Hemogram

Western Pennsylvania Chapter of the National Hemophilia Foundation

Fall 2013

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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**

CAMP HOT-TO-CLOT HIGHWAY TO HEALTH!

This year, Camp Hot-to-Clot rocked--literally! With the Rock 'n Roll—Highway to Health theme, camp was sure to be a hit with everyone! Even the dining hall was rocking! You just never knew when the entire camp was going to join in and sing along to the music, dance, and play air guitars!

In Camp Hot-to-Clot tradition, this energetic week was packed with fun and activities from sun up 'til way after the sun went down. The Rock 'n Roll—Highway to Health theme was carried out in activities throughout the week. Campers learned the importance of physical activity for good health. For example, each camper was issued an age-appropriate pedometer to record their steps each day. The campers also built individual compost containers and learned how to compost during the week. Other activities included swimming, boating, fishing, archery, gaga pit, field games, yoga, dance, crafts, a high-ropes course, a climbing wall, and more! In addition, each night the campers with the cleanest cabin were rewarded with a pizza!

Wednesday night was the traditional carnival night. This year's carnival ended with a pie eating contest…uh, I mean whipped cream fight. Hmmm…70+ kids with pie tins full of whipped cream…did anyone see that coming? ;) The fun continued on Thursday night when each group of campers performed a rock 'n roll themed skit and then enjoyed the movie Camp Rock—the perfect movie for this year's theme! Friday night concluded with a beautiful, candle-lit ceremony around a pond. The "Big Stick" award was given to those campers who self-infused for the first time at camp. "Sticking Together" awards were given to siblings and other campers who don't infuse with Factor, but bravely learned the process of self-infusion to help support their siblings and friends. Many campers were also recognized and rewarded for other achievements that were observed during the week.

The campers had a great week and are already talking about next year. Here are a few quotes from their evaluation forms:

What do you like best about camp and why? "The kindness—because everybody is so nice to me, especially my new friend."

What did you like best about camp? "I loved the carnival. It was really great being able to hang out with everyone doing a bunch of fun activities (especially the whipped cream fight)!!"

"Camp is more than just 'camp.' We became a family for a week. We enjoy each other's company and love it. CAMP IS NECESSARY!"

IT DIDN'T RAIN ON OUR PARADE!

Despite the weather, the 2013 Western Pennsylvania Hemophilia Walk and the Run For Their Lives 5K were a huge success! Over 450 walkers and runners successfully raised over $57,000 to help those affected by

(Continued on page 15)


CAMP
HOT to CLOT
2·0·1·3
I'M ON THE HIGHWAY TO HEALTH

Letter From The President, Scott Miller

Dear Members, Friends and Supporters,

This has certainly been a great summer with an awesome week at camp, many events and the Walk! The staff continues to do a fantastic job with our events. If you look at the event calendar, you will see so many excellent programs planned. As the Chapter expands its geographic outreach efforts, I hope you will take advantage of these diverse educational 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. You will also see information in this newsletter about Take-A-Bough, which has become one of our signature events. This year, we are returning to Station Square, which is exciting for us. Please try to attend the event 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. Keep your eyes open for information about our 2nd Annual Bowling for Bleeding Disorders, which will be held next spring!

As always, thank you all for your efforts and please remember that the Chapter is here to serve you – our members. If there is a program you'd like to see, or if you have ideas for an event, please don't hesitate to get in touch with the Chapter.

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 and that I've already been here a full year! As you know, one of my first goals was to increase the number of educational programs we hold and to diversify the locations in which we hold them. I can say that we have definitely achieved that – we went from 9 events last year to over 20 this year and we went to Altoona for the first time in June!

The Hemophilia Walk took place September 21. We had over 35 teams and raised over $43,000. Thanks to everyone who worked hard to make this year's Walk such a success!

I am glad so many of you joined us this year and I hope more of you plan ahead and join us on September 13, 2014. The 4th Annual Run for Their Lives 5K was held in conjunction with the Walk and we had over 30 registered runners. It was a great run and all proceeds benefited WPCNHF and will help defray the costs of our programs throughout the year.

Things are changing constantly within the bleeding disorders community. Industry is changing rules and regulations for support of Chapter events, but there are also uncertainties ahead in the insurance world. Rest assured, the Chapter will work hard to bring you up to date information regarding the implementation of the Affordable Care Act as it rolls out in early 2014. If you are not currently on the Chapter's e-mail distribution list, please send your e-mail address to info@westpennhemophilia.org, so you can receive timely updates.

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

Sincerely,

Alison Yazer
Executive Director

Seven Ways to BEAT BLEEDS

What's your first reaction when you experience a bleed? Some people with hemophilia A or hemophilia B have little or no reaction – they've become so accustomed to pain, swelling and stiffness that bleeding is now "just part of life." But by working with your hemophilia clinician on a comprehensive treatment plan, and by using today's therapies, you can beat bleeds.

Whether your reactions to a bleed and your long-term goals are to address pain associated with bleeds, stay active, or be there with your family, it's never too late to start taking charge of your health.

