Social Media & The Chronically Ill

Fad Diets and the Immune System
Understanding and Living with HAE

Weight Management for Immune Deficiency
Donating Plasma
Important Safety Information for GAMUNEX-C

Gamunex-C, Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified, is indicated for the treatment of primary humoral immunodeficiency disease (PI), idiopathic thrombocytopenic purpura (ITP), and chronic inflammatory demyelinating polyneuropathy (CIDP).

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Gamunex-C does not contain sucrose. For patients at risk of renal dysfunction or failure, administer Gamunex-C at the minimum concentration available and the minimum infusion rate practicable.

Gamunex-C is contraindicated in individuals with acute severe hypersensitivity reactions to Immune Globulin (Human). It is contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity.

Gamunex-C is not approved for subcutaneous use in patients with ITP or CIDP. Due to the potential risk of hematoma formation, Gamunex-C should not be administered subcutaneously in patients with ITP.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy. Thrombotic events have been reported in association with IGIV. Patients at risk for thrombotic events may include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization and/or known or suspected hyperviscosity.

There have been reports of noncardiogenic pulmonary edema [Transfusion-Related Lung Injury (TRALI)], hemolytic anemia, and aseptic meningitis in patients administered with IGIV.

The high dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Gamunex-C is made from human plasma. Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient’s blood may yield positive serological testing results, with the potential for misleading interpretation.

In clinical studies, the most common adverse reactions with Gamunex-C were headache, fever, chills, hypertension, rash, nausea, and asthenia (in CIDP); headache, cough, injection site reaction, nausea, pharyngitis, and urticaria with intravenous use (in PI) and infusion site reactions, headache, fatigue, arthralgia and pyrexia with subcutaneous use (in PI); and headache, vomiting, fever, nausea, back pain, and rash (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in one subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in one subject (in PI), and myocarditis in one subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).

*CIDP=Chronic inflammatory demyelinating polyneuropathy; PI=Primary immunodeficiency; ITP=Idiopathic thrombocytopenic purpura.


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 adjacent page for brief summary of GAMUNEX-C full Prescribing Information.

Evidence based. Patient proven.
GAMUNEX®-C
Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified

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

GAMUNEX-C, [Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified]
Initial U.S. Approval: 2003

WARNING: ACUTE RENAL DYSFUNCTION and FAILURE
See full prescribing information for complete boxed warning.

• Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients.
• Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMUNEX-C does not contain sucrose.
• For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.

INDICATIONS AND USAGE
GAMUNEX-C is an immune globulin injection (human) 10% liquid indicated for treatment of:
• Primary Humoral Immunodeficiency (PI)
• Idiopathic Thrombocytopenic Purpura (ITP)
• Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

CONTRAINDICATIONS
• Anaphylactic or severe systemic reactions to human immunoglobulin
• IgA deficient patients with antibodies against IgA and a history of hypersensitivity

WARNINGS AND PRECAUTIONS
• IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.
• Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of developing acute renal failure.
• GAMUNEX-C is not approved for subcutaneous use in ITP patients. Due to a potential risk of hematoma formation, do not administer GAMUNEX-C subcutaneously in patients with ITP.
• Hyperproteinemia, with resultant changes in serum viscosity and electrolyte imbalances may occur in patients receiving IGIV therapy.

• Thrombotic events have occurred in patients receiving IGIV therapy. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk of hyperviscosity.
• Aseptic Meningitis Syndrome (AMS) has been reported with GAMUNEX-C and other IGIV treatments, especially with high doses or rapid infusion.
• Hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration. Monitor patients for hemolysis and hemolytic anemia.
• Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
• Volume overload
• GAMUNEX-C is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent.
• Passive transfer of antibodies may confound serologic testing.

ADVERSE REACTIONS
• PI – The most common adverse reactions (≥5%) with intravenous use of GAMUNEX-C were headache, cough, injection site reaction, nausea, pharyngitis and urticaria. The most common adverse reactions (≥5%) with subcutaneous use of GAMUNEX-C were infusion site reactions, headache, fatigue, arthralgia and pyrexia.
• ITP – The most common adverse reactions during clinical trials (reported in ≥5% of subjects) were headache, vomiting, fever, nausea, back pain and rash.
• CIDP – The most common adverse reactions during clinical trials (reported in ≥5% of subjects) were headache, fever, chills, hypertension, rash, nausea and asthenia.

To report SUSPECTED ADVERSE REACTIONS, contact Talecris Biotherapeutics, Inc. at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
• The passive transfer of antibodies may transiently interfere with the response to live viral vaccines, such as measles, mumps and rubella. Passive transfer of antibodies may confound serologic testing.

USE IN SPECIFIC POPULATIONS
• Pregnancy: no human or animal data. Use only if clearly needed.
• Geriatric: In patients over 65 years of age do not exceed the recommended dose, and infuse GAMUNEX-C at the minimum infusion rate practicable.
About IG Living

IG Living is the only magazine dedicated to bringing comprehensive healthcare information, immune globulin information, community and reimbursement news, and resources for successful living directly to immune globulin consumers and their healthcare providers.

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MARK T. HAGGARD
High School Teacher, Football Coach and Parent of PIDD Children

Eating for Life: Healthy Weight Management for Immune Deficiency
“The best thing all people can do is maintain a healthy weight by living a healthy lifestyle that includes good food choices.”

JILL WEISENBERGER, MS, RD, CDE
Registered Dietitian

How to Spot a Fad Diet
“Gaping holes in a diet leave gaping holes in the immune system.”

TRUDIE MITSCHANG
Staff Writer, IG Living magazine

Social Media and Chronic Illness
“The Internet and social media seem to play a part in the healing process by providing people with chronic illnesses opportunities to communicate about health and/or to escape into a virtual world where their health is not the focus.”

KRIS MCFALLS
Patient Advocate, IG Living magazine

Donating Plasma: The Gift of Life
“Donors encounter a time-consuming procedure that requires dedication, attention to personal health and a willingness to answer questions about intimate details of their lives.”

Choosing an Immune Globulin Product
“When considering a change in product, it is important to remember that doing so can have negative and sometimes severe consequences for patients.”
Everyone has a story to tell. But, some life experiences lead to some extraordinarily powerful stories, which is what we at IG Living suspected when we decided to host our first essay contest over the summer.

Living with a chronic illness takes a tremendous toll not just on the body, but also on the psyche. As if it isn’t enough for most chronically ill patients to endure the arduous process of diagnosis, once diagnosed, they must live and relive the “if onlys” that finally led to that diagnosis. “If only I had done this or that!” Knowing this, we asked our readers to enter our contest with an essay that began: “If I knew then what I know now, I would…” Of the 38 submissions we received, we were awe-struck by your emotional insights gained by the struggles caused by your illnesses. The submissions ran the gamut, from sorrowful to upbeat. But, we were especially moved, and somewhat surprised, by the fact that the majority of you who entered said that you wouldn’t have changed a thing and that the journey has had its rewards. What so many of you expressed is that it is the experiences you’ve gained through your struggles that make you who you are today.

That was the message in the powerful essay written not just by the winner of our contest, but also from the runners-up. Trust me: It wasn’t easy to pick a winner and runners-up from so many deserving entries. In our view, everyone who lives with a chronic illness is deserving of the title of winner. But, it was a contest, and so we judged each entry on a scale of one to 10 on five criteria:

- Organization (the writing flows logically with clear structure)
- Mechanics (spelling, capitalization and punctuation are correct)
- Content (subject is discussed clearly and the reader is left with a finished feeling)
- Creativity (content is compellingly interesting for our audience)
- Effectiveness (the whole entry is effective in its purpose for our audience)

Using these criteria, two judges scored each entry, and those scores were totaled to determine a winner and three runners-up.

The winning entry, written by Stacy Oliver, who has multifocal motor neuropathy, appears on page 8. Stacy truly inspired us with her wisdom and her ability to look at the positive side of what so easily could be looked at negatively. We hope that what she shares in her essay will have a positive effect on others.

Our three runner-up essays by Kinsey Moore, Michael Strausbaugh and Michelle Turk also share a message of strength, perseverance and the desire to get on with living life despite the toll that chronic illness continues to take. These essays will appear on IG Living’s blog page on August 19 and 26, and September 2.

A tradition is now underway with the first of what we plan to be an annual essay contest. Thanks to all who participated. We look forward to your participation again next year and to many more readers sharing their stories.

To your health,

Ronale Tucker Rhodes, MS, Editor
Faces of IG Living

There are many faces in the IG Living community, representing hundreds of immune-mediated diseases and countless medical and lifestyle issues. IG Living’s magazine, website, Facebook page and blog are the ways in which our community can connect with one another. Be a part of the community by interacting with us. Your comments could lead you to others who share similar issues, and vice versa. Monday through Friday, we pose a new question on the IG Living Facebook page. Here is what some of our faces of IG Living are saying in response.

IG Living

Finish this sentence: When people doubt the fact that I have a chronic illness, what I really want to say to them is...

Keli Carter
Nothing! I do not have any extra time to waste on someone who clearly does not want to listen. So I go do something constructive with my time and get something accomplished! Why waste time with petty people?!

Sherri Wray
Don’t judge me until you walk a mile in my shoes. You don’t know what I have been through and what it feels like.

Connie Johnson W orthen
“Those who don’t care, don’t matter ... and those who matter care.” There are some who have no clue, and that’s OK … We don’t bother them with details of who has what or is going through what. When we are sick, we stay home; they just don’t see us much sometimes.

IG Living

On a scale of 1 to 10 with 10 being the best, how would you rate your quality of life before immune globulin (IG) treatment? On the same scale, how would you rate your quality of life after IG treatment?

Branson W orthen
I didn’t realize how much of a difference it made until I was taken off after four years. So without or before is a -2. After or with IG is a whoppin’ 15!!! I missed my entire fifth-grade year due to illness when IG was taken away — no friends, no anything, just labs, doc visits and upset parents trying to get things back on track.

Ashley Rau
1 and 10! My life has done a complete 180 thanks to an amazing immunologist and IVIG.

IG Living

People living with a chronic illness often build in standard responses for co-workers and casual friends in response to, “How are you today?” Not wanting to elaborate, we simply answer, “Fine, thanks.” However, for better or worse, some days are different and we struggle for the courage to use the standard answer. What else can you say that won’t scare the person away?

Leigh Anne Moss
My usual response is, “Oh, you know me, I’m a hot mess. How are you?” Because, let’s be honest here, they’re only asking to be polite most of the time, and don’t really want to know. So that’s my standard answer.

Joyce Mayeda-W ong
I like to say, “If I looked like I felt, you’d run screaming!”

IG Living

How can you explain the difference between normal fatigue and the kind of fatigue chronic illness can bring?

Kathy A. Zabliski
Everyone knows “fatigue.” This is the next step beyond that. It needs its own name. When you feel completely exhausted, stay up another 24 hours working hard. You might get close to what it feels like.
IG Living’s First Essay Contest: Winning Entry!

“If I knew then what I know now, I would have…”: That was the introduction we asked IG Living readers to finish when creating their entry for our first essay contest this summer, a contest we plan to hold every year. Thirty-eight individuals submitted essays, each sharing emotionally powerful stories about their personal journeys of living life with a chronic illness. Three runner-up entries were chosen, and featured here is the winning entry. The runners-up will be featured on IG Living’s blog on August 19 and 26 and September 2 at www.IGLiving.com/blogengine.

IF I KNEW THEN WHAT I KNOW NOW, I WOULD HAVE …

not changed a thing. A lesson I learned in college about existentialism still resonates with me after all these years. One of philosopher Jean-Paul Sartre’s beliefs is that all the events that have happened in our lives, good or bad, have brought us to this moment. If we can say we are happy now for one moment, why would we want to change all the events that led up to that moment’s joy? Examples of living this philosophy can be found in actresses Lucille Ball and Kathleen Turner. They never gave up on their dreams, even though they suffered through daily severe chronic pain with rheumatoid arthritis. They chose to embrace their positive moments over the negative ones, and they became legends.

I was diagnosed with multifocal motor neuropathy (MMN) three years ago, at age 39. It was scary. I cried many tears, and it was a huge life change, but in ways it made me stronger. It was then that I made a conscious choice to either be bitter and curl up in a fetal position, or to use my disease as an opportunity to make a difference within myself and maybe even the world around me. To quote Sartre: “Life begins on the other side of despair.” This is where I am; all paths have led me to this moment in my life. Even if I could go back in time and change my struggles through adolescence, poor relationship decisions, or even not-so-flattering hair color choices, I wouldn’t. My painful experiences or not-so-wise decisions led me down paths to the best things in my life: a fulfilling career as an actor, improviser and singer; my jewelry business; various eclectic jobs that led me to my dream vocation at a prestigious university; and, most of all, the amazing man who became my husband and my biggest advocate, who helps me with my chronic illness.

None of us ever knows when the sum of our life’s experiences will come in handy or when they will propel us toward rewarding heights we never knew we could reach. But being diagnosed with MMN has further opened me up to a whole new community of people and outlets to express myself. I now have a passion for raising awareness about neurological conditions. As a creative person and because of my theatrical background, I was asked to participate in the Grand Rounds at my hospital — an educational event about MMN for 100 neurologists in attendance. And, through my artistic expression making beaded jewelry, I now have a website where I can sell necklaces and donate 15 percent of the proceeds to The Neuropathy Association.

Are there days my spirit is down because I’m fatigued and my body isn’t working well? Of course. But, there have been many bright moments in my life since being diagnosed with MMN. If I had changed one footstep of my life’s path, I wouldn’t be who I am now, sharing this with you. So, when you have one of these moments, remember: You are at the dot on the map that says “YOU ARE HERE”; the next steps you take are your choice. Who says you’ll get lost? For all you know, you just might find something special you weren’t even looking for.

STACY OLIVER was diagnosed in 2008 with multifocal motor neuropathy (MMN.) She is the assistant director of the Center for the Writing Arts at Northwestern University, a jewelry and accessory artist (www.dancingstonesjewelry.com), and she is working on her secret super hero identity as Neuropathy Girl.
RECURRENT AND/OR CHRONIC sino-pulmonary infections (sinusitis, throat infections, ear infections, bronchitis or pneumonia) are the hallmark of antibody deficiency, including X-linked agammaglobulinemia, specific antibody deficiency and common variable immune disease (CVID). But to make an accurate diagnosis of an antibody deficiency, a physician must rule out other possible causes of these infections. And to do this, he or she must evaluate the patient's immune system.

Step 1: Evaluating Antibodies

The immune system is made up of the body’s humoral components, which include the complement system and the immunoglobulins (antibodies). When evaluating antibodies, the physician's first step is to verify that some other process is not the major contributor for causing the infections. For example, someone who smokes tobacco products may have recurrent respiratory infections but not have an immunodeficiency. Infants and young children in daycare settings may develop numerous viral respiratory infections, one after another without any breaks, but not have an immunodeficiency. On the other hand, either of these examples of exposures could compound the problems in someone with an antibody deficiency. Other medical issues resulting in or worsening respiratory illnesses include allergic disease, gastroesophageal reflux, mannan-binding lectin deficiency, cystic fibrosis, alpha-1 antitrypsin deficiency, etc. Therefore, for complete clarification, a physician will evaluate these conditions at the same time as evaluating the patient's immune system.

The immune evaluation consists of several items, which can be performed sequentially or simultaneously. First, a complete blood count (CBC) is evaluated. In that evaluation, the red blood cell portion of a CBC will determine whether anemia is present, and the platelet count will indicate whether there is thrombocytopenia. Either of these could be an indicator of an autoimmunity, which commonly occurs with an antibody deficiency, such as CVID. A low neutrophil count may also be an indicator of autoimmunity.

To detect an immune deficiency, the lymphocyte count is the most relevant. Approximately 20 percent of lymphocytes are B lymphocytes (which produce antibodies), and approximately 75 percent of lymphocytes are T lymphocytes. A significant deficiency of the lymphocyte count may indicate a reduction of T lymphocytes, which is a relatively common finding in patients with CVID. Therefore, a deficiency of lymphocytes found in the CBC can be an indicator that an immunodeficiency could be present. If an antibody deficiency is suspected, more extensive testing for immune system problems is justified.

More extensive testing begins with one of the early primary tests, which checks quantitative antibody levels, including serum IgG, IgA, IgM and IgE levels. The IgE level can help implicate that allergic disease may be present. Paradoxically, there are a couple of antibody deficiency syndromes, hyper IgM syndrome (HIM) or hyper IgE syndrome (HIES), which are characterized by having elevated IgM or greatly elevated IgE, respectively. Both of these syndromes also have low IgG levels and poor IgG functional antibody responses. In addition, various patterns of immunoglobulin class deficiencies may be detected. Commonly, IgA will be below the detection level, IgG will be variably low and IgM may actually be elevated.

