Hemogram

Western Pennsylvania Chapter of the National Hemophilia Foundation

Spring 2019

Inside this issue

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**

Education Weekend

Fifty families came together for the 2019 Education Weekend, which was held at Seven Springs Mountain Resort, March 23-24.

Saturday was packed with programming. There was something for everyone. Topics included children with bleeding disorders; women and girls with bleeding disorders; musculoskeletal ultrasound; understanding addictions; camp for children with bleeding disorders; medical marijuana; first-aid; insurance; and more! Session sponsors included Takeda, Aptevo, CSL Behring, Hemophilia Federation of America, and Sanofi Genzyme.

Children participated in activities and programs, based on their age. Special programing for children included a Blood Buddies program and Comic Book Writing Workshop, sponsored by Diplomat Pharmacy; a Jr. Scientist program, sponsored by Accredo; and a Cookie Lab, sponsored by Octapharma. The teenagers attended an incredible Leading Edge program, run by GutMonkey and sponsored by Pfizer.

Saturday ended with an optional Jam Session, which was a lot of fun! We certainly have talented people in our Chapter. A couple of

(Continued on next page)

Education Weekend

(Continued from previous page)

people even performed songs that they composed themselves!

Sunday morning we wrapped up the weekend with a choice of four sessions: Infusion Day, Rare Bleeding Disorders, von Willebrand Disease, and Ask the Physical Therapist.

We thank the following for sponsoring this event:

Title Sponsor
Takeda

Presenting Sponsors
CSL Behring
Hemophilia Center of Western PA
Novo Nordisk
Pfizer
Sanofi Genzyme

Supporting Sponsors
Accredo
Aptevo
Cottrill's Pharmacy
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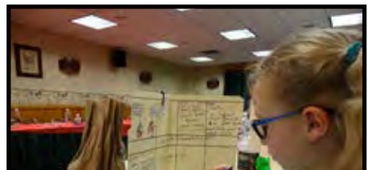
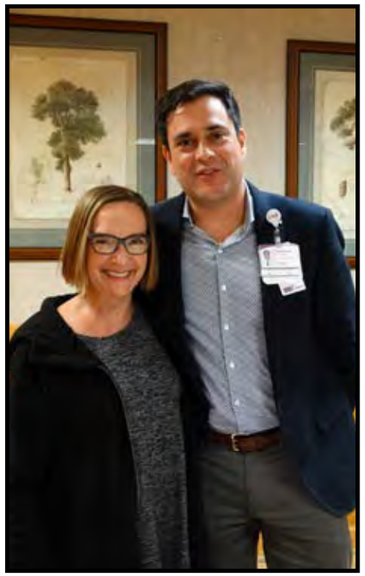

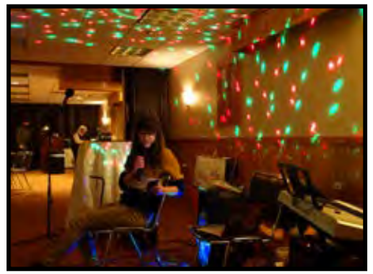


Letter from the Interim Executive Director

Dear Chapter Members and Friends,

Happy Spring! It has been a busy few months for the Chapter as we continue to plan events and actively advocate for the community. Thank you so much to everyone who has volunteered, fundraised, attended events, and supported the Chapter so far this year.

The Bowling for Bleeding Disorders event was a great success! The event sold out and raised over $11,000 for the bleeding disorders community. Thank you so much to everyone who attended and made this event great!

Education Weekend at Seven Springs went off without a hitch. I hope everyone who was able to attend had a great time and came back with a wealth of information. Thank you to Janet and Jessica and the amazing volunteers who put countless hours into making this educational event a success.

As many of you know, I am off on maternity leave. My son, August Samuel, was born on March 23rd. I am absolutely thrilled to begin this new journey as a mother. I will be officially back from leave in July but will be checking e-mail regularly if you need to get in touch with me. Janet and Jessica will also be available to assist you and answer any questions you may have.

Thank you for all that you do on behalf of the bleeding disorders community.

Sincerely,

Kara Dornish

Kara Dornish
Interim Executive Director

Advocacy Update

In early January, the Eastern and Western PA Chapters traveled to Harrisburg to meet with representatives from the Appropriations Committees for the House Republicans and Democrats as well as the Senate Republicans and Democrats. In addition, there were meetings with Sarah Boateng, Executive Deputy Secretary for the Department of Health and Jen Swails, Budget Secretary. Our discussions focused on the Hemophilia Program, which once again was combined with other line items in the Governor's proposed 2019-2020 budget.

Governor Wolf was sent letters supporting the Hemophilia Program as a separate line item with at least level funding from Representative Thomas Mehaffie III, Senator Tom Killion, Representative MaryLouise Isaacsons, Representative Dan Frankel (Chairman-Democratic Health Committee) and Senator Lawrence Farnese, Jr. More letters will be coming.

