The Winning Spirit

Quarterly Newsletter — National Hemophilia Foundation, Delaware Valley Chapter — Spring 2009 Volume 16 Number 2

IN THIS ISSUE

THE HEMOPHILIA STANDARDS OF CARE ACT HB 620 !!!!LAUNCHED!!!! IN PENNSYLVANIA HOUSE OF REPRESENTATIVES!!!!!

The two Pennsylvania Chapters of the National Hemophilia Foundation have been working hard over the last four years to secure access to care for patients affected by bleeding disorders in Pennsylvania. As a result of their efforts, The Hemophilia Standards of Care Act, HB 620, was introduced by Representative Lawrence Curry (D-154) on February 24, 2009!! HB 620 addresses the following issues:

Access to State-Recognized Hemophilia Programs in Pennsylvania

Access to Hospital Coagulation Laboratories

Access to All FDA-Approved Factor Replacement Therapies for the Treatment of Hemophilia and VWD

Access to Options in Pharmacy and Home Supportive Services

Access to Coagulation Testing for Women

Be a part of the DVC's State Advocacy efforts by being willing to help get HB 620 passed in the Pennsylvania House of Representatives!! E-mail your contact information to: hemophilia@navpoint.com

WE NEED YOUR HELP!!!!!! Any questions, call 215-885-6500.

National Hemophilia Foundation
DELAWARE VALLEY CHAPTER
222 S. Easton Road, Suite 122
Glenside, PA 19038
Phone (215) 885-6500
Fax (215) 885-6074
E-mail: hemophilia@navpoint.com
Ann Rogers, Executive Director
Kim Bayer, Administrative Assistant
Christine Rowe, Fund Development Coordinator

The Winning Spirit is published quarterly by the National Hemophilia Foundation, Delaware Valley Chapter. The material in this newsletter is provided for your general information only. The Delaware Valley Chapter does not give medical advice or engage in the practice of medicine. DVC under no circumstances recommends particular treatments for specific individuals and in all cases recommends that you consult your physician or local Treatment Center before pursuing any course of treatment.

Graphic Artist: www.chaley.com

We gratefully acknowledge the pledge of support from the following manufacturers for 2009.

Baxter Bioscience
Recombinate
Hemofil M
Proplex T
Feiba VH
Bebulin VH
Albumin (Human)
Advate

Bayer Corporation
Kogenate FS
Koate-DVI

CSL Behring
Monoclate-P
Mononine
Helixate FS
Humate-P
Stimate

Novo Nordisk
NovoSeven® RT

Wyeth
BeneFix™
ReFacto
Xyntha

Each spring, we introduce our readers to the HPPS participating companies for the coming year!! Each of these companies provides pharmacy and home supportive services to local patients affected by bleeding disorders and has qualified as a 2009 participating company. Each company meets the very high standards of service set by Hemophilia Patient and Program Support, Inc (HPPS).

Meet these companies by going to our website www.hemophiliasupport.org and clicking on the companies' logos. You will be linked directly to their site where you will find detailed information on the services that each company provides. Be an educated consumer and get the information you need to make informed decisions about what you need in a pharmacy. If you or your family member has a bleeding disorder and you haven't registered with the HPPS program in the past, fill out the enclosed HPPS registration and mail it back to the Chapter office. By registering, you will be informed of important issues and events throughout the year.

Hemophilia Patient and Program Support, Inc. is dedicated to providing support to patients and programs within the geographic boundaries of the DVC. Become a member today!!

FACTOR ASSISTANCE PROGRAMS OFFERED BY MANUFACTURERS

Manufacturers of clotting factor concentrates can possibly provide assistance to you in the event of a lapse or loss of health insurance. The following resources can help connect you with a patient assistance program:

