

# HACA News

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## Mission Statement

*HACA's Vision is to improve the quality of life for persons and their families affected by bleeding disorders.*

*HACA's mission is to:*

- ◆ Educate, support and advocate for persons with bleeding disorders and their families.
- ◆ Network with healthcare professionals.
- ◆ Increase public awareness.

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## HACA Beach Party

Please plan to join us for our post-holiday party on February 25, 2007 from 2 pm to 5 pm at the Aquatic Center at George Mason University. We will be swimming, playing games, testing our limbo ability, and having snacks. Please plan to join us as we renew old friendships, make new friendships, and mentally escape the cold. Call the HACA office at 703-352-7641 or send us an email at [hacacares@aol.com](mailto:hacacares@aol.com) and let us know to buy more food because you are joining us!



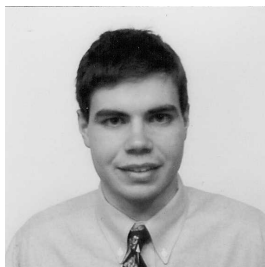
## Couple's Retreat

Plan now to attend our couple's retreat April 13-14, 2007. Of course, this means that you would have to get your taxes done early, but what a great way to celebrate the fact that they are done! Plans for the weekend are incomplete at this venture, but will include a get away for Saturday night, 3 meals on Saturday, a workshop with a nationally recognized speaker whose topic will be relationships, and perhaps, a dance with a DJ. Please let us know if you are interested in attending this event by calling 703-352-7641 or emailing us at [hacacares@aol.com](mailto:hacacares@aol.com) to reserve your space today. Participation may be limited by the funding we receive, so don't lose out by not replying quickly.

## NHF Washington Days

NHF has scheduled the annual visit with Senators and Representatives for Thursday, March 8<sup>th</sup>. NHF will host a reception and "coaching" time on Wednesday evening the 7<sup>th</sup>. If you are interested in taking this time to visit with our Senators and Representatives, please contact the NHF at [www.hemophilia.org](http://www.hemophilia.org), click on advocacy, click on Washington Days, and click on register now and let them know you are coming. Marc Associates, NHF's lobbying firm, will then set up appointments for you to visit with your Senator and Representative.

## HACA Scholarship Program



HACA is proud to announce that John McNeil is the first winner of the George and Linda Price Scholarship. John attends medical school at the University of Virginia in Charlottesville. John has been active in the chapter's Blood Buddies program and has served as a camp counselor and in administrative positions at the Hole in the Wall Gang Camp in Ashford, CT. John, we wish you all the best in your studies and in your future career as a Pediatrician.

Applications for the George and Linda Price Scholarship are available beginning February 1, 2007, and are open to people affected by bleeding disorders, siblings of affected individuals, and parents of affected individuals. You must be a resident of Northern Virginia, Montgomery or Prince Georges counties in Maryland, or the District of Columbia to apply for this \$2,500 scholarship. Qualifying applicants must also demonstrate that they have been active in the bleeding disorders community. DEADLINE to submit applications: **May 1, 2007.**

*(Continued on page 2)*

## Chapter News continued

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### Bruise Brothers Coordinator Needed

We are looking for someone to coordinate the activities for our young people between the ages of 7 and 12. We would like to schedule an event such as a picnic, going to the movies, museum trips, ice cream social, etc. once a quarter. The purpose of our gatherings would be several fold—it would give the young people a chance to meet one another and to know that they were not the only person in this area with a bleeding disorder, it would give parents a chance to talk with one another and share with one another how they are helping to make their lives and the lives of their children easier, and it will give our young people enriching and fun experiences. Please contact the HACA office at 703-352-7641 or e-mail us at [hacacares@aol.com](mailto:hacacares@aol.com) if you are willing to serve as the coordinator.

### DC Hemophilia Open

Our annual golf tournament, the DC Hemophilia Open, has been scheduled at Heritage Hunt Golf and Country Club on May 14, 2007. Cliff Krug, Jr. has generously agreed to chair this event.

You can help make the tournament a success by helping us recruit sponsors, hole sponsors, golfers, and items for the silent auction.

Golfers and sponsors will be able to register for the event at [www.hacagolf.com](http://www.hacagolf.com) beginning March 1, 2007.