In addition, Senator Jay Costa and Representative Maureen Madden are sponsoring a resolution recognizing March, 2019 as "Bleeding Disorders Awareness Month" in Pennsylvania. Senator Costa and Representative Frankel are sponsoring a resolution recognizing April 17, 2019 as "World Hemophilia Day."

Board of Directors

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Interim Executive Director
Kara Dornish

Member Services Manager
Janet Barone

Marketing and Events Intern
Jessica Lee

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.

WPCNHF Wish List

The Chapter is always raising funds 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@wpcnhf.org or call us at 724-741-6160.

- White copy paper by the ream or by the case
- Sticky Notes
- Forever U.S. Postage stamps
- 10 x 13 Ready-seal envelopes for newsletter mailings

Mission Statement:

WPCNHF strives to enrich the lives of those with bleeding disorders in Western Pennsylvania and respond to the needs of the community in a dynamic environment.

Hemogram is published quarterly by the Western Pennsylvania Chapter of the National Hemophilia Foundation. The contents of this newsletter may be reproduced freely. The material in this newsletter is provided for your general information only. WPCNHF does not give medical advice or engage in the practice of medicine. WPCNHF under no circumstances recommends particular treatments, and always recommends that you consult your physician or treatment center before pursuing any course of treatment.

Calendar of Upcoming Events

April 4-7, 2019
HFA Symposium
San Diego, CA

April 6, 2019
Cornhole Tournament
Oakdale, PA

April 9, 2019
State Advocacy Day
Harrisburg, PA

May 21, 2019
Women's Group
Greentree, PA

July 13, 2019
New Parent Network
Pittsburgh, PA

July 25, 2019
Annual Meeting & Walk Kickoff
Homestead, PA

August 4-10, 2019
Camp Hot-to-Clot
Fombell, PA

August 24, 2019
Summer Program
Erie, PA

September 7, 2019
United for Bleeding Disorders Walk
Run for Their Lives 5K
Cornhole Tournament
Allison Park, PA

October 3-5, 2019, NHF's Bleeding Disorders Conference, Anaheim, CA

October 24, 2019
Women's Group
Pittsburgh, PA

November 2, 2019
New Parent Network
Pittsburgh, PA

November 16, 2019, Take A Bough, Oakdale, PA

December 8, 2019
Winterfest
Oakland, PA

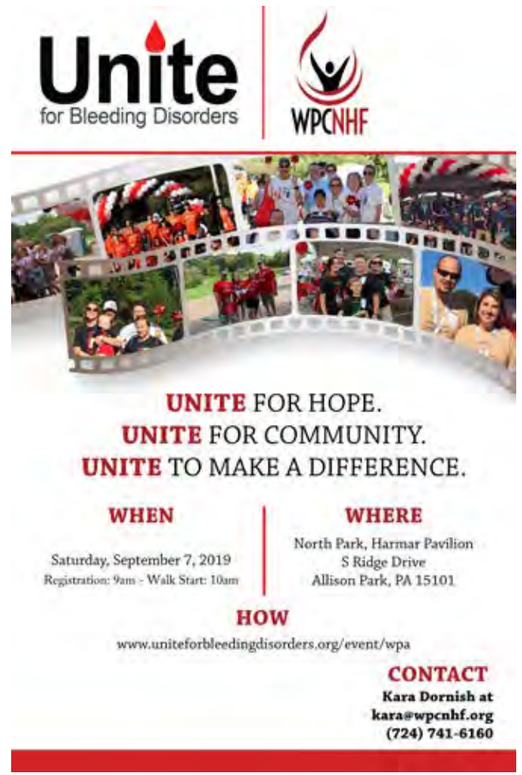
Ask us about sponsorship opportunities and how you can help!

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



HCWP Corner

Warm Wishes from your HCWP:

It was wonderful to spend time with so many of you at the Chapter's Education Weekend in Seven Springs. The educational content, networking, and relationship building was so impactful, and we at the Center were grateful to be a part of it.

Our Amish Outreach Clinics will begin in April and go through May. We are getting closer to camp registration time beginning May 1st and going through June 30th. Please make sure you pay attention to those deadlines! It's a great time to call and get those annual clinics scheduled in anticipation of summer months. Our teens that are approaching graduation and considering post-secondary plans should look to the NHF website and contact your local HTC social worker to investigate the available scholarships.

Thank you to all of our patients who continue to give us feedback via the patient satisfaction surveys distributed in clinic. Please know that we also have a Consumer Advocacy Committee that meets three times per year. It offers patients, parents, and caretakers the opportunity to voice their concerns, challenges, and suggestions to the HCWP staff regarding programs and patient care issues. Please contact Katherine or Kathaleen at the Center if you would like to participate.

Medication Guide
HEMLIBRA® (hem-lee-bruh)
(emicizumab-kxwh)
injection, for subcutaneous use

What is the most important information I should know about HEMLIBRA?

HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII (FVIII) and the recommended dose and schedule to use for breakthrough bleed treatment.