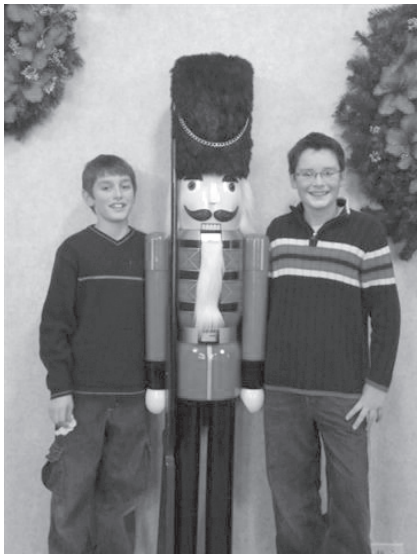
- HANDI, National Hemophilia Foundation's information resource center: 800.42.HANDI or handi@hemophilia.org
- Advocating for Chronic Conditions, Entitlements and Social Services (ACCESS): 888.700.7010
- Patient Services Incorporated: 800.366.7741 or www.uneedpsi.org

Contact the manufacturers directly to learn about program criteria, eligibility guidelines and details or link to their websites from www.hemophiliasupport.org

- Baxter: 888.229.8379 or www.thereforyou.com/patients/insurance/baxter-insurance-assistance/factor-assist-program
- Bayer HealthCare: 800.288.8374 or www.kogenatefs.com/patients/insurance-information.jsp
- CSL Behring: 866.415.2164 or www.cslbehringassurance.com
- Grifols: 888.474.3657 or www.grifolspatientcare.com
- Novo Nordisk: 877.668.6777 or www.novosevenrt.com/patient-resources/sevensecure/index.aspx
- Talecris Biotherapeutics: 877.827.3462 or www.talecris.com/us/talecris-us-reimbursement-support.htm
- Wyeth: 888.999.2349 or www.hemophiliavillage.com

The Central Pennsylvania "After Holiday" Family Party was held on Saturday, January 3, 2009 at *The Gathering Place* in Mount Joy, PA. Families from central and northern Pennsylvania had a great time together celebrating a little "after the holiday" cheer!! A great big thank you to Lorie and Brian Kerstetter (Lititz, PA) for making all the arrangements and putting all the details in place!! We really appreciate it!

Families having fun at the after holiday party.



Evan and Corey

On Saturday, February 21, 2009, "Men Matter" was held in King of Prussia, PA. This day-long workshop focused on issues for men in families dealing with bleeding disorders! A big thank you to Joe Caronna from *Inalex* for bringing this great program to us and to Baxter BioScience for providing an educational grant that made this program possible!! Thanks Tom Wallace (local Baxter rep) for making all of the arrangements!!

Men Matter

Look what's coming up!!

Call the DVC office to get more details!!

2009 Chapter Calendar

May	5	Family Dinner!
	9	CEO Program for Teens!
	16	Re Run Broad Street 5 Miler!
	24	Liberty to Liberty Triathlon!
June	1	Carlino's golf!
July	11-16	Double H Camp Session 1!
August	4-9	Double H Camp Session 2!
September	11	Insurance Transitioning Information Night!
	21	DVC Golf Classic!
	25-27	Family Camp!
October	23	Fall Gala!
November	7	"I Can Run" Race!
December	5	Holiday Party!

PATIENT SERVICES INCORPORATED TO OPERATE THE ACCESS PROGRAM

Patient Services Incorporated (PSI), a leading health advocacy non-profit, is now operating the ACCESS Program (effective 2/19/09). Advocating for Chronic Conditions, Entitlements and Social Services (ACCESS) has become a 501 © (3) non-profit under PSI and will be known as the "PSI ACCESS Program." The program, which will be based in Tampa, Florida, will provide Social Security and disability representation to patients diagnosed with Bleeding Disorders, Alpha 1, Chronic Inflammatory Demyelinating Polyneuropathy, Pulmonary Arterial Hypertension, Amyotrophic Lateral Sclerosis and Primary Immune Deficiency. Call 1.888.700.7010 for more information.

ELECTION ANALYSIS: WHAT DO THE RESULTS MEAN FOR THE BLEEDING DISORDERS COMMUNITY?

By Glenn Mones, NHF Vice President for Public Policy

Now that some of the hoopla over what has certainly been an historic presidential campaign and election has started to settle down, we have an opportunity to take a look at what the results may mean for people with bleeding disorders and other chronic conditions.