In the initial evaluation, checking IgG subclass levels typically does not provide useful information for making an immune deficiency diagnosis. However, once a functional antibody deficiency is diagnosed, checking IgG subclasses may help to categorize the type of antibody deficiency. Overall, many patterns of antibody deficiency may be observed, from all antibodies being low, to individual classes or combinations of the different classes of antibodies being low, or the immunoglobulin levels actually being within the normal ranges for age.

Step 2: Functional Assays

The most imperative assays for detection of an antibody deficiency are the functional assays, which will be discussed in the next issue's Immunology 101 column.

TERRY HARVILLE, MD, PhD, is medical director of the Special Immunology Laboratory at the University of Arkansas for Medical Sciences, and a consultant for immunodeficiencies, autoimmunities and transplantation.

Editor's Note: This Immunology 101 column, introduced in the April-May 2010 issue of IG Living, is intended to be a basic course in immunology.
Did You Know

Donating Plasma: The Gift of Life
By Kris McFalls

IT HAS BEEN said that there are no greater givers than those who give of themselves. The word “donor” is derived from the Latin word *donare*, which means “to give.” Is it any wonder, then, that many recipients of plasma-derived products view plasma donors as givers of life?

Plasma is the key ingredient of many medications that, quite literally, sustain the lives of patients with clotting disorders, immune deficiencies, autoimmune diseases and neurological disorders. Patients in need of plasma-derived therapies have very few treatment options, and they often are faced with a choice between living life with a plasma-derived treatment or not living at all. Still, it can be an unsettling feeling for patients to know that their lives are in the hands of people they know nothing about. Likewise, the survival of the manufacturers of plasma products relies on making sure that donors are healthy, trustworthy and reliable. And, according to the Centers for Disease Control and Prevention (CDC), even though the U.S. blood supply is among the safest in the world, no amount of contamination is acceptable for either the manufacturers or the patients.

Worldwide, 20 million liters of plasma are needed to meet the needs of these patients. Of that, approximately 18 million liters come from the U.S. Plasma collection in the U.S. is regulated by the U.S. Food and Drug Administration (FDA). In addition to FDA standards, many manufacturers adhere to the International Quality Plasma Program (IQPP), a voluntary industry certification program for plasma collection centers willing to exceed government standards for safety. In fact, the FDA recently sought advice about whether to increase its standards to match that of the industry when testing for the hepatitis B virus (HBV).

**Worldwide, 20 million liters of plasma are needed to meet the needs of these patients.**

**Plasma Donations Are Mutually Beneficial**

Choosing to become a plasma donor in the U.S. benefits not only patients and the industry — it also benefits the donors. Small financial considerations are given to donors to compensate them for their time and incentivize them to return. But, donors aren’t going to get rich from donating plasma. For most, it helps to pay the bills. And while the money may help get plasma donors in the door initially, for many it is more about knowing they are helping others that keeps them coming back. Should they fail to return after their first donation, their plasma is discarded.

**Becoming a Donor**

Donating plasma is not an easy process. Donors encounter a time-consuming procedure that requires dedication, attention to personal health and a willingness to answer questions about intimate details of their lives. Before the process can begin, donors must provide valid identification that proves they are between 18 and 64 years of age. Prospective donors must provide proof of a current address and a Social Security card or an immigration card. Additionally, a photo is taken of all donors and kept on file. Prospective

Dwayne Wilson (left) and Jeffrey Aries (right) have undergone the rigorous requirements to donate lifesaving plasma.
donors also are checked against the National Donor Deferral Registry (NDDR) before they are allowed to donate.

Once initial qualifications are met, donors must fill out a questionnaire to help determine their suitability as a donor. They are asked general questions about their health, medications, recent piercings, tattoos and travel. Other questions are asked to evaluate the donors’ risk for HIV.

**Medical Screening**

Donors then proceed through a process that ensures they are healthy enough to safely donate their plasma. Before the first donation and once a year thereafter, donors must receive a physical evaluation. They are weighed to ensure their weight is at or above 110 pounds. Their pulse, blood pressure and temperature are taken. A hematoctrit test is done via a small finger prick to confirm a healthy level of red blood cells. And, a urine sample is required. Then, another series of questions is asked to ascertain if the donors have participated in any high-risk behaviors or have any medical conditions that may disqualify them from donating. In some instances, donors may be asked for medical records from their personal physician.

**The Donation Process**

Once donors pass all of the physical requirements, they are finally ready to begin plasmapheresis, a process that separates each donor’s plasma from the red cells, collects the plasma and then returns the red cells to the donor. Healthcare providers use sterile procedures and equipment to gain access to donors’ veins. In fact, the process of plasmapheresis usually requires a larger needle than that needed for an infusion patient. And, if donors return to donate as much as is allowed (twice per week), they may actually be subjected to more infusion pokes than an infusion patient.

**After the Donation**

Once the plasma donation is made, the plasma is placed on a 60-day hold while it undergoes further testing for viral agents. If the plasma is found to be unsafe, it is discarded. Any donors whose plasma tests positive for hepatitis B, hepatitis C or human immunodeficiency virus (HIV) will be automatically entered into the NDDR and will be permanently barred from donating blood or plasma in the U.S. Additionally, plasma donors are notified of the results and encouraged to seek treatment from their personal physicians.

Choosing to become a regular plasma donor is no small commitment. For the recipients of plasma-derived therapies, that commitment is no small gift. Plasma donation centers can be located at [www.donatingplasma.org](http://www.donatingplasma.org).

**Medications on the Deferral List**

- Accutane (Amnesteem, Claravis, Sotret, isotretinoin) — usually prescribed for severe acne
- Avodart (dutasteride) — usually prescribed for prostate enlargement
- Experimental medication or unlicensed (experimental) vaccine — usually associated with a research protocol
- Feldene (piroxicam) — prescribed for mild to moderate arthritis pain
- Growth hormone from human pituitary glands — typically given to children with delayed or impaired growth
- Hepatitis B immune globulin — prescribed following an exposure to hepatitis B (Note: This is different from the hepatitis B vaccine, which is a series of three injections given over a six-month period to prevent future infection from exposures to hepatitis B.)
- Insulin from cows (bovine, or beef, insulin) — given to treat diabetes
- Plavix (clopidogrel) and Ticlid (ticlopidine) — inhibits platelet function; prescribed to reduce the chance of heart attack and stroke
- Propecia (finasteride) — usually prescribed for baldness
- Proscar (finasteride) — usually prescribed for prostate gland enlargement
- Soriatane (acitretin) — usually prescribed for severe psoriasis
- Tegison (etretinate) — usually prescribed for severe psoriasis

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**Editor’s note:** Deferral for donors taking some medications is temporary. Check with a donor center for more details.
**Education**

**PIDD Summer School to be Held in August**

The 10th Summer School in Primary Immunodeficiency Disease (PIDD) will be held Aug. 25-28, 2011, in Miami, Fla. Conducted by the Clinical Immunology Society (CIS) in collaboration with the United States Immunodeficiency Network, the school is for fellows considering a career in immunology who want to expand their knowledge and learn about new diagnostic tools. It also is an opportunity to interact with leaders in the field and to network with colleagues.

The school’s format is case-based learning, featuring case presentations, large and small group discussions and lecture presentations on PIDD. All applicants must submit a case for discussion. Accepted fellows will be provided with travel grants to assist with airfare, hotel and meal expenses, and selected participants are required to become members of CIS at the conclusion of the school. For more information, contact Michelle Roach, CIS associate director of programs, at mroach@clinimmnsoc.org or (414) 224-8095.

**Support**

**DVD Encourages Patients with Chronic Neuropathy**

A new DVD titled “Coping with Chronic Neuropathy: Tips and Techniques on Living with Neuropathy” was created by patients for patients to encourage them in their struggle with peripheral neuropathy. The one-hour and six-minute DVD, which is distributed by The Neuropathy Association, was produced by 12 professional volunteers, nine of whom live with neuropathy, and includes an introduction by Thomas H. Brannagan III, MD, medical adviser to The Neuropathy Association and director of the Neuropathy Center of Excellence, Columbia University, and a seminar by Eugene B. Richardson, MDiv, EdM, MS, president and founding director of the Neuropathy Support Network.

The DVD is free of charge, but a donation is requested to raise funds for neuropathy research through the Mary Ann Donovan Scientific Research Fund of The Neuropathy Association, a non-profit organization representing more than 50,000 neuropathy patients with 15 neuropathy centers colocated in universities and hospitals across the U.S. To request a copy of the DVD, go to www.neuropathysupportnetwork.org or email gene@neuropathysupportnetwork.org.

**Medicine**

**CSL Behring Discontinues U.S. Distribution of Vivaglobin**

CSL Behring has discontinued distribution of Vivaglobin in the United States market as of April 4. According to a letter sent to Vivaglobin customers, the product was discontinued due to delays in supply. Considering the delays they were experiencing, CSL felt it would be disruptive to bring Vivaglobin back temporarily, only to discontinue it later this year. CSL also manufactures Hizentra, a 20% subcutaneous immunoglobulin replacement therapy for patients with primary humoral immunodeficiency, and a sample program is being offered to Vivaglobin patients that will provide them with a one-month supply of Hizentra to determine if the product is right for them. For more information, contact IgIQ at (877) 355-IgIQ. Patients can also learn more about the product at www.Hizentra.com.
Legislation
California Affordable Drug Coverage Bill Passes

In May, the California Assembly Health Committee passed legislation, authored by Assemblywoman Fiona Ma (D-San Francisco), to protect Californians with life-threatening diseases from escalating insurance costs for medication. The committee passed Assembly Bill 310 with a 12 to 6 vote after hearing compelling testimony. The bill places a $150 co-payment cap for a one-month supply of medication, as well as prohibits health plans and insurers from using co-insurance and places an annual out-of-pocket limit on prescription drug costs if a plan or insurance policy maintains an annual limit.

AB 310, which is sponsored by the Alliance for Biotherapeutics and the Multiple Sclerosis Society, was introduced in response to health plans that are reclassifying drugs into a new tier and adopting a new method of payment for specialty drugs called co-insurance where a patient pays a percentage of the cost of the drug, as opposed to a traditional co-payment. Specialty drugs are used to treat diseases like multiple sclerosis, rheumatoid arthritis, HIV, cancer, hemophilia, primary immunodeficiency diseases and hepatitis. The bill will now go to the Assembly Appropriations Committee.

“AB 310 is about establishing reasonable cost controls for consumers living with chronic and life-threatening illnesses,” said Assemblywoman Ma. “Specialty drug pricing dramatically increases the costs of vital medication, discriminates against the most vulnerable populations and jeopardizes the health of Californians by placing the cost of medications beyond reach. People should not have to choose between bankruptcy or death.”

Last year, New York became the first state to pass a bill that prohibited insurers from creating specialty tiers. Other states, including Indiana, Connecticut, Nebraska, Pennsylvania, Rhode Island and Vermont are considering similar legislation.

Insurance
Grifols Expands PatientCare Program

Grifols Inc. has expanded its PatientCare Program to offer intravenous immune globulin (IVIG) to the primary immune deficiency (PIDD) community. The program will provide Flebogamma 5% DIF (Immune Globulin Intravenous [Human]) or Flebogamma 10% DIF (Immune Globulin Intravenous [Human]) at no cost to patients with PIDD when insurance coverage is not available. The PatientCare Program consists of Grifols Assurance for Patients (GAP), which provides therapy for users of Grifols’ products during a lapse in insurance coverage, and Grifols Patient Assistance (GPA), which provides therapy for individuals in need of temporary assistance.

The GAP program is open to anyone diagnosed with PIDD who has used a Grifols’ product for the three months prior to lapse in coverage. The GPA program is open to anyone diagnosed with PIDD without insurance who is in need of temporary assistance, regardless of whether they have used a Grifols therapy. However, applicants of the GPA program must meet financial eligibility requirements, and both programs require certain insurance ineligibility. To take advantage of the program, patients must complete eligibility forms, which can be downloaded at www.grifolspatientcare.com, and submit them to a Grifols Patient Care representative for verification. Neither program is an emergency program, and if a lapse in coverage is anticipated, the eligibility forms should be submitted ahead of time.

Grifols also operates an Emergency Supply System for physicians seeking to obtain IVIG to treat a specific patient under emergency circumstances. Access to this emergency system does not require the requesting physician to be a current customer of Grifols, and there are no prerequisites other than an emergent need for treatment. For more information about the Emergency Supply System, contact (888) GRIFOLS.
Plasma

Grifols Wins Approval to Buy Talecris

Grifols SA has won U.S. antitrust approval to buy Talecris Biotherapeutics Holdings Corp. for $4 billion after agreeing to sell some assets. Under a consent agreement with the staff of the Federal Trade Commission, Grifols will sell two plasma collection centers, Talecris’ Koate blood-protein unit, and a manufacturing plant in Melville, N.Y. The deal reduces the number of major companies in the blood plasma industry, and gives Grifols, Europe’s largest maker of blood plasma products, a bigger share of the $7 billion U.S. market for blood-based infusions.

Clinical Trials Update

Data from a Phase III pivotal trial of CSL’s Hizentra revealed that the drug provides primary immunodeficiency (PIDD) patients with a safe and effective alternative to other immunoglobulin (IG) therapies when given in equivalent doses. In the study, 51 PIDD patients (3 to 60 years old) who were administered Hizentra after being on other IG therapies experienced similar or increased IG trough levels and were protected from infections.

Results from interim analyses of a Phase III clinical study of Baxter’s HyQ showed that 28 out of 29 patients with primary immune deficiency disease (PIDD) were able to infuse IG under the skin at infusion volumes, intervals and rates equivalent to their previous intravenous (IV) administration of IG. HyQ is an IG therapy facilitated subcutaneously by recombinant human hyaluronidase, a dispersion and permeation enhancer. In the study, the majority of HyQ infusions were administered using a single injection site at a mean maximum infusion rate of 245 mL per hour and a mean infusion time of 2.4 hours, which is comparable to IV administration.

4SC AG, a drug discovery and development company focused on autoimmune and cancer indications, has had positive preliminary results of a Phase IIa study of inflammatory bowel disease with its lead autoimmune compound vidofludimus, an oral inhibitor of interleukin-17. The exploratory, open-label, single-arm study met its primary goal of significantly increasing the response rate in corticosteroid-dependent IBD patients to 88.5 percent, versus an average placebo response across published benchmark clinical trials of approximately 20 percent.

Innate Therapeutics has begun treating patients in a Phase IIa clinical study of its lead molecule MIS416 in patients with progressive multiple sclerosis. The study, which will first examine the safety, tolerability and pharmacokinetics of intravenously administered MIS416 to determine a recommended therapeutic dose and dosing interval for the confirmatory portion of the trial, is expected to be completed at the end of 2011.

Phadia has received FDA 510(k) clearance for two new CLIA moderate complexity EliA autoimmune antibody assays that will provide physicians with additional tools needed to aid in the diagnosis of celiac disease. The new assays, EliA Gliadin IgA and EliA Gliadin IgG (deamidated peptides), have proven to be essential, sensitive and specific markers to aid in the diagnosis of celiac disease.

Maxygen Inc. has initiated a Phase I clinical study to evaluate a next-generation CTLA-4-Ig therapeutic, designated as ASP2408, that is being developed by Perseid Therapeutics LLC, Maxygen’s majority-owned subsidiary, in collaboration with Astellas Pharma Inc. for the treatment of rheumatoid arthritis and potentially other autoimmune indications.
Two new intravenous immune globulin (IVIG) access bills, one in the House and one in the Senate, have been introduced. H.R. 1845, introduced by Representatives Kevin Brady (R-Texas) and Doris Matsui (D-Calif.), and S. 960, introduced by Senators John Kerry (D-Mass.) and Lamar Alexander (R-Tenn.), both titled Medicare IVIG Access Act, provide for a study of issues relating to access to IVIG for Medicare beneficiaries in all care settings and a demonstration project to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home for patients with primary immunodeficiency diseases (PIDDs).

Current law pays for IVIG but prohibits Medicare from reimbursing for nursing services and equipment necessary to infuse a patient in the home setting.

According to an Immune Deficiency Foundation patient survey, when compared to private insurance, Medicare patients share a disproportionate burden of negative consequences as a result of the changes in Medicare IVIG reimbursement policies. Since January 2005, 32 percent of Medicare patients reported they have been forced to change their preferred IVIG treatment location. Many patients now must receive IVIG in hospitals, which is not the ideal location for PIDD patients who are especially susceptible to opportunistic infections.
All of us, regardless of our age, background or economic status, have a need to feel connected. Trending experts say more and more people are turning to online communities to find the support and encouragement they crave. The popularity of online gathering spots like Facebook, Twitter and interest-specific blogs speaks to this trend, which is particularly on the rise among those living with chronic illness.