HEMLIBRA may cause the following serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including:

- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMLIBRA:
  - confusion
  - weakness
  - swelling of arms and legs
  - yellowing of skin and eyes
  - stomach (abdomen) or back pain
  - nausea or vomiting
  - feeling sick
  - decreased urination
- **Blood clots (thrombotic events).** Blood clots may form in blood vessels in your arm, leg, lung, or head. Get medical help right away if you have any of these signs or symptoms of blood clots during or after treatment with HEMLIBRA:
  - swelling in arms or legs
  - pain or redness in your arms or legs
  - shortness of breath
  - chest pain or tightness
  - fast heart rate
  - cough up blood
  - feel faint
  - headache
  - numbness in your face
  - eye pain or swelling
  - trouble seeing

If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.

See "**What are the possible side effects of HEMLIBRA?**" for more information about side effects.

What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

Hemophilia A is a bleeding condition people can be born with where a missing or faulty blood clotting factor (factor VIII) prevents blood from clotting normally.

HEMLIBRA is a therapeutic antibody that bridges clotting factors to help your blood clot.

Before using HEMLIBRA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if HEMLIBRA may harm your unborn baby. Females who are able to become pregnant should use birth control (contraception) during treatment with HEMLIBRA.
- are breastfeeding or plan to breastfeed. It is not known if HEMLIBRA passes into your breast milk.

Tell your healthcare provider about all the medicines you take,

including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use HEMLIBRA?

See the detailed "Instructions for Use" that comes with your HEMLIBRA for information on how to prepare and inject a dose of HEMLIBRA, and how to properly throw away (dispose of) used needles and syringes.

- Use HEMLIBRA exactly as prescribed by your healthcare provider.
- **Stop (discontinue) prophylactic use of bypassing agents the day before starting HEMLIBRA prophylaxis.**
- **You may continue prophylactic use of FVIII for the first week of HEMLIBRA prophylaxis.**
- HEMLIBRA is given as an injection under your skin (subcutaneous injection) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of HEMLIBRA before you inject yourself for the first time.
- Do not attempt to inject yourself or another person unless you have been taught how to do so by a healthcare provider.
- Your healthcare provider will prescribe your dose based on your weight. If your weight changes, tell your healthcare provider.
- You will receive HEMLIBRA 1 time a week for the first four weeks. Then you will receive a maintenance dose as prescribed by your healthcare provider.
- If you miss a dose of HEMLIBRA on your scheduled day, you should give the dose as soon as you remember. You must give the missed dose as soon as possible before the next scheduled dose, and then continue with your normal dosing schedule. **Do not** give two doses on the same day to make up for a missed dose.
- HEMLIBRA may interfere with laboratory tests that measure how well your blood is clotting and may cause a false reading. Talk to your healthcare provider about how this may affect your care.

What are the possible side effects of HEMLIBRA?

- See "**What is the most important information I should know about HEMLIBRA?**"

The most common side effects of HEMLIBRA include:

- redness, tenderness, warmth, or itching at the site of injection
- headache
- joint pain

These are not all of the possible side effects of HEMLIBRA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store HEMLIBRA?

- Store HEMLIBRA in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store HEMLIBRA in the original carton to protect the vials from light.
- Do not shake HEMLIBRA.
- If needed, unopened vials of HEMLIBRA can be stored out of the refrigerator and then returned to the refrigerator. HEMLIBRA should not be stored out of the refrigerator for more than a total of 7 days or at a temperature greater than 86°F (30°C).
- After HEMLIBRA is transferred from the vial to the syringe, HEMLIBRA should be used right away.
- Throw away (dispose of) any unused HEMLIBRA left in the vial.

Keep HEMLIBRA and all medicines out of the reach of children.

General information about the safe and effective use of HEMLIBRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HEMLIBRA for a condition for which it was not prescribed. Do not give HEMLIBRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HEMLIBRA that is written for health professionals.

What are the ingredients in HEMLIBRA?

Active ingredient: emicizumab-kxwh

Inactive ingredients: L-arginine, L-histidine, poloxamer 188, and L-aspartic acid.

Manufactured by: Genentech, Inc., A Member of the Roche Group,
1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No. 1048

For more information, go to www.HEMLIBRA.com or call 1-866-HEMLIBRA.
This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised : 10/2018

HEMLIBRA™
emicizumab-kxwh
injection for subcutaneous use | 150 mg/mL

Genentech
A Member of the Roche Group

Bowling for Bleeding Disorders

The Western Pennsylvania Chapter of the National Hemophilia Foundation Strikes Out Bleeding Disorders

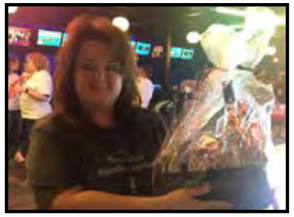
The Sixth Annual Bowling for Bleeding Disorders fundraiser was held at Paradise Island Bowl in Neville Island, Pennsylvania on Sunday, February 17, 2019. The cost to attend was $25 per participant which included an event t-shirt, shoe rental, bowling, pizza, wings, and unlimited soft drinks.

All 16 lanes were filled as 75 bowlers competed for the prize of highest score and best style. Congratulations to Jay Airhart from team Airharts for Ryker who won the award for highest score!

