



# GATEWAY CONNECTION

Summer 2019

## CALENDAR OF UPCOMING EVENTS

### July

12-14 Family Education Weekend  
DoubleTree Chesterfield

### August

17-18 Adult Retreat  
Lake Ozark, MO

22 Wine Tasting Fundraiser  
Farotto's, Rock Hill

### September

23 Tee Off 4 Hemophilia Golf  
Tournament, The Legends

### October

3-5 NHF Bleeding Disorders  
Conference, Anaheim, CA

### November

2 Trivia Night Fundraiser  
The Pavilion at Lemay

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us on social media!**



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@gateway  
hemophilia

## Sign up today for GHA's 29th Annual Tee Off 4 Hemophilia Golf Tournament!

When: Monday, September 23, 2019

Where: The Legends Country Club  
625 Legends Parkway, Eureka, MO 63025

Join us at The Legends Country Club, a Robert Trent Jones, Sr. designed course, for our 29th Annual Tee Off 4 Hemophilia Golf Tournament! This charity event provides crucial funding necessary to support GHA's overall mission, to find better treatments and cures for bleeding disorders and to prevent complications of these disorders through education, awareness, advocacy and research.

In addition to a wonderful day of golf at a premier facility, we invite you to participate in our special contests, raffles, silent auction and live auction that will take place the day of the tournament. This year's Hole-In-One contest will be sponsored by Mercedes-Benz and lunch will be provided by Pappy's Smokehouse.



Mercedes-Benz



For more information and to register for this event, please visit  
[www.gatewayhemophilia.org/events/tee-off-4-hemophilia/](http://www.gatewayhemophilia.org/events/tee-off-4-hemophilia/)



[WWW.GATEWAYHEMOPHILIA.ORG](http://WWW.GATEWAYHEMOPHILIA.ORG)

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## Gateway Hemophilia Association

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# GHA's 50th Anniversary Celebration



On April 17<sup>th</sup>, GHA community members and supporters gathered at the Missouri History Museum to celebrate the organization's 50<sup>th</sup> Anniversary. GHA was founded in 1969 when a group of dedicated families was approached by the National Hemophilia Foundation about starting a local chapter. Over the last 5 decades, GHA has grown and evolved to meet the changing needs of the bleeding disorders community. Today, GHA continues to serve people with bleeding disorders in eastern Missouri and southern Illinois.

As the guests entered the event space, they were greeted with displays showcasing GHA's history and the history of bleeding disorders. These included a photo montage of Camp Notacloamongus, a video compilation featuring news coverage of the HIV/AIDS crisis, and storyboards detailing the history of bleeding disorders and the bleeding disorders community through the decades.



Once everyone was seated for dinner GHA Executive Director Bridget Tyrey welcomed everyone and thanked them for being a part of this monumental occasion. Sonji Wilkes, Director of Advocacy at the Hemophilia Federation of America (HFA) announced HFA's donation of artifacts related to the history of the bleeding disorders community to the Smithsonian Institute's National Museum of American History in Washington, D.C. This donation, which consists of items generously given by community members, is a huge step in formally preserving the history of the bleeding disorders community for future generations. More information will be made available in the future as this project develops.



*Guests listen to the dinner presentation*



*Dr. John Bouhasin, far right, with his family*

The presentation continued with Trudy Stringer, GHA's 50<sup>th</sup> Anniversary Chair, who stressed the importance of advocacy and the impact that the bleeding disorders community has had. Finally, 50<sup>th</sup> Anniversary Committee member and hematology nurse Marykay Thrower presented a Lifetime Achievement Award to Dr. John Bouhasin for his tireless work over the course of his career in the bleeding disorders community.

GHA Board of Directors meetings are open to the public and held the 2<sup>nd</sup> Tuesday of every odd numbered month at 6:00pm at 4976 Eichelberger Street, St. Louis, MO 63109. Changes to these dates may be necessary due to scheduling conflicts and will be announced at [www.gatewayhemophilia.org/about-us/board-of-directors](http://www.gatewayhemophilia.org/about-us/board-of-directors) as soon as they are available.

This event would not have been possible without the hard work and vision of our 50th Anniversary Committee. Thank you Committee Chair Trudy Stringer and Committee members Bill Berger, Bud Guest, and Marykay Thrower. Thank you to our volunteers, Janet Sims and the Kohl's Cares Team.