Over the last 30 years, researchers and clinicians have discovered that the infusion of factor on a regular basis (often called prophylaxis) can actually prevent most bleeds. Today, hemophilia clinicians commonly recommend this approach. There are a number of options available for managing and reducing bleeds. You should partner with your Hemophilia Treatment Center (HTC) to find the treatment plan that works for you.

Here are some tips that you can think about and discuss with your hemophilia clinician:

BEAT BLEEDS TIP #1:
KNOW YOUR ABR
The first thing you can do to reduce or prevent bleeds is to know your annual bleed rate (ABR), which is the number of times you bleed in a year. It's an important number – like knowing your weight, blood pressure, cholesterol or blood sugar levels. Work with your HTC team to determine your goal.

BEAT BLEEDS TIP #2:
TRACK YOUR BLEEDS
Know how often you are bleeding. Begin by tracking your bleeds for a month, capturing the date, location and type (joint, muscle, other) of each bleed you experience. Keep in mind the common signs of a joint bleed: tingling, pain, stiffness, heat, and swelling. Be aware of common signs of a muscle bleed: pain, stiffness, warmth, swelling, tightness of skin, redness, and numbness (this is a late sign).

Notice if your pain has become worse over

(Continued on page 11)

Calendar of Upcoming Events

Sunday, October 13
Girls Only
Sewickley, PA

Saturday, October 19
Educational Program and Fall Fest
Finleyville, PA

Saturday, October 26
Educational Program and Social Event
Erie, PA

Friday, November 22 – Sunday, November 24
Take A Bough
Pittsburgh, PA

Sunday, December 15
Winterfest
Alison Park, PA

Saturday, January 11
The Art of Transition
Johnstown, PA

All events that are organized or sponsored by the Chapter will say "WPCNHF" on the invitation and/or envelope. Any invitations that do not say WPCNHF on them ARE NOT for Chapter events. If you ever have any questions regarding an event, please don't hesitate to call the Chapter office for clarification!

Additionally, WPCNHF neither recommends nor endorses any company providing medications or services. We provide opportunities for our industry partners to exhibit at several events throughout the year so that you – the consumer – can meet with them and make informed decisions that make sense for you and your family.

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

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 this address below or bring them with you to any Chapter event.

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

Ask us about sponsorship opportunites and how you can help!

NOW APPROVED

NEW RIXUBIS [COAGULATION FACTOR IX (RECOMBINANT)]

A recombinant factor IX indicated for routine prophylaxis to treat adults with hemophilia B[1]

Available FALL 2013

For more information, contact your Baxter representative today:

Melanie Zembrzuski
Phone: (412) 400-9565
E-mail: melanie_zembrzuski@baxter.com

To learn more, visit www.RIXUBIS.com

Indications for RIXUBIS [Coagulation Factor IX (Recombinant)]

RIXUBIS is an injectable medicine used to replace clotting factor IX that is missing in people with hemophilia B (also called congenital factor IX deficiency or Christmas disease).

RIXUBIS is used to prevent and control bleeding in adults with hemophilia B. Your healthcare provider may give you RIXUBIS when you have surgery. RIXUBIS can reduce the number of bleeding episodes in adults when used regularly (prophylaxis).

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

Detailed Important Risk Information for RIXUBIS [Coagulation Factor IX (Recombinant)]

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

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 hamsters, are nursing, are pregnant or planning to become pregnant, or have been told that you have inhibitors to factor IX.

You can have an allergic reaction to RIXUBIS. Call your healthcare provider or get emergency treatment right away 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 IX. An inhibitor is part of the body's defense system. If you form inhibitors, it may stop RIXUBIS 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 IX.

If you have risk factors for developing blood clots, the use of factor IX products may increase the risk of abnormal blood clots.

Some common side effects that have been reported with RIXUBIS include: unusual taste in the mouth and limb pain.

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

Please see Brief Summary of RIXUBIS Prescribing Information on following 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.

Reference: 1. RIXUBIS [Prescribing Information]. Westlake Village, CA: Baxter Healthcare Corporation; June 2013.

Baxter

RIXUBIS [Coagulation Factor IX (Recombinant)]
For Intravenous Injection
Brief Summary of Prescribing Information: Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE

Control and Prevention of Bleeding Episodes

RIXUBIS [Coagulation Factor IX (Recombinant)] is an antihemophilic factor indicated for control and prevention of bleeding episodes in adults with hemophilia B.

Perioperative Management

RIXUBIS is indicated for perioperative management in adults with hemophilia B.

Routine Prophylaxis

RIXUBIS is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults with hemophilia B.

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

CONTRAINDICATIONS

RIXUBIS is contraindicated in patients with:

- Known hypersensitivity to RIXUBIS or its excipients including hamster protein
- Disseminated intravascular coagulation (DIC) [see *Warnings and Precautions*]
- Signs of fibrinolysis [see *Warnings and Precautions*]

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported with factor IX-containing products. The risk is highest during the early phases of initial exposure to factor IX concentrates in previously untreated patients (PUPs), in particular in patients with high-risk gene mutations. Early signs of allergic reactions, which can progress to anaphylaxis, include angioedema, chest tightness, hypotension, lethargy, nausea, vomiting, paresthesia, restlessness, wheezing, and dyspnea. Immediately discontinue administration and initiate appropriate treatment if allergic- or anaphylactic-type reactions occur. In case of severe allergic reactions, alternative hemostatic measures should be considered.