For those living with the stigma of illness, escaping into a virtual world to connect with others who share similar experiences can provide much-needed support and encouragement.
A report released in March by the Pew Internet and American Life Project and the California HealthCare Foundation revealed that one in four Internet users living with a chronic ailment has gone online to find others with a similar health condition. In addition, the report states that the Internet and social media seem to play a part in the healing process by providing people with chronic illnesses opportunities to communicate about health and/or to escape into a virtual world where their health is not the focus. “If they can break free from the anchors holding them down, people living with chronic disease who go online are finding resources that are more useful than the rest of the population,” says Susannah Fox, associate director of digital strategy at Pew and author of the report.

*IG Living* magazine joined the virtual world in January 2010, and our readers responded enthusiastically; as this story went to print, our Facebook page had more than 800 fans, with many actively posting comments and opinions daily. Our *IG Living* blog also has garnered quite a following, offering a platform for those in the IG community to share experiences, good and bad. “Before I found social media, I was completely alone with my PIDD illness. It was close to impossible to meet others like me,” says *IG Living* fan Kelly Clardy. “Now, thanks to Facebook, I have close to 200 other friends who get IVIG [intravenous immune globulin] treatment. They help with information, we share experiences, and we commiserate together and try to help keep our spirits up.”

**Giving Patients a Voice**

A quick Google search reveals a vast number of websites and blogs that address patient issues and concerns, from insurance and reimbursement challenges to the social stigmas associated with invisible illness. One popular site, But You Don’t Look Sick (www.butyoudontlooksick.com), has nearly 30,000 Facebook fans and more than 4,000 Twitter followers. The site, and its related social media outlets, was founded by Christine Miserandino, a patient herself. Frustrated after constantly being told “but you don’t look sick” by people who disbelieved her diagnoses of chronic fatigue syndrome, Epstein-Barr and lupus, Miserandino intuitively recognized that her experience was not uncommon, and the seed of an idea took root. Her hunch was right, and today the site has expanded to include an online store featuring products bearing the site’s logo, webcasts and even healthy recipes and personal care products, and its founder is a frequent speaker at various media outlets and health symposiums.

Miserandino is far from alone in her quest to create a platform where the patient’s opinion matters. Jenni Prokopy was diagnosed with fibromyalgia in 1997 and was frustrated by the lack of connection she felt in traditional support groups. Today, Prokopy manages her own online community and blog, ChronicBabe.com, and says her website averages 18,000 hits per day. She has about 32,000 subscribers to her online newsletter, and close to 3,000 Twitter followers. “For a lot of people, social media has opened up lines of communication that were never available to them before. Even people in rural areas who don’t have access to the Internet can get online through MING on their cell phones,” she says. “We reach a lot of people who felt very isolated before this was available.”

Prokopy’s weekly chat room discussions have opened the door to global conversations. Participants log in from as far away as New Zealand to hash over hot topics ranging from parenting chronically ill children to dosing advice. And the connections are not just patient-to-patient either; even physicians are starting to get in on the conversation. “I’ve built relationships with doctors just by being on Twitter,” Prokopy says. “Building those relationships with them is important — there’s a lot of doubt and frustration on the patient side, and many patients mistrust the medical community. I think online dialogue can begin to build a bridge between the communication gaps that exist.”

**Docs Slowly Embracing the Trend**

While many in the medical community have viewed online health forums with skepticism and mistrust, others
have embraced and even helped pioneer communication channels. Dr. Kevin Pho, a board-certified primary care physician in Nashua, N.H., is widely known as “social media’s leading physician voice.” His blog, KevinMD.com, debuted in 2004 and has since skyrocketed in popularity; his viewpoints are often cited by major media, including The Wall Street Journal, The New York Times, The Washington Post, Los Angeles Times and USA Today. More than the musings of a single physician, Pho’s blog voices the viewpoints of various medical experts and patients alike. “Social media provides a certain amount of transparency and allows doctors and patients to see things from each other’s perspective,” Pho says. “When you talk to doctors, they often complain about what’s wrong with our healthcare system, but no matter how bad we have it, patients have it worse. Logging on and reading patient blogs, following Twitter or Facebook, allows us to better understand things from the patient’s viewpoint.”

Critics of healthcare websites and blogs often express concerns that patients might access and share erroneous medical information online, potentially putting them in harm’s way. While there is little question that bogus medical claims abound on the Internet, most patient-centric social networks make it clear that the information on the site should not substitute for medical advice. In fact, the Pew study found that just 2 percent of adults living with chronic diseases report being harmed by following medical advice found on the Internet.

Creating Community Through Shared Experience

When blogger Laurie Edwards launched A Chronic Dose (www.achronicdose.com) in 2006, she did so as a way of reaching out to other young adults diagnosed with chronic illness. Many of her postings evolved into a book titled Life Disrupted, which Edwards markets on her site. Edwards was diagnosed with primary ciliary dyskinesia (PCD) and bronchiectasis in her twenties, and she says social media helped her deal with the isolation she felt living with a rare disease. “There are several reasons why online support groups and chat rooms are often attractive to patients,” says Edwards. “The opportunity to hear from other patients and get advice on treatment and therapies and share common experiences is invaluable.”

Edwards emphasizes that for some with rare diseases, online communities may be the only way patients have of finding someone with a shared experience. But she’s quick to note that the isolating nature of diagnosis and illness in general is a universal concern that drives even patients with more common diseases to seek solace on the Internet. “For the newly diagnosed, it’s helpful to hear from ‘veterans’ and see positive outcomes; for more seasoned patients, it is often really helpful to have a built-in community to ask questions and offer input,” she says.

While many in the medical community have viewed online health forums with skepticism and mistrust, others have embraced and even helped pioneer communication channels.

“My sense is that the utility of these groups and chat rooms ebbs and flows with the trajectory of the illness in question. For instance, hearing from patients in similar situations was so important to me when planning for our extremely high-risk pregnancy because there simply isn’t a lot of data out there. Anecdotal wisdom and experiences were incredibly helpful.”
Hizentra is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin or to components of Hizentra, such as polysorbate 80.

Hizentra is contraindicated in patients with hyperprolinemia because it contains the stabilizer L-proline (see Description [11]).

Hizentra is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity (see Description [11]).

5.3 Transmissible Infectious Agents
Because Hizentra is made from human plasma, it may carry a risk of transmitting infectious agents (e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease [CJD] agent). The risk of infectious agent transmission has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of current virus infections, and including virus inactivation/removal steps in the manufacturing process for Hizentra.

Report all infections thought to be possibly transmitted by Hizentra to CSL Behring Pharmacovigilance at 1-866-915-6958.

5.4 Laboratory Tests
Various passively transferred antibodies in immunoglobulin preparations may lead to misinterpretation of the results of serological testing.

6 ADVERSE REACTIONS
The most common adverse reactions (ARs), observed in ≥5% of study subjects receiving Hizentra, were local reactions (i.e., swelling, redness, heat, pain, and itching at the injection site), headache, vomiting, pain, and fatigue.

6.1 Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, AR rates observed in clinical studies of a product cannot be directly compared to rates in the clinical studies of another product and may not reflect the rates observed in clinical practice.

The safety of Hizentra was evaluated in a clinical study for 15 months in subjects with PI who had been treated previously with IGIV every 3 or 4 weeks. The safety analyses included 49 subjects in the intention-to-treat (ITT) population. The ITT population consisted of all subjects who received at least one dose of Hizentra (see Clinical Studies [14]).

Subjects were treated with Hizentra at weekly doses ranging from 66 to 331 mg/kg body weight during the wash-in/wash-out period and from 72 to 379 mg/kg during the efficacy period. The 49 subjects received a total of 2264 weekly infusions of Hizentra.

No deaths or serious ARs occurred during the study. Two subjects withdrew from the study due to ARs. One subject experienced a severe injection-site reaction one day after the third weekly infusion, and the other subject experienced moderate myositis. Both reactions were judged to be “at least possibly related” to the administration of Hizentra.

Table 2 summarizes the most frequent adverse events (AEs) (experienced by at least 4 subjects), irrespective of causality. Included are all AEs and those considered temporally associated with the Hizentra infusion, i.e., occurring during or within 72 hours after the end of an infusion. Local reactions were the most frequent AEs observed, with injection-site reactions (i.e., swelling, redness, heat, pain, and itching at the site of injection) comprising 98% of local reactions.

<table>
<thead>
<tr>
<th>AE (≥4 Subjects)</th>
<th>All AEs*</th>
<th>AEs* Occurring During or Within 72 Hours of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) of Subjects (n=49)</td>
<td>Number (Rate) of AEs (n=2264 Infusions)</td>
<td>Number (%) of Subjects (n=49)</td>
</tr>
<tr>
<td>Local reactions</td>
<td>49 (100)</td>
<td>1340 (0.592)</td>
</tr>
</tbody>
</table>

Table 2: Incidence of Subjects With Adverse Events (AEs)* (Experienced by 4 or More Subjects) and Rate per Infusion, Irrespective of Causality (ITT Population)
Most local reactions were either mild (93.4%) or moderate (6.3%) in intensity.

### Table 3: Incidence of Subjects With Adverse Reactions (Experienced by 2 or More Subjects) to Hizentra and Rate per Infusion (ITT Population)

<table>
<thead>
<tr>
<th>AE (≥4 Subjects)</th>
<th>All AEs*</th>
<th>AEs* Occurring During or Within 72 Hours of Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (% of Subjects (n=49))</td>
<td>Number (Rate1) of AEs (n=2264 Infusions)</td>
</tr>
<tr>
<td>Other AEs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>13 (26.5)</td>
<td>40 (0.018)</td>
</tr>
<tr>
<td>Cough</td>
<td>8 (16.3)</td>
<td>9 (0.004)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7 (14.3)</td>
<td>8 (0.004)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>6 (12.2)</td>
<td>6 (0.003)</td>
</tr>
<tr>
<td>Back pain</td>
<td>5 (10.2)</td>
<td>11 (0.005)</td>
</tr>
<tr>
<td>Nausea</td>
<td>5 (10.2)</td>
<td>5 (0.002)</td>
</tr>
<tr>
<td>Abdominal pain, upper</td>
<td>5 (10.2)</td>
<td>5 (0.002)</td>
</tr>
<tr>
<td>Rash</td>
<td>5 (10.2)</td>
<td>7 (0.003)</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>5 (10.2)</td>
<td>4 (0.003)</td>
</tr>
<tr>
<td>Migraine</td>
<td>4 (8.2)</td>
<td>5 (0.002)</td>
</tr>
<tr>
<td>Pain</td>
<td>3 (6.1)</td>
<td>4 (0.002)</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>4 (8.2)</td>
<td>6 (0.003)</td>
</tr>
<tr>
<td>Pharyngolaryngeal pain</td>
<td>4 (8.2)</td>
<td>6 (0.003)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>4 (8.2)</td>
<td>5 (0.002)</td>
</tr>
</tbody>
</table>

* Excluding infections.
1 Rate of AEs per infusion.

Table 3 summarizes the most frequent ARs (i.e., those AEs considered by the investigators to be "at least possibly related" to Hizentra administration) experienced by at least 2 subjects.

### Table 3: Incidence of Subjects With Adverse Reactions (Experienced by 2 or More Subjects) to Hizentra and Rate per Infusion (ITT Population)

<table>
<thead>
<tr>
<th>Adverse Reaction (≥2 Subjects)</th>
<th>Number (% of Subjects (n=49))</th>
<th>Number (Rate1) of Adverse Reactions (n=2264 Infusions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local reactions1</td>
<td>49 (100)</td>
<td>1338 (0.591)</td>
</tr>
<tr>
<td>Other AEs:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>12 (24.5)</td>
<td>36 (0.016)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3 (6.1)</td>
<td>3 (0.001)</td>
</tr>
<tr>
<td>Pain</td>
<td>3 (6.1)</td>
<td>4 (0.002)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>3 (6.1)</td>
<td>3 (0.001)</td>
</tr>
<tr>
<td>Contusion</td>
<td>2 (4.1)</td>
<td>3 (0.001)</td>
</tr>
<tr>
<td>Back pain</td>
<td>2 (4.1)</td>
<td>3 (0.001)</td>
</tr>
<tr>
<td>Migraine</td>
<td>2 (4.1)</td>
<td>3 (0.001)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2 (4.1)</td>
<td>2 (&lt;0.001)</td>
</tr>
<tr>
<td>Abdominal pain, upper</td>
<td>2 (4.1)</td>
<td>2 (&lt;0.001)</td>
</tr>
<tr>
<td>Nausea</td>
<td>2 (4.1)</td>
<td>2 (&lt;0.001)</td>
</tr>
<tr>
<td>Rash</td>
<td>2 (4.1)</td>
<td>2 (&lt;0.001)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>2 (4.1)</td>
<td>2 (&lt;0.001)</td>
</tr>
</tbody>
</table>

1 Rate of AEs per infusion.

Most local reactions were either mild (93.4%) or moderate (6.3%) in intensity.

### 6.2 Postmarketing Experience

Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure.

The following adverse reactions have been identified and reported during the postmarketing use of IGLV products:

- **Infusion reactions**: Hypersensitivity (e.g., anaphylaxis), headache, diarhrea, tachycardia, fever, fatigue, dizziness, malaise, chills, flushing, urticaria or other skin reactions, wheezing or other chest discomfort, nausea, vomiting, rigors, back pain, myalgia, arthralgia, and changes in blood pressure.
- **Renal**: Acute renal dysfunction/failure, osmotic nephropathy.
- **Respiratory**: Apnea, Acute Respiratory Distress Syndrome (ARDS), TRALI, cyanosis, hypoxemia, pulmonary edema, dyspnea, bronchospasm.
- **Cardiovascular**: Cardiac arrest, thromboembolism, vascular collapse, hypotension.
- **Neurological**: Coma, loss of consciousness, seizures, tremor, aseptic meningitis syndrome.
- **Integumentary**: Stevens-Johnson syndrome, epidermolyis, erythema multiforme, dermatisms (e.g., bullous dermatitis).
- **Hematologic**: Pancytopenia, leukopenia, hemolysis, positive direct antiglobulin (Coombs’) test.
- **Gastrointestinal**: Hepatic dysfunction, abdominal pain.
- **General/Body as a Whole**: Pyrexia, rigors.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

### 7.1 Live Virus Vaccines

The passive transfer of antibodies with immunoglobulin administration may interfere with the response to live virus vaccines such as measles, mumps, rubella, and varicella (see Patient Counseling Information [17]).

### 7.2 Serological Testing

Various passively transferred antibodies in immunoglobulin preparations may lead to misinterpretation of the results of serological testing.

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Hizentra. It is not known whether Hizentra can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hizentra should be given to pregnant women only if clearly needed.

#### 8.3 Nursing Mothers

Hizentra has not been evaluated in nursing mothers.

#### 8.4 Pediatric Use

Hizentra was evaluated in 10 pediatric subjects (3 children and 7 adolescents) with PI. No pediatric-specific dose requirements were necessary to achieve the desired serum IgG levels. Hizentra was not evaluated in neonates or infants.

#### 8.5 Geriatric Use

Of the 49 subjects evaluated in the clinical study of Hizentra, 6 subjects were 65 years of age or older. No overall differences in safety or efficacy were observed between these subjects and younger subjects.

### 15 REFERENCES


Manufactured by: CSL Behring AG
Bern, Switzerland
CSL Behring LLC
Kankakee, IL 60901 USA

Distributed by: CSL Behring LLC
Based on March 2010 version
Vivaglobin® Immune Globulin Subcutaneous (Human) is indicated for the treatment of patients with primary immune deficiency (PID).

**INDICATIONS AND USAGE**

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- **Non-injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Sinus, Urine abnormality.
- **Injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Skin disorder, Tachycardia, Urine abnormality.

**WARNINGS**

- **Aphthous Stomatitis**
- **Agammaglobulinemia**
- **Seizure Activity**
- **Serum sickness like Reactions**
- **Anaphylactic or anaphylactoid reactions**
- **Risk of transmission of viral agents**

**PRECAUTIONS**

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**ADVERSE REACTIONS**

- **Non-injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Sinus, Urine abnormality.
- **Injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Skin disorder, Tachycardia, Urine abnormality.

**INDICATIONS AND USAGE**

Vivaglobin® Immune Globulin Subcutaneous (Human), is indicated for the treatment of patients with primary immune deficiency (PID). Before prescribing, please consult full prescribing information, a brief summary of which follows:

- **Non-injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Sinus, Urine abnormality.
- **Injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Skin disorder, Tachycardia, Urine abnormality.