Although there's never any guarantee that a campaign promise will be fulfilled in its original form, the campaign rhetoric is the best starting place for determining what changes the new administration might make to healthcare. During his campaign, Barack Obama outlined a plan designed to let people who had satisfactory employer-provided health insurance stay with their existing coverage, while offering new options to people who did not have adequate coverage. These new options, offered through a National Health Insurance Exchange, would include a public health insurance plan similar to Medicare, as well as a range of private plans. Important features of Obama's plan, with particular significance for people with bleeding disorders and other high-cost conditions, include the following:

- All children would be required to have health insurance. Many would be covered through an expansion of the Children's Health Insurance Program (CHIP).
- Medicaid would also be expanded to cover more families with lower incomes, as well as individuals with special needs.
- All Americans would have access to the new public health insurance plan and other "guaranteed issue" plans. This would offer more options for coverage, especially for those who live in states that don't currently have guaranteed issue policies and where high-risk pools are underfunded.
- Premiums for new plans would be reasonable and could not be based on health status. Subsidies would be offered to those who cannot afford the premiums and there would be no exclusions for pre-existing conditions.

Most of this sounds pretty good, but the question people are asking now is "will it really happen, and if so, when?" Many Americans are still smarting from the failed efforts of the Clinton administration to make substantial changes to healthcare. On the plus side, the Obama plan is in many ways less radical than the Clinton plan, particularly in the way it seeks to preserve the status quo for the many Americans who feel they are already well-served. Also, healthcare reform was high on the Democratic campaign platform and the transition team has indicated that it remains a very high priority. In addition, the alignment between the incoming president and the majority in both houses of Congress can help clear the way for a variety of changes, including some of the reform measures that elected officials have already been seeking. For example, the new political climate may make it easier to advance the bill to raise lifetime insurance caps, which the National Hemophilia Foundation (NHF) and others in the bleeding disorders community have been promoting. Further, President Obama has indicated his intention to use executive orders where possible to institute changes, circumventing the need for some legislation. It may be possible for him to make some significant changes to programs like Medicaid and CHIP using such orders.

Even so, don't expect to open the newspaper tomorrow and read about too many imminent changes, or to open your mailbox the next day and get a mailing describing your new insurance options. Insiders are saying that 2010 is probably the earliest we are likely to see the first signs of healthcare reform, with most of it coming much later. This is due in part to the normal time it takes to design and implement major new programs, but also to the likely effect the economic crisis will have on this and anything else that comes with a price tag. The new administration may find it necessary to put anything that doesn't immediately affect the economy on a back burner. Also, it may scale back some of the costlier items until such time as the economy rebounds and/or sufficient savings can be realized from other areas. We should also be wary of the cost-savings measures that can adversely affect access to healthcare. At the state level, we have already seen payers attempt cost-cutting measures like tiered formularies or preferred drug lists. These lists restrict access to the full range of available treatments. This disrupts the ability of the physician, in consultation with the patient, to make the best medical decision for that patient. It is certainly possible that, as the new President and Congress look for ways to pay for healthcare reform, they will also be considering ways to save costs that may not be acceptable for people with bleeding disorders.

If anyone imagines that this is the time to sit back and let the newly elected pro-healthcare administration and Congress do their work, they'd better think again. This is the time for Americans who care about healthcare reform to remind all elected officials how important access to quality healthcare is for all of us. This is also the time for Americans with bleeding disorders and other chronic conditions to remind elected officials of who we are. We need to make sure our specific concerns and needs are fully considered as new programs are developed. Finally, we must use all the tools at our disposal, through NHF and other national organizations, our Chapters and local organizations, Washington Days and State Advocacy Days and our treatment centers. We must use all means at our disposal to make our voices heard and make meaningful healthcare reform a reality.

Previous article taken from the January/February 2009 issue of *HemAware*, a publication of the National Hemophilia Foundation.

NATIONAL TREASURE

By Sarah Aldridge

Russell Crowe is expertly groomed and soaks up attention from adoring caretakers. He also gets chew toys. Russell is a research dog at the University of North Carolina at Chapel Hill. The colony of hemophilic dogs there has served as a live animal model that has proven invaluable to bleeding disorders researchers for more than 60 years. Rodents, pigs and primates have also served the research community in ways no computer model could.

