

# IDF ADVOCATE

THE NATIONAL NEWSLETTER OF THE IMMUNE DEFICIENCY FOUNDATION



### Immune Deficiency Foundation Mission:

To improve the diagnosis and treatment of patients with primary immune deficiency diseases through research, education and advocacy

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## IDF Survey Reveals New Statistics- Diagnosis of PIDD Approximately 250,000 in U.S.

Landmark findings were reported in a peer-reviewed article by Dr. Rebecca Buckley and Dr. John Boyle in the September 2007 Journal of Clinical Immunology. The article details an Immune Deficiency Foundation commissioned national probability survey that demonstrated that the frequency and incidence of diagnosed primary immunodeficiency diseases (PIDD) in the United States may be higher than previously indicated.



The common question, “How many people in the United States have primary immunodeficiency disease?” has never been easy to answer. There have never been reliable estimates. Major health surveys conducted by the government in the U.S., such as the National Health Interview Survey and the National Health and Nutrition Examination Survey, do not collect information on PIDD. Since there is no screening for these defects at birth or at any time during life, those statistics have been nonexistent. While the Immune Deficiency Foundation (IDF) has conducted surveys of patients known to the Foundation concerning their condition and treatment experiences, there have been no comprehensive surveys of PIDD in the general population until the 2007 probability prevalence survey. The findings include--

- Population prevalence of diagnosed PIDD in the U.S. is estimated at approximately 1 in 1,200 people
- Only a minority of PIDD patients with antibody deficiencies are being treated with immunoglobulin replacement, pointing to a serious problem of under treatment of PIDD patients in the general population.

“The results are exciting for us all,” said John Boyle, co-author of the peer-reviewed article and IDF board member. “Until now, we have been working in the dark. Now we have a credible baseline.”

### Survey Process

The survey was conducted by telephone among a national sample of 10,005 households selected at random. All respondents were asked: “Has anyone in your household ever been diagnosed with a primary immunodeficiency disease, such as common variable immunodeficiency, IgA deficiency, IgG subclass deficiency, or any other immunodeficiency? If they answered yes, they were asked for the number of persons in the household diagnosed with PIDD, that person’s age, gender and specific type of PIDD.

*continued on pg.5.*

This newsletter is sponsored by an educational grant from Talecris Biotherapeutics.



## Update Your Contact Info

If you are a patient, and you have not updated your IDF contact information, now is the time! IDF will keep you informed of the latest news regarding treatment, education, recalls and public policy issues.

Please visit [www.primaryimmune.org](http://www.primaryimmune.org) to complete the electronic form or give us a call at 1.800.296.4433 for a hard copy form.

## IDF Advocate

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*Marcia Boyle*

## A Message from IDF President & Founder

Remember when you first learned about primary immunodeficiency diseases?

What would you tell a newly diagnosed patient or parent of a child with a primary immunodeficiency disease? Would you tell them you understand the denial and the fear? Would you share that you know only too well, the panic as you searched for information about a condition you had never heard of?

Would you tell them to contact IDF?

For the past 27 years, IDF has been the place to turn for help and support for all patients and their families dealing with primary immunodeficiencies. I've heard from senior citizens as well as teens; baby boomers and parents of newborns, all certainly with different needs, but still sharing the same challenges of living with these disorders. We want them to know that they are not alone. IDF offers everyone information and resources, family and patient support and a powerful force encouraging fair access to care—advocating for the best medical practices.

We are amazed at the energy, enthusiasm and strong support exhibited by the families who came to our national conference and local patient meetings to take advantage of the workshops, lectures, programs and camaraderie of our IDF community. We are grateful for our dedicated medical professionals—providing teaching and consulting services, to expand the knowledge of primary immunodeficiency in the medical community.

This past year, we have been heartened by the effort and dedication of those IDF volunteers who worked as grassroots advocates and contacted their Members of Congress about the Medicare access to IVIG issues. We are proud that our IDF Patient Survey influenced the Centers for Medicare and Medicaid Services to continue the temporary “pre-administration-related services” add-on for IVIG in 2007.

Now, as we look forward to the coming year, I consider the remarkable array of work that we have accomplished together! The constituents and supporters of IDF are the backbone of the organization. There is much work to be done, and your financial support is what makes IDF possible.

