. Koate-DVI Package Insert. August 2012.

For more information: **Grifols Biologicals Inc.**
Tel. 888-GRIFOLS (888-474-3657)

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ALPHANATE®

Antihemophilic Factor/von Willebrand Factor Complex (Human)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Alphanate safely and effectively. See full prescribing information for Alphanate.

ALPHANATE (ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX [HUMAN])

Sterile, lyophilized powder for injection.

Initial U.S. Approval: 1978

----------INDICATIONS AND USAGE ----------

Alphanate is an Antihemophilic Factor/von Willebrand Factor Complex (Human) indicated for:

- Control and prevention of bleeding in patients with hemophilia A.
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand Disease in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery.

----------DOSAGE AND ADMINISTRATION ----------

For Intravenous use only.

Alphanate contains the labeled amount of Factor VIII expressed in International Units (IU) FVIII/vial and von Willebrand Factor:Ristocetin Cofactor activity in IU VWF:RCo/vial.

Hemophilia A: Control and prevention of bleeding episodes

- Dose (units) = body weight (kg) x desired FVIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL).
- Frequency of intravenous injection of the reconstituted product is determined by the type of bleeding episode and the recommendation of the treating physician.

von Willebrand Disease: Surgical and/or invasive procedure in adult and pediatric patients except Type 3 undergoing major surgery

- Adults: Pre-operative dose of 60 IU VWF:RCo/kg body weight; subsequent doses of 40-60 IU VWF:RCo/kg body weight at 8-12 hour intervals post-operative as clinically needed.
- Pediatric: Pre-operative dose of 75 IU VWF:RCo/kg body weight; subsequent doses of 50-75 IU VWF:RCo/kg body weight at 8-12 hour intervals post-operative as clinically needed.

----------DOSAGE FORMS AND STRENGTHS ----------

- Alphanate is a sterile, lyophilized powder for intravenous injection after reconstitution, available as 250, 500, 1000, 1500 and 2000 IU FVIII in single dose vials.

----------CONTRAINDICATIONS ----------

- Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

----------WARNINGS AND PRECAUTIONS ----------

- Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with Alphanate should be discontinued, and emergency treatment should be sought.
- Development of activity-neutralizing antibodies has been detected in patients receiving FVIII containing products. Development of alloantibodies to VWF in Type 3 VWD patients has been occasionally reported in the literature.
- Thromboembolic events may be associated with AHF/VWF Complex (Human) in VWD patients, especially in the setting of known risk factors.
- Intravascular hemolysis may be associated with infusion of massive doses of AHF/VWF Complex (Human).
- Rapid administration of a FVIII concentrate may result in vasomotor reactions.
- Plasma products carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

----------ADVERSE REACTIONS----------

The most frequent adverse events reported with Alphanate in > 5% of patients are respiratory distress, pruritus, rash, urticaria, face edema, paresthesia, pain, fever, chills, joint pain and fatigue.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Biologicals Inc. at 1-888-GRIFOLS (1-888-474-3657) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: No human or animal data. Use only if clearly needed.
- Pediatric Use: Hemophilia A - Clinical trials for safety and effectiveness have not been conducted. VWD - Age had no effect on PK.

GRIFOLS

Grifols Biologicals Inc.
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U.S. License No. 1694

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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
- Sticky Notes
- Forever U.S. Postage stamps
- 10 x 13 Ready-seal envelopes for newsletter mailings
- Paper towels
- Apartment-sized refrigerator

WALK AND RUN FOR THEIR LIVES 5K

(Continued from the Cover)

from the Walk and Run will benefit the Western Pennsylvania Chapter of the National Hemophilia Foundation and will provide educational programs and support to the bleeding disorders community in Western Pennsylvania.

Thank you to our sponsors and participants!
Special thanks to Trau & Loevner for donating our Hemophilia Walk t-shirts

Hemophilia Walk
Top Fundraising Team:
Luke's Lineup: $7,620
Top Fundraisers:
Scott Miller: $1,925
Analise Baker: $1,135
Jennifer Miller: $825

Run For Their Lives
Top Overall Finishers:
1st Place: Matthew Puleio: 18:44.16
2nd Place: Gary Puleio: 21:15.72
3rd Place: Anna Homitsky: 21:23.77

Mark your calendars for the 7th Annual Western Pennsylvania Hemophilia Walk on September 12, 2015!

Camp Hot-to-Clot 2014 – Campers Vs. Wild

(Continued from page 3)

enough to burn through a rope and drop a stone, "hunt" at the archery range, and use their first aid skills in fictional scenarios. Thursday night the Red Hawks and Green Lions (teenagers) continued their challenges as they packed an overnight bag (including factor), hiked to another part of the camp, slept out all night, built a morning fire and cooked breakfast over it.

Friday brought exhaustion and mixed emotions as the week was winding down and the campers were sad to be leaving their friends soon, but happy to be returning to their families and their own beds on Saturday. At dinner, the campers were recognized for their achievements during the week and received appropriate pins reflecting their accomplishments as well as decorated award sticks for infusing or learning to infuse. Friday night's closing ceremony was located at the pond. It began with the counselors recognizing the achievements of their individual cabins and introducing one of their own campers to speak on their experience at camp. One candle was lit and from its flame every candle ignited until all present shone in gorgeous candle light. Tears and smiles were shared as well as conversations and excitement for next year.

Spotlight on the Member: Brendon Simpson

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behalf. There have been many changes over the years and he wants to make sure that this particular population within the community continues to have access to specialists who know them as individuals. He also wants to make sure that history isn't forgotten. He likes to keep up with what's going on in the bleeding disorders community and feels that he can speak on behalf of others who aren't up-to-date on changes or potential changes that could affect access to care. He's not afraid to ask questions. He feels that if something is on his mind, chances are there are others in the community who have similar questions or concerns. He feels that others might either be afraid to ask questions or assume that someone else has already asked, so he feels it's his responsibility to do so.

Brendon's advice to others is to trust the doctors; however, don't be afraid to ask questions and don't be afraid to say you don't understand something. He also recommends reaching out to someone who has been in your situation before. Chapter events are a good way to meet other individuals and families with bleeding disorders. Brendon also believes that if you want to do something and you have the physical capabilities to do it, you shouldn't let your diagnosis hold you back. He says don't be afraid to try something new. Know your limits and coordination abilities, take precautions, prepare yourself, and go for it!

Having issues with co-pays or gaps in coverage for your **hemophilia A** treatment ???

We may be able to help.

Bayer offers a range of programs that can help you **navigate insurance questions about your hemophilia A** treatment. If you're having issues with co-pays or gaps in coverage, we may be able to offer assistance. Speak with one of our case specialists to find out more.

Call **1-800-288-8374** and press 1 to speak to a trained **insurance specialist!**

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