Mark June 6th on your calendar for a wonderful day of fun for the whole family…. This year’s walk will be the biggest ever—at a new location!! We outgrew Bird Park and are moving to Prowse Farm in Canton, MA. We have an awesome day in store with Bayer’s luncheon BBQ, “Good Vibes” spinning the tunes, “Animal Craze Petting Zoo” in Octapharma’s Kidz Zone, and more wacky fun in store!

The Incentive Program was so successful last year that we’ll do it again! The more that you raise, the more great prizes that you can earn… You should already be seeing emails.

Have your office fundraise with you—Jeans Day for a $5 donation; Ice Cream Sundaes in the office for $5 donation, Movie Nights, Wine Tastings, Restaurant Nights, Garage Sales, etc. These are all ways to make more money for your walk team…..Don’t forget to check and see if your workplace matches donations.

If you haven’t already signed up to walk, go to www.hemophilia.org/walk and click on the MA walk!

Bring the family, bring the friends….. But this year, DOGS ARE NOT INVITED. Sorry folks, but there is a large pond on the premises, and the park does not allow pets.
Dear NEHA Member,

In New England, like many other places in the country, we have a very rich history and certainly have acquired some of the greatest capital knowledge on the subject (and life) of Hemophilia and bleeding disorders. Because our community is very high functioning, one might conclude that we have arrived at a level of complacency that, in some aspects, insulates us from taking in the “big picture” - through a wider lens, so-to-speak.

The reality of our situation is that the greatest amount of Hemophilia (alone) is outside the US and very much out of our view. Of the roughly 497,000 people affected worldwide, here in the US there are less than 21,000. If we do the simple math, greater than 95% of those affected are in places very far from us.

On April 17th, NEHA participated in World Hemophilia Day, an event celebrated across the globe and uniquely marked by many communities across the country, including ours here in New England. I would like to take the opportunity to express our sincere gratitude to Biogen for their outstanding efforts to commemorate the occasion by lighting various landmarks in Boston (in red of course) and across the country. In addition to the Zakim Bridge, Prudential Center, and South Station, Niagara Falls was illuminated to mark the occasion as well – very impressive! The night was not complete of course without some very artistic renderings – a collection of pictures painted by attendees of all ages. Again our sincere thanks to Biogen for adding a creative twist to the evening.

This event was a valuable opportunity to revisit our situation and consider the magnitude and impact that Hemophilia and bleeding disorders have had and continue to have across the globe. It is a stark reminder that access to care, treatments, education, and awareness can easily be taken for granted in our world – many others are not nearly as fortunate as we are in New England and across the country.

For me, the celebration served as an inspiration and call to action for our organization and us as individuals. A call to think about the possibilities of sharing our capital knowledge and expertise to drive impact in places that may otherwise be forgotten. Sharing our knowledge, capabilities, and experiences is something we should be compelled to do, if even on a small scale. I hope that those who attended the celebration were equally as inspired!

Lastly – many thanks to all who participated in the camp cleanup day at Geneva Point…looking great and ready for another year!

Warmest Regards,
Patrick Mancini, NEHA President
Washington Days 2015 Draws a Crowd

Nothing About Us Without Us, Coming Together as One Voice

The National Hemophilia Foundation (NHF) is excited to report that we had a record number of participants in this year’s Washington Days, February 25-27, 2015. More than 300 attendees from 45 states and Puerto Rico gathered for our community advocacy event. They represented 150 Congressional districts and participated in 240 Hill visits, 100 of which were meetings scheduled with senators and representatives.

This year we asked Congress to:

1) Support maintaining funding for the federal hemophilia programs at the Maternal and Child Health Bureau (MCHB) and Centers for Disease Control and Prevention (CDC) in their appropriations requests;

2) Co-sponsor Representative Aaron Schock’s (IL-18) legislation to improve access to skilled nursing facilities (SNFs) for hemophilia patients in the House or introduce companion legislation in the Senate; and

3) Co-sponsor the Patients’ Access to Treatment Act (House) or introduce companion legislation (Senate) to increase access to life-saving drugs on specialty tiers by prohibiting insurers from imposing exorbitant co-insurance requirements on patients.

Following the full day of Hill visits, participants relaxed and enjoyed the State Advocacy Recognition dinner Thursday night. There, chapter leaders and key advocates were recognized and celebrated for their successful state advocacy initiatives undertaken throughout the year, courtesy of Novo Nordisk.

Washington Days concluded with a State Advocacy Workshop on Friday. Advocates participated in an in-depth discussion of three emerging trends and corresponding legislative efforts related to each that have the potential to affect the bleeding disorders community: out-of-pocket costs, preferred drug lists and standardization of prior authorization. During the first part of the workshop, advocates heard from NHF’s public policy team about the real impact these issues are having on the community, as well as how to frame these issues. During the second half, participants broke into groups to develop talking points on these issues based on the discussion.

NHF wants to take this opportunity to thank all those who participated, and gave their time and energy to advocating on behalf of the entire bleeding disorders community—we couldn’t have done it without you! We will keep you informed as the legislation we support is introduced. Please remember: if a legislator or his/her staff person contacts you, or if you have any questions, please feel free to contact a member of NHF’s public policy team.

The NEHA staff would also like to extend its thanks to the 22 volunteers from New England who attended Washington Days and represented our interests in meeting with local senators and representatives. It was a strong turnout and we appreciate the leadership provided to the group by both Diane Lima and Greg Price, NEHA Board members, who led the NEHA team in Washington.
Selecting a theme for our Family Camp is always challenging, but that extra bit of fun really adds to the week’s enjoyment! We believe that all attendees last year would agree that Spy Camp was a huge success. It added a bit of flavor and action to the week’s activities. Remember all those spies sneaking around with their mustaches and decoder rings!

