

IDF ADVOCATE

THE NATIONAL NEWSLETTER OF THE IMMUNE DEFICIENCY FOUNDATION



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Bayer HealthCare
Biological Products Division

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Immune Globulin Intravenous (IGIV) A Brief Primer for Patients and Families



Immune Globulin, Intravenous, is a life-saving biologic agent used by approximately 70% of the patients served by the Immune Deficiency Foundation. IGIV is also known to patients and physicians as IVIG and gamma globulin. What makes IGIV so useful is that it contains antibodies to fight bacteria, fungi, and viruses that may affect those with primary immune deficiency diseases. The antibodies are present as a result of the immunization and infectious disease histories of the donors whose plasma is used to manufacture IGIV.

IGIV was first licensed in the United States in 1981. Prior to that time, only an intra-muscular preparation was available. The volume of the intra-muscular product

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The Changing Face of Primary Immune Deficiency Diseases:

“Treatment Experiences and Preferences of Patients with Primary Immune Deficiency Diseases: First National Survey”

The face of primary immune deficiency diseases is changing. IDF recently released data from a comprehensive survey of Americans affected by primary immune deficiency diseases, and the results reveal that what was once considered primarily a pediatric disease now affects more adults than children. This is the only

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A MESSAGE FROM THE EDITOR

I hope you enjoy this issue of the *IDF Advocate*. As the new editor of our national newsletter, I'd like to take this opportunity to introduce myself.

With more than 10 years in marketing and communications, I bring to this position experience in media relations, copywriting, public relations, publishing, graphic design, and market research.

Aside from my responsibilities as editor, I will also be working on the overall marketing and communications program to advance IDF's mission: to improve the diagnosis and treatment of primary immunodeficiency diseases through research, education and advocacy.

I am very excited to be part of IDF and the primary immune deficiency patient community, and I look forward to working with all of you.

Pamela Mooring

IDF ADVOCATE

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needed to help protect those with a primary immune deficiency diseases was quite large, often painful to deliver in "shots," had to be given several times each month and did not achieve blood antibody levels that physicians were seeking. The licensure of the IGIV form of immunoglobulin allowed the administration of larger doses of the product on a less frequent and less painful basis.

Several U.S. and European companies have been granted licenses to market and distribute their IGIV product in the U.S. Prior to licensure, each company has to perform clinical trials in a significant number of research subjects to prove that the formulation is safe and effective. The currently licensed products are listed in **Table A**.

Many of the IGIV manufacturers have performed additional clinical studies in disorders other than primary immune deficiency diseases. As a result, the Food and Drug Administration has approved IGIV for the treatment of these disorders for some of the products. These additional indications include Idiopathic Thrombocytopenic Purpura (a low blood platelet disorder), Kawasaki Disease (a multi-system inflammatory disorder affecting especially the heart), Chronic Lymphocytic Leukemia, pediatric HIV disease, and Graft Versus Host Disease following bone marrow transplantation. However, about one-fourth of all the IGIV that is manufactured is prescribed for individuals with primary immune deficiency diseases.

Use of IGIV for Treatment of the Primary Immune Deficiency Diseases

Typically, patients with primary

immune deficiency diseases receive an infusion of IGIV every three or four weeks. Over half the patients are infused every four weeks and more than a quarter receive infusions every three weeks. Some patients are infused more frequently.

Doses are usually approximately 0.4 grams per kilogram of body weight. This means that for a 25 kg (55 pound) child, 10.0 grams will be infused. As a child grows, the dose has to be recalculated each year based on the current weight. This is an important part of management.

The time needed for the infusion varies from patient to patient. If it is the first infusion, it will be given more slowly initially and then the rate of the infusion will be increased over time. The infusion will probably take several hours. Some patients experience side effects like headache, fever, nausea, vomiting, and chills if the infusion is given too fast for them. Hydration, slower rates of infusion and the use of pre-medications such as anti-histamines or steroid medicines may help alleviate these side effects.