There have been reports in the literature showing an association between the occurrence of a factor IX inhibitor and allergic reactions. Evaluate patients experiencing allergic reactions for the presence of an inhibitor.

RIXUBIS contains trace amounts of Chinese hamster ovary (CHO) proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Inhibitors

Evaluate patients regularly for the development of factor IX inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor IX inhibitor concentration if expected factor IX activity plasma levels are not attained, or if bleeding is not controlled with an expected dose. Contact a specialized hemophilia treatment center if a patient develops an inhibitor.

Patients with factor IX inhibitors are at an increased risk of severe hypersensitivity reactions or anaphylaxis if re-exposed to RIXUBIS. RIXUBIS may not be effective in patients with high titer factor IX inhibitors and other therapeutic options should be considered.

Nephrotic Syndrome

Nephrotic syndrome has been reported following attempted immune tolerance induction in hemophilia B patients with factor IX inhibitors. The safety and efficacy of using RIXUBIS for immune tolerance induction have not been established.

Thromboembolic Complications

The use of factor IX containing products has been associated with the development of thromboembolic complications (e.g., pulmonary embolism, venous thrombosis, and arterial thrombosis). Due to the potential risk for thromboembolic complications, monitor patients for early signs of thrombotic and consumptive coagulopathy, when administering RIXUBIS to patients with liver disease, with signs of fibrinolysis, peri- and post-operatively, or at risk for thrombotic events or DIC. The benefit of treatment with RIXUBIS should be weighed against the risk of these complications in patients with DIC or those at risk for DIC or thromboembolic events.

Monitoring Laboratory Tests

- Monitor factor IX activity plasma levels by the one-stage clotting assay to confirm that adequate factor IX levels have been achieved and maintained [see *Dosage and Administration in full Prescribing Information*].
- Monitor for the development of inhibitors if expected factor IX activity plasma levels are not attained, or if bleeding is not controlled with the recommended dose of RIXUBIS. Assays used to determine if factor IX inhibitor is present should be titered in Bethesda Units (BUs).

ADVERSE REACTIONS

The most common adverse reactions observed in >1% of subjects in clinical studies were dysgeusia, pain in extremity, and positive furin antibody test.

Clinical Trials 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 the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During clinical development, in a combined study, 91 male previously treated patients (PTPs; exposed to a factor IX-containing product for ≥150 days) received at least one infusion of RIXUBIS as part of either on-demand treatment of bleeding episodes, perioperative management of major and minor surgical, dental, or other invasive procedures, routine prophylaxis, or pharmacokinetic evaluation of RIXUBIS. Six subjects (6.6%) were <6 years of age, 10 (11%) were 6 to <12 years of age, 3 (3.3%) were adolescents (12 to <16 years of age), and 72 (79%) were adults (16 years of age and older). The subjects received a total of 7,353 infusions with a median of 85 infusions of RIXUBIS (range 3 to 212 infusions), for a median of 83 exposure days (range 83 to 209 days).

A total of 161 adverse events were reported in 48 (52.7%) of the 91 subjects. Adverse reactions that occurred in >1% of subjects are shown in Table 3.

Table 3: Summary of Adverse Reactions

System Organ Class	Adverse Reactions (AR)	Number of ARs (N)	Number of Subjects (N=91) n (%)	Percent per Infusion (N=7353)
Nervous System Disorders	Dysgeusia	2	1 (1.1%)	0.03%
Musculoskeletal and Connective Tissue Disorders	Pain in extremity	1	1 (1.1%)	0.01%
Investigations	Positive furin antibody test[a]	1	1 (1.1%)	0.01%
	Factor IX or furin antibodies of indeterminate specificity[a]	9	7 (7.7%)	0.12%

[a]See Immunogenicity.

Immunogenicity

All 91 subjects were monitored for inhibitory and binding antibodies to factor IX, and binding antibodies to CHO protein and furin, at the following time points: at screening, at 72 hours following the first infusion of RIXUBIS and the commercial recombinant factor IX product in the cross-over portion of the pharmacokinetic study, after 5 and 13 weeks following first exposure to RIXUBIS, and thereafter every 3 months. Antibodies against furin were tested by an in-house enzyme-linked immunosorbent assay (ELISA). A titer of 1:20 or 1:40 was considered to be indeterminate for the above validated assay, as these titers were too low to be verified by the confirmatory assay.

No subjects developed neutralizing antibodies to factor IX. Thirteen subjects (14.3%) developed low-titer, non-neutralizing antibodies against factor IX at one or more time points. Two of these 13 subjects were found to have these antibodies at screening, prior to receiving RIXUBIS. No clinical adverse findings were observed in any of these 13 patients.