At our Camp Planning Committee meeting in March, a proposal was made to select Rock Star Camp, or some version of the word Rock Star as our theme for 2015 and it was unanimously accepted by the committee. And to match the theme to an activity, we decided that a Talent Show would headline the many talents of our campers and counselors! So if you’re coming to Family Camp 2015, all of our Rock-Stars should start working on your talent for the show! Singing, playing an instrument, juggling, a comedy routine, dancing, tapping, and more, can all be part of the Show! Individual and Group talent are all welcome. So start practicing now... Campers have less than 3 months to work on their routines!
We knew it was going to be BIG when the applications starting arriving in batches. NEHA’s Family Camp usually has about 42 families and about 200 total participants. And that’s a very FULL camp for NEHA to host. But this year, applications just flowed in…..and totaled more than 53 families and 240 participants, a 30% increase! If we had the whole camp to ourselves, we probably could make it work easily, but since we typically share Camp with the group from Kazitstan, there was no way we could accommodate this size. We did some brain-storming first to see if an easy solution was present, but ran into a wall. So we did the natural thing- we asked our members for help!

And our Members responded in great numbers and with very positive attitudes! Some offered to share cabins when two small families could make that happen. Some offered to “tent out” under the stars so that others could have a cabin. Some small groups were pushed to the Inn. And some gave the ultimate sacrifice by offering to drop out of Camp this summer to allow others to attend!

Sooooooo, it looks like we will be able to accommodate all those families that got their applications in before the deadline. We really want to extend our thanks to all those families that offered to tent out, share cabins, etc… It was only through their generosity that we were able to accommodate so many families this year. And as usual, we started a waiting list for a few extra families that applied after the deadline date.

But we still need HELP! Due to our size, we still need lots of Counselors for Camp this summer. If you have been a Counselor or wish to be considered, please contact Heather Case ASAP to get on our list for this year. We know it’s hard to commit this far in advance but we need YOU! We are still about 12 counselors short this year. If you have any friends that would be great counselors, have them contact Heather to discuss the job.

Gears for Good is a charity bike ride offered by the Hemophilia Federation of America (HFA) to raise funds for its one-of-a-kind financial assistance program, Helping Hands. The West Virginia to Washington DC ride has been going on since 2011, and in 2014, we launched a second ride in New England with great success! Last year’s New England ride was attended by a strong showing of NEHA members.

5th Annual Gears for Good Ride- DC: 4 states; 156 miles; West Virginia to Washington, DC; September 25-27, 2015. Riders from all over the country meet in West Virginia and pedal on a crushed rock trail to Washington DC over 3 days .

2nd Annual Gears for Good Ride - New England: 70 miles; Farmington, CT; June 27-28, 2015. This two day ride is a blast. Riders gather Friday night or Saturday morning for a 40 mile first day on the Farmington River Trail (a paved trail). Sunday’s ride is a shorter, 30 mile journey. Lunches and dinners included.

To participate or for more information, please contact the HFA at 800-230-9797 or at info@hemophiliafed.org, or check out www.gearsforgood.com.
The New England Hemophilia Association (NEHA) is pleased to announce the conduct of a new Women’s Seminar designed for women and girls 13 years+. Supported by an educational grant provided by CSL Behring, this new event will be held on October 16-17, 2015 at the Wylie Inn and Conference Center in Beverly, MA. Local speakers from New England will be highlighted at the event which will focus on topics of interest to women, both Hemophilia and vWD patients, caregivers, as well as Carriers. Our keynote speaker will be Stacy E. Croteau, MD, MMS, Attending Physician, Pediatric Hematology/Oncology and Associate Director, Boston Hemophilia Center.

The entire event is free to participants, but does require registration. Activities start with dinner on Friday night followed by Rap Sessions. Saturday’s program starts at 9:00am and concludes by 4:00pm. All expenses for the event including one night’s hotel accommodations, all meals, materials and speakers will be managed by NEHA with support from CSL Behring.

A formal invitation will be distributed in early summer to all NEHA members and HTC patients. Please HOLD-THE-DATE for now until more information is available. Contact NEHA if you have any questions.

Baseball and NEHA: Perfect Together!

Please help the Stoneham Sabers raise money for the Yawkey Baseball League and the New England Hemophilia Association!

The Yawkey Baseball League is one of the elite amateur baseball leagues in New England. The YBL has organized a "Biking for Baseball" Cyclathon event at the Boston Sports Club on Station Landing in Medford, MA, on Saturday, June 20th, 4:00 pm, to raise money for essential league operating costs. Each Yawkey League team will square off with 12 players riding for 30 minutes each. The Stoneham Sabers will donate 50% of the proceeds received to the New England Hemophilia Association. Both the Yawkey Baseball League and the New England Hemophilia Association are non-profit 501(c)(3) organizations. Any donation amount would be greatly appreciated by the team!

Facebook.com/StonehamSabers
newenglandhemophilia.org
Yawkeybaseball.com
As most of you know by now, ABC television ran a recent episode of “Secrets and Lies” which aired on March 15, 2015. In the episode an inaccurate statement about the cause of hemophilia was made by an actor. This statement caused immediate outrage and numerous responses from the bleeding disorders community nationwide. Formal letters from the NHF, HFA, and many of the local Chapters, were forwarded to ABC TV sharing our concerns and asking for a correction and remediation of some sort. To date, we have not received a response from ABC. Below is a copy of the letter forwarded to ABC TV from NEHA President Pat Mancini:

March 16, 2015

Mr. Ben Sherwood, President ABC Disney Television
Mr. Paul Lee, President ABC Entertainment
ABC Entertainment Group, etc…..