**WARNINGS**

- **Aphthous Stomatitis**
- **Agammaglobulinemia**
- **Seizure Activity**
- **Serum sickness like Reactions**
- **Anaphylactic or anaphylactoid reactions**
- **Risk of transmission of viral agents**

**PRECAUTIONS**

- **General**
- **Laboratory Tests**
- **Drug Interactions**
- **Geriatric Use**
- **Pregnancy Category C**
- **Local Injection Site Reactions**

**ADVERSE REACTIONS**

- **Non-injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Sinus, Urine abnormality.
- **Injection Site Reactions**: Headache, Nausea, Rash, Asthenia, Gastrointestinal disorder, Fever, Skin disorder, Tachycardia, Urine abnormality.
Because Vivaglobin®
The risk that such plasma-derived products will transmit an infectious agent has been reduced by screening

Thus, the risk of transmission of infectious agents cannot be

Any infections thought by a physician to have been possibly transmitted by this product should be reported by the

When initiating therapy with Vivaglobin®
The immunizing physician should be informed of recent therapy with Vivaglobin®

There were no apparent differences in the safety and efficacy profiles as compared to adult subjects.
The safety and efficacy of Vivaglobin®

Reactions similar to those reported with administration of other immune globulin products may also

Rarely, immediate anaphylactoid and hypersensitivity reactions may occur. In exceptional cases, sensitization to

Table 5 summarizes the most frequent adverse events by subject reported in the clinical study, and Table 6 summarizes the most frequent

Only three subjects in the US and Canada study and one subject in the Europe and Brazil study discontinued

Note: Analysis is confined to 70 infusions.

Your physician will monitor for reactions associated with IVIg treatment that might occur with Hizentra, including renal dysfunction/failure, thrombotic events, aseptic meningitis syndrome (AMS), hemolysis, and transfusion-related acute lung injury (TRALI).

Patients receiving Ig therapy for the first time, receiving a new product, or not having received Ig therapy within the preceding eight weeks may be at risk for developing reactions, including fever, chills, nausea, and vomiting. On rare occasions, these reactions may lead to shock.

Ig administration could impair the effect of live virus vaccines, such as measles, mumps and rubella. Before getting any vaccination, inform your doctor that you are being treated with Hizentra or Vivaglobin.

In their clinical studies, Hizentra and Vivaglobin were effective in pediatric patients without specific pediatric dose adjustments. With either treatment, no overall differences in safety or efficacy have been observed in patients over 65 or in pediatric patients.

Please see brief summary of full Prescribing Information for Hizentra and Vivaglobin, including Patient Product Information, on previous pages.

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.

*In a clinical study, the median length of a weekly infusion ranged from 1.6 to 2 hours.

Important Safety Information
Hizentra and Vivaglobin are indicated for the treatment of patients with primary immunodeficiency (PI).

If you have a history of anaphylactic or severe systemic response to immune globulin preparations or selective immunoglobulin A deficiency, check with your physician as neither Vivaglobin nor Hizentra should be used. If your physician suspects you are having anaphylactic or anaphylactoid reactions, treatment will be discontinued. Because Hizentra contains the stabilizer L-proline, you cannot be treated with Hizentra if you have hyperprolinemia. Hizentra and Vivaglobin are derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

In separate clinical trials for Hizentra and Vivaglobin, the most frequent adverse event was injection-site reaction, consisting of mild or moderate swelling, redness, and itching. With Vivaglobin, no serious local site reactions were observed, and reactions tended to decrease substantially after repeated use. Other adverse events with Vivaglobin, irrespective of causality, included headache, gastrointestinal disorder, fever, nausea, sore throat, and rash. Adverse reactions to Hizentra, observed in 5% or more of clinical trial subjects, were local injection-site reactions, headache, vomiting, pain, and fatigue.

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Vivaglobin is manufactured by CSL Behring GmbH and distributed by CSL Behring LLC.
Vivaglobin is a registered trademark of CSL Behring GmbH.

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Of course, baring your soul — and symptoms — online has potential pitfalls for all types of patients; the unintentional sharing of private health information could have negative ramifications, from identity theft to being denied insurance coverage. And with many people in chat rooms using make-believe monikers, it’s hard to know exactly whom you are talking to. Then there’s the potential emotional toll: hanging around chat rooms where erroneous or negative postings abound also can create problems; patients seeking validation and support may come away feeling fearful, sad or discouraged. “If you hang out on a message board where people are very negative, you can easily adopt a negative attitude about your disease,” said Paul Albert, digital services librarian at Weill Cornell Medical Library in New York, who has researched how social networks meet the needs of patients with chronic diseases. “On the other hand, if people are hopeful, you might be better off.”

For Laurie Edwards and many of our IG Living readers we’ve spoken with, the latter has proved true. “More than anything else, participating in online dialogues has shown me that there is a thriving community of patients who are younger adults — people trying to manage education and professions and relationships while balancing chronic illness,” says Edwards. “I’ve met inspiring people who have become friends, and I’ve had the good fortune to have this incredibly supportive network of readers, followers and fellow social media users. As a writer and as a patient, these relationships are incredibly important.”

TRUDIE MITSCHANG is a staff writer for IG Living magazine.

References
Safe

Reliable

Convenient

Specialty solutions in Chronic Care.
Making a difference—one patient at a time.
Offering safe, convenient & reliable solutions for home infusion and critical-care products.

Immune Globulin Subcutaneous
Immune Globulin Intravenous
Antihemophilic Factors

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In the early 1900s, some dieters smoked cigarettes instead of reaching for a sweet. Others swallowed a tapeworm that would then eat food from their gastrointestinal (GI) tracts. Few people would argue that the Tapeworm Diet and the Cigarette Diet are healthy ways to lose weight. Parasites lead to stomach distress and a host of diseases including death, and smoking stains teeth and causes cancer and heart disease.

What made waist watchers follow these and other unsafe plans 100 years ago? Probably the same thing that makes dieters embrace fad diets today. “They promise

It’s easy for people to go on fad diets because they don’t involve cutting calories and engaging in exercise. But, these diets are unhealthy and don’t result in permanent weight loss. The best advice includes sound nutritional choices and behavior change provided here by registered dietitians.

By Jill Weisenberger, MS, RD, CDE
quick results,” says Registered Dietitian Heidi McIndoo, MS, RD, author of What to Eat When, which was published this year. Plus, the interesting and mysterious “diet rules” are more exciting than the usual guidance to cut calories and exercise more. One of the wackiest diets with strict rules, McIndoo shares, is the 7-Day Diet. Dieters eat nothing but fruit on one day, vegetables on another, then fruit and vegetables on one day, bananas and milk the next and so on, she explains. This appeals to people looking for a plan that doesn’t require them to make many decisions and to people who are more comfortable taking the word of others over scientific evidence.

In many instances, people feel desperate to lose weight, says New York-based Registered Dietitian Keri Gans, MS, RD, author of The Small Change Diet, also published this year. Some overweight people feel stigmatized, and others fear obesity-related complications. The manufacturers of weight-loss supplements and programs and the authors of gimmicky books know this and appeal to these dieters’ insecurities and desperation. Add to that the chatter and support among Hollywood stars and it’s no wonder people embrace these unsafe and unsustainable plans.

Fad Diets Are Risky

Following a severely restricted diet puts anyone’s immune system at risk, explains Gans, but it’s even more of a concern for individuals with immune deficiency diseases. A good diet doesn’t eliminate whole food groups or saddle individuals with a long list of taboo foods that leave their bodies lacking vitamins, minerals, essential fatty acids, antioxidants and more. Gaping holes in a diet leave gaping holes in the immune system. There is no supplement or diet aid that includes the thousands of important compounds available from a balanced diet rich in fruits, vegetables and whole grains — regardless of the claims manufacturers make.

In addition to leaving individuals open to infections, extreme diets have a host of unwelcome side effects, including muscle loss. It’s not uncommon to lose some muscle when dieting, but the more drastic the diet, the more muscle one can expect to lose, and that can get in the way of physical activity, overall good health and remaining strong during aging.

Beauty also fades. Individuals’ skin may look dull and feel dry, and they may lose hair along with the weight. Hair requires protein, vitamins, minerals and fatty acids, so any unbalanced diet can damage the hair follicle. Additionally, very-low-calorie diets resulting in rapid weight loss shock the body and cause a shift in hormones that trims the hair’s lifespan. The effect isn’t noticeable right away; shedding hair usually occurs several months after the offending diet begins and may continue for several months after the diet improves.

Those nutrient deficiencies and hormonal shifts may be responsible for a lack of efficiency at work and a few more spats at home, too. Poor concentration, irritability, disturbed sleep and fatigue all are common consequences of poor diet.

Gans also warns of gallstones. Rapid weight loss pushes too much cholesterol into bile, causing stones. The gall-bladder fails to empty properly, as well, compounding the problem.

There are no easy ways to lose weight.

Another risk is a financial one. Instead of throwing money away on questionable pills, potions and programs, individuals should invest some time, effort and money in the things that matter: wholesome food, help around the house to free up time for exercise and cooking, a meeting with a registered dietitian to develop a personalized plan, a gym membership and other reasonable steps.

Red Flags of Fads

There are no easy ways to lose weight. “If it sounds too good to be true, it probably is,” warns Gans. Do a “gut check.” If it feels phony, find another diet plan. Use these tip-offs to spot a fad. Steer clear of a plan or product claiming any of the following:

• Eat all you want and lose weight without exercise: To lose weight, you must burn more calories than you consume.
• The program or product works for everyone: Just as some drugs don’t work for everyone, no diet plan or supplement will either. Diets should be individualized to the dieter’s preferences and medical history.
• Calories don’t count: Actually, they do count.
• Drop 10 pounds in one week: Healthful weight loss is about 1 to 2 pounds per week, perhaps a little more initially.
• The weight loss is permanent: Lasting weight loss requires permanent lifestyle changes, including balanced eating and regular exercise.
Additionally, watch out for programs that do any of the following:

- Bases claims on before-and-after photos and testimonials from dieters: Nutrition is a science, so be skeptical if the only “proof” is someone’s emotional story and air-brushed picture.
- Uses words like “breakthrough,” “secret formula” and “miraculous”: Magic bullets and secret cures for weight loss don’t exist. If there were easy ways to lose weight, everyone would know about it.
- Requires one to commit a large sum of money: Be skeptical of expensive, limited-time offers.
- Calls salespeople “health counselors” or “nutritionists”: Unfortunately, in many states, there are no legal definitions for these words, and anyone can claim to be a health counselor or nutritionist.
- Eliminates a large list of foods or whole food groups: Balance and variety are keys to good health, and diets that forbid a large number of foods are difficult to follow for very long.
- Claims to detoxify the body: The best natural cleanse is a diet rich in fiber, fruits, vegetables and water.
- Requires odd food combinations or has a long list of diet rules: The odder the plan is, the less sustainable it is. Once an individual quits following it, they’re likely to gain back the weight.

**Some Popular Diets**

**Cabbage Soup Diet.** Description: Individuals can eat as much as they like as long as they stick to the short list of allowed foods and eat two bowls of low-calorie cabbage soup each day. Weaknesses: It provides inadequate nutrition, it’s monotonous and it doesn’t lead to permanent lifestyle change.

**Cookie Diet.** Description: Along with a low-calorie dinner of about 5 ounces of meat and a large serving of vegetables, several high-fiber, high-protein cookies are eaten each day. Weaknesses: The cookies are used like Slim Fast and other meal replacements. Calorie intake is low to very low, it provides inadequate nutrition and it doesn’t lead to permanent lifestyle change. Furthermore, the emphasis on sweet foods might encourage the desire for more sweet foods.

**Food combining.** Some examples are Fit for Life, The New Beverly Hills Diet and Suzanne Somers’ Sumersizing. Description: They require that individuals eat specific combinations of foods, and other combinations are forbidden. For example, fruit must be eaten before other foods and not for dessert. Some plans prohibit mixing chicken with rice because they claim proteins and carbohydrates shouldn’t be eaten together. Weaknesses: These diets have complex rules that are not based in science and are complicated to follow. The assumption that the digestive tract cannot process mixed foods is false. In fact, most individual foods are a mix of fat, protein and carbohydrate.

**Gluten-free diet.** Description: Avoid all foods that contain gluten, a protein in wheat, rye and barley. Individuals with gluten intolerance or celiac disease, an immune disorder affecting the GI tract, must follow a gluten-free diet. Weaknesses: Though critical for people with celiac disease, a gluten-free diet is not a weight-loss diet. A well-planned gluten-free diet is nutritionally adequate, but individuals who rely on gluten-free cookies and other highly processed foods to keep full will not meet their nutritional needs.

**Low-carbohydrate diet.** Some examples are Dr. Atkins’ New Diet Revolution, The Dukan Diet, Protein Power and The Carbohydrate Addict’s Diet. Description: These plans are based on the premise that eating too many carbohydrates (such as fruits, milk, yogurt, grains, starches and many vegetables) causes obesity. Individuals are encouraged to eat all they’d like of meats, butter, cheese and some vegetables. Weaknesses: These diets provide inadequate nutrition, they are monotonous, they are high in saturated fat and they provide a low intake of the foods shown to help prevent chronic diseases such as cancer, heart disease and diabetes. Some studies show that low-carbohydrate diets impair cognition.

**Individuals should keep a record of what they eat, how much, where, when and how they feel while eating.**

**HCG Diet.** Description: Dieters eat about 500 calories per day and take injections of hC G (human chorionic gonadotropin) — a hormone in the urine of pregnant women. Weaknesses: This diet is severely low in calories, provides inadequate nutrition, doesn’t lead to permanent lifestyle change and there are risks associated with any injection. Many experts question the safety of hormone injections.

**Maple Syrup Diet.** Description: This is promoted as a 10-day cleansing diet meant to rid the body of toxins while losing
10 to 20 pounds. The only food individuals are permitted to have is a beverage made of water, real maple syrup, lemon juice and cayenne pepper. Laxatives are taken while on the program, as well. Over the course of a day, individuals will consume 500 to 800 calories. Weaknesses: This diet is severely low in calories, provides inadequate nutrition, doesn’t lead to permanent lifestyle change, and results in frequent trips to the bathroom and loss of “healthy” bacteria in the GI tract. The body cleanses itself through the liver, kidneys and GI tract, so it does not require a special diet to do so.

**What the Experts Say**

**Write it down.** Individuals should keep a record of what they eat, how much, where, when and how they feel while eating. This will enable them to be able to identify bad habits to change and those that simply need tweaking. “What is a food challenge for one person isn’t necessarily a challenge for the next person, so a food diary allows you to craft your own personalized plan,” says Indiana-based Registered Dietitian Marcia Crawford, MS, RD. The simple act of recording food intake improves eating habits too because individuals become accountable to themselves.

**Slow down.** People need to enjoy their food with all their senses. “Often, we are so on-the-go that we eat too quickly or eat while we are doing something else,” says Rosanne Rust, MS, RD, LDN, co-author of *Calorie Counter Journal for Dummies*. People need to look at their food, take in the aroma, savor the flavor and notice the mouth feel. It’s much easier to satisfy themselves with less quantity when they actually notice and remember the eating experience.

**Take baby steps.** “Get lasting results with small steps,” says Georgia Kostas, MPH, RD, author of *The Cooper Clinic Solution to the Diet Revolution*. “Take 50 calories off each of three meals or snacks,” she suggests. Other smart steps: Decrease or eliminate soda, bake instead of fry, share a meal in a restaurant, eat dessert less often, remove poultry skin before eating, give up second helpings. Individuals can use their food record to help set goals. And they shouldn’t forget exercise. “Add a 15- to 20-minute walk daily,” urges Kostas. Be consistent, and, in time, the pounds fall. “The scale will follow our behaviors,” explains Linda M. Gigliotti, MS, RD, CDE, program director at the University of California, Irvine, Weight Management Program.

**Understand yourself.** Being successful long-term requires individuals to understand what drives their behaviors. “Knowing what to do is the easy part,” explains Washington-based Registered Dietitian Sally Hara, MS, RD, CSSD, CDE. “The difficult part is figuring out why we do what we know we shouldn’t.” Some self-reflection and a good review by individuals of their food record will help them with this.

**Make a lifestyle change.** Permanent weight loss requires permanent behavior changes. Before starting a new diet plan, individuals should ask themselves if they can accomplish those changes in a year, suggests Elisa Zied, MS, RD, CDN, author of *Nutrition at Your Fingertips*. If there are so many difficult rules to follow, it’s clearly not the right program.

**Get the facts.** “Go to reputable sites like the [www.mypyramid.gov](http://www.mypyramid.gov),” urges Registered Dietitian and Food Safety Consultant Toby Amidor. The American Dietetic Association (ADA) at [www.eatright.org](http://www.eatright.org) has a registered dietitian locator. A registered dietitian can answer individuals’ questions, help them assess their current diet and devise a plan just for them. Additionally, the ADA shares the pros and cons of popular diet books ([www.eatright.org/Media/content.aspx?id=6442452237](http://www.eatright.org/Media/content.aspx?id=6442452237)).

JILL WEISENBERGER is a registered dietitian, certified diabetes educator, nutrition and health writer, speaker, spokesperson and culinary expert based in southeast Virginia. Her website, All That’s Nutrition, can be accessed at [www.allthatsnutrition.com](http://www.allthatsnutrition.com).