Please help us ensure that IDF will continue to thrive and improve the diagnosis and treatment of patients with primary immunodeficiencies. Renew your current annual gift or increase your level of giving. If you have not made a gift to IDF in the past, please consider making a generous first time contribution. Please know that your gift makes a difference and is greatly appreciated.

Thank you.

Marcia Boyle  
President & Founder  
Immune Deficiency Foundation



## Dr. Rebecca Buckley Appointed to HHS Advisory Committee

The Immune Deficiency Foundation congratulates Dr. Rebecca H. Buckley on her recent appointment to the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. The Advisory Committee is one of the programs under the Maternal and Child Health Bureau in the Department of Health and Human Services' Health Resources and Services Administration.

Nominated by IDF, Dr. Buckley, currently the J. Buren Sidbury Professor of Pediatrics, and Professor of Immunology at Duke University Medical Center, has spent most of her career addressing genetic disorders of the immune system and for the past decade has been a strong proponent of newborn screening for these types of diseases. She directs the IDF Center of Excellence at Duke University and has served as chair of the Medical Advisory Committee of the IDF for six years.

Dr. Buckley's prolific background perfectly meets the mission of the Advisory Council which was established in 2003 to advise the Secretary, U.S. Department of Health and Human Services. The Advisory Committee provides advice and guidance regarding universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

IDF knows Dr. Buckley for her tireless work with our Foundation and our community and we know her tenure with the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children will be filled with success and accomplishment.

## Talk to someone who's been there— IDF Peer Support Program

### What is it?

IDF Peer Support Program puts you in touch with one of our trained volunteer peer supporters, who has had a personal experience living with primary immunodeficiency disease.

This resource is for anyone personally affected by primary immunodeficiency—a patient, parent or other family member, friend or care giver, and is confidential and totally free.

### How does it help?

Feeling like no one understands what you are going through and coping with the everyday effects of living with a primary immunodeficiency can be isolating. Sometimes you simply need to talk freely about how you're feeling.

Our volunteer peer supporters are from diverse backgrounds and ages. They are patients and family members who are ready to listen, offer skilled emotional support and share their

experiences and understanding.

### How do I get in touch with someone?

It's easy...just contact IDF at [idf@primaryimmune.org](mailto:idf@primaryimmune.org) or call 800-296-4433. Let us know what you are looking for; perhaps you want to talk to a patient living with the same primary immunodeficiency as you, or speak with an experienced parent of a child. Maybe you want to be put in contact with someone who lives in the same area to share ideas.

An IDF staff member will contact you and get to know you and your needs. She will make arrangements for a volunteer peer consultant to contact you by phone or e-mail, however you prefer. Remember, you are not alone, IDF is here to help.

# A Letter to the Primary Immunodeficiency Community

I am a retired School Guidance Counselor. For thirty-five years, I battled chronic fatigue, unexplained joint and muscle pain, numerous bouts of pneumonia, and recurrent bacterial sinus and respiratory infections, which required continual antibiotics. I will always be grateful to the young resident who ordered the simple blood test that finally diagnosed my condition, Common Variable Immune Deficiency, in 2004.

My physician told me that without regular, infused plasma treatments called IVIG (intravenous immune globulin) I would remain at risk for serious illness and death.

I began infusions of IVIG and although I was thrilled that my infections had finally diminished; I was dismayed that I experienced other distressing symptoms. I was having a reaction to the IVIG product brand, so I had to change brands.

Ten months later, my physician informed me that he could no longer infuse me at his office since my IVIG brand was more expensive. Despite the fact I am very susceptible to infection, I was transferred to a hospital to get my infusions, exposing myself to all kinds of infection.

Fortunately, my IVIG treatments continued to increase my gamma globulin levels, resulting in fewer and less severe infections. By May 2006, I had been consistently antibiotic free for over three months.

However, a month later, my world was turned upside down. At my next treatment, my IVIG dosage was decreased by 50%.

Medicare had changed the reimbursement rates for IVIG so the hospital could no longer afford to provide IVIG to Medicare patients without adopting strict rules. The hospital also feared that private health insurance plans would assume Medicare guidelines, so it initiated Medicare's rules for all IVIG treatments. My IVIG dosage was lowered. Within a week, I contracted a severe pulmonary infection and experienced months of consistent infections.

Finally, my dedicated primary care physician agreed to manage my infusion therapy. Because I have private health insurance coverage, I was able to obtain medically appropriate IVIG product and dosage.