Dear Gentlemen:

It is possible by now that one or both of you have received feedback regarding a recent episode of Secrets and Lies, S1E4, “The Sister”, which aired March 15th. This letter is as much a plea as it is a grievance seeking your focused and timely assistance in remediation.

At the end of the Episode, the statement “Hemophilia is a nasty byproduct of Incest” was made, which is entirely inaccurate – shared with as many as seven million viewers. For the more than 20,000 people diagnosed with Hemophilia in the US and close to 500,000 worldwide, the statement (not only disgusting), represents a devastating regression in our efforts to educate and advocate for Hemophilia here in the US and across the globe. If this had been accurate and factual, it would have effectively educated millions of people across the US and beyond.

The episode clearly exposes a deficiency in your process to ensure accurate content, even in the context of a fictionalized story. We now have hundreds, perhaps thousands of people subject to unfair and unwarranted discrimination due to these circumstances. Step back just for a moment to imagine how you would feel if your own son, daughter, or grandchild arrived home after a day being chastised by their peers? How would you respond and what actions would you be prompted to take? Can you also imagine the humiliating and cruel permutations that would manifest under these circumstances?

The absence of competence on behalf of the producers of the show has caused extensive concern at the World, National, and local chapter level for all factions of Hemophilia as well as our community at large. This following link: (http://www.wfh.org/en/page.aspx?pid=644), explains in simple terms, how a person “gets” Hemophilia – incest is not the way it happens.

There is so much information available on the subject across the internet that really there is no excuse for this blatant misrepresentation. Do you still feel like you have the brightest and best producing the show?

On behalf of the New England Hemophilia community, our local chapters (New England Hemophilia Association, Connecticut Hemophilia Society and Hemophilia Alliance of Maine), National, and World organizations, we are requesting that you take appropriate corrective actions to remedy this most unfortunate predicament. Ideally since this is a situation that has worldwide impact – a short session as part of ABC World News with David Muir would be the ideal setting to take corrective actions on the misrepresentation as well as educate millions of users on the real story. This is an outstanding opportunity for ABC to demonstrate unprecedented citizenship. Note: April 17th is World Hemophilia Day – the perfect day for ABC to take action.

Please consider this request closely; I would be very happy to work with your ABC New York staff on any and all questions or matters that would allow us to collaborate and make this happen.

Sincerely,

Patrick L. Mancini, Chairman and President
New England Hemophilia Association
World Hemophilia Day Celebration in Boston! A Great Success!

Last year it was the Zakim Bridge. This year, it was the Zakim Bridge, Prudential Tower and South Station, all lit up in red lights on April 17th to celebrate World Hemophilia Day, and to bring special attention to the needs of hundreds of thousands of people worldwide that have a bleeding disorder. April 17th was a special day as the New England Hemophilia Association joined forces with Biogen leadership and staff to offer an evening of recognition, celebration and fun! Over a hundred guests started the evening with dinner and social time, followed by presentations. Representative Tim Tommey arranged for a State Resolution claiming April 17th as World Hemophilia Day and presented it to Kevin Sorge, Executive Director of the New England Hemophilia Association. He was followed by Representative Joseph McKenna who told his own heartfelt story of growing up with hemophilia, and the importance of our efforts. He then presented Kevin with a Proclamation signed by Governor Charles Baker claiming April 17th as World Hemophilia Day!

Following lots of pictures and conversations with our guests, the audience was invited to participate in a Paint Bar exercise in which everyone has their own canvas and painted a picture following the directions of a local artist. The pictures were then taken home to be displayed. A great activity that showed how much talent we truly have in our Community!
Plant-Based Inhibitor Therapy Continues to Evolve

Scientists from the University of Florida in Gainesville (UF-G) and the University of Pennsylvania (U-Penn) continue to investigate an experimental, plant cell-based approach to preventing inhibitors and allergic reactions (anaphylaxis) to clotting factor therapies in people with hemophilia. An update on their progress was published online, December 16, 2014, in Scientific American, a division of Nature America, Inc.

Lead investigator Henry Daniell, PhD, director of translational research at the U-Penn School of Dental Medicine, and Roland W. Herzog, PhD, a molecular biologist at UF-G, have, for several years, been working on a technique that involves encapsulating an orally administered “tolerance-inducing protein” such as factor IX (FIX) within plant cell walls. When ingested, the bio-encapsulated protein safely travels through the stomach before reaching the small intestines. The plant cell wall shields the FIX from being prematurely broken down by stomach acid. Eventually, microorganisms eat away the cell wall, gradually releasing the protein.

Building on earlier studies (2010) that successfully used bioengineered tobacco plant cells to prevent inhibitors and anaphylaxis in mice with hemophilia B (FIX deficiency), Daniell and Herzog are now turning to freeze-dried lettuce leaf cells engineered to trigger a high concentration of FIX. Each lettuce leaf cell contains approximately 10,000 chloroplasts, each structured in such a way to hold very large volumes of the FIX protein. Chloroplasts are subunits of plant cells, most often known as crucial components of photosynthesis. Although these chloroplast-rich plant cells are not equipped to prevent bleeding--plants are unable to make human clotting factors biologically active--they have shown an ability to induce tolerance in the immune system to FIX.

Researchers have been developing this novel therapeutic approach for several years to create potential vaccines against malaria and cholera, and genetically engineered insulin to help prevent diabetes.