**Sources**


Introducing

Flebogamma® 10% DIF
Immune Globulin Intravenous (Human)

Shaping the future

Highly purified IGIV
- Trace amounts of IgA: <0.006 mg/mL $^1$
  (specification value: <0.1 mg/mL)
- Very low sodium content
- Sorbitol stabilized

Demonstrated benefits in replacement therapy
- In the pre-approval clinical trial: $^2$
  - 0.025 serious bacterial infections/patient/year
  - Well tolerated: Does not put patients at increased risk for any adverse events other than those that could be reasonably expected in primary immune deficiency patients who are receiving an infusion of intravenous immune globulin

Broad pathogen safety margin
- Seven validated pathogen elimination steps including:
  - 20 nm nanofiltration
  - Dual specific inactivation:
    - pasteurization and solvent detergent
- Highly effective process:
  - $\geq 15.0$ log reduction of PPV (PVB19 model)
  - $\geq 13.3$ log reduction of EMCV (HAV model)
  - $\geq 6.2$ log reduction through 4% PEG precipitation and $\geq 5.5$ log reduction through 20 nm nanofiltration of an experimental agent considered a model for the vCJD and CJD agents $^3$

Please see reverse for Important Safety Information and Black Box Warning.

$^1$ Data on file, Instituto Grifols, S. A.
For your convenience

- Liquid
- Room temperature storage 2-25° C (36-77° F) for the entire 2-year shelf life
- Three presentations: 5, 10 and 20 gram vials

Enhancing our commitment to you

- Every vial is laser etched with its own unique identifier number*, which helps to deter tampering and counterfeiting
- PediGri® On Line, unique to Grifols, offers full traceability from donation to the final product at www.pedigri.grifols.com

Important Safety Information

Flebogamma® 10% DIF is a human immune globulin intravenous (IGIV) that is indicated for the treatment of primary immune deficiency (PI), including the humoral immune defect in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott - Aldrich syndrome.

WARNING: ACUTE RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- Use of immune globulin intravenous (IGIV) products, particularly those containing sucrose, has been reported to be associated with renal dysfunction, acute renal failure, osmotic nephropathy, and death (1). Patients at risk of acute renal failure include those with any degree of pre-existing renal insufficiency, diabetes mellitus, advanced age (above 65 years of age), volume depletion, sepsis, paraproteinemia, or those receiving known nephrotoxic drugs (see Warnings and Precautions [5.2]). Flebogamma® 10% DIF does not contain sucrose.

- For patients at risk of renal dysfunction or failure, administer Flebogamma® 10% DIF at the minimum infusion rate practicable (see Dosage and Administration [2.3], Warnings and Precautions [5.2]).

Flebogamma® 10% DIF is contraindicated in patients who have had a history of anaphylactic or severe systemic reactions to the administration of human immune globulin and in IgA deficient patients with antibodies to IgA and a history of hypersensitivity. In case of hypersensitivity, discontinue Flebogamma® 10% DIF infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for immediate treatment of acute hypersensitivity reactions.

In patients at risk for developing acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine, and urine output. Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving Flebogamma® 10% DIF therapy.

Thrombotic events may occur during or following treatment with Flebogamma® 10% DIF. Monitor patients at risk for thrombotic events, including those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and known or suspected hyperviscosity.

Aseptic meningitis syndrome (AMS) may occur infrequently with Flebogamma® 10% DIF treatment. AMS may occur more frequently following high doses and/or rapid infusion of IGIV.

Flebogamma® 10% DIF may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and hemolysis.

Non-cardiogenic pulmonary edema [Transfusion-Related Acute Lung Injury (TRALI)] may occur in patients following Flebogamma® 10% DIF treatment. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient serum.

All patients, but especially individuals receiving Flebogamma® 10% DIF for the first time or being restarted on the product after a treatment hiatus of more than 8 weeks, may be at a higher risk for the development of fever, chills, nausea, and vomiting. Careful monitoring of recipients and adherence to recommendations regarding dosage and administration may reduce the risk of these types of events.

Because Flebogamma® 10% DIF is made from human plasma, it may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob (CJD) agent. No cases of transmission of viral diseases or CJD have ever been identified for Flebogamma® 10% DIF.

The most common adverse reactions (reported in ≥ 5% of clinical trial subjects) occurring during or within 72 hours of the end of an infusion were headache, chills, fever, shaking, fatigue, malaise, anxiety, back pain, muscle cramps, abdominal cramps, blood pressure changes, chest tightness, palpitations, tachycardia, nausea, vomiting, cutaneous reactions, wheezing, rash, arthralgia, and edema. The most serious adverse reactions observed with Flebogamma® 10% DIF were back pain, chest discomfort, and headache (2 patients); and chest pain, maculopathy, rigors, tachycardia, bacterial pneumonia, and vasovagal syncope (1 patient).

Please refer to enclosed Flebogamma® 10% DIF full prescribing information for full prescribing details, including comprehensive adverse event profile and black box warning.

See the difference today
**INDICATIONS AND USAGE**

Flebogamma® 10% DIF is a human immune globulin intravenous (IGIV) that is indicated for the treatment of primary immune deficiency (PI), including the humoral immune defect in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott – Aldrich syndrome.

**DOSAGE AND ADMINISTRATION**

The recommended dose of Flebogamma® 10% DIF for patients with PI is 300 to 600 mg/kg body weight (3.0 to 6.0 mL/kg), administered every 3 to 4 weeks.

The infusion of Flebogamma® 10% DIF should be initiated at a rate of 0.01 mL/Ag body weight/minute (1.0 mg/kg/minute). If there are no adverse drug reactions, the infusion rate for subsequent infusions can be slowly increased to the maximum rate of 0.08 mL/kg/minute (8 mg/kg/minute).

Ensure that patients with pre-existing renal insufficiency are not volume depleted. For patients judged to be at risk for renal dysfunction or thrombotic events, administer Flebogamma® 10% DIF at the minimum infusion rate practicable, and consider discontinuation of administration if renal function deteriorates.

**CONTRAINDICATIONS**

Flebogamma® 10% DIF is contraindicated in patients who have had a history of anaphylactic or severe systemic reactions to any of its components. It is also contraindicated in patients with a history of IgA deficiency.

**WARNINGS AND PRECAUTIONS**

**WARNING: ACUTE RENAL DYSFUNCTION AND ACUTE RENAL FAILURE**

- Use of immune globulin intravenous (IGIV) products, particularly those containing sucrose, has been reported to be associated with renal dysfunction, acute renal failure, osmotic nephropathy, and death (1).

  Patients at risk of acute renal failure include those with any degree of pre-existing renal insufficiency, diabetes mellitus, advanced age (above 65 years of age), volume depletion, sepsis, paraproteinemia, or those receiving known nephrotoxic drugs (see Warnings and Precautions [5.2]). Flebogamma® 10% DIF does not contain sucrose.

- For patients at risk of renal dysfunction or failure, administer Flebogamma® 10% DIF at the minimum infusion rate practicable (see Dosage and Administration [2.3], Warnings and Precautions [5.2]).

- Weigh the potential risks and benefits of Flebogamma® 10% DIF against those of alternative therapies in all patients for whom Flebogamma® 10% DIF is being considered.

- Before prescribing Flebogamma® 10% DIF, the physician should discuss risks and benefits of its use with patients.

**Hypersensitivity**

Severe hypersensitivity reactions may occur. In case of hypersensitivity, discontinue Flebogamma® 10% DIF infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for immediate treatment of acute hypersensitivity reactions.

**Renal Dysfunction/Failure**

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of Flebogamma® 10% DIF and at appropriate intervals thereafter. If renal function deteriorates, consider discontinue use of Flebogamma® 10% DIF.

In patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure, administer Flebogamma® 10% DIF at the minimum rate of infusion practicable.

**Hyperproteinemia**

Hyperproteinemia, increased serum viscosity, and hypotension may occur in patients receiving Flebogamma® 10% DIF therapy. It is clinically critical to distinguish true hyperproteinemia from a pseudo-hyperproteinemia that is temporally or causally related to hyperproteinemia with concomitant decreased calculated serum osmolarity or elevated osmolar gap, because treatment aimed at decreasing serum free water in patients with pseudohypoproteinemia may lead to volume depletion, a further increase in serum viscosity and a higher risk of thrombotic events.

Thrombotic events may occur during or following treatment with Flebogamma® 10% DIF. Monitor patients at risk for thrombotic events, including those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and known or suspected hyperviscosity.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammapathies, because of the potentially increased risk of thrombosis.

If signs and/or symptoms of hyperviscosity are present after an infusion of Flebogamma® 10% DIF, perform appropriate laboratory testing for confirmation.

If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies and anti-HLA antibodies in both the product and patient serum.

**Hemolysis**

Flebogamma® 10% DIF may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and hemolysis (5-6). Delayed hemolytic anemia may develop subsequent to Flebogamma® 10% DIF therapy due to enhanced RBC sequestration (7), and acute hemolysis, consistent with intravascular hemolysis, has been reported.

Monitor patients for clinical signs and symptoms of hemolysis. If signs and/or symptoms of hemolysis are present after Flebogamma® 10% DIF infusion, perform appropriate confirmatory laboratory testing (see Patient Counseling Information [17]).

**Transfusion-Related Acute Lung Injury (TRALI)**

Non-cardiogenic pulmonary edema may occur in patients following Flebogamma® 10% DIF treatment (11). TRALI is characterized by nonspecific respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Symptoms typically appear within 1 to 6 hours following treatment.

Monitor patients for pulmonary adverse reactions (see Patient Counseling Information [17]). If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies and anti-HLA antibodies in both the product and patient serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

**Infusion Reactions**

All patients, but especially individuals receiving Flebogamma® 10% DIF for the first time or being restarted on the product after a treatment hiatus of more than 8 weeks, may be at a higher risk for the development of fever, chills, nausea, and vomiting. Careful monitoring of recipients and adherence to recommendations regarding dosage and administration may reduce the risk of these types of events (see Dosage and Administration [2.3]).

**Transmissible Infectious Agents**

Because Flebogamma® 10% DIF is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob (CJD) agent. No cases of transmission of viral diseases or CJD have ever been identified for Flebogamma® 10% DIF. All infections suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Biologics at 1-888-474-3657. Before prescribing or administering Flebogamma® 10% DIF, the physician should discuss the risks and benefits of its use with the patient (see Patient Counseling Information [17]).

**Monitoring: Laboratory Tests**

- Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of Flebogamma® 10% DIF and at appropriate intervals thereafter.

- Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammapathies, because of the potentially increased risk of thrombosis.

- If signs and/or symptoms of hyperviscosity are present after an infusion of Flebogamma® 10% DIF, perform appropriate laboratory testing for confirmation.

**Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and O) may cause a positive direct or indirect antiglobulin (Coomb's) test.

**Adverse Reactions**

The most common adverse reactions (reported in a 5% of clinical trial subjects) occurring during or within 72 hours of the end of an infusion were headache, chills, fever, shaking, fatigue, malaise, anxiety, back pain, muscle cramps, abdominal cramps, blood pressure changes, chest tightness, palpitations, tachycardia, nausea, vomiting, cutaneous reactions, wheezing, rash, arthralgia, and edema. The most serious adverse reactions observed with Flebogamma® 10% DIF were back pain, chest discomfort, and headache (2 patients); and chest pain, maculopapular, rashes, tachycardia, bacterial pneumonia, and vasovagal syncope (1 patient).

**Interference with Laboratory Tests**

After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological test results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and O) may cause a positive direct or indirect antiglobulin (Coomb’s) test.

**Table 2. Treatment-related Adverse Events Occurring in <5% of Subjects with PI during a Flebogamma® 10% DIF Infusion or within 72 Hours After the End of an Infusion**
In this study, the upper bound of the 1-sided 95% confidence interval for the proportion of Flebogamma® 10% DIF infusions associated with one or more AEs was 37.8% (total infusions: 208; actual proportions: 34.6%). The average percent of infusions with AEs during or within 72 hours after the end of an infusion for each individual subject was 36.7% and the upper bound of the 1-sided 95% confidence interval was 43.9%.

AE reporting was based upon a clinical protocol precluding pre-medication against AEs. Pre-medication could be utilized only after the first 2 infusions only in those patients that exhibited adverse events.

Forty-three of the 46 subjects enrolled in this study had a negative Coombs test at baseline. Of these 43 subjects, 10 (23.3%) developed a positive Coombs test at some time during the study. However, no subjects showed evidence of hemolytic anemia.

Post-marketing Experience

Because adverse reactions are reported voluntarily post-approval from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to product exposure. The following adverse reactions have been identified during post approval use of intravenous immune globulins, including Flebogamma® 5% (see References [15]).

**Infusion reactions**

Hypersensitivity (e.g., anaphylaxis), headache, diaphoresis, fever, fatigue, dizziness, malaise, chills, flushing, urticaria or other skin reactions, wheezing or other chest discomfort, nausea, vomiting, rigors, back pain, myalgia, arthralgia, and changes in blood pressure

**Renal**

Acute renal failure, failure, osmotic nephropathy

**Respiratory**

Apnea, Acute Respiratory Distress Syndrome (ARDS), Transfusion-Related Acute Lung Injury (TRALI), cyanosis, hypoxemia, pulmonary edema, dyspnea, bronchospasm

**Cardiovascular**

Cardiac arrest, thrombembolism, vascular collapse, hypotension

**Neurological**

Corna, loss of consciousness, seizures, tremor, aseptic meningitis syndrome

**Integumentary**

Stevens-Johnson Syndrome, epidermolysis, positive direct antiglobulin (Coombs) test

**Musculoskeletal**

Back pain

**Gastrointestinal**

Hepatic dysfunction, abdominal pain

**General/Body as a Whole**

Pyrexia, rigors

**Drug Interactions**

Passive transfer of antibodies may transiently impair the immune response to live attenuated virus vaccines such as measles, mumps, and rubella. Inform the immunizing physician of recent therapy with Flebogamma® 10% DIF so that appropriate measures may be taken (see Patient Counseling Information [17]).

**Use in Specific Populations**

**Pregnancy**

Pregnancy Category C. Animal reproduction studies have not been performed with Flebogamma® 10% DIF. It is also not known whether Flebogamma® 10% DIF can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Flebogamma® 10% DIF should be given to a pregnant woman only if clearly needed. Immunoglobulins cross the placenta from maternal circulation increasing after 30 weeks of gestation.

**Nursing Mothers**

Use of Flebogamma® 10% DIF has not been evaluated in nursing mothers.

**Pediatric Use**

Three (3) pediatric patients with primary humoral immunodeficiency (two between the ages of 6 and 10, and one 16 year old) were included in the clinical evaluation of Flebogamma® 10% DIF. This number of subjects is too small to establish safety and efficacy in the pediatric population (see Clinical Studies [14]).

**Geriatric Use**

Use caution when administering Flebogamma® 10% DIF to patients over 65 years of age who are judged to be at increased risk for developing certain adverse reactions such as thromboembolic events and acute renal failure (see Boxed Warning, Warnings and Precautions [5.2]). Do not exceed the recommended dose, and infuse Flebogamma® 10% DIF at the minimum infusion rate practicable.

One (1) patient with primary humoral immunodeficiency at or over the age of 65 was included within the clinical evaluation of Flebogamma® 10% DIF. This number of geriatric patients was too small for separate evaluation from the younger patients for safety or efficacy (see Clinical Studies [14]).

**How Supplied/Storage and Handling**

Flebogamma® 10% DIF is supplied in single-use, individually laser etched vials containing the labeled amount of functionally active IgG.

The following presentations of Flebogamma® 10% DIF are available:

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Fill Size</th>
<th>Grams Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>61953-0005-1</td>
<td>50 mL</td>
<td>5g</td>
</tr>
<tr>
<td>61953-0005-2</td>
<td>100 mL</td>
<td>10g</td>
</tr>
<tr>
<td>61953-0005-3</td>
<td>200 mL</td>
<td>20g</td>
</tr>
</tbody>
</table>

Each vial has an integral suspension band and a label with two peel-off strips showing the product name and lot number.

**DO NOT FREEZE.**

When stored at room temperature (up to 25 °C [77 °F]), Flebogamma® 10% DIF is stable for up to 24 months, as indicated by the expiration date printed on the outer carton and container label.

Keep Flebogamma® 10% DIF in its original carton to protect it from light.

Manufactured by INSTITUTO GRIFOLS, S.A.
Barcelona - Spain
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Understanding Hereditary Angioedema

By Ronale Tucker Rhodes, MS

HAE is a life-threatening disease that is difficult to diagnose, and only recently has medication been approved by the FDA to treat it. Yet, even with these new treatments, the disease continues to plague patients, so learning how to live with the condition is imperative.

The blog is titled “Di Has Stories... (and they’re all true).” Diana won’t reveal her last name because she doesn’t want her “students finding me like they did on Facebook.” But she does provide some details about herself. She’s 35, and she’s spent the last “15 years being beaten down by a disease” that has caused her to be “too sick.” According to Diana, she has been too sick to go out with friends, too sick to wear certain clothes and shoes, too sick to make plans for the future in case she has to cancel them, too sick to travel, too sick to get in shape, too sick to take up hobbies, and in 2008, she...
became too sick to work. After nine years of living with a mysterious illness, she was diagnosed at the age of 29 with hereditary angioedema (HAE).