Congratulations to John Yunghans who won the award for Best Style!

We are extremely grateful for everyone who participated in this event. We are excited to report that over $11,000 was raised from this event! All of this money will go toward emergency and medical patient assistance, educational programs, and support groups to benefit the bleeding disorders community in Western PA. The sponsors of the event included The Hemophilia Center of Western Pennsylvania, CSL Behring, Novo Nordisk, Bayer, and 91.3 WYEP.

WPCNHF would like to thank all who participated in and sponsored this event. We can't wait to see you all at our next Bowling for Bleeding Disorders event coming soon!



Mid-Atlantic Region III Annual Meeting

By John Yunghans

Christina and I felt honored to attend the Mid-Atlantic Region III HTC's Annual Meeting. We learned valuable information about new treatment options and their effect on our community. The Consumer breakout alone was eye opening around what challenges our community is experiencing and how other chapters in different areas are dealing with them. We have developed a clearer understanding about insurance, medical, and engagement issues facing our community. Through the sessions and networking, we deepened our understanding of the HTC perspective on Bleeding Disorders care and how NHF/HFA chapters can partner with them. We are thankful for this opportunity and will be taking our experience back to our home chapter!

Young Hope Society

On Thursday, January 24th the Western Pennsylvania Chapter of the National Hemophilia Foundation held its first Young Hope Society event at Top Golf in Bridgeville, PA. The Young Hope Society is a young professionals group that was created to inspire the next generation of young philanthropic leaders supporting the bleeding disorders community. Open to individuals aged 21-40, the Young Hope Society provides critical support to medical research, healthcare advocacy, and community education efforts designed to improve the lives of those in the bleeding disorders community.

To learn more or to join the Young Hope Society visit: www.hemophilia.org/joinYHS

When you contribute a minimum of $5 a month (or an annual gift of $60 or more) as a Young Hope Society member, you will support life-changing programs and have the opportunity to:

- Support a mission-based organization focused on healthcare advocacy, community education, and medical research
- Participate in national networking events with like-minded young professionals and industry experts
- Build your professional network and leadership skills through the Young Hope Society Speaker Series and exclusive events
- Make a difference in the bleeding disorders community

The Western Pennsylvania Chapter of the National Hemophilia Foundation will be holding a number of Young Hope Society networking events throughout the year. Be on the lookout for our next Young Hope Society event coming this summer.

Dinner Programs

We thank Genentech, Sanofi Genzyme, and Takeda for sponsoring the 2019 New Parent Network series of events.

New Parent Network

The first program in the 2019 New Parent Network series of events was held on March 22, in Seven Springs, PA. New Parent Network programs are for families who have a child age six and under, with a bleeding disorder. The families attended dinner and a roundtable discussion with Dr. Frederico Xavier, Associate Director of the Hemophilia Center of Western PA, and Hematologist at Children's Hospital of Pittsburgh. Dr. Xavier provided an overview of bleeding disorders and identifying bleeds, answered questions, and addressed many of the concerns parents of young children with bleeding disorders have. Childcare was provided, in a separate room, so the parents could participate and focus on the program.

Teen & Parent Dinner Program

Sixty-eight people were present at the teen and parent dinner, in Seven Springs, on Friday, March 22! The program: Getting Real, was presented by Michael Sager, Patient Affairs Liaison, Pfizer. The program's content, which was geared toward teenagers and young adults, included self-advocacy, independence, and other considerations for that age group. We thank Pfizer for sponsoring this program.

Zoo Overnight

Lions, tigers, and porcupines, oh my! The WPCNHF Youth Group held its first event at the Pittsburgh Zoo & PPG Aquarium. The night started off with a behind the scenes tour, which allowed us to see lions and tigers up close and learn more about them.

The group headed back to the Education complex where they used their investigative skills to look over evidence and determine which animals committed "crimes." We were all impressed with their crime solving skills!

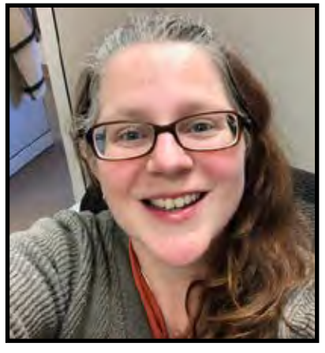
Next, everyone headed back outside and went on an investigative scavenger hunt to solve one more mystery! Back inside we had animal visits and up close encounters with an armadillo, snake, and porcupine. Before departing the next day, three more animals came to visit us and we learned some fascinating facts about them.

The zoo overnight was a fun and unique experience and I'm sure that both the kids and the chaperones will remember it for a long time to come. We thank Delores Johnson Huber for suggesting the youth group event. Based on the success of this event, we look forward to planning more in the future!

We also thank Cottrill's Pharmacy for sponsoring this event. And a special thank you to Melissa Kendrick, Cottrill's Pharmacy, for her help with organizing the event.