Daniell and Herzog recently took the next step and tested this approach in two dogs with hemophilia B. They fed both dogs their normal food along with the engineered lettuce cells converted into a green powder form. There have been no reports of anaphylaxis or inhibitors in the mice from the earlier study or in the dogs that recently received the plant-based therapy. “So far, it’s going very well,” reported Daniell. If this novel oral therapy continues to prevent treatment complications in animal models, the next step will be to replicate that success in human clinical studies.

Source: Scientific American, December 16, 2014

Novo Nordisk Announces Launch of Novoeight®

Novo Nordisk recently announced the launch of Novoeight®, the company’s new recombinant factor VIII therapy. The product is approved by the US Food and Drug Administration for use in adults and children with hemophilia A for the control and prevention of bleeding, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Approval of Novoeight® is based on results from a large set of clinical studies known as the guardian™ trials. 91% of bleeds experienced by patients in the guardian™1 and guardian™3 trials were controlled with one or two doses. Patients who took Novoeight® prophylactically had a median of 3.1 bleeds per year. Some patients from those trials continued prophylaxis with Novoeight® in a safety extension trial. An interim analysis as of September 1, 2012, showed that these patients had a median of 1.7 bleeds per year. The most common adverse reactions were injection site reactions (2.3%), increased hepatic enzymes (1.4%) and pyrexia (0.9%).

According to Novo Nordisk press release, the product can be stored at 86 degrees Fahrenheit for up to 12 months and can be kept at that temperature for up to four hours after reconstitution. It was shown to be safe and effective in clinical trials with zero inhibitors confirmed in 213 previously treated patients with hemophilia A.

“Hemophilia patients have unique, individualized needs, so it is critical for them to have access to different therapies,” said Roshi Kulkarni, MD, Professor of Pediatric Hematology/Oncology and Director of Pediatrics at the Centers for Bleeding and Clotting Disorders, Michigan State University. “Today’s patients are looking for options that fit into their busy lives, and it’s encouraging to see new treatment options that further serve patients within the bleeding disorders community.”

Novo Nordisk plans to make Novoeight® available by mid-April 2015.
Five New Developments In Hemophilia

(Originally posted on March 9, 2015 by Ellis Neufeld, MD, PhD. Dr. Neufeld is a hematologist at Dana-Farber/Boston Children’s Cancer and Blood Disorders Center.)

From new longer-acting drugs to promising gene therapy trials, much is changing in the treatment of hemophilia, the inherited bleeding disorder in which the blood does not clot. Hemophilia Awareness Month comes at a time of both progress and remaining challenges.

1. **Many more treatment products are being introduced, including some that last longer.**

   People with hemophilia lack or have defects in a “factor”—a blood protein that helps normal clots form. Of the approximately 20,000 people with hemophilia in the U.S., about 80 percent have hemophilia A, caused by an abnormally low level of factor VIII, and most of the rest have hemophilia B, caused by abnormally low levels of factor IX. Many patients with severe hemophilia give themselves prophylactic IV infusions of the missing factor to prevent bleeding (which otherwise can lead to crippling joint disease when blood seeps into the joint and enzymes released from blood cells erode the cartilage).

   Hemophilia factors traditionally have such a short half-life that we tend to treat patients every other day with factor VIII and twice a week with factor IX. The first two longer-lasting products came onto the market within the past year, and more are on the way. So now, with factor IX, it is possible to get an infusion just once a week and not bleed. This is really changing how we think about the disease. So far, the longer-acting factor VIII products are not yet long-lasting enough to make as dramatic a difference in the frequency of infusions. And creating really long-acting factors remains a challenge.

2. **Other new products are coming to market as factors go off patent.**

   The expiration of patents opens up a field that was limited to a few products as recently as 2014. Some companies are considering making bio-similars—generic-like products for complex protein molecules—for the more expensive factors.

   Meanwhile, clinicians are trying to cut through the hype that often accompanies the introduction of new products to help patients understand what’s actually happening. I am about to lead an observational study for the American Thrombosis and Hemostasis Network that will follow patients as they switch to the newer products and evaluate how well the products perform in terms of safety and how well they prevent bleeds. We’re trying to take this kind of observational study out of the exclusive hands of drug companies, which conduct proprietary studies of their particular products, and instead collect data that cuts across brands.

3. **Gene therapy is the next big thing.**

   Gene therapy is progressing much faster for factor IX than for factor VIII, because the factor VIII gene is so physically large that it doesn’t fit perfectly into the vector that delivers gene therapy. In the case of factor IX, however, the vector can be delivered through an IV infusion. It then travels directly to the liver, which is where the factor is produced. The therapy appears to be very safe, according to early results published in 2011 and updated in 2014. Although it doesn’t work for everybody, researchers are getting to the point where they believe they can reliably turn severe hemophilia into moderate or mild disease. If they can really turn severe hemophilia into mild hemophilia with one IV infusion, it would completely change the whole field of hemophilia, making factor prophylaxis a thing of the past. The gene therapy trials are starting with adults; therapy will be more difficult in children because the added gene would get diluted by the growing liver.

4. **New regimens require less frequent prophylactic infusions, even with less long-lasting products.**

   Traditionally, U.S. clinicians had patients infuse themselves two or three times a week to boost the missing factor to one percent of their blood, under the theory that this was the threshold needed to prevent bleeds. Canadian researchers showed you can start treating only once a week, and a number of U.S. centers are now following this regimen. If it prevents bleeding, then the patient stays on a once-a-week regimen even if his factor level is below one percent. If it doesn’t prevent bleeding, then the frequency of infusion is increased. We now often use this regimen with our young children. If once a week works, a home care nurse can come in and give an IV instead of surgically inserting a port. It also helps us learn what the patient really needs.