I hesitate to even reflect on my present situation if Medicare was my primary source of insurance coverage. The Medicare Modernization Act, designed to provide patients better benefits, unintentionally created an IVIG access problem. Medicare's reimbursement payments are below the cost many providers pay for IVIG, so many providers are unable to afford to treat patients on Medicare. Many have stopped providing the treatment. Other providers, recognizing that private health insurance companies may soon adopt Medicare guidelines, have accepted the restrictive Medicare criteria for all IVIG access and limit product availability for all patients.

Fortunately, I am now able to access my IVIG treatment. I feel blessed to have access to a private health insurance plan that, thus far, consistently and adequately compensated all IVIG providers. However, I live in constant fear that my situation will change at any moment and my private insurance will begin to follow Medicare's lead. Without action, many of us will be facing debilitating illnesses. Without IVIG treatment, we could die. That's the bottom line.

But there is hope. Working with IDF, I learned about legislation in the House of Representatives. The "Medicare IVIG Access Act" provides a solution by setting up a process for reviewing IVIG reimbursement policies and adjusting the rates as appropriate. The bill also authorizes Medicare to pay the costs of administering IVIG in the home, giving patients an alternative option for treatment location.

Similar legislation has not yet been introduced into the Senate, but it is important that Senators are made aware of the issue so they will also include IVIG access legislation in their Medicare package this fall.

Now is the time to act. The Congressional policymakers who control Medicare funding need to know this. Something must be done now!

Please, contact your U.S. Senators and Representatives and ask them to fix the IVIG access issue. This is a serious problem that is gravely affecting a growing number of Americans. We can't afford to wait. We need your help now!

Annette Randall  
Schenectady, New York

# Call to Action

Now is the time for the entire **IVIG** community to contact their Representatives and Senators to urge them to act now to fix the **IVIG** problem.

## Contact your Representative:

Contact your Representative and express your pleasure that Democratic and Republican leaders of the Ways and Means Committee pledged to work on getting something done on **IVIG** issues and ask them to do so this year. Set up a meeting when your

Representative is in the district office. Write to your Representative through **IDF Action Alert** and explain the importance of finding a solution this year. Ask the Representative to press the leaders of the Ways and Means Committee to include an **IVIG** fix in any compromise legislation that emerges this year.

**Contact your Senators:** As you did with your Representative, contact both of your Senators and ask them find a solution to **IVIG** problems this year. Visit them in their home offices when they are home. Write to them through **IDF Action Alert** and request that they go to leaders of the Senate Finance Committee (which has jurisdiction over Medicare and its provisions dealing with payment for **IVIG**) and ask that the **IVIG** problem be included in the Senate's Medicare package of amendments and in any agreement that emerges from discussions with the House.

**IDF Action Alert-** [www.primaryimmune.org](http://www.primaryimmune.org)  
For more information, call **IDF**, 410-321-6647.



## *IDF Survey Continued.*

In 131 (1.3%) of the total surveyed households, the respondents reported that one member had been diagnosed with **PIDD**. However, when asked the specific diagnosis, most respondents (66%) identified a diagnosis other than **PIDD**, often an auto-immune disease or one that had an immunological component. Nonetheless, a total of 23 members of 18 households reported a specific diagnosis for **PIDD**. (CVID, IgA, IgG, XLA, SCID, and CGD)

## Significant Findings—Far Reaching Implications

The findings indicate a population prevalence of diagnosed **PIDD** of 1 in 1,200 persons in the United States. When this sample rate is applied to the total population, it suggests that there are approximately 250,000 persons diagnosed with **PIDD** in the United States. Allowing for variability in population estimates, the number should be no lower than 152,000 and no higher than 361,000 diagnosed persons (with a 95% confidence level).

This prevalence rate indicates that primary care health providers should expect to encounter **PIDD** cases among their patient caseload. They should be on alert to identify **PIDD** as a possible underlying cause for frequent, repeated or unusual infections in their patients. Additionally, the prevalence rate is sufficiently high enough that a strong case can be made for more systematic screening for these diseases.