Thirteen subjects (14.3%) had signals for antibodies against furin (indeterminate specificity). Four of these 13 subjects expressed signals for antibodies at screening, prior to RIXUBIS treatment. An additional subject had an antibody signal after treatment with the comparator product and prior to RIXUBIS treatment. Another additional subject had a positive titer of 1:80 that was not present when checked at a later time point and therefore considered transient. A second subject had a positive antibody signal after the data cutoff date that was also transient. No clinical adverse findings were observed in any of these 15 patients.

In a study of 500 normal volunteers, using the same assay as in the clinical trial, 7% had titers of 1:20 or 1:40 and 1.2% had higher titers ranging from 1:80 to 1:320. These antibodies are thought to be part of a natural immune system response. To date, these antibodies have not been associated with any clinical adverse findings.

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.

Thrombogenicity

There was no clinical evidence of thromboembolic complications in any of the subjects. Out-of-range values for thrombogenicity markers (thrombin-antithrombin III, prothrombin fragment 1.2, and D-dimer), determined during the pharmacokinetic portion of the combined study, did not reveal any pattern indicative of clinically relevant thrombogenicity with either RIXUBIS or a comparator factor IX-containing product.

Post-marketing Experience

Because the following 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.

No post-marketing adverse reactions have been reported with RIXUBIS.

The following class adverse reactions have been seen with another recombinant factor IX: inadequate factor IX recovery, inhibitor development, anaphylaxis, angioedema, dyspnea, hypotension, and thrombosis.

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U.S. License No. 140 Issued JUN 2013
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Don Groves Memorial Scholarship

This year the Don Groves Memorial Scholarship was awarded to Michael Zolotnitsky! Michael is currently enrolled in the Doctor of Physical Therapy Program at Chatham University. When he receives his degree, he feels it will be his privilege and responsibility to motivate patients to overcome physical obstacles by promoting good health, advocating daily exercise, and encouraging an overall healthy life style.

Michael believes that living a life with hemophilia has strongly influenced his decision to pursue a career in the medical field. He saw how health professionals changed his life and helped him to overcome obstacles that he did not believe were possible.

Michael's long-term goal is to open an orthopedic private practice. In addition, he would like to initiate a program for children with bleeding disorders. He wants to help patients overcome the adversity and fear of physical activity that he had experienced as a child.

The Don Groves Memorial Scholarship is sponsored by the Miller and Groves families, in memory of Don Groves, who passed away in 2002 of complications associated with hemophilia. The Miller and Groves families are proud to offer this scholarship to Michael Zolotnitsky. We all wish the best for Michael as he earns his degree and pursues his goals!

Getting' in the Game Junior National Championship

William McCarthy, age 11, was selected by WPCNHF to represent Western Pennsylvania in the Gettin' in the Game Junior National Championship (JNC), held September 20-22 in Phoenix, Arizona. The JNC is generously sponsored by CSL Behring. Will, who has Hemophilia B, lives with his family in Erie, PA.

A total of 101 kids, from 54 different chapters/organizations competed in the golf and baseball tournaments. Throughout the weekend, participants and their parents/guardians had opportunities to attend educational sessions to learn more about their bleeding disorders and the importance of physical fitness and healthy lifestyles. The children also learned about the fundamentals of golf and baseball, proper stretching techniques, and the importance of safety on and off the field. Will participated in the Golf competition and attended skill building sessions, such as putting, chipping, and driving, with Perry Parker. Perry is a professional golfer who also has hemophilia.

On Saturday, Will played nine holes of golf on the beautiful Devil's Claw golf course. It was 98 degrees when Will teed off! According to his mother, Stacy, who accompanied him, he shot 45 which is a great score for him. She said he had some tough competition and she was very proud of him! Later that night at the awards dinner, Perry Parker announced the second place winner, Will McCarthy, and stated that he has a good chance of winning the competition in a few years! Will received a plaque, trophy, and a rolling athletic bag from CSL Behring.

Stacy mentioned that Perry Parker and all of the CSL Behring staff and volunteers were incredibly kind, helpful, and dedicated to all of the young athletes. Stacy said it was an unbelievable experience for these kids to compete with their peers and learn that as long as you play safe and smart you can achieve and exceed your goals!

NHF Annual Meeting

We have just returned from Anaheim, where we attended the NHF Annual Meeting. There were so many interesting sessions – from financial planning for people in the bleeding disorder community to what's coming down the pipeline in terms of new treatments and cutting-edge research that's being conducted.

Consumers who attend this meeting always say that there's nothing like it and they highly recommend that ANYONE affected by a bleeding disorder try to attend. Next year, the meeting is much closer to home, in Washington, D.C. While we always offer scholarships to a few members, next year, we'd like to send as many people to the conference as possible. Please mark your calendars for September 18-20, 2014 and plan to join us in DC! Details about scholarships will be available in the near future, so please stay tuned!

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Antihemophilic Factor (Recombinant), Plasma/Albumin-Free

Prefilled for fast and easy ALL-IN-ONE reconstitution.

Available in:

250 IU *500 IU* *1000 IU* *2000 IU* *3000 IU*

Get a 1-month supply up to 20,000 IU of XYNTHA at no cost to you—

talk to your health care provider to see if XYNTHA® SOLOFUSE® is right for you. One-time offer.*

Terms and Conditions can be found at *FreeTrialXyntha.com*

* You must be currently covered by a private (commercial) insurance plan. If you are not eligible for the XYNTHA Trial Prescription Program, you may find help accessing Pfizer medicines by contacting Pfizer's RSVP program at 1-888-327-RSVP (7787).