5. **The biggest challenge: reducing the risk of inhibitor antibodies that keep factors from working.**

   If a patient’s body treats the factor as a foreign protein and makes an antibody that keeps it from working, it’s as if he hadn’t even been given a dose. We can get rid of inhibitors in two thirds of patients who get them through Immune Tolerance Induction—by giving

(Continued on page 12)
The outlook for children with hemophilia in the US keeps getting better. Treatments are safer and easier to administer, and extended half-life products are becoming available. Parents of children newly diagnosed with hemophilia can feel hopeful about their children’s future. Nevertheless, having a child with a chronic illness presents many challenges. There is much to learn, much to understand, and a great deal to adjust to. Concerns about bleeds, joint damage, inhibitors, and pain are very real. And because hemophilia is rare—1 in 5,000 male births for hemophilia A—many families find themselves initially coping alone with a mystifying disorder, with no sense of what lies ahead.

Thankfully, specialists at comprehensive hemophilia treatment centers (HTCs) across the country offer innovative treatments while advancing national standards of care. Experts at these centers give patients and families access to the latest clinical and research developments, and offer sound medical advice and support. Yet the journey from receiving an initial diagnosis to feeling capable and in control at home means more than just connecting with a team at an HTC. Myriad other resources all play major roles in a family’s capacity to cope.

What are these resources that have proven so helpful? From listening to families, I have learned that a key support comes from a sense of being part of the bleeding disorder community. The need for this kind of shared experience has provided a wealth of programs, camps, and community get-togethers throughout the country and world! If families are able to attend these programs, there is nothing more supportive and invigorating than finding others “in the same boat” to share thoughts and feelings and exchange ideas and resources.

What if these community resources aren’t available, or parents don’t quite feel ready to reach out to others in the community? Obtaining educational materials is another valuable way to understand what having a child with hemophilia is all about. Many people want to learn and explore in the privacy of their homes, at their own pace. Fortunately, we have lots of material to choose from: books, pamphlets, videos, movies, webcasts, and Internet resources offer wonderful opportunities to learn about all aspects of hemophilia and other bleeding disorders in a way that fits each person’s unique learning style. Educational materials are constantly being published and updated.

Coauthors Ziva Mann, Allie Boutin, and I recently published The Gift of Experience II, a book for families with a newly diagnosed or young child with hemophilia. We understood that many families aren’t lucky enough to have other hemophilia families close by, or to travel to national meetings. So we decided to provide a book of parents’ discussions about raising their children from birth to age six. This resource provides excerpts of conversations with 19 parents (15 mothers and 4 fathers) of children with hemophilia A or B. The children have mild, moderate or severe hemophilia and come from a variety of backgrounds. Some of the parents interviewed knew that they might give birth to an affected child, but to others, hemophilia came as a complete surprise. All the parents speak frankly about their journey, from the shattering diagnosis until, finally, the realization that their world has become manageable—even normal.

Despite each family’s unique challenges, they all faced similar heartaches and struggles, made huge achievements, and saw unanticipated rewards. This book of experiences is their gift to families embarking on the same journey: the strategies, perspectives, and encouragement offer guidance, hope, and support. Parents who read The Gift of Experience II can feel like members of our supportive community, perhaps even imagining standing in a kitchen with other parents, drinking coffee, while their children with hemophilia laugh, play, and learn.

(Originally published in PEN Newsletter, 02/15, AS I SEE IT. Laura Gray is projects director of Boston Hemophilia Center (BHC). She was the social worker for many years in both the adult and pediatric centers of BHC. She is the author, along with Christine Chamberlain, of The Gift of Experience, the first book in this series. She coauthored The Gift of Experience II, with Ziva Mann and Allie Boutin, two mothers of children with hemophilia. Both books are available on amazon.com.)

Five New Developments (Continued from page 11)

enough factor (daily, for months or even years) to confuse the immune system and make it forget it’s a foreign protein. About 10 percent of patients, however, are left with high-titer inhibitors that we can’t overcome, which is life-altering and can be terrible. There are hints from experiments in mice that some of the newer factors might lower the incidence of inhibitors in people with severe hemophilia. But mice aren’t people. If this does turn out to be true in humans, it would be a major breakthrough.
QUALITY
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IN 25 YEARS, we’ve developed a reputation. To families, we’re a team who offers the highest quality care. And to bleeding disorders organizations, we’re a supporter whose commitment and contributions have never stopped.

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

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- Fewer syringes

Isn’t it time you tried ALPHANATE?

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

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

Important Safety Information
ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components. Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with ALPHANATE should be discontinued, and emergency treatment should be sought.

Development of activity-neutralizing antibodies has been detected in patients receiving FVIII containing products. Development of alloantibodies to FVF in Type 3 von Willebrand disease (VWD) patients has been occasionally reported in the literature. Thromboembolic events may be associated with AHF/VWF Complex (Human) in VWD patients, especially in the setting of known risk factors. Intravascular hemolysis may be associated with infusion of massive doses of AHF/VWF Complex (Human).

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

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

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

Please see brief summary of ALPHANATE full Prescribing Information on adjacent page.

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

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

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

ALPHANATE (ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX [HUMAN])
Sterile, lyophilized powder for injection.
Initial U.S. Approval: 1978

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

DOSAGE AND ADMINISTRATION
For Intravenous use only.
Alphanate contains the labeled amount of Factor VIII expressed in International Units (IU) FVIII/vial and von Willebrand Factor:Ristocetin Cofactor activity in IU VWF:RCO/vial.