Record keeping is critical. The product name, lot number (a unique identifier), and date of expiration should be recorded for each infusion. The doctor or hospital chart is a consistent and logical place to keep the information. In addition, some patients keep this information in their personal medical diary. This information is very important if a manufacturer or the Food and Drug Administration decide that there is a problem with a particular brand or lot number. Knowing the name of the product and the lot numbers can assist patients and families to

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Table A: Currently Licensed IGIV Products

Manufacturer	Alpha Therapeutic Corporation, Los Angeles, CA	Baxter Healthcare Corporation, Glendale, CA	Bayer Biologic Products-US RTP, NC	Aventis Behring LLC, King of Prussia, PA	ZLB Bioplasma Inc., Glendale, CA	American Red Cross (Distributor) Washington, DC
Brand Name	Venoglobulin®-S, 5% and 10%	Gammagard® S/D IVEEGAM EN	Gamimune N®, 10%	Gammar®-P I.V.	Carimune™ NF	Panglobulin®, Polygam® S/D

Table B: Some IGIV Product Characteristics

Brand Name	Venoglobulin®-S	Gammagard® S/D IVEEGAM EN	Gamimune N®	Gammar®-P I.V.	Carimune™ NF	Panglobulin® Polygam® S/D
Supplied As	5 and 10% liquid	Lyophilized Powder Lyophilized Powder	10 % Liquid	Lyophilized Powder	Lyophilized Powder	Lyophilized Powder Lyophilized Powder
Sugar Content (Stabilizer)	5% D-Sorbitol	2% Glucose 5% Glucose	None	5% Sucrose	~ 5% Sucrose	~ 5% Sucrose 2% Glucose
Osmolality (Non IGIV particles in solution)	5% 300 mOsm/L 10% 330 mOsm/L	5% = 636 mOsm/L 10% = 1250 mOsm/L >=240 mOsm/L	274 mOsm/L	309 mOsm/L	192 – 1074 mOsm/L (3 to 12% reconstitution)	192 – 1074 mOsm/L (3 to 12% reconstitution) 330 mOsm/L
IgA Content	15.1 µg/mL (5% solution) 20 - 50 µg/mL (10% solution)	<1.2 µg/mL <10 µg/mL	120 µg/mL	<50 µg/mL	720 µg/mL	720 µg/mL 1.2 µg/mL
pH (Acidity)	5.2 – 5.8	6.8 6.4 – 7.2	4.25	6.8	6.6	6.6 6.8

determine quickly if they may be affected. An easy way to learn of these types of problems is to register for the National Notification System. This can be done online at www.notify1.com; by telephone at 1-888-UPDATE-U.

Safety Information

The plasma that is the source of the immunoglobulin is collected from donors who undergo questioning about risk behaviors and medical problems that are associated with certain blood borne diseases, who are examined medically, and whose donations are evaluated in the laboratory using sophisticated techniques like Nucleic Acid Testing (NAT). NAT actually identifies whether or not a particular virus is present in a plasma pool that is being considered for use in the

manufacture of IGIV.

The purification process known as Cohn-Oncley fractionation, or its modifications, uses alcohol, which can inactivate potentially contaminating viruses. In addition, all manufacturers use dedicated viral inactivation or removal techniques that have been shown to be very robust. These techniques include: Acidification, Caprylate, Nanofiltration, Pasteurization, PEG-Bentonite, Pepsin exposure, Solvent-Detergent Treatment, and Trypsin exposure.

Some Product Differences

Due to their unique manufacturing steps, IGIV products from the various manufacturers have differences that may be important for some patients. (Table B)

The most obvious difference among

products is that some are liquids and some are lyophilized (freeze-dried) powders that require the addition of a sterile diluting fluid before use.

Sugars are used to help stabilize the IGIV products. Different manufacturers use different sugars in their products. Some products contain sucrose which has been associated with kidney problems in certain types of patients, generally those with autoimmune diseases who receive higher doses. Some products have higher IgA content which can cause problems if an individual is IgA deficient. Some of the products are packaged in more concentrated forms, or can be reconstituted in a more concentrated form (up to 12%) from the lyophilized powder.

For those who use smaller veins for

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infusions, products that are more acidic (lower pH) may be less well tolerated. Also some products may have more non-IGIV substances dissolved in the solution such as sodium. For some patients, products with a higher osmolality may cause problems during infusion. Normal serum osmolality, a measure of these particles in solution in blood, is 285-290 mOsm/L. Products range from 192 to 1074 mOsm/L.

Recommended rates of infusion of the various products vary somewhat. All should be administered at the lowest rate of infusion for the initial infusion and then at a faster rate based on how well the patient tolerates the infusion.