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.

Wyeth® Manufactured by Wyeth Pharmaceuticals Inc.

Marketed by Pfizer Inc.

Printed in USA/September 2012

xyntha

Antihemophilic Factor (Recombinant), Plasma/Albumin-Free

xyntha solofuse

Antihemophilic Factor (Recombinant), Plasma/Albumin-Free

℞ only

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.

Wyeth®

Manufactured by Wyeth Pharmaceuticals Inc.

Marketed by Pfizer Inc.

Pfizer

Printed in USA/June 2012

Voluntary Recall Issued For Certain Lots Of Monoject™ Prefill Flush Syringes

Covidien, a healthcare products company, initiated a voluntary recall of certain lots of Monoject™ prefill flush syringes due to the syringes being filled with water that had not been subjected to their autoclave sterilization process.

These products can be either labeled as "sodium chloride" flush or "heparin lock" flush. Some of the syringes have a mismatched syringe tip cap, syringe label, fill volume and wrapper. However, the company states that "for the sodium chloride flush syringes with matched tip cap, syringe label, filled volume and wrapper, there are no visual cues for the clinician to identify the problematic products."

These syringes are primarily used with peripheral PICC lines, port catheter lines, and Broviac and Hickman lines to flush the lines after use. If non-sterile fluid is administered to an individual, there is a risk of life-threatening infection in the blood stream or other parts of the body. Also if an individual uses the heparin lock flush syringe which contains instead only water on peripheral or central venous catheters, the patency of the intravascular device may not be maintained, and clotting may occur. This could result in non-functional intravenous access, requiring the device to be replaced.

The affected lots are as follows:
See Chart Below

According to the company's release, only Monoject™ prefill flush syringes from the lot numbers above are affected by this action. The lot numbers can be found on the shipper case, carton and individual syringe. These products were only sold in the United States and Bermuda.

NHF feels that it is important to inform the community of this recall and suggests that if you have any products from these affected lots, you contact your hemophilia treatment center (HTC) or homecare provider to request a replacement.

It is unclear whether Covidien manufactures any of the prefilled syringes that are supplied with factor products. NHF is contacting the factor manufacturers and will issue an updated medical advisory if necessary.

Healthcare professionals and consumers may report any adverse events related to the use of these products to FDA's Med Watch Adverse Reporting program by calling 1-800-332-1088 or via their webpage at http://www.fda.gov/medwatch/report.htm

PHYSICIANS: Please distribute this information to all providers in your area who treat patients with hemophilia.

CHAPTERS: Please distribute this information to your membership.

Please sign up for the Patient Notification System (PNS) to be notified directly about the latest recall or withdrawal of

Product ID	Description	Lot #
8881570121	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 10 mL Fill	13A0084N 13A0094 13B0364 13C0504 13C0514
8881570123	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 3 mL Fill	13A0084N
8881570125	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 5 mL Fill	13A0084N
8881580121	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 10 mL Fill	13A0084N
8881580123	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 3 mL Fill	13A0084N
8881580125	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 5 mL Fill	13A0084N
8881590121	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 10 mL Fill	13A0084N
8881590123	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 3 mL Fill	13A0084N
8881590125	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 5 mL Fill	13A0084N 13D0824N

recombinant and plasma products. The system is confidential and time sensitive. It is administered by an independent third-party organization and is free of charge. To enroll in the PNS, please call (888) UPDATE-U or go online at http://www.patientnotificationsystem.org

This material is provided for your general information only. NHF does not give medical advice or engage in the practice of medicine. NHF under no circumstances recommends treatment for specific individuals and in all cases recommends that you consult your physician or local hemophilia treatment center before pursuing any course of treatment.

Seven Ways to BEAT BLEEDS

(Continued from page 3)

time, and if so, how. Record how often in a month you have had to miss school, work, or other activities because of bleeds.

BEAT BLEEDS TIP #3:
SET YOUR GOALS

Many people want zero bleeds. How many fewer bleeds do you want to have? What motivators might help you achieve your goals? What obstacles might get in the way of achieving your goals? Talk with your hemophilia clinician to set appropriate and realistic goals for you.

BEAT BLEEDS TIP #4:
MAKE YOUR PLAN

To beat bleeds, you need a plan. Work with your HTC to create a treatment regimen that will help you accomplish your goals. Your plan will also focus on overall health. Keeping your joints and muscles strong now and in the future can be critical to help prevent bleeds. Exercise and eating well are key to staying strong and reducing stress on joints by maintaining a healthy weight.

A good plan helps you take charge, reduce bleeds, and minimize pain associated with bleeding. A great plan will help you do it in a way that works with your life. The key is to create a routine you can stick with over the long term. That way, it's easier for you to realize the benefits of reducing bleeds. Be sure to talk with your HTC about your overall health needs and goals.