What Is HAE?

HAE, a rare and potentially life-threatening genetic condition that occurs in approximately one in 10,000 to one in 50,000 people in the U.S., is an immune-mediated disease that is often treated by immunologists. HAE is caused by an autosomal dominant disorder of C1 inhibitor (C1-INH) deficiency. There are three types of HAE. Type I HAE occurs when there are low plasma levels of a normal C1-INH protein. Type II HAE occurs when there are normal or elevated levels of a dysfunctional C1-INH. Men and women are equally affected with HAE types I and II. Type III HAE has been recently identified as an estrogen-dependent inherited form of angioedema occurring mainly in women with normal functional and quantitative levels of C1-INH. Diana has type III HAE.

Typically, HAE is hereditary because the genetic defect is passed on in families, which is why the disease is so named. If one of a child's parents has HAE, the child has a 50 percent chance of inheriting it. However, 20 percent of HAE cases are not hereditary. Instead, they are a result of a spontaneous mutation of the C1-INH gene at conception. Diana’s HAE is not hereditary. According to Diana, she is a “mutant, meaning that I have no family history of HAE … [but] I am not as alone as I thought I was.”

Diagnosing HAE

It is common for those with HAE to remain undiagnosed for years. Symptoms of HAE include episodes of edema (swelling) in various body parts, including the hands, feet, face and airway — all of which are both disfiguring and disabling. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that are caused by swelling in the intestinal wall. Unfortunately, frequent and severe abdominal pain is often inappropriately diagnosed. Oftentimes, patients undergo unnecessary exploratory surgery, and in many cases, physicians diagnose abdominal pain as psychosomatic. Undiagnosed HAE also has been known to result in narcotic dependence.

For type I HAE and type II HAE patients, symptoms usually become apparent in the first or second decade of life. Approximately 40 percent of people with HAE experience their first episode before age 5, and 75 percent before age 15. Type III HAE, however, is not found until the second decade of life or later and occurs only rarely before puberty.

There are some clinical characteristics that should lead a physician to suspect HAE. These include attacks that may be preceded or accompanied by a nonpruritic, flat, erythematous mottling (redness of the skin where swelling occurs) or erythema marginatum (pink rings on the trunk and inner surfaces of the arms and legs); prolonged attacks that increase over the first 24 hours and then slowly subside over the next 48 to 72 hours before full resolution; periods when swelling does not occur for several weeks or more after an attack; and failure of attacks to respond to treatment with epinephrine, antihistamines or corticosteroids.

However, clinical characteristics of HAE must be confirmed by laboratory tests that will confirm a C1-INH deficiency. According to Professor of Medicine Bruce L. Zuraw, a physician/researcher at the University of California at San Diego, patients should be initially screened by measuring complement C4 antigenic levels, which are typically low even when patients are not swelling and, in most cases, low during a swelling attack. If the C4 level is decreased, or if the level is normal but all of the clinical characteristics are met, C1-INH antigenic and functional levels should be tested. And, because the test for C1-INH function used in the U.S. is insensitive and may be inaccurate, it is recommended to repeat the C4 and C1-INH functional levels during an HAE attack. In addition, patients who have no family history of HAE and report onset of symptoms in the fourth decade of life should be screened for acquired angioedema by testing the C1q component.
Patients needing assistance with an HAE diagnosis can get help locating doctors in their area who treat HAE patients. This list is available from the U.S. Hereditary Angioedema Association (HAEA) by contacting Michelle Williamson, director of patient services and clinical programs, at michellewilliamson@haea.org or (972) 814-5205.¹

**Treating HAE**

Prior to 2008, HAE patients were prescribed anabolic steroids to treat HAE. But, while they were shown to be useful, they were not well-tolerated by many women, and they were directly linked to liver toxicity and caused an increase in cholesterol levels. Plus, they were unable to be used to treat children.²

Then, in late 2008, Cinryze, a C1-inhibitor for preventing HAE attacks in teenagers and adults, was approved by the FDA. Manufactured by ViroPharma Inc., Cinryze is administered intravenously and is approved for home infusion. In late 2009, the FDA approved Berinert to treat acute facial and abdominal attacks in HAE patients. Manufactured by CSL Behring, it also is delivered intravenously. Shortly thereafter in 2009, the FDA approved Kalbitor to treat sudden and potentially life-threatening fluid buildup that can occur in patients 16 years and older with HAE. Kalbitor is manufactured by Dyax Corp., and unlike the other two drugs, it is administered through subcutaneous injections.³

There also are two other HAE therapies that are under investigation. Firazyr, manufactured by Shire HGT, is an acute attack therapy that is administered subcutaneously and is already approved in Europe. Shire filed a complete response to the FDA in February based on positive results from its FAST-3 study and an ongoing self-administration study, as well as the previously published FAST-1 and FAST-2 studies. Rhucin, from Pharming Group NV, is a recombinant human C1 inhibitor protein that is derived from the milk of genetically altered rabbits. Pharming is in the process of applying for a U.S. license for Rhucin.⁴

There are some medicines that HAE patients must avoid, including ACE inhibitors and estrogen-derived medications (birth control pills and hormone replace-

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**Social Networking Sites for HAE Patients and Their Families**

- **All About HAE** (www.allabouthae.com/consumer)
  
  All About HAE is a community for patients and family members with HAE that provides resources and tools to manage and treat an HAE attack.

- **Canadian Hereditary Angioedema Network [CHAEN]** (www.haecanada.com/m.php?p=ehome)
  
  CHAEN is dedicated to increasing awareness of issues affecting care and treatment of HAE patients, encouraging peer support and information sharing, and encouraging research that will continue to improve care and result in a cure for HAE.

- **HAE and Me** (www.haeandme.com)
  
  This online community, launched by ViroPharma Inc. in March, unites teens and adults with HAE through shared experiences to help them better manage their disease. It features information about HAE, video stories, firsthand tips from patients, and expert advice about living with the disease.

- **HAE Hope** (www.haehope.com)
  
  HAE Hope helps patients and loved ones cope with HAE through helpful tips and information about living with HAE.

- **HAE International Patient Organization** (www.hai.org)
  
  HAI is a global organization established to promote cooperation, coordination and information sharing between HAE specialists and national HAE patient associations in order to help facilitate the availability of effective diagnoses and management of C1 inhibitor deficiencies throughout the world.

- **U.S. Hereditary Angioedema Association** (www.haea.org)
  
  HAHA is a nonprofit patient advocacy organization dedicated to serving persons with angioedema resulting from C1-Inhibitor deficiency.
ment drugs), which increase the frequency and intensity of HAE attacks. The list of ACE inhibitors to avoid include captopril (Capoten), benazepril (Lotensin), enalapril (Vasotec), lisinopril (Prinivil, Zestril), fosinopril (Monopril), ramipril (Altace), perindopril (Aceon), quinapril (Accupril), moexipril (Univasc) and trandolapril (Mavik).  

Living with HAE

Most patients with HAE are able to successfully manage their condition. Nevertheless, HAE is a chronic disease. The severity of the disease, as well as the frequency, type and timing of HAE attacks, vary widely among individuals. And, the pattern of attacks can be inconsistent within any given person, such as having greater or fewer episodes during one life stage compared with another. According to Diana, “I am both in better shape than I thought, and in worse shape than I thought.” She explains that while other HAE patients seem to have more severe attacks to their face and throat more often than she does, she has more overall attacks than normal.

For adults, the key to managing HAE lies in recognizing the specific conditions that trigger attacks and how to handle them. For instance, attacks can be triggered by physical or emotional stress, a change in hormonal levels, and as a result of other medications. For children, the key lies more in communicating with first responders at school and other locations so that they will know what to do when a child with HAE has an attack. It’s also a wise idea for children to carry a patient information card with them. For teens, the key is to gradually shift the responsibility for managing their condition from the parents to themselves. This means being able to recognize personal triggers and warning signs, as well as to understand how to deal with the attacks.

While HAE attacks mostly occur suddenly and without warning, some patients are able to recognize the early signs of an attack known as prodromal symptoms. Patients may notice sudden mood changes, rash, irritability, aggressiveness, anxiety, extreme fatigue or a tingling sensation of the skin where the swelling will begin. And, these symptoms may occur minutes or hours before an attack, or they may occur a day or two before a full attack begins. The most serious attacks are intestinal swelling and throat swelling, both of which require immediate medical attention. In fact, an estimated 15 percent to 33 percent of HAE patients will die as a result of laryngeal edema and asphyxiation.

The Future of HAE?

In October 2008, Diana attended the U.S. HAEA National Conference. She said she learned that “the quality of life for people with HAE, statistically, is less than that of people with diseases such as Crohn’s. I’d once heard that our quality of life is comparable to that of a cancer patient.” But, recently, she started taking thyroid medication for “chronic hiving, itching and swelling … And, lo, I have not had an attack since I started thyroid medication.” Diana says she’s lucky. “The people [whom] I’ve met with this disease are far more incapacitated than I ever was by it. They will never see a way out. There is no cure, only imperfect, expensive and life-consuming treatment.”

There may not yet be a cure for HAE, but at least now there is treatment. And, with the research being conducted in the area of gene therapy, it is hoped that, one day, there will be a cure. Until then, HAE patients need to ensure they are in the care of physicians experienced in the management of this rare condition, seek out support groups to stay connected and informed (see the sidebar listing social networking sites) and know that they can learn how to individually manage their condition.

RONALE TUCKER RHODES, MS, is the editor of IG Living magazine.

References

Christina: I was diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP) in June 2000 at age 18. Since then, I have received intravenous immune globulin (IVIG) treatments at increasingly spread-out intervals. I now receive treatments once every 12 weeks. I recently got married and my husband and I are considering starting a family. However, I am concerned about how IVIG treatments and CIDP may affect pregnancy. Through my research, I discovered IVIG is considered a category C drug, which means the medical community is unsure whether IVIG will cause harm during pregnancy. Are there case studies of women who have CIDP and have received IVIG treatments during pregnancy?

Kris: Congratulations on your marriage and best wishes on starting your family. I found little research on pregnancy and CIDP. However, articles on the subject did say that pregnancy increases the risk of a CIDP relapse.

In the August 2007 issue of IG Living (pages 14 and 15), we addressed some issues with IVIG, pregnancy and breastfeeding for women with common variable immune deficiency (CVID). This article highlights one mother who had two pregnancies while receiving IVIG. And, although CVID is not the same disease as CIDP, it still might help you to formulate questions to ask your doctor. To access that article, go to www.igliving.com and click on magazine and past issue archive.

I also asked Dr. Todd Levine of Phoenix Neurological Associates to respond to your question.

Dr. Levine: This is a very complex case, and it is better if you discuss these issues with your doctor. We do know that steroids (prednisone or Solu-Medrol) are safe to take during pregnancy. However, the other oral medications (azathioprine, mycophenolate, cyclosporine) should be avoided at all costs. Although there have been no studies concerning IVIG and CIDP, we do believe that receiving IVIG therapy during pregnancy is safe. In fact, infertility doctors will sometimes use IVIG if a woman has antibodies against sperm to help with fertility. So, IVIG can be a very valid choice if you need therapy during pregnancy.

Receiving IVIG therapy during pregnancy is safe.

Mark: Is it true that Medicare will only pay for the Freedom 60 pump for subcutaneous immune globulin (SCIG)? I have been using another pump and would like to continue to do so once I become eligible for Medicare, but my homecare provider says that they cannot get paid by Medicare for any other pump than the Freedom 60.

Kris: In June 2007, the Centers for Medicare and Medicaid Services (CMS) issued a statement announcing that the Freedom 60 infusion pump is the only allowable pump for the administration of SCIG therapy. Providers who chose to upgrade the pump to a more expensive option could do so and still attain partial payment that was no greater than the allowable amount for the Freedom 60 pump.

However, on December 16, 2010, CMS instructed CMS Durable Medical Equipment Medicare Administrative Contractors (DMEMAC) that as of February 4, 2011, CMS will no longer make partial payments for such claims unless the item submitted for reimbursement is the least costly alternative (LCA). Furthermore, if a provider bills for an item other than the LCA, the entire claim, including the drug, will be denied as not medically necessary. This change applies to all claims for which the date of service for the initial rental month is on or after February 4, 2011. Subsequent claims with a determination LCA prior to that date will continue to be adjudicated using the LCA determination of that rental period.
HAVE YOU EVER looked at someone and seen a little speck of glitter on their nose or in their hair? They have no idea that it is there, and they go on with their daily activities while the glitter keeps sparkling. Yet, we know the glitter is there, and it’s all we can stare at. We wonder: Should we tell them about it? But, we don’t; we ignore it, because we know that such a small piece of glitter isn’t easy to just wipe off — it usually ends up somewhere else.

People like me with chronic illnesses have glitter on our faces all the time. Our glitter is our illness and it sparkles all the time. On most days, it goes unnoticed. Then there are days when it hits the sunlight just enough to be faintly seen. And then there are days when the glitter is sparkling so brightly that it can’t help but be noticed by everyone.

I try my best to stay out of the sun so the sparkle from my glitter is kept to a minimum. But that isn’t always realistic. After all, I’m not always aware of the way the light is hitting me at any given moment, just as I can’t always help it if my illness acts up and tires me or makes me feel run down. My glitter has a mind of its own. Sometimes a glint of it can be seen in the dimmest light and, other times, it can blind me! Its prominence fluctuates.

Last week, I could be seen glowing from down the street. And, I admit, I hid. I didn’t get out of bed for five days. It was all I could do to cope with the blinding glare. Then, eventually, it dimmed, and I was ready to get back out there.

Because my illness is usually invisible to those around me, it is noticed when I let it go around the edges. If I am tired, I tend to sparkle much brighter. Sometimes, I forget that I need to take things a little slower than others and I run myself into the ground. On those days, I may as well have rolled myself into a second-grade classroom on arts and crafts day, because there is absolutely no hiding the fact that something is wrong with me.

Should those of us with chronic illnesses hide from the light? If we do hide, does it mean that we are living in fear of our glitter sparkling too brightly? Or, should we embrace the light and let our glitter shine for everyone to see? After all, there is no brushing it off, so why not accept what makes us shine? Yes, I know. It’s a positive outlook. But let’s face it: If we aren’t optimistic about our glitter on the outside, then our insides will go dim.

EVER FECSKE was diagnosed with CVID and interstitial lung disease in 2004. She is a fashion design student, loves spending time with her fiancé, family and bulldog, Dunkin, and can’t get enough of writing, cake decorating and anything that sparkles!
For the McGivney family, it all began with a limp. Tami McGivney first noticed her son Dylan might be ill when he was just shy of 4 years old. It was late summer, and Dylan’s grandparents commented that his leg seemed to be bothering him; they encouraged Tami to have him seen by his pediatrician. “I asked Dylan if he had any pain or had fallen at school or at home, and he said no,” recalls Tami. Concerned, she made a doctor’s appointment the following week, and so began her journey toward a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP). CIDP is a rare disorder of the peripheral nerves characterized by gradually increasing weakness of the legs and, to a lesser extent, the arms. It is caused by damage to the myelin sheath, an insulating layering that covers the nerves. It can start at any age and occurs in both genders.

**Trudie:** Tell us how Dylan was diagnosed.

**Tami:** I took him to his pediatrician and they referred me to a pediatric orthopedic specialist. The orthopedic doctor took several X-rays of his hip, knee and leg. He said everything looked great, and then referred me to a pediatric neurologist. As a pediatric licensed practical nurse (LPN), I instinctively knew I should take him to Children’s Hospital of Philadelphia (CHOP) so he would get the best possible care. After several neurologists came in to look at him, they couldn’t figure out what was wrong, so we waited for the head of the neuromuscular program, Dr. Richard Finkel, and it was worth the wait. When we first saw the doctor, I had a great feeling of relief because he listened to what we had to say as parents. His expertise led us to three primary neurological diagnoses, one being CIDP. After tests were conducted the next month, including a nerve conduction test and electromyography (EMG), Dr. Finkel was almost positive it was CIDP. But Dylan had a biopsy and lumbar puncture to confirm his diagnosis. Then, he was admitted to the hospital for his first intravenous immune globulin (IVIG) therapy.

**Trudie:** How did Dylan respond to his infusions?

**Tami:** The first time he got an infusion, he was pretty good, as long as he didn’t look when the nurse put the needle in. He said, “Cover my eyes and don’t let me peek.” He has an IV pump and it is in a little black bag with a shoulder strap, so he is perfectly mobile. He thinks it’s cool to walk from room to room with the pack across his chest. “I can do it by myself!” he says all the time.