The population characteristics of this national probability sample are similar to two large scale, non-probability **IDF** surveys conducted in 1997 and 2003. The majority of the diagnoses in all three surveys involve antibody deficiencies for which intravenous immunoglobulin (**IVIG**) therapy is the standard of care. However, only 22% of the patients in the 2007 probability sample were currently receiving **IVIG** compared to 70% in the first **IDF** survey and 67% in the second **IDF** survey. This suggests that there may be significant under treatment of antibody deficiencies in the general population of patients with **PIDD**, with only a minority being treated with immunoglobulin replacement.

Back to the question, “How many people in the United States have primary immunodeficiency disease?” Since the **IDF** national probability survey of U.S. households is based on self-reported diagnoses, it does not address the prevalence of undiagnosed cases. However, if the average time from symptom onset to diagnosis is nine years (based on a previous **IDF** survey) is true for the general population, then the size of the symptomatic, but undiagnosed population with **PIDD** may equal or exceed the size of the population of diagnosed **PIDD** patients. This suggests that primary immunodeficiency diseases are not as rare as once thought.

This **IDF** commissioned survey was underwritten, in part, by an unrestricted educational grant from Talecris Biotherapeutics. To read the full article, “Population Prevalence of Diagnosed Primary Immune Deficiency Diseases in the United States” from the September 2007 *Journal of Clinical Immunology*, go to [www.primaryimmune.org](http://www.primaryimmune.org).

# Keep your Envelopes! A Cautionary Case Study

## Background

Steve has Common Variable Immunodeficiency and relies on monthly IVIG infusions. In 2005, he lost his job in a corporate acquisition, but having prepared for the possibility, Steve knew to make continuation of his insurance coverage a priority.

The Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) provides temporary continuation of health coverage to terminated employees at group rates. Steve's initial qualifying event (termination) entitled him to 18 months of his former employer's insurance coverage. He was also entitled to an extension of 11 months if he received a ruling from the Social Security Administration (SSA) that he was disabled.

So Steve enrolled in COBRA immediately upon his dismissal and applied to the SSA for disability benefits. In April of the next year, he received an approval letter from the SSA, but the letter was dated in January. For some unknown reason, the letter had been delayed. Steve threw away the envelope and sent the letter to the vendor that administered COBRA benefits for Steve's former employer.

## The Challenge

In order to extend his benefits, he needed to provide the letter within 60 days of receipt. Although Steve did provide it immediately after he received it, because of the late delivery, it looked like he didn't make the deadline. The COBRA vendor saw the letter with the original date (January) and Steve was denied the 11 month extension.

Had Steve kept the date stamped envelope, he would have been able to prove when he received the letter from SSA. Going to the local Social Security Administration office did not help.

## The Solution

One of the many services IDF's patient advocacy program offers is assistance to patients with treatment access or insurance concerns. Steve called the IDF and told the Patient Advocate his situation. She called the COBRA vendor, and inquired about case notes regarding Steve in their system. A March note in the COBRA vendor's computer system indicated Steve had no knowledge of the letter or his approval from the SSA. Fortunately Steve had been very proactive in calling the COBRA vendor to inquire about the extension.

Not backing down on approving the extension for Steve, the COBRA vendor remained firm in its denial of benefits. However, after working for weeks with the Compliance



Department, the Patient Advocate challenged their decision to deny him benefits and she successfully convinced them to overturn the denial of benefits. Steve has been granted the 11 month extension of benefits.

## What's Next?

The Patient Advocate also encouraged Steve to apply for Medicare, which could cover him after the eleven months of COBRA coverage expired. Through the IDF Patient Advocate, Steve became more aware of the need to work with the provider of his insurance...and to not dispose of timely information that may have future treatment implications, even envelopes!

## Helpful Tips

1. Keep all your notification of COBRA rights in one file.
2. Keep all Health insurance information in another file.
3. Keep a copy of everything that you fax or send in the mail.
4. Pay your insurance premiums on time.
5. Keep important dated envelopes as well as their contents.
6. Understand your health care plan benefits. If you have questions, call the health plan's Customer Service Department.
7. Download a copy of "An Employee's Guide to Health Benefits Under COBRA" at [www.dol.gov/ebsa](http://www.dol.gov/ebsa).

# GIVING BACK TO IDF

# IDF CAN'T DO IT WITHOUT YOU!

**YOU** can make a real difference in the lives of those facing primary immunodeficiency diseases by supporting the Immune Deficiency Foundation (IDF).