Getting to Know HCWP Staff

Featuring: Katherine Bush, LCSW (AKA Kit)



Birthplace: Baltimore, MD

First job: Not sure which came first… picking strawberries or babysitting!

Accomplishment you're proudest of: Having to give an unexpected speech in front of 60 people and being ok with it!

What three words describe you best? Determined, open-minded, and silly

Dream vacation: Taking my time exploring all sorts of little towns in Italy at my own pace.

Things you can do without: Lima beans, slushy roads, and animatronics.

Person you'd most like to have dinner with: Ellen

Movie you could see anytime: Monty Python and the Holy Grail

TV show you try not to miss: The Walking Dead

Three things that can always be found in your refrigerator: Yogurt, some kind of fresh fruit, and eggs

Secret vice: Herr's Honey Cheese Curls… yum!!!

Who would play you in the movies? I had no idea so I asked Kathaleen. She said a young Diane Lane. I'll take it!

Your pet peeve about Pittsburgh: POTHOLES!!!!!

People may be surprised to know that: I own wayyyyy too much yarn. I love knit, crochet, and yarn of any kind!

Thank you for participating in the Red Tie Campaign!

YETI

By Julia Shoemaker

I recently traveled to Oregon to attend the YETI (Youth Effectively Transitioning to Independence) conference. It was an amazing trip. It was the first time I flew on a plane and it was worth it. Everyone there was very kind and welcoming, even though I hardly knew anyone.

YETI is all about helping teenagers who are involved in the bleeding disorder community become independent and stay active in the community. It was also an opportunity to expand ourselves. We talked about how to build resumes, what to put on them, and what to maybe leave out. For example, YETI is a great thing to have on a resume. It shows that you took initiative and are a leader to others. However, it could also show that you are a part of the bleeding disorder community and may have a bleeding disorder. You may not want others to know that. In that case, you would just put YETI on the resume, and when you discuss it in an interview, you could state that it was a conference that built up leadership qualities.

We also learned how to communicate with others who have different personality types and communication preferences. For example, someone who may be more introverted may not want to communicate with others. However, when introverts try to discuss their opinions with another group of people, their opinions normally get pushed away because they are so quiet and shy. We learned that introverts should push themselves outside their comfort zone a little bit, so that they may grow a little bit and become better at communicating with others.

It was an educational weekend that felt like a vacation. It was a truly wonderful experience that I thank the Chapter for providing me.

[Julia is a high school junior and Co-Coordinator for our Teen Group. She is also a Leader-in-Training during Camp Hot-to-Clot. She attended YETI with Janet Barone, Member Services Manager (WPCNHF) and Activities Coordinator for Camp Hot-to-Clot, and Katherine Bush, Mental Health Professional (HCWP) and Co-Director for Camp Hot-to-Clot. YETI was hosted by the Hemophilia Foundation of Oregon.]

Who Makes the Decision?

By Derek L. Markley

It has been more than eight years since St. Jude Children's Research Hospital, University College London, and the Royal Free Hospital began a clinical trial using gene therapy to treat people with hemophilia B.

That same year, our family welcomed a new baby, Bubba, who has severe hemophilia B. We had recently located to central Illinois from east Tennessee when I accepted a position with Eastern Illinois University. Bringing a new child into the world is a wonderful and stressful time for any family. As parents who had no experience with bleeding disorders, my wife and I were wholly unprepared for a hemophilia diagnosis.

Six months after Bubba was born, I was headed to lunch with a friend after meetings in the state capitol building. I can still tell you exactly where I was standing when my friend handed me her phone and asked if I'd seen the New York Times article about gene therapy and hemophilia B.

Fast forward a few years, and we again relocated, this time to Tupelo, Mississippi. We were very fortunate to become patients at St. Jude. Little did we know that Bubba's physician would be one of the primary investigators in the gene therapy clinical trial. All of a sudden, the world of gene therapy was thrust directly in front of us.

We are now in a position, like many other hemophilia families, where the reality of a cure for hemophilia seems within reach. Presently, three phase III trials are beginning to test the efficacy of gene therapy in treating hemophilia B. Clinical research does not move quickly, but advancements in gene therapy over the past eight years have been amazing. The FDA has released new guidelines regarding gene therapy development, and funding for these ventures is in overdrive.

If gene therapy treatment becomes a reality, I'm forced to ask these questions: Is this a decision we can make for our son? Do the parents get to decide? How do we talk to our son about the risks and rewards of such a treatment? Bubba is only eight now, but it seems wise to begin thinking about how we'd handle this situation. Of course, the question is moot if insurers, treatment providers, and pharmaceutical companies can't agree on a feasible reimbursement strategy. There are a lot of variables at play, yet the advancement of gene therapy treatment demands that Bubba's mother and I begin thinking about how we will make decisions if a gene therapy treatment becomes available for our son.

It's amazing that, of all the health conditions in our world, science and medicine have combined to put a treatment for our son's type of hemophilia at the forefront of gene therapy.

Bubba is a very active kid. My wife describes him as "all boy." His condition has done nothing to slow him down. Bumps, bruises, cuts, or scrapes, he weathers them all and refuses to be limited by his uncooperative blood.