**The advice I would give for parents of a child with any unexplained or chronic illness is to stay focused, try not to get overwhelmed and just take it one step at a time.”**
the time, so my husband and I back away. He gets a little tired since we premedicate him with Tylenol and Benadryl to make him more comfortable and to avoid any itching or rashes. But kids are resilient, and Dylan has a very confident way about himself. He has been a trooper so far.

**Trudie:** How long do his infusions take?

**Tami:** The infusions last about five hours each time. Sometimes he falls asleep, and other times, we rent special movies to watch. I want him to be calm and not running around. We also read some books and do puzzles.

**Trudie:** Any side effects?

**Tami:** The side effects have been pretty mild. The first couple of times with IVIG therapy, he got headaches, nausea and vomiting after the first day or so. They have since slowed the rate down, so it is much better. The doctor and nurse work very well to minimize the side effects. Dylan is so independent. Once, I went down the hall and the nurse had already left and he was in his room with his garbage pail telling me that he just threw up but he was OK. He seems to adjust to just about anything, not being too dramatic about it, which is nice.

**Trudie:** The diagnosis process can be difficult. What advice do you have for other parents?

**Tami:** The advice I would give for parents of a child with any unexplained or chronic illness is to stay focused, try not to get overwhelmed and just take it one step at a time. You need a good doctor/patient relationship, and finding a doctor who will listen is critical. Also, always write down your questions and ask them, even if they sound stupid.

**Trudie:** Have you had any insurance challenges?

**Tami:** Financially, we have been very fortunate that we do have a good plan that covers 100 percent of all supplies and treatment with no maximum limit. The IG medication is so expensive — $10,000 every time.

**Trudie:** You have another child. How has this impacted your family?

**Tami:** Dylan’s older brother, Aidan, age 9, is extremely protective and compassionate. He is involved in every aspect of his brother’s treatment. Although he is in school most of the time while Dylan’s treatments are being administered, he kisses him goodbye and always says: “Good luck with your treatment today, and I’ll see you after school.” We are very open and tell both of them exactly what is going on so we can work together as a family. Friends and family have been nothing but supportive in our long journey with his illness. While my husband, John, and I were both in the hospital with him for several days, everyone stepped up to watch Aidan and to make him feel comfortable and safe while we were away. And, when we have to venture to Philadelphia Children’s Hospital or have testing done, they are always there for us. We have an excellent support system.

**Trudie:** What has been your greatest triumph?

**Tami:** Our greatest triumph would be getting through every month and Dylan getting stuck for the IVIG therapy. Now he’s a pro!

**Trudie:** What have you learned about yourself and your family through this?

**Tami:** We learned that if we keep a positive attitude and work together as a family, we can accomplish anything.
SOMEONE RECENTLY ASKED me if I take liberties when writing my articles for IG Living. Scratching my head and deep in thought, I responded: “I’m the kind of person who tries to see humor in everything.” Did I dodge the question?

Maybe. In fact, I think telling the truth, the whole truth and nothing but the truth (when it comes to my articles) is like asking Mickey Mouse for a back-lot tour of Disneyland; it’d spoil the magic and wonderment of the “Happiest Place on Earth”!

It’s not lying, necessarily; it’s more like an exaggeration of life’s events. I "rewrite" calamity into hilarity. I take the normal, everyday occurrence and make it, I think, funny.

How does this humor happen? Sometimes humor finds me, so I don’t
have to work too hard at it. For example, when preparing for this column, I consulted Merriam-Webster for its take on the word “humor.” According to this source, humor is defined as, among other bodily functions, “one of the four fluids entering into the constitution of the body and determining by their relative proportions a person’s health or well-being.” Isn’t it hilariously wacadoodle that the definition of humor isn’t funny!

On the other hand, being a caretaker of three primary immune deficiency disease (PIDD) kids and a freshly diagnosed PIDD patient myself, not everything is funny. In fact, I have days that I find it hard to laugh at anything. On those days, my funny bone isn’t ticklish; it aches from the sting that arthritis and cool weather patterns bring. Even if something is funny, like my backing into a parked hearse, I’ll let it marinate and then crack up. Like this:

It is a well-known fact that I don’t like going to the mailbox. Every day, I am inundated with bills on top of bills. And if I don’t get a bill, I get a “pre-bill,” better known as an explanation of benefits (EOB) from my insurance company. Then, I grip both ends of the envelope, shake it and with clenched teeth cry, “I don’t need a reminder that our family suffers with multiple chronic conditions!”

Recently, I received what I thought was an EOB, but it was outlined with red lettering that read “Do not discard.” It was one of those days when I felt like a human barometer and I was quite sure my innards were having a heated argument over which of them wanted to make me the sickest. The rebellious side of me really wanted to shred the letter on the “slow death” setting, but I decided my financial future might be in deep doo-doo if I didn’t heed the warning inscribed on the letter.

I thrust the blade of the sharpest steak knife I owned deep into the belly of the letter, skimming the edge of the delicate paper, avoiding pertinent information within. I flipped open the letter hoping to find an invitation to order the latest in men’s fashions or to take a whiff of a pricey perfume, neither of which happened.

It’s a good thing I opened the letter; it was from a collection agency (read: Oh fudge! but with an “R”-rated attitude).

Now, I’m uber-organized when it comes to our family’s medical stuff. I have manila folders for my manila folders, if you get my drift. With four chronically ill people under one roof, I am forced into being organized, whether I want to or not! So receiving such a letter really put a damper on my day. To add to the problem, I didn’t get just one letter, but two others!

“How could I have missed three medical bills in a row?” I yelled at myself! Distraught, I showed my husband, Mark, the three thorns in my side. One look my way as I thrust the letters into Mark’s hands told him these were not happy notes.

“Who is Donndelle Collections? Don’t you keep really sharp tabs on our medical stuff?” Mark asked as he read the letterhead.

“Yeah! You bet I do! This has me so spittin’ mad right now! How dare someone send us to collections! This is ridic…” I continued on, getting angrier with every second. And just when I was revving up to say something I’d probably later regret, Mark’s giggling saved me from blowing a fuse.

“What’s so funny?” I asked, wiping my brow.

Mark pointed to some numbers at the bottom of the first page.

I couldn’t believe what I was reading.

“This has to be a mistake,” I fumbled my words like a quarterback trying to gain control of the football after a bad snap. There they were in plain daylight:

This account has been assigned to our office for collection for $1.82.

“A dollar eighty two! Is this for real?” I squealed with delight.

And it got better. The other two charges were $8.97 and $4.18!

Come to find out: My former hospital was acquired by another and its computer system booted me and a whole lot of other patients to its collection agency. They apologized for the mix-up and took care of the bill for me, which was legit. Talk about nickel and diming a person, sheesh!

So whether the content of my articles need a little humorous bent or they come to me pure as the driven snow, I try my best to enjoy the ride.

Even if my ride is the passenger seat of a tow truck hauling my SUV after that hearse incident. ☺
THERE IS NO better education than personal experience. But sometimes, personal experience comes at a great cost. When Eric Weintraub was just 2 years old, serious health issues began to taunt him. His health conditions were not those of a typical 2-year-old, because they developed into something much more serious — more severe and more uncommon than what typically plagues small children. By the time Eric turned 20, he had been diagnosed with autoimmune hemolytic anemia and pure red cell aplasia, as well as deep vein thrombosis (DVT). Early on, his doctors began to give him low-dose infusions of immune globulin (IG) therapy.

2004 Was a Big Year

In 2004, at the age of 20, Eric was in his third year at the University of Miami working toward his degree in music. Up until this time, his medical conditions had been under control. However, during summer vacation in Florida, Eric says, “I had a relapse of my DVT and hemolytic anemia and went into septic shock,” while several hundred miles away from his hematologist. Eric’s New York-based parents had to fly down to Florida in order to be with their very sick son. After an emergency trip to the hospital and a period of recovery, Eric says, his “parents requested that I attend a different university, one that was no farther than one hour away from my hematologist.”

Eric acquiesced and left Miami to attend Rutgers University in New Jersey. Within five years, Eric graduated with his Bachelor of Arts degree in sociology. During this time, Eric had a major turning point in his life. Still in 2004, after his frightful emergency room episode, Eric underwent some more testing to see if something else might be wrong. He says that his “doctors diagnosed me with common variable immunodeficiency (CVID) and immunodyregulation polyendocrinopathy enteropathy X-linked syndrome (IPEX).” Eric’s doctors wanted to start him on IG therapy. He informed them that he had been given low doses of IG since he was a child. After this disclosure, Eric says his doctors told him that the gamma globulin was probably “the only thing keeping me alive.”

Something else important happened in 2004. Facebook, the social networking service, got its start. Eric, a self-proclaimed techie, was naturally drawn to the Facebook communication platform. So, in 2004, he started the Common Variable Immunodeficiency (CVID) Facebook group. Eric says that he started his Facebook group “because I wanted to see who else had CVID, because it’s not a common disease.” He also was curious to see just how common, or uncommon, this illness really was. For Eric, the CVID Facebook group was a “way to connect with people who also have my diagnosis.” He says that he “just wanted to see what would happen. Would many people, or anyone, join my group?” Well, seven years and 1,110 members later, Eric made the right choice in creating a group devoted to a condition that is unknown to most people.

Knowledge, Comfort and Camaraderie

Eric didn’t just start his CVID group for his own benefit. He knew that if he had questions about his new diagnosis, so would others who share the same illness. Eric was right. People from
People from around the world visit his CVID page “to share their … insight, help and experience, [as well as] what they are going through at that moment and get feedback from others with the disease.”

Patients who have recently been diagnosed with CVID also find the page devoted to their illness to be educational. Another member commented that the CVID group had given her more knowledge about living with this disease than any doctor had been able to offer her in nearly a year. Just as Eric started the Facebook group to “learn about the disease and find out how common it was,” those newly diagnosed visit for the exact same reasons.

And, they find out one of the best pieces of information they’ll ever learn: They are not alone. According to Eric, his Facebook group has helped CVID patients “connect and find other people with this rare disease, and allows everybody to see they are not alone; [they are not] the only people with these issues. Also, it allows people with the disease to find people close to them in the same state or area, and connect with each other if they want to become closer. Finally, it allows patients to share their experiences with the disease, both good and bad.”

**IDF Connection**

In June 2009, Eric attended the Immune Deficiency Foundation (IDF) National Conference at Walt Disney World in Orlando, Fla. He says that while he was at the conference, he was able to “meet a lot of people,” and also introduced himself as “the guy who started the [CVID] Facebook group.” That got him immediate recognition, and he soon became fast friends with many other CVID patients in attendance, several of whom were already fans of his page.

Eric always makes sure to ask people: “Are you on Facebook? Join the group! Meet other people who share your experiences.”

This year, Eric and many other IG patients had planned to attend the IDF National Conference in June in Phoenix, Ariz. ■

**CARLA SCHICK** is a staff writer for IG Living magazine.
Eating for Life: Healthy Weight Management For Immune Deficiency

There is no magic supplement or food that will enhance an immune-deficient individual’s immune system, but a healthy lifestyle that includes good food choices that help to maintain a healthy weight can help people live healthier.

By Mark T. Haggard

WHEN MY DAUGHTER was a toddler with common variable immune deficiency (CVID), she was struck with respiratory syncytial virus (RSV). One of the side effects of RSV is acute diarrhea. Someone reported to my wife that diarrhea can be controlled by eating clay. It had not occurred to me that common backyard dirt was a simple prescription to ease the effects of primary immunodeficiency (PIDD). Nevertheless, I did not test that theory. I stuck to the wisdom that had been passed down from our immunologist. After being rehydrated with intravenous fluids and a few rounds of antibiotics, my daughter was once again healthy.

On another occasion, my wife was at church explaining our son’s immune deficiency to whom it seemed was an interested soul. It turned out that she was the local distributor of “Immuno-Gummies,” flavored immune system boosters. She offered us a year’s supply for $49.99, which is $15 off of the suggested retail price!

There are several perspectives out there about what people can do to enhance their immune system, including consuming clay and supplements. But, the truth is, the best thing all people can do is maintain a healthy weight by living a healthy lifestyle that includes good food choices.

The Medical Perspective

The alternative medicine website, altMD.com, suggests several nutrients that can be added to a person’s diet to promote better immune health. A diet rich in vitamin C increases production of white blood cells and levels of interferon, the antibody that coats cell surfaces and prevents the entry of viruses. Vitamin E stimulates the body’s production of killer cells and enhances the production of B cells. Omega-3

What is best for immune-compromised individuals is what is best for the public as a whole: healthy weight maintenance.
fatty acids increase the activity of phagocytes, the body’s first defense against infections. Garlic stimulates the production of white blood cells and killer cells. And, diets high in zinc increase production of white blood cells and boost killer cell activity, while selenium increases the production of killer cells.

Dr. Neil Kao, a fellow of the American Academy of Allergy, Asthma and Immunology, is not so sure about altMD.com’s suggestions: “Much is written in the lay press and medical literature about foods that may be good for our immune system,” he warns. “Nothing is fact.” As a medical professional, Dr. Kao cites clinical tests, which show that there is no magic food to protect our immune systems. What is best for immune-compromised individuals is what is best for the public as a whole: healthy weight maintenance.

Body mass index (BMI) is an indicator of healthy weight management; it is calculated by dividing weight (in kilograms) by height (in meters). Optimum BMI is between 19.0 and 24.0. But even healthy weight maintenance is a non-issue: “There is no known effect of obesity on immune deficiencies,” states Dr. Kao. Being overweight might cause unnecessary stress on the heart and kidneys, but it will not do any more damage to the immune system than has already been done. The same is true of those who are below their ideal body mass. “That being said,” he adds, “it is my opinion that those who live a good lifestyle (exercise routinely, eat a low-fat and low-salt diet, don’t use tobacco products, drink alcohol, at most, mildly) are more likely to live longer.”

**The Nutritionist Perspective**

Knowing that there may be no particular food that will enhance compromised immune systems, and knowing that bodies will operate best within their appropriate body mass, what should a diet look like for PIDD patients? There are numerous myths and diets, as well as late-night television infomercials selling the next best diet plan, but according to Dr. Jill Weisenberger, there is no “best diet.” Weight management is simply a matter of calorie reduction. “Write your own diet book that works for you,” she says. But keep in mind that a reduction in the wrong kinds of calories has the potential to wreak havoc on the body. The optimum is to eat 1,800 calories per day, but 1,800 calories in the form of lollipops is a terrible idea.

Dr. Weisenberger warns that there are numerous “myths” floating around American society about how to best lose weight. For the most part, they are just that: myths. Some people believe that they can control their weight by skipping breakfast. This tends to create a false belief that a person can eat more calories later on. Many people who skip breakfast or lunch end up eating nonstop from 5 p.m. in the evening until bedtime. There is another myth that eating before bed will cause weight gain. According to Dr. Weisenberger, “The body doesn’t care how late we eat.” Five p.m. to 11 p.m. is a long time, though; if you are hungry, you should eat. “Eating late might interrupt your sleep,” she says, “but it will not make you fat.”

Another weight-loss tactic has been to eat six small meals during the course of the day, rather than three large meals. Dr. Weisenberger suggests that eating six meals instead of three affords people six opportunities instead of three to overeat. For overweight men, she found that eating three large meals during the course of the day improves appetite control; men feel satiated after a large meal. Her conclusion is that there is essentially no benefit to frequent eating.

Much of eating is psychological. According to Dr. Weisenberger, “We don’t listen to our stomachs, we listen to our senses.” One suggestion impacting our eating psychology is to use a small plate rather than Grandma’s monster platter. In most cases, we will only eat a portion that is the size of the plate. Dr. Brian Wansink of Cornell University and author of *Mindless Eating: Why We Eat More Than We Think* invited a...
num ber of his friends to ice cream at a local parlor, indiscriminately giving different sized bowls and scoops to his guests and inviting them to serve themselves. Those guests receiving the biggest bowls served themselves the biggest portions. Those receiving the smallest bowls served themselves the smallest portions. His conclusion was that smaller plates are a cue to the brain to take smaller portions. A similar test group met at a restaurant for hot wings. For one group, the server took the bones away with each new platter; for the other group, the server left the bones at the table. The group that had the bones left at its table ate substantially fewer wings—the bones being a visual cue for eaters to not eat so much.

Is there anything that will curb our eating at meal time? Research by Dr. Barbara Rolls of Penn State University and author of The Volumetrics Eating Plan has shown that eating low-calorie vegetables or a low-calorie salad or soup prior to an entrée will cut caloric intake during the rest of the day.

Dr. Weisenberger offers a simple model for a well-balanced, low-calorie meal: Divide a 9-inch plate into a quarter, a quarter, and a half. Fill the half of the plate with non-starchy vegetables. Fill one quarter with protein-rich foods and the other quarter with starchy foods.