BEAT BLEEDS TIP #5: TAKE STEPS TO PREVENT OR REDUCE BLEEDS

When factor levels are low, accidental bleeds and spontaneous bleeds are more likely to occur. Instead of only treating a bleed after it happens, infusing prophylactically can keep factor levels up, which has been shown to prevent most bleeds and reduce annual bleed rates (ABRs), or the number of times you bleed in one year. Work with your HTC to determine which regimen is right for you.

Beat Bleeds Tip #6: Track Your Progress

On paper, a computer or smartphone, create a simple tracking system that works for you. Record things like infusions, weight, bleeds (remember the info in Tip #2), and successes. While you're tracking your progress, also note your patterns. What do you need to do to achieve your goals? What barriers are in the way? Every month, take a look at your data and take pride in your progress!

BEAT BLEEDS TIP #7: START TODAY!

Don't wait – put these tips into practice now to better manage your hemophilia, your health, or other areas of your life. By knowing the facts, setting goals, working with your HTC and making good choices, you can minimize the impact of bleeds on your life.

Go to thereforyou.com and sign up to receive a tool to track your annual bleed rate. Prefer to go paperless? Get the Beat Bleeds smartphone app to track your bleeds, set up infusion schedule reminders, and monitor your progress toward reaching your ABR goal.

This article was prepared by Baxter for the bleeding disorders community.

Spotlight on The Member: Meet Mike Clancey

Born in 1947, during a time when the only treatment options for hemophilia were ice, pressure and whole blood transfusions, Mike has witnessed firsthand the challenges and advances in diagnosis and treatment for people with hemophilia. Mike was raised in the small town of Havre, MT. As a young child, he was often bruised and his mother would treat him with ice, pressure, and wrappings. He didn't experience his first bleed requiring hospitalization until he was approximately six years old and in first grade, when he developed a bleed in one of his legs for no apparent reason. Although hemophilia was known, it was a time when people were often misdiagnosed. His mother, who was originally from West Virginia, had relatives back home who were "bleeders." She was a nurse and knew that blood transfusions could help Mike. After numerous attempts, she convinced the doctors that he might have a bleeding disorder and they treated him with blood transfusions. By the time they started the transfusions, the bleed had progressed and Mike's leg was very swollen. He spent several weeks in the hospital and missed the last 4-5 months of school while he recovered.

Within the next couple of years, Mike's family took at trip to visit relatives in West Virginia. While they were on that trip, Mike's father flew with him to Ohio, so he could be evaluated at the Cleveland Clinic. At the time of his appointment, he wasn't experiencing an active bleed, so the doctors based their diagnosis on the symptoms and experiences that Mike and his father relayed to them. Mike's pattern of bleeds was inconsistent. He was a very active child and could go lengths of time without a serious bleed and then suddenly have a bleed for no apparent reason. The doctors suspected that he had Christmas Disease (hemophilia B/ Factor IX Deficiency).

That diagnosis stayed with Mike until about 1972-1973, when Mike broke his foot. He was living near Chicago at the time. Advancements in diagnosis and treatment had been made over the years and he was now diagnosed as having mild hemophilia A (Factor VIII Deficiency) and was successfully treated with Factor.

Shortly thereafter, Mike moved to Ohio and then to Colorado. He was living in Denver, Colorado in 1982, when he developed spontaneous bleeds in both forearms and both calves. He received Factor over an extended period and was hospitalized for a good part of that time. He was rehabilitated and received care from a Hemophilia Center for the first time.

Although treatment options improved over time and were increasingly more effective in helping to control bleeds, they came with some unwanted consequences. Mike had contracted Hepatitis B in 1973 and Hepatitis C in 1981 both of which were transmitted through the use of blood products. At one point in 1982, Mike was also told that he had developed an inhibitor. During the better part of the next decade, Mike avoided factor products unless they were absolutely necessary.

During the 1990's Mike experienced a severe GI bleed which resulted in the loss of a lot of blood. By this time, Factor products had become safer as new screening and viral inactivation methods were implemented and new Factor products were being developed using recombinant technologies. Mike was hospitalized for a few days, received blood to replace the blood he had lost, and received Factor to control the bleed.

Mike is now 65 years old and is still very active. He experiences occasional bleeds and still has no set pattern for what triggers a bleed. Fortunately, he has no detectable viral loads for hepatitis and does not have an active inhibitor.

Mike is retired and resides in Grove City, PA, with his wife, Beth, a Nurse Practitioner. They have lived in Grove City since 1986. They have two daughters, Sara and Jessica, and have four grandchildren. Two of their grandsons have hemophilia. Mike mentioned that one of his grandsons was life-flighted to receive care for a cranial bleed when he was born, but both boys are currently doing fine.

Although Mike is retired, he stays busy and has a full schedule. He frequently travels, enjoys fishing, does some consulting work, is involved with community work, and serves on the board of directors for several organizations. He serves on the advisory committee for ATHN (American Thrombosis & Hemostasis Network) and he serves on the Executive Committee for Region III Hemophilia Centers. Mike is also an active member of the Chapter. He supports the Chapter's fundraisers, has participated in our advocacy day in Harrisburg and has participated in Men's Group events.