### Gates Earns Eagle Scout Award

Congratulations to Harvey Gates, Jr. for earning his Eagle Scout award on December 2, 2006. As part of his Eagle Scout Project,



Harvey collected 500 pairs of used eyeglasses for distribution in the village of Wale Wale in Ghana, West Africa. Harvey also traveled with a Medical Mission team to Ghana where he assisted traveling dentists. During his church testimony about his project, Harvey stated that his missionary assignment and his Eagle service project taught him "To complain less, to want less, and to be more grateful for what God has blessed

me with." HACA salutes Harvey for achieving the rank of Eagle Scout.

### Calendar of Events

**February 25** Beach Party at George Mason University Aquatic Center, 2-5 pm.

**March 2-4** HFA Annual Meeting, Albuquerque, NM

**March 7-9** NHF Washington Days

**March 15** Summer Camp Applications due at HACA office.

**April 14-15** Couples Retreat. Subject: Relationships. Site: TBA

**May 14** DC Hemophilia Open at Heritage Hunt Golf and Country Club, Gainesville, VA. 12 noon shotgun start.

**June 8-14** Summer Camp at Hole-in-the Wall Gang Camp, Ashford, CT

**July 30-Aug 4** Summer Camp at Victory Junction in Randleman, NC

**Sept 21-23** Retreat for Women Living with vWD. Site: TBA

**October 13** Hemophilia Half-Hundred

**October 27** HACA Educational Seminar and Annual Meeting

### 2007 Board of Directors Meetings

General Board Meeting

February 5, 2007

General Board meetings begin at 7:00 p.m. and are open to all interested HACA members. Because of security regulations at our meeting place, please notify the HACA office that you will be attending. Directions and site will be shared with you at that time.

## Access to Investigational Drugs

The Food and Drug Administration (FDA) is proposing to amend its regulations on access to investigational new drugs for the treatment of patients. The proposed rule would clarify existing regulations and add new types of expanded access for treatment use. Under the proposal, expanded access to investigational drugs for treatment use would be available to individual patients, including in emergencies; intermediate size patient populations; and larger patient populations under a treatment protocol or treatment investigational new drug application (IND). The proposed rule is intended to improve access to investigational drugs for patients with serious or immediately life-threatening diseases or conditions, who lack other therapeutic options and who may benefit from such therapies. (Ed. Note: *Think Hepatitis C.*)

Submit written or electronic comments by **March 14, 2007**. The docket number for this rule is: 2006N-0062 and the RIN number is: RIN 0910-AF14. To submit comments electronically, go to the Agency Web site at <http://www.fda.gov/dockets/ecomments> and follow the directions posted.

For a PDF copy of the proposed regulation, call the HACA office at 703-352-7641 or send an email to [hacacares@aol.com](mailto:hacacares@aol.com).



## Congratulations

Congratulations and best wishes are extended to the Prohett family on the birth of Bridget Murphy on Friday, December 15<sup>th</sup>. Bridget was born at 1:20

pm, weighed 7lb. 3 oz. and was 20 1/8 inches tall. Bridget is having a good time getting acquainted with her mom and dad, Eileen and Chris, and with her big brother, Jack, and sister, Molly.

We also extend congratulations and best wishes to Meredith and Tim Holland on the birth of their daughter, Grace Elizabeth. Grace was born on January 5<sup>h</sup> at 11:30 pm, weighed 7 lb. 15 oz. and was 20 inches tall. Grace's mother, Meredith, serves on HACA's board of directors and her father, Tim, is active on HACA's golf committee.

## Sincere Sympathy

Our deep sympathy is extended to Mary Nagler on the occasion of the death of her husband, Rick. Rick, 55, passed away during his sleep on January 9, 2007. Rick was active on HACA's Board of Directors and served several terms as the Chairman of the Board. Rick also taught several of our young people to self-infuse. Rick and Mary moved to Ft. Collins, Colorado several years ago. Rick's mother and father, Nan and Gordon, were among those responsible for the creation of this chapter.

## From Our Mailbag

December 28, 2006

Dear Sandi:



I am writing to thank you for HACA's continued support of the Georgetown University Hemophilia Men's Group. The dinners that HACA provides make it a little easier for the men to fit the group into their busy schedules. And food and conversation just go together!

As you know, the Georgetown University Hemophilia Men's Group was started about twenty years ago by a courageous group of men faced with the questions of living with HIV and hemophilia. Mary Waterbury, MSW was the social worker who facilitated the group from its beginning. We appreciate her dedicated efforts to make the group a safe place from its beginning to grow and explore any and all of the challenges and joys of living with hemophilia. After Mary, several other social workers facilitated the group. I became facilitator in 2003 when I came to Georgetown from the West Virginia University HTC.