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

vWillebrand Disease: Surgical and/or invasive procedure in adult and pediatric patients except Type 3 undergoing major surgery
- Adults: Pre-operative dose of 60 IU VWF:RCO/kg body weight; subsequent doses of 40-60 IU VWF:RCO/kg body weight at 8-12 hour intervals post-operative as clinically needed.
- Pediatric: Pre-operative dose of 75 IU VWF:RCO/kg body weight; subsequent doses of 50-75 IU VWF:RCO/kg body weight at 8-12 hour intervals post-operative as clinically needed.

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

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

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

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

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Biologicals Inc. at 1-888-GRIFOLS (1-888-474-7357) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS
- Pregnancy: No human or animal data. Use only if clearly needed.
- Pediatric Use: Hemophilia A - Clinical trials for safety and effectiveness have not been conducted. VWD - Age had no effect on PK.
THE FIRST AND ONLY FACTOR VIII WITH A PROLONGED HALF-LIFE

Learn how a prolonged half-life may affect your infusion schedule

Meet your CoRe Manager Lisa Schmitt
E: Lisa.Schmitt@biogenidec.com  T: 978-407-7713
This information is not intended to replace discussions with your healthcare provider.

Indications
ELOCTATE™ [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for: control and prevention of bleeding episodes, perioperative management (surgical prophylaxis), and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. ELOCTATE is not indicated for the treatment of von Willebrand disease.

Important Safety Information
Do not use ELOCTATE if you have had an allergic reaction to it in the past.

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

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

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

Common side effects of ELOCTATE are joint pain and general discomfort. These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, and if bleeding is not controlled after using ELOCTATE.

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

Please see enclosed Prescribing Information.
FDA-Approved Patient Labeling

Patient Information

ELOCTATE™ /el’ o k’t ate/
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

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

What is ELOCTATE?

ELOCTATE is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency).

Your healthcare provider may give you ELOCTATE when you have surgery.

Who should not use ELOCTATE?

You should not use ELOCTATE if you had an allergic reaction to it in the past.

What should I tell my healthcare provider before using ELOCTATE?

Talk to your healthcare provider about:
- Any medical problems that you have or had.
- All prescription and non-prescription medicines that you take, including over-the-counter medicines, supplements or herbal medicines.
- Pregnancy or if you are planning to become pregnant. It is not known if ELOCTATE may harm your unborn baby.
- Breastfeeding. It is not known if ELOCTATE passes into the milk and if it can harm your baby.

How should I use ELOCTATE?

You get ELOCTATE as an infusion into your vein. Your healthcare provider will instruct you on how to do infusions on your own, and may watch you give yourself the first dose of ELOCTATE.

Contact your healthcare provider right away if bleeding is not controlled after using ELOCTATE.

What are the possible side effects of ELOCTATE?

Common side effects of ELOCTATE are joint pain and general discomfort.

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

Your body can also make antibodies called, “inhibitors,” against ELOCTATE, which may stop ELOCTATE from working properly. Your healthcare provider may give you blood tests to check for inhibitors.

How should I store ELOCTATE?

- Keep ELOCTATE in its original package.
- Protect it from light.
- Do not freeze.
- Store refrigerated (2°C to 8°C or 36°F to 46°F) or at room temperature [not to exceed 30°C (86°F)], for up to six months.
- When storing at room temperature:
  - Note on the carton the date on which the product is removed from refrigeration.
  - Use the product before the end of this 6 month period or discard it.
  - Do not return the product to the refrigerator.
- Do not use ELOCTATE after the expiration date printed on the vial or, if you removed it from the refrigerator, after the date that was noted on the carton, whichever is earlier.

After reconstitution (mixing with the diluent):
- Do not use ELOCTATE if the reconstituted solution is not clear to slightly opalescent and colorless.
- Use reconstituted product as soon as possible
- You may store reconstituted solution at room temperature, not to exceed 30°C (86°F), for up to three hours. Protect the reconstituted product from direct sunlight. Discard any product not used within three hours.

What else should I know about ELOCTATE?

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

Manufactured by: Biogen Idec Inc.
14 Cambridge Center, Cambridge, MA 02142 USA
U.S. License # 1697
44279-01
ELOCTATE™ is a trademark of Biogen Idec.

Issued June 2014
ADVATE [Antihemophilic Factor (Recombinant)] Important Information

Indications
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 may give you ADVATE when you have surgery.
ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).
ADVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

You should not use ADVATE if you:
• Are allergic to mice or hamsters.
• Are allergic to any ingredients in ADVATE.
Tell your healthcare provider if you are pregnant or breastfeeding because ADVATE may not be right for you.
You should tell your healthcare provider if you:
• Have or have had any medical problems.
• Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
• Have any allergies, including allergies to mice or hamsters.
• Have been told that you have inhibitors to factor VIII because ADVATE may not work for you.

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

You can have an allergic reaction to ADVATE.

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.
Side effects that have been reported with ADVATE include: cough, headache, joint swelling/aching, sore throat, fever, itching, unusual taste, dizziness, hematoma, abdominal pain, hot flashes, swelling of legs, diarrhea, chills, runny nose/congestion, nausea/vomiting, sweating, and rash.

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

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

Please see following page for Brief Summary of ADVATE full Prescribing Information.

ADVERSE REACTIONS (Anaphylactoid Factor [Recombinant])
Lyophilized Powder for Reconstitution for Intravenous Injection
Brief Summary of Prescribing Information: Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE
ADATE (Anaphylactoid Factor [Recombinant]) is a recombinant anaphylactic factor indicated for use in children and adults with hemiplegia A congenital factor VIII deficiency or classic hemophilia for:
- Control and prevention of bleeding episodes.
- Perioperative management.
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
ADATE is not indicated for the treatment of von Willebrand disease.