IDF has provided innovative services and resources to patients and their families, medical programs for healthcare professionals and funding for groundbreaking research. As the leading advocate for patients and their families, IDF has championed access to safe and optimal therapies. To continue to thrive as a patient-focused organization dedicated to people living with primary immunodeficiency diseases, IDF needs your financial help. There are many ways you can contribute and we urge you to consider making a financial gift today.

## Ways to Give

### Monthly Giving Program

This program allows donors to make monthly donations through automatic deductions on a credit card. It is a convenient way to consistently give while saving the cost and time of writing and mailing checks. As a monthly donor, you are a vital partner in our success. Your monthly gift provides IDF with steady funding for ongoing programs and services.

### Donate by Mail, Phone or Online

You can make a general contribution, a gift to celebrate the memory of someone or a donation to honor someone special. Consider expressing your appreciation by making gifts in honor of special occasions in your loved one's life, such as holidays, birthdays and anniversaries. Online donations are especially easy—simply go on our Web site, [www.primaryimmune.org](http://www.primaryimmune.org), click the "How You Can Help" tab and use the secure online server.

You can contact us in any of the following ways:

Phone: 800.296.4433 or 410.321.6647

E-mail: [idf@primaryimmune.org](mailto:idf@primaryimmune.org)

Mail: IDF, 40 W. Chesapeake Ave. Ste. 308, Towson, MD 21204

Or, use the Remittance Envelope attached in this newsletter for your donation.

### Planned Giving

Consider including IDF in your estate planning. This can be done by including IDF in your will, trust, as a beneficiary of a

charitable gift annuity or charitable remainder trust or as the beneficiary of a life insurance policy.

### Gifts of Securities

If your donation is made in the form of appreciated securities rather than cash, you might benefit from extra tax advantages and avoid paying a tax on capital gains.

### Workplace Giving

Your donation can be automatically deducted from your paycheck when you designate the Immune Deficiency Foundation as your selected charity with The United Way.

### Matching Gifts

Check to see if your employer offers matching gifts. Many companies offer a matching gift program to encourage their employees to give to charitable organizations. Many programs match dollar for dollar, doubling your donation and helping to maximize your contribution.

For additional information on any of these giving options, please call the IDF at 800.296.4433 or 410.321.6647 or e-mail:

[idf@primaryimmune.org](mailto:idf@primaryimmune.org).

# Influenza Immunizations—It’s a Family Affair

By R. Michael Blaese, MD

Influenza, commonly known as the flu, is a contagious viral disease which typically occurs in the winter months and causes cough, fever, sore throat, headache, chills, muscle aches and fatigue. The virus is transmitted from person to person by airborne droplets formed during coughing and sneezing, that are inhaled or land on mucus membranes or the conjunctiva (thin membrane that covers the surface of the inner eyelid and the white part of the eyeball). For most people, the flu lasts only a few days, but some get much, much sicker. Influenza can lead to pneumonia and is particularly dangerous for people with pre-existing heart and/or lung conditions.

Influenza vaccines are safe and effective and contrary to a common misconception, they do not cause the flu. Currently there are two different types available in the US and both are highly effective in controlling influenza.

## The “Flu-Shot”

The most commonly used vaccine, often called the “flu shot,” is a killed virus vaccine that can be given to individuals ranging from 6 months to senior citizens. This inactivated vaccine can be used by everyone except individuals who have had an allergic reaction to eggs.

This traditional vaccine requires an injection and may cause local swelling and tenderness at the injection site. For children, the first year requires two injections spaced about one month apart, preferably in September and October before the influenza season begins. After two doses in the first year, subsequent years only require a single vaccine dose. Unfortunately, children who only received a single dose of vaccine in the first year often do not develop protective immunity and two doses should be given to the child in the second year.