### Thank you to our Sponsors

**Platinum Sponsors:** Genentech, Hemophilia Federation of America, Kohl's

**Gold Sponsors:** CSL Behring, John & Pam Carleton

**Silver Sponsor:** Washington University in St. Louis



## GHA Presented with 50th Anniversary Resolution



On April 15<sup>th</sup>, GHA Executive Director Bridget Tyrey, GHA staffer Jen McNamee, Board President Anne Parrott, her children Rose and Jack, and 50<sup>th</sup> Anniversary Chair Trudy Stringer attended the City of St. Louis Board of Aldermen meeting. At this meeting, GHA was presented with a Resolution in recognition of its 50 year history of serving the bleeding disorders community. A Resolution is the highest honor bestowed by the City of St. Louis Board of Aldermen.

## 3 Easy Ways to Support GHA!

1

### Schnucks Escript Card

*GHA gets \$\$ every time you shop!*

1. Pick up a free Escript card at your local Schnucks
2. Visit [escript.com](http://escript.com) to enroll and select Gateway Hemophilia Association as your charity
3. Give the cashier your Escript card at checkout!



2

### Amazon Smile

*Amazon donates 0.5% of the price of your eligible AmazonSmile purchases to GHA!*

1. Visit [smile.amazon.com](http://smile.amazon.com)
2. Sign in to your Amazon account (or create an account for free)
3. Select Gateway Hemophilia Association as your charitable organization
4. Start shopping!



3

### Fresh Thyme Giving Bags

*\$1 from the sale of each Giving Bag will be donated to GHA!*

1. Visit any Fresh Thyme Farmer's Market and purchase a reusable Giving Bag with a Giving Tag
2. Direct your donation to Gateway Hemophilia Association!
3. Use your reusable Giving Bag when you shop and help the environment!



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Call 1.844.989.HEMO (4366) Monday through Friday  
from 8:00 AM to 8:00 PM Eastern Time.

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# GHA's Unite For Bleeding Disorders Walk & 5K

GHA's 10<sup>th</sup> Annual Walk & 5K was held on Saturday, May 4<sup>th</sup> at Cricket Field in Forest Park. Though the morning started with a bit of rain, our participants were not deterred, and enjoyed beautiful sunshine by race time. Participants and supporters also enjoyed breakfast, a DJ, face painting, a hydration and treat station for our 4-legged racers, a City of St. Louis Fire Department Fire Truck and visit with firefighters, and an appearance by Billy the Blood Drop.



*Luke's League*

We set an ambitious goal this year to raise \$70,000. With the passion and dedication of our 39 fundraising teams and the generosity of our donors and sponsors, we surpassed our goal for the 2<sup>nd</sup> year in a row, raising \$72,308 to date! The money raised at this event will be used to assist our overall mission to find better treatments and cures for bleeding disorders and to prevent the complications of these disorders through education, awareness, advocacy, and research. To everyone who made this possible, we are extremely grateful.



*The Bruise Brothers*

As the 5K runners and 1-mile walkers gathered at the starting line, the crowd was greeted by GHA Executive Director Bridget Tyrey. She was joined by Jordana Zeger, COO of the National Hemophilia Foundation and Kevin Ellebrect from Takeda. Kicking off the race was GHA Teen Group member Daytona F. who led the Pinwheel Ceremony. This year, we were also grateful to have 2-time Boston Marathon finisher and GHA member Dwayne Hadler serve as Grand Marshall. He and his wife, Angie, led the 5K runners. Congratulations to our 5K winners: 1<sup>st</sup> Place winner Jeff Parrott, with a time of 25:16.22; 2<sup>nd</sup> Place winner Megan Tooley, with a time of 26:15.52; and 3<sup>rd</sup> Place winner Julie Harrison, with a time of 28:10.38.