We're reaching a time where Bubba's questions about hemophilia have

(Continued on page 19)

UNLOCKING YOUR SELF-POTENTIAL

ONLY ADVATE® HAS 15 YEARS OF EXPERIENCE IN THE REAL WORLD AS A RECOMBINANT FACTOR VIII[1]

- Proven in a pivotal clinical trial to reduce the number of bleeding episodes in children and adults when used prophylactically[2]*
- Third-generation full-length molecule, similar to the factor VIII that occurs naturally in the body[1,2]

*Multicenter, open-label, prospective, randomized, 2-arm controlled trial of 53 previously treated patients with severe to moderately severe hemophilia A. Two different ADVATE prophylaxis regimens (standard, 20-40 IU/kg every 48 hours, or pharmacokinetic-driven, 20-80 IU/kg every 72 hours) were compared with on-demand treatment. Patients underwent 6 months of on-demand treatment before 12 months of prophylaxis.[2]

The market leader in hemophilia A treatment†

†Based on 2016 data published July 2017.[3]

The myPKFiT™ for Patients Mobile Application offers visibility into your personalized ADVATE treatment. Talk to your doctor to see if myPKFiT for ADVATE may be right for you. Learn more at ADVATE.com.

ADVATE Important Information

What is ADVATE?

- ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) 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 (HCP) 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

Who should not use ADVATE?

Do not use ADVATE if you:

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

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

What should I tell my HCP before using ADVATE?

Tell your HCP 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.
- Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.
- Are or become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What important information do I need to know about ADVATE?

- You can have an allergic reaction to ADVATE. Call your HCP 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.
- Do not attempt to infuse yourself with ADVATE unless you have been taught by your HCP or hemophilia center.

What else should I know about ADVATE and Hemophilia A?

- 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. Talk with your HCP to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

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What are possible side effects of ADVATE?

- 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 HCP 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.

For additional safety information, please see Important Facts about ADVATE on the following page and discuss with your HCP.

For Full Prescribing Information, visit www.ADVATE.com

myPKFIT for ADVATE Patients Mobile Application Intended Use

- The myPKFiT for Patients Mobile Application ("myPKFiT Mobile App") is intended for use by patients with hemophilia A being treated with ADVATE [Antihemophilic Factor (Recombinant)] who are 16 years of age or older with a body weight of 45 kg or higher, and their caregivers.
- The myPKFiT Mobile App is designed to make it convenient for you to record your infusion and bleed events, track your estimated Factor VIII levels following a prophylactic infusion, and export the data for review by your health care provider ("HCP").
- Your HCP can use the myPKFiT software to generate ADVATE dosage amount and frequency recommendations for routine prophylaxis using your age, body weight information, and laboratory tests that measure your Factor VIII clotting activity. Using myPKFiT software, HCPs can evaluate various prophylaxis dose regimens tailored to your individual needs and treatment plan.
- myPKFiT Mobile App should only be used by hemophilia A patients treated with ADVATE, as per the ADVATE Prescribing Information.
- myPKFiT Mobile App is not indicated for use by patients with von Willebrand disease. myPKFiT Mobile App should not be used by patients who have developed inhibitors to Factor VIII products.

myPKFiT for Patients Mobile Application is Rx only. For safe and proper use of the myPKFiT Mobile App, please refer to the complete instructions for use in the User Manual.

References: 1. Grillberger L, Kreil TR, Nasr S, Reiter M. Emerging trends in plasma-free manufacturing of recombinant protein therapeutics expressed in mammalian cells. *Biotechnol J*. 2009;4(2):186-201. **2.** ADVATE Prescribing Information. **3.** The Marketing Research Bureau, Inc. The plasma proteins market in the United States. 2016. **4.** myPKFiT Mobile Application v2.0 User Manual. 2018.

ADVATE [Antihemophilic Factor (Recombinant)]

my PK FiT

ADVATE
[Antihemophilic Factor (Recombinant)]

Important facts about

ADVATE [Antihemophilic Factor (Recombinant)]

This leaflet summarizes important information about ADVATE. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about ADVATE. If you have any questions after reading this, ask your healthcare provider.

What is the most important information I need to know about ADVATE?

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing ADVATE so that your treatment will work best for you.

What is ADVATE?

ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia). The product does not contain plasma or albumin. Hemophilia A is an inherited bleeding disorder that prevents blood from clotting normally.

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.

Who should not use ADVATE?

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.

How should I use ADVATE?

ADVATE is given directly into the bloodstream.

You may infuse ADVATE at a hemophilia treatment center, at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia A learn to infuse their ADVATE by themselves or with the help of a family member.

Your healthcare provider will tell you how much ADVATE to use based on your weight, the severity of your hemophilia A, and where you are bleeding.

You may have to have blood tests done after getting ADVATE to be sure that your blood level of factor VIII is high enough to clot your blood.

Call your healthcare provider right away if your bleeding does not stop after taking ADVATE.

What should I tell my healthcare provider before I use ADVATE?

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What are the possible side effects of ADVATE?