Over the years the discussion of issues of living with hemophilia has expanded to include not only HIV but also Hepatitis C. The group focuses discussion around these medical topics and treatments but also finds opportunities to explore all areas of men's lives; from marriage, parenting and grand parenting to education, careers and retirement.

We had a delightful holiday celebration this month and invited spouses and guests to the meeting. Thank you for the increased financial support for that evening so that we could include more people and

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upgrade the venue. We met at the Leavy Conference Center at Georgetown and it was a nice change. We are also grateful to the staff at Leavy for donating the use of the room and giving a discount on the food.

The group is open and welcoming to new members. The only requirement is to be an adult man with hemophilia. In order to participate, call Mary Jane Berry, MSW at 202-687-5560 or send an email to: [mjberry@att.net](mailto:mjberry@att.net). The group usually meets the first Monday of the month at Lombardi from 6:30 to 8 pm.

Sincerely,  
Mary Jane Berry, MSW

### Summer Camp

We are currently accepting applications for summer camp. Camp at Hole-in-the-Wall Gang camp will be held June 8-12 in Ashford, CT. Camp at Victory Junction in Randleman, NC is scheduled for July 30-August 4. Campers may attend only one of these camps. Completed applications must reach the HACA office by **March 15, 2007**.

### National Hemophilia Foundation's Medical and Scientific Advisory Council Recommendations

(Complete texts available from [www.hemophilia.org](http://www.hemophilia.org))

#167

**MASAC Recommendation Regarding the Use of Bypassing Agents in Patients with Hemophilia A or B Inhibitors.** (June 3, 2006) MASAC recommends that bypassing agents be used in patients with hemophilia A or B with inhibitors to prevent or control bleeding in settings in which clotting factor VIII or IX would otherwise be used, including before and after surgery and physical therapy.

#168

**MASAC Recommendation Regarding Access to Care for Patients with Bleeding Disorders.** (June 3, 2006) MASAC recommends that access to care at federally funded Hemophilia Treatment Centers be preserved.

#169

**MASAC Recommendation Regarding the Use of Recombinant Clotting Factor Products with Respect to Pathogen Transmission.** (June 3, 2006) MASAC fully endorses this recommendation and calls on industry and the Food and Drug Administration to carry out the Committee's recommendation.

#170 (Replaces #117)

**MASAC Recommendations Concerning Prophylaxis (Regular Administration of Clotting Factor Concentrate to Prevent Bleeding).** (June 3, 2006)

There are no clear cut guidelines as to when to stop prophylaxis. A careful analysis of health risks and benefits must be performed by consumers and their health care providers. MASAC will periodically re-examine this recommendation as new data emerges

#171

**MASAC Resolution on NHF Sponsorship of Gene Therapy and Novel Technologies Workshops.**

(October 15, 2006) MASAC recommends that NHF resume its role as primary sponsor of this event.

#172

**MASAC Recommendations Regarding Women with Inherited Bleeding Disorders.**

(October 15, 2006) MASAC recommends management, outreach, education, and research. NHF should continue to work with NHLBI and CDC to develop a national research agenda on women's bleeding disorders.

#173

**MASAC Recommendations Regarding the Treatment of Von Willebrand Disease.**

(October 15, 2006) Recently developed products have changed the treatment options for individuals with von Willebrand disease.

#174

**MASAC Recommendations Regarding Rare Coagulation Factor Disorders**

(October 15, 2006) MASAC recommends the development of treatment products for these rare bleeding disorders (e.g. Factor VII Deficiency)

#175

**Guidelines for Emergency Department Management of Individuals with Hemophilia**

(October 15, 2006) Guidelines for individuals with bleeding disorder

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ders who present to an emergency department for care should receive appropriate, expeditious management.

#176

**MASAC Recommendations Regarding Radionuclide Synovectomy.** (October 15, 2006) A guideline when considering this procedure in hemophilia patients with chronic synovitis.

#177

**MASAC Recommendations Concerning the Treatment of Hemophilia and Other Bleeding Disorders.** (Revised October 15, 2006)

#### **Medical Advisory #406**

#### **FDA Confirms Low Risk for Creutzfeldt-Jacob Disease**

(November 29, 2006) The Food and Drug Administration (FDA) released documents relating to the Agency's assessment of the risk of acquiring variant Creutzfeldt-Jacob Disease (vCJD), a human form of "Mad Cow Disease", for persons with bleeding disorders who have used US licensed plasma-derived factor VIII products. Although there are still too many uncertainties to allow the Agency to make a precise calculation of theoretical risk without further study of this issue, FDA officials and other experts continue to believe that this risk is exceedingly low but possibly not zero. It is important to note that there have been no known cases of vCJD in users of plasma-derived factor VIII products worldwide, including in the United Kingdom where the prevalence of vCJD in the general population is the highest in the world.