Human's Best Friend

In this community, dogs truly are humans' best friend. "The history of the treatment of hemophilia in humans has been developed in parallel with the dogs," says Timothy Nichols, MD, Director of the Francis Owen Blood Research Laboratory at UNC-Chapel Hill. "Dogs are an excellent model of the human disorder because they bleed in the same places as humans."

The dog colony was started in 1947 when Kenneth Brinkhous, MD, chair of the department of pathology at UNC-Chapel Hill, transported purebred Irish setters to the campus from New York. They had been diagnosed by veterinarians at Cornell University in Ithaca as the first known canine carriers of hemophilia A. Lynne and Nora made the trip south. Soon after, Nora delivered a litter of puppies; the males all had the disorder.

The dogs, now with hemophilia A or B or vonWillebrand Disease (VWD), have trotted alongside researchers across the treatment timeline as each decade produced more advances. In 1953, Brinkhous and colleagues Robert Langdell, MD and Robert Wagner, MD developed the partial thromboplastin time (PTT) screening test. "This could not have been done without some seminal observations with plasma from these dogs," says Nichols. Breeding experiments in the dogs later in the 1950s pinpointed the X chromosome as the locale for the hemophilia gene. "That was an important localization of both the gene and its transmission," Nichols says.

"They used these same dogs to establish the basis for plasma transfusion therapy, long before we had concentrates," says Harold Roberts, MD Kenan Professor of Medicine at UNC-Chapel Hill. "The physiologic basis for plasma transfusion in humans was made from these dogs." Using dog plasma, Brinkhous and Wagner successfully purified factor VIII (FVIII) in 1963 using a glycine precipitation method, which resulted in a more than 100-fold purification of the factor. A year later, Roberts and Phillip Webster, DDS, MS, applied the glycine purification method to purify FVIII from human plasma. The Wagner method was later adopted by Hyland Labs (part of Baxter BioScience) and clinical trials soon followed. "We were the first to use glycine-precipitated factor VIII concentrate in a human patient with hemophilia under experimental conditions," Roberts says.

In the 1980s, when the blood supply became contaminated with the human immunodeficiency virus (HIV), the dog plasma provided a gold mine of information. "Experiments were greatly facilitated by having the canine plasma on hand to experiment with freezing and thawing, pasteurizing, heating and steaming-all the processes that are done in the development of blood products," says Nichols. These experiments helped ensure safer blood products for people.

In the 1990s, the brave new world of gene therapy became a possibility. It was based on pioneering work in the 1960s, transplanting normal livers into dogs with hemophilia A and B, providing the normal FVIII and FIX genes, which then corrected the bleeding disorders. Some of the hemophilia B dogs at UNC are still producing FIX genes a decade or more later.

"Every single product that has come on the market that was tested in the dogs with hemophilia A or B or VWD and was shown to be safe, subsequently was shown to be safe in humans," Nichols says. Conversely, products that were not well tolerated by the dogs were either shelved or reformulated until they were tolerated, he says.

The dogs' Canadian counterparts are housed on the Campus of Queen's University in Kingston, Ontario. The hemophilia A colony was started in 1981 using Brittany spaniels and miniature Schnauzers from the Mayo Clinic in Rochester, Minnesota. Later, beagles were added.

One advantage of using dogs in bleeding disorders research is their size and blood volume. "With large animals, you can get a more robust analysis of blood coagulation," says David Lillicrap, MD, FRCPC, Director of the Molecular Hemostasis Research Group at Queen's University. "The blood volume in a mouse is only about 2 milliliters, whereas in a dog, you can take blood samples fairly regularly and assess them just like a small human being."

The Canadian colony has provided researchers with a viable model for assessing novel proteins, says Lillicrap. "The first recombinant

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NATIONAL TREASURE

FVIII infusions were carried out in the dogs in 1985-86," he says. Further, inhibitors have developed in approximately 25% of the dogs, starting 15-20 years ago. While the cause of inhibitor development is still a mystery, the dogs are shedding some light. "There is certainly a genetic component," Lillicrap says. "The dogs that have developed inhibitors are much more likely to produce inhibitor puppies."