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	rash

Tell your healthcare provider about any side effects that bother you or do not go away.

These are not all the possible side effects with ADVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

What else should I know about ADVATE and Hemophilia A?

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.

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

The risk information provided here is not comprehensive. To learn more, talk with your health care provider or pharmacist about ADVATE. The FDA approved product labeling can be found at www.ADVATE.com or 1-888-4-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.

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Westlake Village, CA 91362 USA
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Issued: 11/2016

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THE EXTENDED-HALF-LIFE rFVIII WITH PROVEN PROTECTION AND UNIQUE STEP-WISE DOSING[1,2]

For patients ≥12 years

Start simply	TWICE **WEEKLY**	**For all prophylaxis patients:** Recommended starting regimen is Jivi **twice weekly** (30-40 IU/kg)[1]
Step up	EVERY **5 DAYS**	**Based on bleeding episodes:** Less frequent dosing of Jivi **every 5 days** (45-60 IU/kg) can be used[1]
Fine tune	⇅	**Based on bleeding episodes:** The dosing frequency may be further **adjusted up or down**[1]

IU, international units; kg, kilograms; rFVIII, recombinant Factor VIII.

INDICATIONS

- Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).
- Jivi is not for use in children below 12 years of age or in previously untreated patients.
- Jivi is not used to treat von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- You should not use Jivi if you are allergic to rodents (like mice and hamsters) or to any ingredients in Jivi.
- Tell your healthcare provider about all of your medical conditions that you have or had.
- Tell your healthcare provider if you have been told that you have inhibitors to Factor VIII.
- Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea.
- Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.
- Your body can also make antibodies, called “inhibitors,” against Jivi, which may stop Jivi from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.

BAYER

FEEL EMPOWERED
to step up to the challenge with Jivi®

Ask your doctor if Jivi® may be right for you. Learn more at www.jivi.com.

IMPORTANT SAFETY INFORMATION (CONT’D)

- If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.
- The common side effects of Jivi are headache, cough, nausea, and fever.
- These are not all the possible side effects with Jivi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

For additional important risk and use information, please see the Brief Summary on the following page.

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

References: 1. Jivi® Prescribing Information. Whippany, NJ: Bayer LLC; 2018.
2. Data on file. Tx Review 0918. Bayer; 2018.

Jivi®
antihemophilic factor (recombinant) PEGylated-aucl

LET’S GO

HIGHLIGHTS OF
FDA-Approved Patient Labeling

Patient Information

Jivi (*JIHV-ee*)

antihemophilic factor (recombinant), PEGylated-aucl

This leaflet summarizes important information about Jivi with vial adapter. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about Jivi. If you have any questions after reading this, ask your healthcare provider.

Do not attempt to self-infuse, unless your healthcare provider or hemophilia center has taught you how to self-infuse.

What is Jivi?

Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A (congenital Factor VIII deficiency).

Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).

Jivi is not for use in children < 12 years of age or in previously untreated patients.

Jivi is not used to treat von Willebrand disease.

Who should not use Jivi?

You should not use Jivi if you

- are allergic to rodents (like mice and hamsters).
- are allergic to any ingredients in Jivi.

What should I tell my healthcare provider before I use Jivi?

Tell your healthcare provider about:

- All of your medical conditions that you have or had.
- All of the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies.
- Pregnancy or planning to become pregnant. It is not known if Jivi may harm your unborn baby.
- Breastfeeding. It is not known if Jivi passes into the milk.
- Whether you have been told that you have inhibitors to Factor VIII.

What are the possible side effects of Jivi?

The common side effects of Jivi are headache, cough, nausea and fever.

Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea. Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.

Your body can also make antibodies, called "inhibitors", against Jivi, which may stop Jivi 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.

If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.

These are not all the possible side effects with Jivi. You can ask your healthcare provider for information that is written for healthcare professionals.

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

How do I store Jivi?

Do not freeze Jivi.

Store Jivi at +2°C to +8°C (36°F to 46°F) for up to 24 months from the date of manufacture. Within this period, Jivi may be stored for a period of up to 6 months at temperatures up to +25°C or 77°F.

Record the starting date of room temperature storage clearly on the unopened product carton. Once stored at room temperature, do not return the product to the refrigerator. The product then expires after storage at room temperature for 6 months, or after the expiration date on the product vial, whichever is earlier. Store vials in their original carton and protect them from extreme exposure to light.

Administer reconstituted Jivi as soon as possible. If not, store at room temperature for no longer than 3 hours.

Throw away any unused Jivi after the expiration date.

Do not use reconstituted Jivi if it is not clear.

What else should I know about Jivi and hemophilia A?

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

This leaflet summarizes the most important information about Jivi that was written for healthcare professionals.

Resources at Bayer available to the patient:

For Adverse Reaction Reporting, contact Bayer Medical Communications 1-888-84-BAYER (1-888-842-2937)

To receive more product information, contact Jivi Customer Service 1-888-606-3780

Bayer Reimbursement HELPline 1-800-288-8374

For more information, visit http://www.Jivi.com

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Whippany, NJ 07981 USA

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Who Makes the Decision?