CONTRAINDICATIONS
ADATE is contraindicated in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product (adenosine, histidine, sodium chloride, thiolate, Tris, calcium chloride, polyethylene glycol, and/or glutathione).

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADATE. Symptoms include dizziness, paresthesias, rash, flushing, facial swelling, urticaria, dyspnea, and pruritus. ADATE contains trace amounts of mouse immunoglobulin G (IgG) ≤ 0.1 Ng/μg ADATE, and hamster proteins ≤ 0.25 μg ADATE. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

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

Neutralizing Antibodies
Neutralizing antibodies (inhibitors) have been reported following administration of ADATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (PMTs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration [see Warnings and Precautions].

Monitoring Laboratory Tests
- Monitor plasma factor VIII activity levels by the one-stage clotting assay to confirm the adequate factor VIII levels have been achieved and maintained when clinically indicated [see Dosage and Administration].
- Perform the Bethesda assay to determine if factor VIII inhibitor is present. If expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADATE, use Bethesda Units (BU) to inhibit factors.
  - If the inhibitor titer is less than 0.01 BU per mL, the administration of additional anaphylactic factor concentrate may neutralize the inhibitor and permit an appropriate hemostatic response.
  - If the inhibitor titer is more than 0.01 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may be followed using ADATE infusions as a result of an anamnestic response to factor VIII. Treatment or prevention of bleeding in such patients may require the use of alternative therapeutic approaches and agents.

ADVERSE REACTIONS
The serious adverse reactions seen with ADATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions observed in clinical trials were:
- Pain at the injection site
- Rash
- Pruritus
- Influenza-like symptoms
- Headache
- Osteomyelitis
- Meningitis

These adverse reactions were reported in patients treated with ADATE in clinical trials and were more frequent in patients treated with ADATE than placebo. The most common adverse reactions observed in clinical trials were:
- Headache
- Osteomyelitis
- Meningitis

The summary of adverse reactions for each adverse event occurring in 5% or more of subjects is provided in Table 3.

Table 3: Summary of Adverse Reactions with a frequency of ≥ 5% (N = 244 Treated Subjects)

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Number of ADRs</th>
<th>Number of Subjects</th>
<th>Percent of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pain</td>
<td>78</td>
<td>56</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>104</td>
<td>49</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Respiratory, thoracic, and mediastinal disorders</td>
<td>Cough</td>
<td>70</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>Infectious and infestations</td>
<td>Nociception</td>
<td>68</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td>Gastrointestinal disorders</td>
<td>Vomiting</td>
<td>30</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Arthritis</td>
<td>44</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Urinary, respiratory, and circulatory disorders</td>
<td>Upper respiratory tract infection</td>
<td>24</td>
<td>26</td>
</tr>
</tbody>
</table>

Respiratory, thoracic, and mediastinal disorders

Pharyngitis, periorbital swelling, and bone pain.

Gastrointestinal disorders

Diarrhea, nausea, vomiting, and constipation.

Genitourinary and administration site conditions

Pruritus, pyrexia, fever.

Skin and subcutaneous tissue disorders

Folliculitis, pruritus.

Infectious and infestations

Infection.

Respiratory, thoracic, and mediastinal disorders

Respiratory tract infection.

Immunogenicity

The development of factor VIII inhibitors with the use of ADATE was evaluated in clinical trials with pediatric PUPs < 10 years of age with > 50 factor VIII exposures and PUPs > 10 years of age with > 50 factor VIII exposures. Of 118 subjects who were treated for at least 10 exposure days or on study for a minimum of 120 days, 16 developed a low-titer inhibitor (β ELI in the Bethesda assay) after 25 exposure days. Eight weeks later, the inhibitor was no longer detectable, and at nine weeks was normal at 1 and 3 hours after infusion of another recombinant inactivated factor VIII concentrate. This single event result in a factor VIII inhibitor frequency in PUPS of 0.95% (95% CI 0.02% and 2.95%) for the risk of any factor VIII inhibitor development. No factor VIII inhibitors were detected in the 53 treated pediatric PUPs in clinical trials that enrolled previously untreated subjects (defined as having had up to 3 exposures to a factor VIII product at the time of enrolment); 3 (6%) of 52 subjects who received ADATE developed inhibitors to factor VIII. No subjects developed high (< 6 BU) or low (< 1 BU) inhibitors. Inhibitors were detected in a median of 1 exposure days (range 7 to 13 exposure days) to investigation product.

Hypersensitivity reactions also were evaluated by measuring the development of antibodies to hemoglobin proteins. 102 treated subjects were assessed for anti-hemoglobin antibodies by ELISA. No antibodies were detected.

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

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of ADATE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure among patients treated with ADATE, cases of serious adverse reactions including anaphylactic reactions have been reported with factor VIII inhibitor formation (observed predominantly in PUPS in Table 4) represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Term.

Table 4: Most Frequently Reported Post-Marketing Adverse Reactions as MedDRA Preferred Terms

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>MedDRA Preferred Term</th>
<th>Number of ADRs</th>
<th>Number of Subjects</th>
<th>Percent of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary system (MedDRA Primary SOC)</td>
<td>Urinary system disorders</td>
<td>63</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Factor VIII inhibition</td>
<td>63</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Injection site reaction</td>
<td>63</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

Blood and lymphatic system disorders

Fatigue, Malaise, and chest discomfort/pain.

Less-than-expected therapeutic effect

*These reactions have been manifested by dizziness, paresthesias, rash, flushing, facial swelling, urticaria, and/or pruritus.