When asked if he has any advice to share with our community, Mike said, "Don't over protect your kids." He said that when he was growing up, he was allowed to take part in almost all of the sports and activities he wanted. He thinks that sometimes when kids are told repeatedly that they can't do things, that message subconsciously carries over into other areas of their lives and they can become fearful of trying anything new. He suggests guiding them and giving them other options if necessary, but don't limit or over protect them.

The Hemophilia Center of Western Pennsylvania Merges with The Institute for Transfusion Medicine

The Hemophilia Center of Western Pennsylvania (HCWP) would like to announce its new subsidiary relationship with The Institute for Transfusion Medicine (ITxM). In June 2013, HCWP merged into the ITxM family by becoming a subsidiary of ITxM.

ITxM is one of the nation's foremost organizations specializing in transfusion medicine and related services. Their two blood centers, Central Blood Bank in Pittsburgh and LifeSource in Chicago, provide nearly a million units of lifesaving blood products annually. ITxM Diagnostics is the leading source of therapeutic and coagulation reference testing services while ITxM Clinical Services focuses on the pre-transfusion testing and delivery of vital blood products to patients.

The merger was a progression of the working relationship established between HCWP and ITxM as the two entities have collaborated with one another on many projects, including most notably the creation of the Vascular Medicine Institute with the University of Pittsburgh in 2008 to promote clinical and translational research in hemostasis and thrombosis and vascular biology. Other plans include collaborating with the University to plan a larger clinic with more space to accommodate the growth of HCWP and to promote the care of individuals with disorders in hemostasis, thrombosis, and benign hematology. The comprehensive care model that has been so integral to the hemophilia program will continue strong.

The new relationship between HCWP and ITxM will enhance the pursuit of the Center's strategic goals established by its Board of Directors. It is the hope of HCWP's board that the Center will be able to extend its exceptional patient care into other disciplines with the creation of the aforementioned benign hematology center. As a result of the merger, HCWP is better positioned to accomplish this goal with the added expertise and experience of the professional resources of ITxM.

This organizational change will serve to strengthen the resources required to provide the state-of-the-art patient care the Center provides. HCWP remains committed to the bleeding disorder community and will continue operating as a hemophilia treatment center providing outstanding comprehensive patient care to the residents of Western Pennsylvania with hemophilia and other bleeding disorders. Patients will continue to come first and will continue to receive the excellent care that they deserve and have grown accustomed to receiving.

Meet The HCWP Staff

Courtney Igne , Senior Regulatory Coordinator
Courtney Igne is an Iowa native. She went to Iowa State University where she graduated in 2009 with a Bachelor's in exercise science, and in 2013 obtained her Master's in Exercise Physiology from the University of Pittsburgh. She has four years of experience as a research coordinator working at the University of Pittsburgh in geriatric medicine under Dr. Stephanie Studenski where she coordinated studies focusing on balance, mobility, and cognition. On the side Courtney teaches group fitness classes, is involved with wellness coaching, and is an avid cyclist.

Dr. Lynn Malec
Dr. Lynn Malec is a Hematology/Oncology Fellow at Children's Hospital of Pittsburgh. Originally from Madison, Wisconsin, Dr. Malec completed her undergraduate and medical school studies at the University of Wisconsin. She then completed residency in both Internal Medicine and Pediatrics at UPMC/Children's Hospital of Pittsburgh prior to beginning her specialty training in hematology/oncology. Dr. Malec's focus is on caring for patients with bleeding and clotting disorders. She currently sees pediatric and adult patients at the Hemophilia Center of Western Pennsylvania under the guidance of Drs. Ragni, Ritchey and Cooper. Dr. Malec also has an interest in clinical research. She is currently performing clinical research related to diagnosing vonWillebrand Disease in children with Dr. Ragni and is obtaining a Master of Science in Clinical Research at the University of Pittsburgh. Outside of work, Dr. Malec enjoys staying active playing basketball and golf.

Dr. Craig Seaman
Dr. Craig Seaman went to medical school at Marshall University in Huntington, WV, and completed his internal medicine residency at UPMC. He is completing his three-year hematology/oncology fellowship at Pitt/UPCI. His research interests are in hemostasis and thrombosis. Currently, his research includes thrombosis and sickle cell disease projects on which he is working with Dr. Ragni. He is also working towards a Master of Science in Clinical Research at the University of Pittsburgh. He loves sports and, as a native of South Western Pennsylvania, he is a huge Steelers, Pirates, and Penguins fan.

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Bookkeeper & Office Assistant
Kara Dornish

Fundraising & Events Manager
Brittani Reed

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

IT DIDN'T RAIN ON OUR PARADE!

(Continued from the Cover)

bleeding disorders. This year, there was a rock climbing wall, gaga pit, video game trailer, face paint artist, balloon artist and more! The gift baskets that were raffled off included something for the entire family… even an iPod Nano! Money raised from the Walk and Run will fund research toward better treatments and cures; provide education to help people with bleeding disorders avoid debilitating complications and live longer, more active and healthier lives; conduct advocacy initiatives at local and national levels to help ensure access to medical care and equitable insurance reimbursement for all; build awareness of bleeding disorders and promote early diagnosis; and advocate and create awareness for overall blood safety.