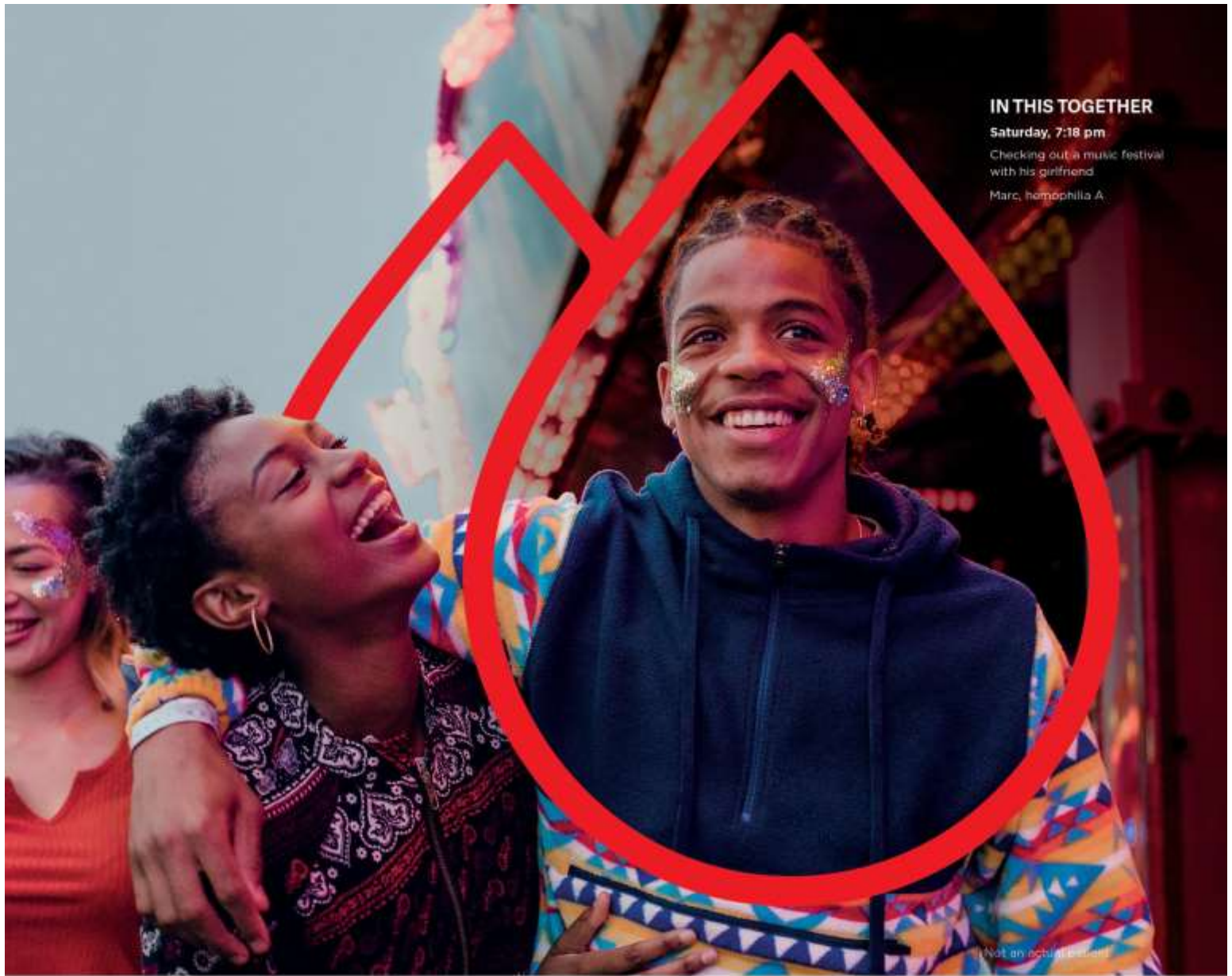
*The A Team*

Though we are grateful to all who contributed to GHA's Unite Walk, special recognition was given at the event to those teams and individuals who went above and beyond to make this year's Walk a success. The Top Fundraising Team was Luke's League who, led by Stephanie Bauman, raised an incredible \$8,956! Stephanie was also recognized for her efforts in raising awareness by receiving the most individual donations to her team! Joining Luke's League as VIP Teams, recognized for raising over \$2,500 were The Bruise Brothers, led by Kristina Klein, The A Team, led by Bridget Tyrey, and Blood and Thunder, led by Trudy Stringer. Danielle Flores was recognized as our Top Individual Fundraiser, raising an impressive \$2,725! Individual fundraisers who raised more than \$500 were recognized as "Factor Club" members. This year's members were: Judy Bagato, Stephanie Bauman, Pam Carleton, Bob & Gina Eschbacher, Pat Fitzmaurice, Danielle Flores, Jen McNamee, Trudy Stringer, and Bridget Tyrey. The Bruise Brothers won the Team Spirit award with their "Blues Brothers" inspired costumes! Kate Addie, team captain of Andrew's Entourage, was awarded "Rookie of the Year" for raising \$2,025 as a new team! Carly Magee, team captain of The Power of X, was awarded "Most Improved" for raising \$1,517, a 173% increase from last year!