On December 15, the agency will convene a panel of consumers, medical professionals and other experts to advise them on how best to broadly communicate this information to the public.

*Editor's Note: See report from Advisory Panel meeting on December 15<sup>th</sup> on page 9 of this issue of HACA News.*

#### **Dr. Craig Kessler to Head MASAC**

On November 30<sup>th</sup>, the NHF announced that Dr. Craig Kessler has been appointed as Chair of its Medical and Scientific Advisory council (MASAC). Dr. Kessler will serve a three term in this position.

Dr. Kessler earned his bachelor's degree from Duke

University and his medical degree from Tulane University School of Medicine in New Orleans. He was a fellow in special hematology at Johns Hopkins Hospital in Baltimore before becoming senior staff physician in hematology service at the National Institutes of Health in Bethesda, MD. From 1982-1997 he served as the director of the Special Coagulation Laboratory, Department of Medicine at the George Washington University Medical Center in Washington, DC, and director of its Adult Component of the Washington Area Hemophilia Comprehensive Care Center. From 1991-1997, he was the director of the Center for Blood Disorders. Since 1997, Dr. Kessler has been on the faculty of the Georgetown University Medical Center. He has been its Chief of the Division of Hematology-Oncology, Department of Medicine at the Lombardi Comprehensive Cancer Center since 2000.

#### **Hemophilia Federation Annual Meeting**

The Hemophilia Federation of America will be holding their annual meeting on March 2-4, 2007 at the Albuquerque Embassy Suites in Albuquerque, New Mexico. For more information or to register for the meeting, please log onto the HFA web site at [www.hemophiliafed.org](http://www.hemophiliafed.org). You must register for this meeting by February 15, 2007.

#### **New Opportunity to Talk About, Read About, Bleeding Disorders - Join Today**

CLOT, the newsletter, is a bimonthly collection of thought provoking **C**olumns, **L**etters, **O**pinions, and **T**easers. It is a forum for people, organizations, institutions and manufacturers who want to talk about innovation in the bleeding disorder community. People with bleeding disorders, their healthcare providers, their homecare providers and the manufacturers of clotting factor are the ones who write the articles and letters in CLOT. Don't miss an issue!

For a free subscription by mail, or to download a copy from the internet, visit [www.hemophiliainnovation.com](http://www.hemophiliainnovation.com) and click on CLOT Newsletter. Hemophilia Innovation, the publisher of CLOT, serves as a catalyst for people, organizations, institutions, and industries that work to improve quality of life, treatment, education and funding.

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## FDA Proposes Labeling Changes to Over-the-Counter Pain Relievers

The FDA has proposed to amend the labeling regulations on certain over-the-counter drug products. Included in these changes are products containing Acetaminophen and NSAIDs. The labels on products containing Acetaminophen would be required to contain warnings which would highlight the potential for liver toxicity, particularly when using acetaminophen in high doses, when taking more than one product with acetaminophen, and when taken with moderate amounts of alcohol. An example of an Acetaminophen product is Tylenol™. The NSAID labels would be required to contain new warnings which would highlight the potential for stomach bleeding in persons over age 60, in persons who have had prior ulcers or bleeding, in persons who take a blood thinner, when taking more than one product containing an NSAID, when taken with moderate amount of alcohol, and when taking for longer time than directed. Examples of NSAIDs include aspirin, ibuprofen, naproxen and keoprofen.

## Infusion Tracker Software

NuFACTOR offers complimentary software called *Infusion Tracker 2* as an innovative way to document, analyze, visualize and report your bleed and infusion history. Infusion Tracker 2 presents your history, for any selected range of dates, on a color-coded body map. You can print and email your usage reports.

*Infusion Tracker 2* helps you: identify target joints; track effectiveness of your prophylaxis schedule; recognize seasonal bleed patterns; record your lot numbers permanently; compute statistical information, including average time between bleeds and average dosage; prepare for the coming changes in healthcare and insurance that may require accurate documentation of factor usage.