Mark your calendars for the 6th Annual Western Pennsylvania Hemophilia Walk on September 13, 2014!

National Hemophilia Foundation and Western Pennsylvania Chapter of NHF Present
HEMOPHILIA walk '13
Every step makes a difference

Top Fundraising Team:
Brody's Bruisers: $5,592.90

Top Fundraisers:
Scott Miller: $1,960.00
Debbie Lang: $1,357.90
Dawn Rotellini: $1,100.00
Cameron Cedeno: $890.00

RUN FOR THEIR LIVES

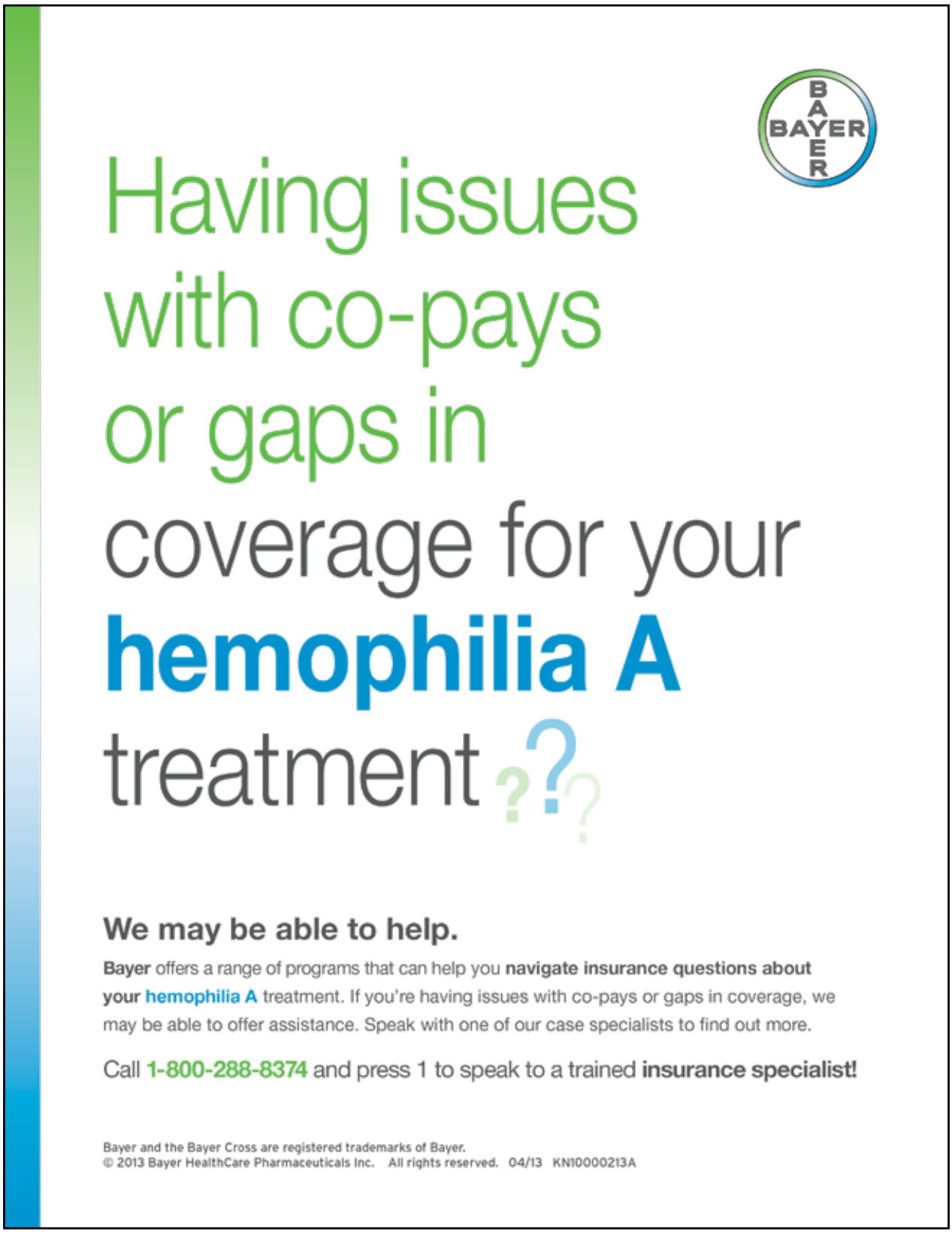
Men's Division:
1st Place: Michael Zolotnitsky: 20:31
2nd Place: Gary Puleio: 20:52
3rd Place: Robert Sforza: 21:13

Women's Division:
1st Place: Carrie Schade: 23:44
2nd Place: Claudia Medica: 24:18
3rd Place: Melissa Conely: 26:22

Youth Division:
1st Place: Matthew Pulieo: 19:48
2nd Place: Juliet Tonkin: 23:43
3rd Place: Maria Dysert: 23:47

Thank you to our sponsors and participants!

Special thanks to Trau & Loevner for donating our Hemophilia Walk t-shirts and to Faraone Brothers for donating their DJ service.



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WPCNHF