(Continued from page 13)

become more mature, requiring us to be more introspective when talking with him. The greatest question we face is how do we determine his role in a decision about treatment if gene therapy becomes a reality? It is his life, and, like all parents, we hope that he'll be around for a long time after we're gone.

Bubba views infusions as an inconvenience. We know he secretly wants to play quarterback or wide receiver. He knows that hemophilia makes him different from his friends. Different isn't always easy for kids to understand or accept.

The problem is that his mother and I have more complex questions, not that Bubba's questions are unimportant. What if our government decides to once again unfairly punish people with pre-existing conditions? What if Bubba is in a serious accident? What if he develops a target joint? There are a million tough questions. What makes the situation even harder is that these questions are about things over which we have little or no control. There are far more questions than answers.

The best answer we have right now is that we're thankful for the treatment presently available for our son and the prospect of what some are beginning to call a cure. There are too many parents with children afflicted by conditions that have no available, effective treatments. When we picked Bubba up after his first bleeding disorder camp last summer, he told us that some of the kids said he was lucky because he only infused once a week. I think those interactions gave him his first insight into the fact that living with hemophilia is not the same for everyone.

Science can do amazing things. As a species, we're quite ingenious at times. I have no doubt that hemophilia will cease to exist one day, but I have no idea when that day will come. As parents, we can only put our son's best interests first, stay informed about medical advances, and trust that our team at St. Jude will continue to help us make the best decisions based on the options available.

Bubba won't want to hear it, but his mom isn't going to let him play football anyway.

Derek lives in Saltillo, Mississippi, with his wife Ashley and their children Abbey and Bubba. He is the executive director of two University of Mississippi regional campuses and an assistant professor in the School of Education. Ashley is a fifth-grade math teacher in the Tupelo Public School District. Derek is the author of The Bubba Factor, available on Amazon in Kindle format and in paperback.

Publication: PEN 2.19
Column: As I See It

WPCNHF's Winning Women

It's an exciting year for the WPCNHF's Winning Women group. You might be asking yourself what is the WPCNHF's Winning Women, what is our purpose, what can you expect from the group, and who is the person writing this article? Let's start with the "who am I"; my name is Maria Steele Voms Stein, I am a wife, a mother, a daughter, a friend, a full time working professional, volunteer, and I am a woman living with a bleeding disorder (VWD.)

The WPCNHF's Winning Women group was formed to provide women affected by bleeding disorders with the education, support, skills and resources they need to advocate for their and/or their family's healthcare, financial and social needs. The group is open to all women in our chapter; to include women diagnosed with bleeding disorder and/or an affected family member. Our programming includes valuable life skills, educational experiences that are independent of bleeding disorder diagnosis, and having a lot of fun! We have some really exciting WPCNHF's Winning Women events scheduled for 2019. Upcoming event dates: May 21st and October 24th, be sure to mark your calendars!

I encourage everyone to participate in WPCNHF's Winning Women and other chapter events, as well as considering a role as a volunteer for chapter events. If you have ideas for future events or are interested in volunteering at any of the upcoming chapter events, please feel free to contact me at (412) 722-8559 or via e-mail at marsil36@aol.com. I hope to see you at one of the WPCNHF's Winning Women group events or other chapter event in the near future!

7th ANNUAL

TAKE A BOUGH

HOLIDAY TREE AUCTION TO BENEFIT WPCNHF

Save the Date

SATURDAY
NOVEMBER 16, 2019
CORNERSTONE AT
TONIDALE

Holiday Tree and Wreath Auction and Wine Tasting Event

DOORS OPEN: 6:30 PM
WINE TASTING TICKETS: $25
NON-TASTING (DESIGNATED DRIVER) TICKETS: $10
MORE INFORMATION AT: WPCNHF.ORG

We Need Your Help!

There are many ways to participate in this event and we need your help! We need help acquiring donations, decorating trees and wreaths, and making the onsite event inviting, festive, and fun for all to enjoy.

How Can You Help?

1.) **Volunteer** - Volunteers are needed to help decorate trees and wreaths at the Chapter Office starting on November 1st. We will also need volunteers to help transport auction items from the Chapter Office to the Cornerstone at Tonidale and help set up on November 15th, as well as event day volunteers on November 16th.

2.) **Donate** - Donations of artificial trees and wreaths, holiday decor, gift cards, raffle basket items, and monetary donations are needed.

3.) **Participate** - Come and enjoy this fun and festive event! We invite you to attend this event and encourage you to invite your friends, family, and co-workers. It's a great way to kick off your holiday season! We will also have all of the auction items available for bid online so even if you can't attend the event in person we encourage you to participate in the online auction.

To sign up to volunteer or coordinate donation drop offs
contact Kara at kara@wpcnhf.org

Western Pennsylvania Chapter of the National Hemophilia Foundation
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Cranberry Township, PA 16066
Phone: 724-741-6160 Toll Free: 800-824-0016 Fax: 724-741-6167
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WPCNHF