Bred For A Purpose

Both dog colonies are expanded with forethought and planning. Since inbreeding can cause purebreds to produce offspring with congenital problems, such as hip dysplasia, outbreeding is used to encourage hybrid vigor. "About every four or five generations, we bring in another dog to try to increase the gene pool," Lillicrap says. Sophisticated software calculates the degree of inbreeding for specific matings. At UNC, the hemophilia A dogs were originally Irish setters; the hemophilia B dogs were Cairn terrier/Beagle crosses; and the VWD dogs were Scottish terriers. "Now all have been outbred for logistical reasons, to exclude unwanted traits that occur in different strains," Nichols says.

"All of our breeding is for a purpose—to maintain the gene lines. Researchers design their experiments with planned breeding in mind, to have enough dogs for their studies," says Nichols. Pregnant dogs with hemophilia receive prenatal care similar to pregnant women—factor levels are measured before labor and delivery and product is given to prevent complications. "We transfuse the mother dogs weeks before delivery and continue until their postpartum bleeding stops," Nichols says.

The blood for the hemophilia dogs' transfusions comes from a separate colony of blood banking dogs. Most are large breeds with easily accessible veins, such as hound dogs or greyhounds. Like human blood, the donor dogs' blood is typed. "We have about eight dogs that are donors," says Lillicrap. "They have their blood taken every week or two."

Canine Care

The dogs at both colonies are cared for by trained veterinary technicians, some of whom have worked with them for more than 25 years. "The people who work here love animals and are extremely knowledgeable about them," says Nichols. At UNC, the dogs have indoor/outdoor runs and an acre of outdoor play area to romp in. "They're not kept in cages, but in runs that are cleaner than our hospital," says Roberts, partially joking. "They're out in paradise next to University Lake."

The dogs are socialized with each other and receive plenty of human contact. Just like family pets, they are taught commands and receive treats as rewards. "The dogs are in the lab all the time with people," says Nichols. Since they stay there for years, they become more than just lab animals. "They become companion animals," says Lillicrap. "They are very well looked after and nurtured."

The dogs have names. At the Canadian facility, litter mates receive names starting with the same letter of the alphabet—Mindy and Matteo, for instance are siblings. At the UNC lab, the dogs are named for personality or looks. "One of our inhibitor dogs, Cliffy (named for Clifford the Big Red Dog), is the lab prince right now." One of the vet techs is a dog groomer and gives Cliffy's black-and-white coat special attention. "He is groomed to look like he has a great big mustache," Nichols says with a laugh.

"Most of the dogs live out their lives at the labs, being used for research in middle and older age," Lillicrap says. "We don't breed for a specific experiment and then euthanize the dog. We now have dogs that are 13 years old."

Other Animal Models

Researchers cannot limit their animal subjects to only one species. Protocol requires them to progress from rodents, for instance, to larger animals, if the experiment is successful at each stage. Larger animals help researchers obtain the proper scale in terms of physiology and anatomy. Eventually, experiments are approved for human studies, called clinical trials. This progression from one animal model to another and eventually to humans can take years.

Michele Calos, PhD, professor in the genetics department at the Stanford University School of Medicine in California is a bleeding disorders researcher who uses a variety of lab animals. "A huge amount of work has been done on mice throughout genetics because they are less expensive, have a shorter life span and you can do experiments with such larger numbers," she says.

Previous article taken from the January/February 2009 issue of *HemAware*, a publication of the National Hemophilia Foundation.

2008 FRIENDS OF THE DVC

FACT: In 2008, the Delaware Valley Chapter provided more than $352,000 in direct support to local patients and programs!!

In December, the Delaware Valley Chapter mailed the *2009 DVC Annual Request for Support* to our members with the 2008 DVC Annual Report. We were amazed at the number of people in our area (and beyond) who responded so generously. Following is a list (incomplete and some anonymous) of those who donated within the designated categories. We extend a sincere thank you to our supporters...many who contribute several times during the year. Their support will help us to address the needs of patients and programs in 2009!! Thank you from the bottom of our hearts!! If you are able to respond, even in a small way, it's not too late to support our great Chapter!! We depend on you!! Your donation is 100% tax deductible!!