*Team G-Rex*

The success of the Unite Walk would not have been possible without the dedication of our fundraising teams. Thank you to all of those who raised awareness and gathered support for GHA and the bleeding disorders community! Our fundraising teams were: Luke's League, The Bruise Brothers, The A Team, Blood and Thunder, Team Moramarco, Team G-Rex, Super Jack, Andrew's Entourage, The Power of X, Luke's Squad, Kyle's Crusaders, Mac's Factor, Bayer, The Coagulators-Wash U/SLCH,



#### IN THIS TOGETHER

Saturday, 7:18 pm

Checking out a music festival  
with his girlfriend

Marc, homophilia A

Not an actual patient

Takeda is here to support you throughout your journey and help you embrace life's possibilities. Our focus on factor treatments and educational programs, and our dedication to the bleeding disorders community, remain unchanged. And our commitment to patients, inspired by our vision for a bleed-free world, is stronger than ever. **Let's make today brilliant.**

[bleedingdisorders.com](http://bleedingdisorders.com)



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Bagato's Bruisers, The O'Rieley Factor, Kari's MIDSCI Maulers, Nick's Blood Clotters, Garrett's Bruisers, Got Factor?, Team Fitz, Nate the Great, Team Sidekicks, Daytona's Destiny Fighters, The Von Willies, Cruising 4 Conway's, Takeda, Andrea's Clotters, VW Bleedles, Sanofi Genzyme, The Fishsticks, Blood Brothers, CVS Specialty-St. Louis, Blood Brother's CBCh, Screaming Liam's, Team Meyer, HemoLife, Team Lilbug, and von Wille-Braids.



*The Coagulators-Wash U/SLCH*

Thank you to our sponsors for your continued support: National Presenting Sponsor-Takeda; Official Sponsors-Bayer, BriovaRx, CVS Specialty, Grifols, Pfizer, Sanofi Genzyme; Partner- Accredo; Gold Sponsors-Genentech, Novo Nordisk, Octapharma; Silver Sponsors-Accurate Rx, Brothers Healthcare, CSL Behring, CVS Specialty, DoubleTree by Hilton, Heritage Biologics, Sanofi Genzyme, Takeda; Bronze Sponsors-Aptevo Therapeutics, Faratto's Pasta & Pizzeria, JB Marine Services, Inc., Kohl's, Paragon Healthcare, State Farm-Joshua Arnold; Kilometer Sponsors-AquaTeam PowerWash, ARJ Infusion Services, Inc., Athletico Physical Therapy, Charpentier Law, Glendale Chrysler Jeep Dodge Ram, Great Southern Bank, Seamus McDaniels, Superior Biologics, To The Moon Marketing, UMB Bank. Give-Away Bag Sponsors-Accurate Rx, Apex Specialty Pharmacy, AquaTeam PowerWash, ARJ Infusion Services, Inc., Athletico Physical Therapy, Bayer, Club Fitness, CSL Behring, CVS Specialty, Novo Nordisk, The Pasta House Co. Walk Newspaper advertiser-Genentech.



*Nick's Blood Clotters*

Finally, a heartfelt thank you to our dedicated group of volunteers who worked behind the scenes in the months leading up to the event, as well as those who gave their time the day of the event. Walk Committee: Co-Chairs Danielle Flores and Andrea Lewis, Committee members Stephanie Bauman, Kristina Klein, and Liz LaFlamme. Event volunteers: James & Sandy Addie, Jake Bauman, Lydia Bohler, Tina Charpentier, Corrine

Colvin, Arturo Espino Cosas, Dustin Doell, Christine Finck, Tony Flores, Kelia Gonzalez, Pat Gute, Michelle Hanneken, Jack Hoagland, Dan Johannes, Nicki Jones, Jinwon Kang, Shannon Keys, Kohl's Cares Team, Kate LaFlamme, Ellen Lawrence, Tommy Lee, Mike Lewis, Jason Lin, Yann Mafouta, Randy Moore, Joe Nuccio, Susan Preis, Chris Schneider, Mike Schneider, Rieley Schneider, Evonne Siampos, Janet Sims, Dirk & Trudy Stringer, MaryKay Thrower, Salvatore Vittellaro, Alyson Welch, Lisa Wildhaber, City of St. Louis Fire Department, and STARS.