*Infusion Tracker 2* is available at no charge to the entire bleeding disorders community. You do not have to be a client of NuFACTOR to receive the software. All you need is a computer with Windows 98 Second Edition or higher and few minutes to load the software. Contact the HACA office at 703-352-7641 for the name and number of the NuFACTOR representative in our area.

## HHS College Scholarship

The Hemophilia Health Services Memorial Scholarship fund is now accepting applications for one of multiple scholarships worth \$1,500 and more. They awarded 15 scholarships in 2006.

Apply today at [www.FactorCare.com](http://www.FactorCare.com). The access key is HEMO. Enrollment is open from January 1, 2007-May 1, 2007. For more information, please call Sally Johnson at 1.800.289.6501 X 5175. DEADLINE for application: May 1, 2007.

## Did You Know...



- You can contact your local Fire Department (nearest your home) and get your family member with a bleeding disorder registered with 911 Dispatch. Ask to speak to the EMS Coordinator. In some cities, it has been found that your loved one will also get "care flight" priority within the city limits.
- You can contact your Electric Company and ask to be put on their "priority list". When there is a power outage in your area, people on this list will get their power restored more quickly. Most cities will require a physician's verification of your disorder before placing you on the list.
- You can become legislatively active for your community by going to your State Capitol or local representative's home office and telling your story.
- You can sign up for "Google Alerts" by going to [www.google.com](http://www.google.com), selecting "alerts" and type in the key word "hemophilia" to gain useful and noteworthy information on a daily basis sent right to your email address. You can never learn too much!

Excerpted from *The Prophy Dose*, Fall 2006

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## Making Better Food Choices

### Expert Advice for People with Bleeding Disorders

By Jennifer LaFranco RN, BSN and Diane Delorma, RD

Eating healthy is easier said than done, especially for people who are managing a chronic condition like a bleeding disorder. The stress of trying to keep up with a busy schedule can often lead to overeating, eating on the run and/or poor food choices. In our hurry-up lifestyle, zipping to a fast-food restaurant is often more convenient and less expensive than preparing a home-cooked meal. But when we eat out for lunch or dinner, we have a tendency to consume larger portions and foods with more calories that we would normally eat. So how do these choices affect your health if you hemophilia? Increased weight strains your joints and muscles and can lead to further complications, including increased bleeds in susceptible joints. And during times of bleeds you are often more sedentary and not able to participate in appropriate exercise to burn those excess calories.

If you have a tendency to increase food consumption when you are inactive, this can add to the dilemma if you are already overweight or obese.

The Center for Disease Control and Prevention reports teens and children with hemophilia are almost twice as likely to become overweight as the general population. This means it's more important than ever for patients with hemophilia to be eating a balanced diet and controlling portion size.

In addition, of particular concern is the predisposition of osteoarthritis (arthritis where there is loss of cartilage) in people with hemophilia after repeated episodes of bleeding into a joint. Obesity causes and complicates osteoarthritis by increasing the mechanical stress on the cartilage within the joint. In fact, next to aging, obesity is the most powerful risk factor for osteoarthritis of the knees. Gentle exercise usually does not aggravate osteoarthritis when it's done at a level that does not cause joint pain.

And if those problems aren't enough for people with bleeding disorders, the complications associated with obesity alone are serious. According to the World Health Organization, there are 300 million obese adults worldwide and 18 million children are classified as overweight. Obesity causes more than 300,000 potentially avoidable deaths each year. It contributes to heart disease, osteoarthritis, diabetes, stroke, hypertension, cancer and sleep apnea.

So what can you do to ensure that you are as healthy as you can be? Exercise and proper nutrition must be incorporated into a healthy lifestyle plan in order for you to maintain a healthy weight. Improving your nutrition and

physical exercise program should begin with a visit to your physician to make sure you are able to endure physical activity with no health risks. Appropriate exercise should then be performed. Thirty minutes of exercise daily is recommended to maintain weight; 60 minutes per day to lose weight.

Gradual changes in eating habits, such as the ones mentioned here, are most likely to yield long term results:

Be aware of portion sizes, read labels and avoid snack foods. Steer clear of foods that are high in fat and calories and offer little in the way of nutritional value. Be mindful of "hidden" or overlooked sources of excess calories, such as large glasses of juice and soft drinks.

Increase your consumption of fruits and vegetables. Dark, leafy greens and orange fruits and vegetables are excellent sources of vitamins and minerals. They are also a rich source of fiber, which helps you to "fill up" and maintain intestinal health.