## FluMist

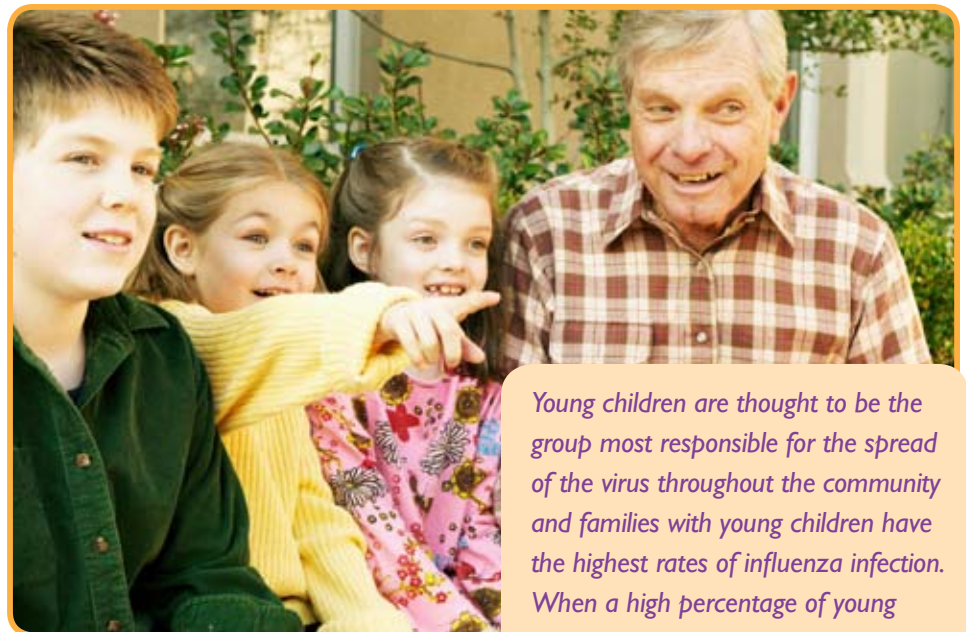
The other vaccine is a live attenuated influenza virus vaccine that is administered by droplets given into the nose (FluMist). Attenuation means that the virus has been weakened so that it does not cause illness in normal healthy people.

FluMist is approved for individuals ranging from 2 years to 65. Administration does not require any injections, a clear advantage for those who particularly dislike needles. Studies comparing

the efficacy of the two types of vaccine suggest that the live attenuated vaccine may provide a slight advantage in generating an effective immune response. However, as a live virus, this vaccine has some theoretical risk for patients with defective immunity and it is the general recommendation that patients with primary immunodeficiency do not use this form of influenza vaccine (FluMist).

The IDF has reviewed this issue carefully with the FDA and the manufacturer of FluMist and plans to conduct additional studies to help clarify the actual level of risk to our patient population. There seems little reason to expect increased risk for patients with CGD or complement disorders. Patients with HIV infection and some immunodeficiency have been given this live agent vaccine without problem, but there have been no studies of patients with primary immunodeficiency.

As with any live virus vaccine, we are concerned about the possible spread of the vaccine virus from an immunized person to a close contact such as a family member with PID. Studies looking for such spread in nursery schools where only some children received the FluMist found the level of spread to non-immunized classmates was very low. This observation gives us some reassurance that the risk of the spread of this agent in families from a FluMist immunized child or adult to an immunodeficient family member should also be low.



*Young children are thought to be the group most responsible for the spread of the virus throughout the community and families with young children have the highest rates of influenza infection. When a high percentage of young children in a community have received the influenza vaccine, the death rates from influenza in the elderly of that community drop significantly.*



## Family Plan

Nevertheless, for families with a member who has PIDD-- we recommend that that all members of the family group should be given the inactivated (killed) vaccine. The vaccines usually become available in August or September. Studies have shown that immunization can still be effective when given well into February or March in some years, so it is important to ask for the vaccine even if the New Year has passed.

Why do we recommend that everyone be immunized? First, some patients with a primary immunodeficiency may benefit from the vaccine; even if they don't, there is little down side to receiving the inactivated vaccine. However the major reason is that the best way to protect someone from influenza is by immunization; family members who are able to respond to the vaccine will be protected (a good thing in its own right).

Furthermore, even if the patient with PIDD may not respond to the immunization, with everyone in the family protected from infection and not susceptible to bringing the virus home with them, the patient will have lower exposure. We want to see a "protective cocoon" of immunized persons surrounding our patients so that they have less chance of being exposed. It would be a good strategy to encourage employers to provide influenza immunization programs at the place of work and schools to similarly encourage immunization of the student body to further extend this "cocoon."

Finally, anti-viral drugs are now available that can lower the severity of influenza in exposed individuals if given early enough following exposure. Tamiflu should be considered by any patient with PIDD who has had a close exposure to someone with influenza. Some experts recommend taking this drug for a few weeks during the peak of the local influenza season. Patients should discuss this with their doctors and develop a plan in case exposure occurs or influenza seems to have started.