*Kohl's Cares Volunteers*

Teams Pictured Below: Luke's Squad, Super Jack, Nate the Great, Kari's MIDSCI Maulers, Garrett's Bruisers





# Wild West Adventures

**“May your heart be brave, your mind fierce, and your spirit free.” - Unknown**

After 10 years at Living Well Village in Imperial, MO, Camp Notacloamongus found a new home this year at Camp Wyman in Eureka, MO. The staff and LITs arrived early in the week to turn their new camp home into the “Wild West” before campers arrived on Wednesday.

When the campers arrived, they were greeted by a cast of cowboys and cowgirls who helped them get checked in and settled into their “bunkhouses” before “chowtime at the chuck wagon.” As dinner was ending, the campers were surprised by “miners” who rushed in shouting about all the “gold” they found in the field! After the “Sheriff” went over the rules and warned everyone to be on the lookout for bandits, the Gold Rush game was on. Campers raced through the field in search of “gold” that could be exchanged for “money” to spend at the General Store, the Saloon, the Tattoo Parlor, and the Fortune Teller. As the evening came to a close, campers and staff gathered in the chuckwagon, only to be surprised by the “deputies” who found the “bankers” tied up and robbed! Worst of all, the “bandits” had kidnapped “Belle”, the most beautiful woman in town! The game was not over, because now the “Sheriff” needed everyone to be on the lookout that week for the “bandits” and “Belle!”

On Thursday, with “Belle” and the “bandits” on everyone’s mind, the campers started the day creating tie-dye shirts to wear on Saturday and set off to the lake for canoeing. The fun continued throughout the day with swimming and education, and finished with a Waterin’ Hole Rodeo at the pool.

Friday at Camp Notacloamongus is “Infusion Day” and this year, every camper touched a needle! Special congratulations to Aaliah, Garrett, Damauri, and Logan on achieving their “Big Stick” Award and to Aaliah, Damauri, Grayson, and Gregory on achieving their “Sharpshooter” Award!



In the spirit of giving back, campers also spent Friday morning planting flowers in front of the Med-Shed as part of GHA’s June for Joint Health initiative. This was followed by tomahawk throwing, a visit from Bank’s the miniature horse, and games at the basketball court and gaga pit. For dinner that evening, campers experienced an authentic “Wild West” meal by preparing their food over a campfire. When everyone’s bellies were full, they were surprised to learn the “bandits” had been captured and were going to face trial. In a shocking twist, “Belle” appeared at the trial and we learned she had been the real “bandit” all along! Now that justice had been served and “Belle” was headed for jail, the campers were ready to settle in for the Friday night campfire.

Saturday came quickly and it was time to pack up camp, so we all wished each other...

**“Happy trails to you,  
until we meet again.”**



# at Camp Notaclotamongus



## Thank you to the best Camp Staff in the West!

**Camp Directors:** Makenzie Sledd & Bridget Tyrey

**Counselors:**

Gamblers: Kevin Ellebrecht, Cody York

Desperados: Todd Daube, Johnny Schuppe

Gold Diggers: Craig MacDonald, Joe Wigge, Justin Senger

Bushwhackers: Josh Swanson, Steve Kreher, Gabi Flores

Jr. Outlaws: Kirstie Hilty, Rieley Schneider

Outlaws: April Littrell, Maggie Poronto

**Sharpshooters:** Lynn Golec, Lydia Johnson, Angela Kaminski, Kathy Logan, Jessica Lovercamp, Stephanie Naumann, Sue Pardeshi, Dr. John Puetz, Becky Toman, Catie Toman, Dr. David Wilson

**Additional Wranglers:** James & Sandy Addie, Austin Belschner, Angela Brown, Danielle & Tony Flores, Alex Graff, Austin Hanse, Kevin Harris, Edgar Martinez, Jen McNamee, Maria Mohler, Anne Parrott, Brian Rodgers, Chris & Abby Schneider, Dirk & Trudy Stringer