Try to eat a least half of your grains from whole grain products. Try oats, barley, whole wheat, flax seed, bran, brown rice, and pasta. Whole grains help to satiate the appetite, lower cholesterol and stabilize blood glucose levels to avoid an afternoon "slump". Eat baked snack items instead of fried.

Use low-fat dairy sources such as 1% or skim milk and low-fat cheeses. These contain plenty of vitamins and minerals without the fats that have been linked to heart disease. (If you cannot consume milk, look for other sources of calcium, such as calcium fortified orange juice.)

Bake, broil or grill lean meats, poultry and fish. Avoid heavy gravies, sauces and toppings that are often full of calories from fat. Include some meatless meals during the week by incorporating dried beans, nuts and seeds into your menus. Dried beans provide an excellent source of protein, and are high in fiber and low in fat, with no cholesterol. (Cholesterol is found only in animal-derived food sources, such as meats, eggs and milk)

Reduce fat intake and increase the use of "good fats." These include olive and canola oils. Limit the use of butter, stick margarine, shortening and lard.

A few other nutritional suggestions are especially important for people with hemophilia. In addition to maintaining

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healthy weight, people with bleeding disorders need to maintain normal blood volume and blood cell production. There are several nutrients involved in blood cell production, such as: iron, protein, copper, vitamin C, vitamin B12, vitamin B6, vitamin E and folic acid. But it would be wise for patients to avoid vitamin E supplements since they may increase the risk of bleeding. A diet that incorporates all of the food groups should provide nutrients adequately.

During a bleed, it is estimated that a miniscule amount of iron—roughly .75 micrograms—is lost with each tablespoon (15 ml) of blood. Maintain your iron levels by eating naturally iron-rich foods such as liver, lean red meat and poultry, all of which provide the best and most readily absorbed iron sources. Other excellent sources of iron are leafy green vegetables, broccoli, dried beans, grains, and raisins. Combining iron-rich foods with good sources of vitamin C (such as orange juice) can enhance iron absorption.

Being realistic, you know that you're not going to make perfect choices at every meal, but it is important to make the effort to try to improve your diet. It's OK to indulge in a piece of cake at a birthday party, but don't forget to eat lots of fresh vegetables at the next meal. In other words, spend your calories as wisely as you would your money.

When you Eat Out...

- Keep portions small. Large portions are the biggest assault on good diet intentions, especially when ordering out. Avoid "biggie" combos or meal packages that entice you to overeat.
- Avoid fried side dishes or order a small size. Baked snacks such as pretzels are low in fat and calories.
- Take half of your meal home and make another meal out of it later.
- Watch out for "hidden" calories in smoothies and coffee drinks. Some have as many as 400 calories per 12 oz. serving
- Cut the calories in your order by avoiding high-fat, high calorie condiments such as mayonnaise. Mustard has no calories.
- Opt for whole-grain choices if available. These will help fill you up and give you the benefits of whole grain nutrients and fiber.
- Ask for your salad dressing on the side so YOU control the amount used. The nutritional value of a salad is lost if it's loaded with high-fat, high-calorie dressings.
- Opt for lean meats such as turkey vs. higher-fat cold cuts. Skip the cheese or opt for a low-fat cheese if available.

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## Panel Tells FDA: Get Better Data on vCJD Risks From Factor VIII

FDA Week, December 22, 2006

FDA needs to play a larger role in scientific oversight and data collections—as well as offering physicians, patients and consumers clear-cut messages—on the possible link between human mad cow disease and plasma-derived anti-hemophilic factor VIII products (pdFVIII) used in transfusions, said an advisory panel Friday (Dec.15). The panel's message echoed testimony by hemophilia patient advocacy groups calling for greater FDA research and intergovernmental collaboration.

The Transmissible Spongiform Encephalopathies (TSE) Advisory Committee criticized an updated FDA assessment of possible exposure to the TSE pathogen known as variant Creutzfeldt-Jacob disease (vCJD), an incurable, fatal brain disorder, with the use of pdFVIII products. The panel said much of the evidence presented over-relied on industry and animal studies and lacked independent, scientific data.

FDA says the risk of potential exposure is very low from pdFVIII products, but is not zero. The agency readily admits it cannot accurately and fully gauge the rate of infection or who is actually susceptible because it lacks crucial human data, cannot establish a set determination of the agent amount in the blood necessary to pose infection, and still can't gauge the incubation period of the disease, which one FDA document says can be up to 30 years.

FDA says its hands are tied as there is only limited data available in the United States and data coming out of the United Kingdom, where TSE first emerged a few years ago, is mostly based on animals. Under-reporting is also a problem, FDA admits, as vCJD can be asymptomatic.