While Dr. Weisenberger does not advise avoiding any particular foods, she does suggest limiting intake. For those with a craving for salty snacks, her suggestion is a 1-ounce serving of salted nuts, but a 1-ounce serving of chips, crackers or pretzels are OK, too. She also suggests pairing salty snacks with something else, like a few vegetables. Using the idea of visual cues, she advises eating nuts that have to be shelled, since a pile of shells will show how much of your snack you have eaten. Those with a sweet tooth should have a small amount of whatever they want—1 ounce—as long as they have no other dessert during the course of the day. Dr. Weisenberger likes dark chocolate best. Other suggestions are dried tart cherries or fruit dipped in chocolate, caramel or non-fat Greek yogurt.

Dr. Kao offers his own suggestion for a diet to best combat PIDD: “Try eating a 100 percent organic diet with as few additives as possible. This will eliminate potentially disease-causing chemicals from contact with the already partially functioning immune system.”

**Conclusion: No Magic Food**

I can honestly say that I was disappointed that there is no magic food that best helps a compromised immune system. It would be nice to feed my kids something and have their B cells and phagocytes firing on all cylinders. But no such luck. And it doesn’t hurt to be mindful that during these hard economic times, people selling “Immuno-Gummies” and mining clay are trying to make a living, too.

MARK T. HAGGARD is a high school teacher and football coach, and has three children, two of whom have CVID. He and his wife, Cheryl, also operate Under the Hood Ministries at www.underthehoodministries.org.
But You Look Good! is a 56-page book that gives those living with chronic illness and pain a voice about how they feel, what they need and how others can be an encouragement to them. The book explains why family and friends have difficulty understanding ongoing illness and pain, and serves as a tool to help explain to loved ones how extreme fatigue, pain, dizziness, cognitive impairments and other symptoms can be limiting, even though the person may not look sick or in pain. Included are practical ideas about how loved ones can be supportive.

Diet Easy — Coping with Restricted Diets

Ray Johnson wrote this book after he was placed on a restricted diet and, to help him conform to it, he created charts to identify food groups. It is an educational cookbook on how and what to do to cope with the confusion, stress and anxiety of restrictive diets and includes methods and techniques for modifying recipes to eat well and meet restrictions. The methods are suitable for the reader’s own recipes, but it also includes more than 200 recipes. The book is written for the average kitchen, budget and skill level. It is in 12-point type for easy reading while cooking or studying, and it shows the reader how to do record keeping and the math needed to tailor their recipes to their needs, to read labels and more.

The Complete Idiot’s Guide to Gluten-Free Cooking

This book makes it easy to prepare delicious gluten-free meals and to make substitutions in one’s favorite recipes. Included are more than 220 recipes covering every meal of the day, especially breakfast, with recipes for pancakes and waffles; numerous breads, buns, biscuits, muffins and cracker recipes; recipes for pizza crust, pasta, noodles, dumplings and stuffing; one flour mix used for all recipes; dessert recipes, including cakes, cupcakes, pie crust, brownies, cookies, bars, crepes and blintzes; resources for finding gluten-free off-the-shelf foods; dairy-free alternatives; and menu plans for all occasions.

Guillain-Barré Syndrome, CIDP and Variants: Guidelines for Physical and Occupational Therapy

This 20-page booklet was written for physical and occupational therapists to help them understand the physical limitations and the therapeutic needs of their patients with Guillain-Barré Syndrome, chronic inflammatory demyelinating polyneuropathy and variants of these diseases. It includes a discussion of what each of the diseases are, what patients are feeling, how to evaluate each patient to determine their needs, and how to treat them in the individual stages of their disease.
Treating Sinusitis

By Kris McFalls

**SINUSITIS IS AN** inflammation of the nasal passageways and is probably one of the most common conditions doctors treat. Its symptoms, which include pressure, pain and mucus buildup, can be caused by both infectious and noninfectious agents. Infectious triggers include viruses and bacteria. Noninfectious causes include anatomical defects, environmental triggers and allergies. Yet, no matter what the cause, reducing the risk of sinusitis is the key to controlling symptoms. And, sticking to a regular regimen helps minimize the amount of inflammation sinus irritants can cause.

**Finding the Cause**

The most important part of treating sinusitis is to get to the root of the problem, which can eliminate it altogether or at least make it easier to control. In some cases, the cause is anatomical in nature, meaning the sinuses are not able to drain properly because the pathway is either blocked or crooked. Patients with anatomical conditions should consult with an otolaryngologist to see if the problem can be corrected.

**Controlling the Environment**

If sinuses can physically drain, patients need to explore environmental causes of inflammation. Contrary to what one might think, dry nasal passages can be a trigger for inflammation. When the nasal passages are too dry, mucus does not clear effectively and, as a result, can build up and block drainage. Controlling the environment as much as possible to make sure the air in one’s living space is a moderate temperature and well-ventilated can help. Regardless, it is not always possible to avoid dry environments, so there are products that are specially formulated to keep nasal passages from drying out.

**Washing Away Irritants**

While avoiding known irritants is the best way to minimize sinus problems, even the best efforts won’t totally prevent irritants such as dust, pollen and dander from accumulating in the nasal passages. Likewise, once an infectious process has started, it is important to keep mucus from building up and blocking nasal passageways. Many doctors recommend patients regularly irrigate nasal passageways with a saline rinse. But, when using
these products, it is particularly important to follow the directions on the package insert and to make sure to use distilled water and clean equipment to prevent introducing contamination into already sensitive mucus membranes.

**Prophylactic Treatments**

Even after all irritants are washed away, many sinusitis sufferers will still need daily treatments to treat and prevent inflammation. A number of prescription nose sprays are specially formulated to do just that. Steroidal- and antihistamine-based nose sprays applied locally into the nasal passages work to decrease and prevent inflammation with little effect on the body when used as prescribed. But, not all nose sprays are made the same. Patients should make sure to discuss all of their options with their doctor before starting nasal spray treatments.

**NeilMed Pharmaceuticals Inc.**

NasoGel Moisturizer for Dry Noses is a drug-free saline-based water-soluble nasal gel formulated with sodium hyaluronate to provide nasal moisture. It comes packaged in a tube and in a drip-free spray bottle.

(877) 477-8633; www.neilmed.com/usa/nasogel.php

**Med-Systems Inc.**

SinuCleanse Squeeze is a convenient, clean and effective squeeze bottle that features anti-backflow technology to prevent contamination of saline solution and a wide-mouth design for easy filling and cleaning.

(888) 547-5492; www.sinucleanse.com/product/products.htm?link_id=2

**Omnaris**

Omnaris, a once-a-day prescription-only steroidal nasal spray, reduces the sneezing, runny, itchy nose and congestion caused by allergic inflammation in a taste-free, scent-free, alcohol-free nasal spray. Symptom relief begins within 24 to 48 hours after the first dose.

(888) 394-7377; www.omnaris.com/aboutOmnaris/about-omnaris.html

**Sinus Dynamics**

Perosolized Sinus Therapy delivers an aerosolized antibiotic, antifungal and anti-inflammatory medication directly into hard-to-reach regions within the sinuses. It comes in three lightweight nebulizer devices: SinuTouch, SinusAero and SinusAero Dx. Each treatment is completed in approximately three to five minutes.

(877) 447-4276; www.sinusdynamics.com

**Alcon**

Patanase Nasal Spray is a steroid-free prescription nasal spray that fights the symptoms of seasonal allergic rhinitis, commonly known as hay fever, in patients 6 years of age and older. It is fast-acting, long-lasting and steroid-free.

(800) 862-5266; www.patanase.com

**Source**

KRIS MCFALLS is the full-time patient advocate for IG Living magazine.

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**Directory of Sinusitis Products**

**Treating an Infection**

Despite all best efforts, patients with a dysfunctional immune system are still prone to sinus infections. And while rest and plenty of fluids are still part of the standard of care for any infection, sometimes antibiotics are needed to treat bacterial-caused sinusitis infections. However, it may not always be necessary to take a systemic antibiotic when only the sinuses need treating. Some patients are finding relief with a nebulized antibiotic designed to be delivered directly to the nasal passages.

For most people, sinusitis clears up if treated early and appropriately. For patients with immune dysfunction sinusitis, it can definitely be more of a challenge. Therefore, it is important that all patients follow the regimens prescribed by their doctors to minimize their risk.
General Resources
These organizations provide information about various disease states, which can be found by conducting a search of the disease state name.

- Advocacy for Patients with Chronic Illness: www.advocacyforpatients.org
- The Alliance for Biotherapeutics (fair access to plasma therapies): www.bioalliance.org
- American Autoimmune Related Diseases Association (AARDA): www.aarda.org
- American Chronic Pain Association (ACPA): www.theacpa.org
- Band-Aides and Blackboards: www.lehman.cuny.edu/faculty/jfleitas/bandaides
- Cleveland Clinic: www.clevelandclinic.org/health
- eMedicine from WebMD: emedicine.medscape.com
- FamilyDoctor.org: www.familydoctor.org
- Johns Hopkins Medicine: www.hopkinsmedicine.org
- KeepKidsHealthy.com (pediatrician’s guide to children health and safety): www.keepkidshealthy.com
- Mayo Clinic: www.mayoclinic.com
- National Committee for Quality Assurance (detailed report cards on health plans, clinical performance, member satisfaction and access to care): www.ncqa.org
- National Infusion Center Association: www.infusioncenter.net
- National Institutes of Health: www.niams.nih.gov/hi/topics/pemphigus/pemphigus.htm
- National Organization for Rare Disorders (disease-specific support groups and virtual communities for patients and caregivers): www.rarediseases.org
- Office of Rare Diseases Research: rarediseases.info.nih.gov
- Patient Advocate Foundation (patient access to care, maintenance of employment and financial stability): www.patientadvocate.org
- WebMD (medical reference): www.webmd.com

IG Manufacturer Websites
- Baxter: www.baxter.com
- CSL Behring: www.cslbehring.com
- Grifols: www.grifolsusa.com
- Octapharma: www.octapharma.com
- Talecris: www.talecris.com

Disease-State Resources
Ataxia Telangiectasia (A-T)

Websites
- A-T Children's Project: www.atcp.org

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Websites
- GBS/CIDP Foundation International: www.gbs-cidp.org
- The Neuropathy Association: www.neuropathy.org

Evans Syndrome
Online Peer Support
- Evans Syndrome Research and Support Group: www.evanssyndrome.org

Guillain-Barré Syndrome (GBS)

Websites
- GBS/CIDP Foundation International: www.gbs-cidp.org
- The Neuropathy Association: www.neuropathy.org

Online Peer Support
- GBS/CIDP Foundation International Discussion Forums: www.gbs-cidp.orgforums

Idiopathic Thrombocytopenic Purpura (ITP)

Websites
- ITP Support Association – UK: www.itpsupport.org.uk
- Platelet Disorder Support Association: www.pdsa.org

Kawasaki Disease

Websites
- American Heart Association (how the disease affects the heart): www.americanheart.org/presenter.jhtml?identifier=4634
- Kawasaki Disease Foundation: www.kdfoundation.org

The nonprofit Patient Services Incorporated, www.patientservicesinc.org, specializes in health insurance premium, pharmacy co-payment and co-payment waiver assistance for people with chronic illnesses. (800) 366-7741

For a more comprehensive list of resources, visit the Resources page at www.IGLiving.com.
Mitochondrial Disease

Websites
- United Mitochondrial Disease Foundation: www.umdf.org

Multifocal Motor Neuropathy (MMN)

Websites
- The Neuromuscular Center at Washington University: www.neuro.wustl.edu/neuromuscular
- The Neuropathy Association: www.neuropathy.org

Multiple Sclerosis (MS)

Websites
- All About Multiple Sclerosis: www.mult-sclerosis.org/index.html
- Multiple Sclerosis Association of America: www.msaa.com
- Multiple Sclerosis Foundation: www.msfacts.org
- National Multiple Sclerosis Society: www.nationalmssociety.org

Online Peer Support
- Friends with MS: www.FriendsWithMS.com
- MSWorld’s Chat and Message Board: www.msworld.org

Myasthenia Gravis (MG)

Websites and Chat Rooms
- Myasthenia Gravis Foundation of America (MGFA): www.myasthenia.org

Online Peer Support
- Autoimmune Information Network Inc.: www.aininc.org

Myositis

Websites

Online Peer Support
- Myositis Association Community Forum: www.myositis.org
- Myositis Support Group: www.myositisupportgroup.org

Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus (PANDAS)

Websites
- P.A.N.D.A.S. Network: pandasnetwork.org

Pemphigus and Pemphigoid

Websites
- The International Pemphigus and Pemphigoid Foundation: www.pemphigus.org

Peripheral Neuropathy (PN)

Websites and Chat Rooms
- Myasthenia Gravis Foundation of America (MGFA): www.myasthenia.org

Online Peer Support
- Autoimmune Information Network Inc.: www.aininc.org

Primary Immune Deficiency Disease (PIDD)

Websites
- The Immune Deficiency Foundation (IDF), www.primaryimmune.org, is the national patient organization dedicated to improving the diagnosis, treatment and quality of life for persons with primary immunodeficiency diseases through advocacy, education and research. (800) 296-4433

Jeffrey Modell Foundation
The Jeffrey Modell Foundation, www.info4pi.org, is dedicated to early and precise diagnosis, meaningful treatments and, ultimately, cures for primary immunodeficiency. (212) 819-0200

- The National Institute of Child Health and Human Development (NICHD), www.nichd.nih.gov, is part of the National Institutes of Health. Go to the "Health Information and Media" tab on the website and do a search under
- American Academy of Allergy, Asthma & Immunology: www.aaaai.org
- International Patient Organization for Primary Immunodeficiencies (IPOPI): www.ipopi.org
- Michigan Immunodeficiency Foundation: www.midf.org
• National Institute of Child Health and Human Development (NICHD) (Click on “Health Information and Media” tab and search for “primary immunodeficiency”: www.nichd.nih.gov
• New England Primary Immunodeficiency Network: www.nepin.org
• Rainbow Allergy-Immunology: www.uhhospitals.org/tabid/132/Default.aspx
• Team Hope (for families and patients in New England): www.teamhope.info

Online Peer Support
• IDF Common Ground: www.idfcommonground.org
• IDF Discussion Forum: http://idffriends.org/forum
• IDF Friends: http://idffriends.org
• Jeffrey Modell Foundation Message Board: www.info4pi.org
• Rhode Island peer group: http://health.groups.yahoo.com/group/RhodeIslandPIDD

Scleroderma
Websites
• Scleroderma Foundation: www.scleroderma.org
• Scleroderma Research Foundation: www.srfcure.org
• Scleroderma Center: http://www.hopkinsmedicine.org/rheumatology/clinics/scleroderma_center.html

Online Peer Support
• CureZone.com: curezone.com/forums/f.asp?f=404
• International Scleroderma Network: www.sclero.org/support/forums/a-to-z.html

Stiff-Person Syndrome (SPS)
Websites
• American Autoimmune Related Diseases Association Inc.: www.aarda.org
• Autoimmune Information Network Inc.: www.aininc.org
• Living with Stiff Person Syndrome (personal account): www.livingwithspss.com
• Stiff Person Syndrome: www.stiffpersionsyndrome.net

Other Resources
Education and Disability Resources
• Americans with Disabilities Act of 1990: www.ada.gov
• Individuals with Disabilities Education Improvement Act of 2004: http://idea.ed.gov/explore/home
• National Disabilities Rights Network: www.ndrm.org
• Social Security: www.ssa.gov/disability
• U.S. Department of Education Website: www.ed.gov

This federal government website offers a parents section titled “My Child’s Special Needs.”
• Spells out your rights under Section 504 of the Rehabilitation Act.

Medical Research Studies
• ClinicalTrials.com: www.clinicaltrials.com
• This site has a registration form to request that you be notified about recruitment for future studies.
• ClinicalTrials.gov: www.clinicaltrials.gov
• A registry of federally and privately supported clinical trials conducted in the United States and around the world.

Food Allergies
• Allergic Disorders: Promoting Best Practice: www.aaaai.org
• American Partnership for Eosinophilic Disorders: www.apfed.org
• Food Allergy and Anaphylaxis Network: www.foodallergy.org

Product Information
• Influenza and the influenza vaccine: www.cdc.gov/flu or call (800) CDC-INFO: (800) 232-4636
• IVIG Flebogamam 5% DIF and 10% DIF: www.grifols.com/portal/en/US/products
• IVIG/SCIG Gammagard Liquid: www.gammagardliquid.com
• IVIG Gammagard S/D: www.baxter.com/patients_and_caregivers/products/gammagard_sd_5.html
• IVIG Gammplex: www.gammplex.com
• IVIG Privigen: www.privigen.com
• SCIG Hizentra: www.hizentra.com

Pump and Infusion Sets Websites
• EMED Corporation: www.safetymedicalproducts.com
• Graseby Marcal Medical: www.marcalmedical.com
• Intra Pump Infusion Systems: www.intrapump.com
• Micrel Medical Devices: www.micrelmed.com
• Norfolk Medical: www.norfolkmedical.com
• Repro Med Systems, Inc: www.rmsmedicalproducts.com
• Smith Medical: www.smiths-medical.com/brands/cadd

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