President's Circle Donor: $1001+

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Marion Sutton (for Michael B. Sutton, Esquire)
Susan Zammer (for Rob, Renet & Everett)

Champion: $30-$50

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James & Theresa Gallello (for a cure)
Russell & Donna Gibson
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Mindy & Adam Gusdorff, Esquire
Karen Kephart
John & Jill Nicolosi
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M. Robert Stribula
Charlotte Walsh

Supporter: $10-$25

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Angela M. DiSimone
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Grayce Ford
Caroline Graham
Betty Kichline
Mary Purdy
Michael & Kathleen Schlosbon
John W. Taraschi, Sr.

BLEEDING DISORDER LEGAL HOTLINE

The Delaware Valley Chapter is pleased to announce the Bleeding Disorder Legal Hotline. This free, confidential phone line is manned by an attorney, Beth Sufian, in Houston, Texas. She has over 17 years of experience helping people with chronic conditions understand the laws intended to protect them regarding health insurance and school/work issues. This Hotline was initiated by the Lone Star Chapter of the National Hemophilia Foundation in 2006. Hotline callers have reported that the information was helpful and would have been difficult to find without the help of this service. The Hotline can provide information on the issues listed below:

1. Obtaining and maintaining private health insurance.
2. Obtaining coverage from insurers for medical treatment.
3. How a small business can obtain health insurance.
4. Legal rights regarding Medicaid & Medicare.
5. Applying for Social Security benefits.
6. Appealing a denial of application for Social Security benefits.
7. Protection in the workplace from discrimination.
8. Family Medical Leave/Reasonable Accommodations in the workplace.
9. Insurance issues related to transitioning young adults.
10. Legal rights of children with medical conditions in the school setting.

The Bleeding Disorder Legal Hotline is open to people affected with a bleeding disorder and the medical professions that provide care for them. Quite simply, the Hotline is designed to bridge the gap between the laws and the people who need to know about them. Call 1-800-520-6154 and get informed.

The Hotline is recognized by the National Hemophilia Foundation as a valuable resource to the bleeding disorders community.

WONDER WHERE THOSE COINS GO?

Question: Do you ever wonder where all of those coins go that you throw into fountains at your local shopping mall?

Answer: The Willow Grove Park Fountain, located at the Willow Grove Mall just a few miles from the DVC office, donated coins collected from the mall fountain to the Delaware Valley Chapter!! The total collected was $422.55. A great big "thank you" to Ashlyn Martin, Assistant Marketing Director and PREIT (Pennsylvania Real Estate Investment Trust Property) for making our Chapter the recipient!! What a generous contribution!!! Fantaaaaaaaaaastic!!

PLANNED GIVING

When you make a future or planned gift, you help so many people. Remembering the Delaware Valley Chapter in your estate plans or will directly impacts the lives of people living with hemophilia and related bleeding disorders and their family members. You will also touch the lives of those who might someday be affected by a bleeding disorder. Arrangements can be made to leave a legacy in your will for the Delaware Valley Chapter. You can leave a specific amount or a percentage of your assets. Gifts may include, but are not limited to: stocks, bonds, guaranteed investment certificates, real estate, art and jewelry. Speak with your financial advisor about Planned Giving. Your gift can make a real difference!!

DELAWARE VALLEY CHAPTER SUPPORT NETWORK

In an effort to increase our service and help to families in areas outside of the central Philadelphia area, we have established five branches of the Delaware Valley Chapter. The purpose of the branches is to help network patients and families affected by hemophilia and von Willebrand Disease (VWD). If you are a patient or parent/s of a patient and would like to socialize with others who share your issues, please contact one of the following team leaders to get involved. These branches meet informally, in private homes, for social events and support. There is no charge for being involved.....just networking with families just like you!! These branches are not open to any person who works or has a family member who works for any industry or company directly or indirectly involved in products or services for patients with bleeding disorders.

Camp Hill Branch

Shannon & Jay Penica
717-975-2897

Delaware Branch

Gail & Luke Vannicola
302-378-1278

Lititz/Lancaster Branch

Lorie & Brian Kerstetter
717-626-9679

Mount Carmel Branch

Jolene & Sam Scicchitano
570-339-4137

Reading/Pottstown Branch

Tina & Jeff McMullen
610-582-1731