*Dr. Blaese is the Medical Director at IDF and is an active member of the IDF Medical Advisory Committee.*

*In the average year, 82 million Americans are infected with an influenza virus, 30 million need medical attention, 200,000 are hospitalized and 36,000 die – mostly elderly. At the height of the epidemic, 3000 people die every 10 days – more than were killed on 9/11 or at Pearl Harbor.*



# Get your whole family immunized every year!

# INDUSTRY NEWS

## Grifols Reports Reductions in the Environmental Impact of its Operations

Through a robust Environmental Management System, Grifols has dramatically reduced its environmental footprint relative to its increased production of life-saving plasma therapies and other healthcare products. Grifols recently reported the results of its 2006 environmental management and monitoring program which included significant reductions in key environmental outputs and the announcement of a number of new initiatives to further reduce the company's environmental impact. Grifols' announcement builds on a history of environmental responsibility and sets the stage for significant environmental achievements in the future.

Grifols has established an Environmental Management System that incorporates centralized oversight with a network of division-specific teams to develop and implement environmental objectives. Grifols helps its employees fulfill their responsibility through training programs and ongoing communications about environmental performance.

Building on its strong history of innovation, Grifols has applied a number of creative technology solutions to achieve significant environmental gains. *Excerpted from Grifols Inc. News Release, September 20, 2007*

## Baxter and Halozyme Announce Collaboration for Development of Subcutaneous GAMMAGARD LIQUID™ Administration Using Enhance™ Technology

Development of New Route to Administer GAMMAGARD LIQUID™ 10% Could Make Home Therapy More Accessible

Baxter International Inc. and Halozyme Therapeutics, Inc. announced today they have entered into an agreement to apply Halozyme's proprietary Enhance™ Technology to the development of a subcutaneous route of administration for Baxter's GAMMAGARD LIQUID™ 10% [Immune Globulin Intravenous (Human)] (IGIV) (known as KIOVIG™ in Europe). For patients using GAMMAGARD LIQUID 10% -- currently administered intravenously -- subcutaneous administration with Enhance Technology may increase overall convenience and improve the dispersion of the therapy.

Baxter's GAMMAGARD LIQUID 10% is a large molecule therapy made from human plasma that is indicated for the treatment of primary immunodeficiency disorders associated with defects in immune system. Enhance Technology is Halozyme's proprietary drug delivery technology based on rHuPH20. rHuPH20 is a form of human enzyme that temporarily clears space in the matrix of tissues underlying the two outer layers of the skin to increase absorption and spreading of injected drugs. *Excerpted from Baxter International Inc. News Release, September 10, 2007*

## Gamunex® is Now Latex-Free

Talecris Biotherapeutics, Inc. announced that all new releases of Gamunex® (Immune Globulin Intravenous [Human], 10%, Caprylate/Chromatography Purified) in the United States are latex-free. With the elimination of latex from the rubber stoppers used in the product packaging, physicians can confidently use Gamunex in their patients with latex allergy. Furthermore, the product enhancement for Gamunex demonstrates the Talecris effort to recognize and respond to the growing healthcare trend to establish entire medical environments as "latex-free". This move represents the Talecris commitment to continuous enhancement of the safety profile of its life-saving and life-enhancing products. The new latex-free vials are currently being shipped and are becoming available to U.S. healthcare practitioners and patients. *Excerpted from Talecris Biotherapeutics Inc. News Release, August 14, 2007*

## CSL Behring completes enrollment for Phase III registration trial of next generation of subcutaneous immunoglobulin

CSL Behring announced that it has completed patient enrollment for a Phase III clinical trial of a 20 percent formulation of subcutaneous immunoglobulin (SCIg) to treat patients with primary immunodeficiency (PI) who require immunoglobulin replacement therapy. The study will assess the efficacy, tolerability, safety and pharmacokinetics of SCIg stabilized with proline (IgPro20) in subjects with PI. A multicenter, open-label, registration trial, the study incorporates 13 sites across the United States, with 54 patients now enrolled. Data from the trial will support a market application submission to the U.S. Food and Drug Administration. *Excerpted from CSL Behring News Release, July 12, 2007*