## Thank you Sponsors!

**Platinum Sponsors:** Carney's Kids Foundation, Pfizer, Takeda

**Gold Sponsors:** Bayer, CVS Specialty, CSL Behring, Novo Nordisk


**Silver Sponsors:** ARJ Infusion Services, Grifols, Sanofi Genzyme, Kiwanis Club of Hampton Midtown

**Camper Give-Away Sponsors:** Accredo, ARJ Infusion Services, Inc., Bayer, CVS Specialty, Diplomat, Grifols, Novo Nordisk, Superior Biologics



**THE EXTENDED-HALF-LIFE  
rFVIII WITH PROVEN  
PROTECTION AND  
UNIQUE STEP-WISE  
DOSING<sup>1,2</sup>**

**For patients  $\geq 12$  years**

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

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.



**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](http://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](http://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.

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antihemophilic factor  
(recombinant) PEGylated-aucI  
**LET'S GO**

**HIGHLIGHTS OF  
FDA-Approved Patient Labeling  
Patient Information**

**Jivi (JHIV-ee)  
antihemophilic factor (recombinant), PEGylated-auct**

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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6710900BS1

*Dear Addy,*

*My son is starting kindergarten this fall and I'm concerned about what will happen if he has a bleed at school. What are his rights at school and how do I ensure he has the same opportunities as other students?*

*Signed,  
Proactive Parent*



Dear Proactive,

With the new school year approaching, this is a great time to be in contact with your child's school about making a plan to manage his bleeding disorder. Use [HFA's Back to School Toolkit](#) to educate the school nurse, administrators, and teachers about bleeding disorders and your son's needs.

Here are resources to help you advocate for your child:

- [Section 504 of the Rehabilitation Act of 1973](#) is a federal civil rights law to stop discrimination against people with disabilities, including a documented medical condition. One of its main protections is to assure that a child with a bleeding disorder will not be discriminated against in school and has the accommodations and modifications necessary to access any and all activities, lessons, events, etc. A 504 plan is a legally binding document, created with the parent, teacher, and an administrator.
- An [Individualized Education Plan \(IEP\)](#) is a document designed to accommodate and modify the curriculum and its delivery to meet your child's learning needs. A child will not qualify for an IEP unless they have one of the disabilities covered under IDEA and they need special education to make progress. With hemophilia, a child can qualify for an IEP because of hemophilia, but not all children with a bleeding disorder will need a IEP. A student that would need special education services will need an IEP. An IEP is a legally binding document created with the parent, teacher, administrator, school psychologist, and special education teacher.

- With the school nurse, write an [individual health plan \(IHP\)](#) for your child. Distribute this "what to do, when" plan to your son's teachers as well. For example: if your son hits his head: send him to the nurse immediately. The nurse will then have a separate plan with more details on what to do.

Before talking with your son's school, prepare yourself with these tools and tips. Ask questions and keep detailed records of your conversations and the paperwork you are required to submit to the school. Just like when you were a student, preparation and follow through are key to a successful academic year!

Sincerely,  
Addy

*HFA frequently receives questions from the bleeding disorders community related to advocacy issues. The questions often impact the entire community. In an effort to reach the largest audience possible with our responses to these widely applicable questions, HFA developed "Dear Addy." Questions submitted to this column are edited in order to protect privacy and should be considered educational only, not individual guidance.*

*Links to resources can be found in the original article at the website below.*

*Source: <https://www.hemophiliafed.org/news-stories/2016/08/dear-addy-back-to-school-secondary-education/>*

# Evolution and Revolution in the Treatment of Hemophilia A

By: Morey A. Blinder MD and William Berger, MSW  
Washington University School of Medicine, St. Louis, MO

## An Overview to the Treatment of Hemophilia A

Targeted therapy for the treatment of people with hemophilia A began in earnest with the development of cryoprecipitate in the 1960s. Since that time, new generations of therapies have emerged, improving the lives of many people with bleeding disorders. At times, progress has been erratic and has been met with major setbacks. Most notable among these, was the transmission of life-threatening infections through blood products which affected a generation of patients, families, partners and other community members in the 1970s and 1980s. In addition, the development of factor inhibitors in some patients continues to plague some patients today. Ongoing research conducted by government agencies, academic medical centers and the pharmaceutical industry continues to lead to new advances which has now placed us on the verge of new therapeutic options including the possibility of curing hemophilia.