Risk estimates of vCJD in pdFVIII patients diverge wildly: FDA gauges the risk at 1.8 out of 1 million, according to an epidemiological model estimate, but at 237 infections per 1 million, according to a tissue surveillance model.

"I think surveillance in this country has been very poor," said committee member Laura Manuelidis, a Yale university neuropathology professor. "I think this is a risk that doesn't have to be there."

FDA, Centers for Disease Control and Prevention, and National Institutes of Health have constructed a draft statement explaining vCJD and its rarity, but also asking physicians and consumers to be aware of the risks.

To date, no cases of vCJD have been identified in recipients of plasma-derived clotting factors. Still, "the absence of cases does not rule out the possibility of exposure that could potentially result in illness in some recipients at some time in the future," FDA states in documents on its

Web site.

Hemophilia advocacy groups call for FDA to collaborate with CDC and other regulatory bodies to ensure manufacturing processes, where infection is most likely to happen, are tightened. The National Hemophilia Foundation stated: "Government, industry, and the medical and scientific community must dedicate resources to doing research that will narrow our knowledge gaps. They must also develop methods of screening, manufacturing, and deactivation to identify and eliminate not only TSE, but all prions and other potentially infectious agents from all products, plasma-derived and recombinant."

FDA had convened the committee to discuss the risk assessment, revised after 2005 meetings, and whether to set a minimum TSE agent reduction factor in the manufacturing of pdFVIII products, a move the plasma product industry cites as burdensome when they have established internal controls. To date, FDA has approved labeling claims for TSE clearance for three products.

The concern vCJD infections could be transmitted by blood products arose after the UK reported since 2003 three vCJD infections apparently acquired through red-blood cell transfusions. Since plasma is pooled from thousands of donors, blood clotting disorder patients may have used large amounts of pdFVIII over their lifetime, and pdFVIII products vary in level of TSE clearance, FDA has relayed concern about infections in the United States.

In 1999, the FDA began requiring deferral of blood and plasma donors who had traveled or lived for six months or longer in the UK from the start of its BSE outbreak in 1980 until the end of 1996.

There is no test yet available to detect vCJD infection in healthy donors or recipients.

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## ProToCall

Dear ProToCall,

*I was at a chapter meeting recently and someone brought up the topic of dose-to-assay management. I didn't know what this was all about, so I didn't say anything, but what is this and how does this affect my child's care? Should this be something I should be concerned about?*

Dale from Dallas

Dear Dale,

The concept of dose to assay management can be quite confusing. First, let's start off with the words behind this concept. Then we'll discuss how this affects your child's care.

**Dose:** Your physician prescribes factor base on a calculation using your child's weight, which is multiplied by the desired percentage of correction. The calculation is different for hemophilia A and hemophilia B. Here's how doses are figured:

### Hemophilia A:

Formula: Weight in pounds divided by 4.4 multiplied by factor level desired equals number of factor VIII units needed. Example: your son weighs 80 pounds and needs to raise his factor level to 30%.  $80 \text{ divided by } 4.4 \times 30 = 545 \text{ units}$

### Hemophilia B:

Formula: Weight in pounds divided by 2.2 multiplied by factor level desired equals number of factor IX units needed. Example: your son weighs 80 pounds and needs to raise his factor level to 30%.  $80 \text{ divided by } 2.2 \times 30 = 1091 \text{ units}$

**Assay:** For clotting factor, an assay measures the potency or amount of factor in that vial. That measurement can be called an international unit ("unit") or the "assay." One unit of factor is the amount of factor activity found in 1cc (or 1ml) of fresh plasma. For example, a vial that has 545 units of factor has less potency than a vial containing 1091 units. In this case, the assays are 545 and 1091 respectively. Because of the unique manufacturing process for clotting factor, assay sizes vary from lot to lot.

Now, let's look at the phrase "dose to assay." Dose to assay refers to how closely the physician's prescription matches the amount of factor dispensed (as a percentage) and can be calculated as follows:

Dose to Assay = Amount of Factor Dispensed (units) – Prescribed Dose (units) divided by The Amount of Factor Prescribed (units) = plus or minus Dose to Assay Percentage

Multiply the dose to assay amount calculated by 100 to get the percentage.

Let's say the physician prescribed a dose of 1000 units for your child. To make this an easy illustration, we have the following sizes on hand: 1014, 984 and 1224 units. Remember vial sizes typically aren't easy numbers like exactly 1000. The object is to match the prescribed amount as closely as possible.