## Talecris Plasma Resources Supplements Its Collection: Acquisition Adds New Centers

Talecris Biotherapeutics, Inc. announced that its wholly owned subsidiary, Talecris Plasma Resources, has entered into a deal with International BioResources, LLC (IBR) to purchase three plasma collection centers and open up to 10 additional centers to further supply Talecris Biotherapeutics. The three centers purchased by Talecris are located in Las Vegas, Nevada; Montgomery, Alabama; and Rockford, Illinois. The plasma donated at Talecris Plasma Resources provides the source material for the production of Talecris Biotherapeutics' critical care protein therapies, used in the treatment of life-threatening disorders in a variety of therapeutic areas, including immunology, pulmonology, and hemostasis. In November of 2006, Talecris acquired 58 plasma centers from IBR and launched Talecris Plasma Resources. *Excerpted from Talecris Biotherapeutics, Inc. News Release, June 12, 2007*

## Eric Marder Scholarship Program of the Immune Deficiency Foundation

The Immune Deficiency Foundation awards scholarships to undergraduate students living with primary immunodeficiency diseases. IDF is honored to assist students who have lived with the challenges of these diseases and plan on completing their secondary education. The Program is open to patients with a primary immunodeficiency as classified by the World Health Organization. Scholarships are intended for undergraduate students attending or entering college or a technical training school.

The Eric Marder Scholarship Program of the Immune Deficiency Foundation is made possible from unrestricted donations to the Eric C. Marder Scholarship Fund.

Interested applicants can apply at [www.primaryimmune.org](http://www.primaryimmune.org), or call 800.296.4433 or e-mail [dgill@primaryimmune.org](mailto:dgill@primaryimmune.org) for an application.

Applications must be received by IDF no later than March 31, 2008. The scholarship awards will be announced by May 2008.



*IDF Duke Center of Excellence Patient Education Meeting*

Patients, family members and healthcare professionals met at Duke University Medical Center on Saturday, September 15, 2007, to learn more about primary immunodeficiency disease. This patient meeting is an outreach activity of the IDF Center of Excellence at Duke. Presenters included (From Left to Right) Douglas Lee, PhD, Sr. Director Pathogen Safety, Talecris Biotherapeutics; Laurie A. Lee, MD, Assistant Professor of Pediatrics; Debra Sedlak, CPNP, Duke Pediatric Immunology; Joseph Roberts, MD, PhD, Assistant Professor of Pediatrics; Marcia Boyle, IDF President & Founder; and Rebecca Buckley, MD, J. Buren Sidbury Professor of Pediatrics and Professor of Immunology and Chair, IDF Medical Advisory Committee

## IDF CALENDAR OF EVENTS

### November 1, 2007

LeBien Visiting Professor – Mary Ellen Conley, MD  
Children's Hospital of Pittsburgh  
Pittsburgh, PA  
For more information contact Tamara Brown at [tbrown@primaryimmune.org](mailto:tbrown@primaryimmune.org)

### November 20, 2007

LeBien Visiting Professor – William Shearer, MD, PhD  
Baystate Children's Hospital  
Springfield, MA  
For more information contact Tamara Brown at [tbrown@primaryimmune.org](mailto:tbrown@primaryimmune.org)

### June 18-20, 2009

2009 IDF National Conference at Disney's Contemporary Resort in Lake Buena Vista, FL

### Look for 2008 IDF Patient and Family Education Meeting in

Alabama, California, Colorado, Connecticut, Georgia, Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New York, Ohio, Oklahoma, South Carolina, Tennessee, Mississippi, Pennsylvania, Texas, Wisconsin and Washington



In Minnetonka, Minnesota, Kathy Antilla, Director of Education and Volunteer Services at IDF (center) was presented with a check for \$2,335 from the General Mills Federal Credit Union from employee planning committee members: Lisa Lorenzen, Jay Gostonczik, Dan Shannon, Kevin DeLozier & Melanie Pepin. The gift is in honor of a staff member's nephew, Jaycob Harstad, who has a primary immunodeficiency. Employees organized a silent auction and took advantage of the opportunity to purchase special healthy jeans days throughout the year. Great Job!

# IDF ACTION ALERT--

Encourage your Representative to cosponsor H.R. 2914, the Medicare IVIG Access Act 2007, and ask both your Senators and Representative to include a Medicare IVIG provision in Medicare Legislation this year.

Visit our Web site, [www.primaryimmune.org](http://www.primaryimmune.org), and click on "IDF Action Alert" to personally send out the alert to Congress.

## Core Service Sponsors 2007

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