## Standard Half-life (SHL) Factor VIII Replacement

Plasma-derived and recombinant factor products have been the mainstay of treatment for over 50 years. Early factor products were replaced with newer products that were screened and treated for viral contamination including HIV, eliminating this problem. Recombinant products became available in the United States in the 1990s, providing further product purity and safety. These products continue to be used today and provide reliable factor replacement for the prevention and treatment of bleeding in most individuals. Currently, there are 10 SHL factor VIII products available in the United States. Some vary in their protein structure (for example Xyntha has a deleted “B domain”). Other characteristics that vary among the products include the “shelf-life” before reconstitution, stability after reconstitution, the available doses and the ease of reconstitution. These advances represent a slow evolution in the improvement of treatment products.

## Extended half-life (EHL) factor VIII replacement

Beginning with approval of Eloctate in 2014, a new generation of factor VIII replacement arrived. Currently there are 6 different EHL products available in the United States, all of which have been modified from recombinant factor VIII. Several different strategies have been used by

pharmaceutical companies to allow the products to last longer than the native factor. The result is that the half-life (the time it takes for one half of the product to break down) is improved from about 13 hours to about 20 hours so that the number of infusions needed for prevention of bleeding is lower. While these newer products have proven to be of benefit to some people, unanswered questions remain. These include the possibility of inhibitor development, the approach to treatment in a person after receiving an EHL product, and whether there is any long-term risk from the changes necessary to extend the half life.

## Non-Factor Therapy Products

Despite these advances in replacement therapy, people with hemophilia still face a tremendous burden. In children, breakthrough bleeding and progressive joint disease, and the risk of inhibitors are of special concern. A major advance in the approach to therapy occurred with the availability of emicizumab (Hemlibra) in 2018. This represents the first of a group of new agents that are not coagulation factors but work to decrease bleeding by a variety of different techniques. Emicizumab functions similar to factor VIII – a bridge to bring other blood clotting factors together and promote normal clotting. Since its structure is completely different than factor VIII, there is no risk of inhibitors, and in fact, has been utilized for treatment of people with inhibitors. Studies in patients with factor VIII inhibitors show a decrease in annual bleeding rate by about 90%. Even more recently, this agent has now been approved for usage in individuals with hemophilia without inhibitors. A distinct advantage for this medication is that it is administered as a subcutaneous injection (rather than an IV) as infrequently as once every 4 weeks and so may be particularly useful for toddlers and children. As with all new advances, important questions remain including how to monitor the treatment in the laboratory, how to treat breakthrough bleeding and whether this treatment is appropriate for individuals who have undergone immune tolerance. Although not yet commercially available, other products that target the ability of the body to “turn off” blood clotting are being studied. One example of this approach is the medication concizumab which blocks a naturally-occurring factor called TFPI. Normally, TFPI helps regulate blood clot formation so when this is decreased additional factors are available to slow the bleeding.

## Gene Therapy

Potentially the most exciting approach to the treatment of hemophilia is gene therapy. This holds the promise of providing a lasting cure with a single treatment. The technique generally involves the use of DNA from viruses (known as vectors) that has been engineered to express blood clotting factors including factor VIII. The vector targets the liver where the gene begins to manufacture the blood clotting factor. The viral vector that has had the most success is adeno-associated virus (AAV). A number of studies are ongoing using this vector to treat both hemophilia A and B. The earliest human studies were initiated by BioMarin Pharmaceuticals Inc. using their product BMN 270. To date, in these studies higher doses of vector increased the factor VIII levels substantially but were associated with some degree of liver inflammation. Other studies using alternate AAV vectors are also ongoing and the outlook is promising. Potential concerns to this approach are also described and include the possibility that the vector will insert itself into the normal DNA of the liver cells in places that might lead to a cancer. Another potential toxicity is that the liver cells may become overly stressed by making the factor VIII and lead to liver injury.

## Where Do We Go From Here

The number of available factor VIII products is high so the choices among these therapies are large. The evolution of these products is now being overtaken by the non-factor therapy products and the potential for gene therapy so a potential revolution in hemophilia treatment may be on the doorstep.

Further discussion of this topic can be heard during the session, "New Product Update" presented by Dr. Morey Blinder at GHA's Family Education Weekend at the DoubleTree Chesterfield Hotel on July 13th.

The authors report no conflict of interest.

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