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Baxter Healthcare Corporation, Westlake Village, CA 91361 USA

U.S. License No. 140 Issued 04/2014 US585-2014-0110
WHAT IS XYNTHA?
XYNTHA® Antihemophilic Factor (Recombinant) is indicated in adults and children for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for the prevention of bleeding during surgery in patients with hemophilia A.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated for 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, difficulty breathing, chest tightness, turning blue (look at lips and gums), fast heartbeat, swelling of the face, hives, rash, low blood pressure, 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.

• Across all clinical studies, the most common side effects (10% or more) with XYNTHA in adult and pediatric previously treated patients (PTP) were headache (26% of subjects), joint pain (25%), fever (21%), and cough (11%). Other side effects reported in 5% or more of patients were diarrhea, vomiting, weakness, and nausea.

• 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 for XYNTHA and XYNTHA SOLOFUSE on the next 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.

You must be currently covered by a private (commercial) insurance plan if you are not eligible for the Ideal prescription program. You may find help accessing Pfizer medicines by contacting Pfizer’s RxPathways program. For questions about the XYNTHA Trial Prescription Program, please call 1-800-722-5791 or write us at XYNTHA Trial Prescription Program, Administrative Medco, PO Box 5714, Playa Vista, CA 90095-5714.

The chemically defined cell culture medium in which the Chinese hamster ovary (CHO) cells are grown contains recombinant insulin but does not contain any materials derived from human or animal sources.

This card will be accepted only at participating pharmacies. This card is not health insurance. No membership fee.

Need help accessing Pfizer medicines? Pfizer’s RxPathways program may be able to help. Call 1-888-327-7787 or visit www.PfizerRxPath.com.
**XYNTHA®**
Anthemophilic Factor (Recombinant)

**XYNTHA® Solofuse**
Anthemophilic Factor (Recombinant)

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**Brief Summary**

See package insert for full prescribing information, including patient labeling. For further product information and current patient labeling, please visit XYNTHA.com or call Pfizer Inc toll-free at 1-800-979-3477.

Please read the 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. Your healthcare provider may give you XYNTHA when you have surgery.

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:

- have any allergies, including allergies to hamsters.
- 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.

**How should I infuse XYNTHA?**

Step-by-step instructions for infusing 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 ask 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 side effects of 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
- difficulty breathing
- chest tightness
- turning blue (look at lips and gums)
- fast heartbeat
- swelling of the face
- faintness
- rash
- hives

Common side effects of XYNTHA are:

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

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°F to 46°F (2°C to 8°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 the refrigerated at 36°F to 46°F (2°C 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 gray 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)] Prescribing Information (LAB-0516-5.0, revised 10/14, and LAB-0560-3.0, revised 10/14).

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www.cslbehring.com
1-800-676-4266  2/2014
Electronic (.pdf) versions of this newsletter are available on request. Contact the NEHA office for information!

**Mission Statement**

The New England Hemophilia Association is a non-profit organization dedicated to improving the quality of life for persons with bleeding disorders and their families through education, support, and advocacy.

Services include:
- Information and referral
- Medical symposia and educational programs
- Social and recreational activities for children and families
- Family Camp
- Teen Programs
- Spanish-language programming
- Peer support groups
- Emergency financial assistance
- Advocacy and Legislative Support

Please contact the office for more information

**Phone:** (781) 326-7645  
**e-mail:** info@newenglandhemophilia.org  
**Website:** www.newenglandhemophilia.org

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**CALENDAR OF UPCOMING NEHA EVENTS**

For further information about these or other events, call NEHA at (781) 326-7645

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 6, 2015</td>
<td>Hemophilia Walkathon</td>
<td>Canton, MA</td>
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<tr>
<td>June 9, 2015</td>
<td>NEHA Board of Directors Meeting</td>
<td>Waltham, MA</td>
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<tr>
<td>July 11, 2015</td>
<td>PAW SOX Game</td>
<td>Pawtucket, RI</td>
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<tr>
<td>July 21—25, 2015</td>
<td>NEHA Family Camp</td>
<td>Moultonborough, NH</td>
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<tr>
<td>August 13—15, 2015</td>
<td>NHF Annual Conference</td>
<td>Dallas, TX</td>
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<td>August 29, 2015</td>
<td>Blood Brother Activity</td>
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<tr>
<td>September 14, 2015</td>
<td>NEHA Golf Tournament and Auction</td>
<td>Boylston, MA</td>
</tr>
<tr>
<td>September 15, 2015</td>
<td>NEHA Board of Directors Meeting</td>
<td>Waltham, MA</td>
</tr>
<tr>
<td>September 18-19, 2015</td>
<td>Dads in Action Campout</td>
<td>Touisset, RI</td>
</tr>
<tr>
<td>September 26, 2015</td>
<td>HFA Gears for Good Bike Ride</td>
<td>Connecticut</td>
</tr>
<tr>
<td>October 3-4, 2015</td>
<td>Hispanic Heritage Month Conference</td>
<td>Location TBD</td>
</tr>
<tr>
<td>October 16-17, 2015</td>
<td>Women’s Conference</td>
<td>Beverly, MA</td>
</tr>
<tr>
<td>November 6, 2015</td>
<td>Blood Brotherhood Activity</td>
<td>Location TBD</td>
</tr>
<tr>
<td>November 7, 2015</td>
<td>Fall-Fest</td>
<td>Providence, RI</td>
</tr>
<tr>
<td>December 6, 2015</td>
<td>NEHA Holiday Party</td>
<td>Norwood, MA</td>
</tr>
</tbody>
</table>

New England Hemophilia Association  
347 Washington St.  Suite 402  
Dedham, MA  02026  
Address correction requested