**Scenario One** (Note: in this scenario the amount dispensed was over the prescribed dose.)

$$\text{Dose to Assay} = \frac{1014-1000}{1000} = +.014 \times 100 = +1.4\%$$

$$\text{Dose to Assay} = +1.4\%$$

**Scenario Two** (Note: in this scenario the amount dispensed was over the prescribed dose)

$$\text{Dose to Assay} = \frac{1224-1000}{1000} = .224 \times 100 = +22.4\%$$

$$\text{Dose to Assay} = +22.4\%$$

**Scenario Three** (Note: in this scenario the amount dispensed was under the prescribed dose, hence the negative number)

$$\text{Dose to Assay} = \frac{984-1000}{1000} = -.016 \times 100 = -1.6\%$$

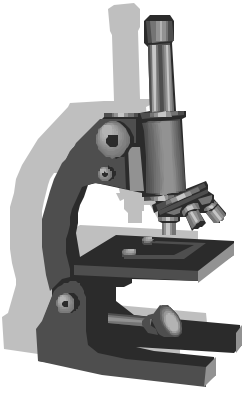
$$\text{Dose to Assay} = -1.6\%$$

Using these scenarios, which dose is closest to the prescribed dose? Scenario One is only 1.4% over the prescribed dose which is the closest amount above or below the recommended dosage amount.

Now for your last question: How does assay to dose affect your child's bleeding disorder? Many consider dosing within 10 percent of ordered units as an accepted practice. We know what happens when we use significantly less than the prescribed amount of factor—it may take more infusions to resolve the bleed, more chances of breakthrough bleeding, etc., costing more in the long run. Using more factor than prescribed isn't harmful; it's just simply a waste. Both scenarios eat up your child's health insurance lifetime maximum

Excerpted from *Bloodstone Magazine*, Autumn 2006

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## Gene Therapy Research Focuses on Nonviral Delivery

Researchers from the U.S. and Switzerland recently reported on the potential for nonviral gene therapy using a transposon known as *piggyBac*. A transposon, or jumping gene, is a sequence of DNA that can move to different positions within the genome of a single cell. Much of gene therapy research has focused on different viral modes of gene delivery. While viruses seem well suited to deliver therapeutic genetic material, they are also effective at entering a host organism's DNA. A significant drawback in using this therapy has been that it can trigger immune reactions or activate cancer-causing genes. The theoretical advantage of using a *piggyBac*, in contrast, is that the gene can be delivered safely to a specific location in the genome, where it can achieve the desired therapeutic response. Scientists believe that this type of gene therapy could have multiple applications, including the correction of single gene disorders such as muscular dystrophy and hemophilia.

Researchers have had success using this mode of delivery in insects and foresee other applications. "We can do it in insects," said Stefan Moisyadi, PhD, one of the scientists collaborating on the project, and an assistant researcher in the Department of Anatomy, Biochemistry and Physiology at the University of Hawaii. "I think it's a short step to take it to a targeting mechanism we can use in mammals." After comparing it with other transposons, the team concluded that *piggyBac* is a good candidate because of its receptivity to modification and efficiency in delivering genetic material to the human genome.

"Typically, viruses and transposons will integrate anywhere along the genome," said Joseph Kaminski, MD, a research team member and an assistant professor in radiology at the Medical College of Georgia. "If they integrate just anywhere, it can obviously cause harm. If we can target the integration—be able to insert the gene at a safe spot in the genome—that would be beneficial."

The study, "*PiggyBac* is a Flexible and Highly Active Transposon as Compared to *Sleeping Beauty*, *Tol2*, and *Mos1* in Mammalian Cells," was published in the October 10, 2006 issue of the *Proceedings of the National Academy of Sciences*.

Source: Ascribe Newswire, October 5, 2006

## Tax Deduction Reminder

If you itemize your tax return, remember that medical and many healthcare-related expenses that cumulatively exceed 7.5% of your adjusted gross income are deductible. There is a long list of items which are deductible (check Internal Revenue Service publications or visit [www.irs.gov](http://www.irs.gov)), including your out-of-pocket cost for prescriptions, health insurance premiums and health-related transportation.

For 2006, if you used your personal auto to get to doctors, a pharmacy, therapist or other medical destination, you may deduct \$0.18 per mile driven (and for 2007 that rate becomes \$0.20). If you traveled by taxi, bus, or other transport, that verifiable cost is also deductible.

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