The differences in the IGIV products may be important for some patients. Patients should consult with their treating physicians to see if these differences are important for them.

IGIV products are a life-saving treatment for those with primary immune deficiency diseases. Their availability has helped thousands of affected individuals to better health and a better life. The products currently available and on the near horizon offer choices as well as safety improvements. ■

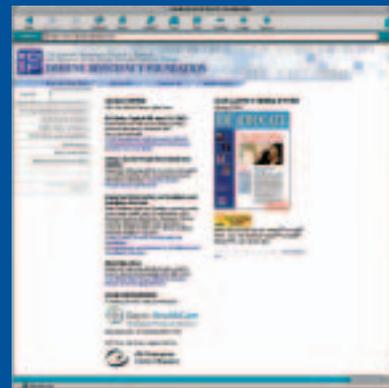
IDF Launches New Web Site

Check out www.primaryimmune.org! The Immune Deficiency Foundation launched a new web site this spring to celebrate Primary Immunodeficiency Awareness Week. The new web site features the most up-to-date information on primary immune deficiency diseases and IDF's programs and services. The web site offers expanded information on health insurance, a new section on genetics and inheritance of primary immune deficiency diseases, and an "In the News" section highlighting research, IDF events and initiatives and other important information.

While visiting www.primaryimmune.org you can make a charitable contribution to the IDF, access and download all IDF publications including the *Patient and Family Handbook*, learn about recent IGIV recalls and sign up for the Patient Notification System. If you are looking to chat with others affected by primary immune deficiency diseases, you can enter one of five password protected discussion forums.

The current forum topics include:

- Living as an Adult with a Primary Immune Deficiency Disease
- Parenting a Child with a Primary Immune Deficiency Disease
- Experiences with Immune Globulin Therapy
- Coping with a New Diagnosis
- Teen Talk: Teens living with a Primary Immune Deficiency Disease.



We encourage you to log on today!

The IDF web site is sponsored by an educational grant from Bayer Corporation.

www.primaryimmune.org

Founder of Clinical Immunology Remembered



1909-2003

“The patient is first — and last always”

-Colonel Ogden C. Bruton, M.D.

The Immune Deficiency Foundation is sad to acknowledge the death of Colonel Ogden C. Bruton, M.D. earlier this year. Colonel Bruton was widely respected in the medical community as a pediatrician, educator and especially for the discovery and treatment of Agammaglobulinemia.

In 1952, Colonel Bruton first described X-Linked Agammaglobulinemia (XLA). This disease is sometimes called Bruton’s Agammaglobulinemia, in his honor, or Congenital Agammaglobulinemia. The disease is an inherited immunodeficiency disease in which patients lack the ability to produce antibodies that make up the gamma globulin fraction of blood plasma. This monumental discovery became the stimulus for further studies in fields such as infectious disease, immunology and genetics. He gained recognition as a founder of clinical immunology which has impacted medical fields as diverse as immunization practices and bone marrow transplantation.

A native of North Carolina, Colonel Bruton received many military, medical and humanitarian honors and medals including recognition from the Immune Deficiency Foundation for his breakthrough discoveries in the field of immunology. An ardent advocate for children, Dr. Bruton will be remembered for his important contributions to medicine and his caring nature.



For Today and Future Generations

THE CAMPAIGN TO ENDOW THE
IMMUNE DEFICIENCY FOUNDATION

Please watch your mailbox for the *IDF Advocate* Special Issue, which provides more information about IDF’s first endowment and capital campaign, *For Today and Future Generations*, chaired by Founder

Marcia Boyle. We encourage you to give serious consideration to the many benefits the campaign will enable IDF to provide, today and in the future, and to make a commitment to supporting IDF in this vital initiative.

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current national survey of individuals affected by primary immune deficiency diseases and provides the best representation of the population now available.

Demographics and Diagnosis

The survey entitled “Treatment Experiences and Preferences of Patients with Primary Immune Deficiency Diseases,” was compiled from responses of nearly 2,000 partici-

pants. It revealed a dramatically changing face of primary immune deficiency diseases, highlighted by a marked shift from child to adult patients. Initial diagnoses are being made in many adolescent and young adults, and primary immune deficiency disease patients are maintaining daily health and longevity—a result of education about disease recognition, diagnostic testing and appropriate treatment. Despite these advances, there still remains an average nine year delay

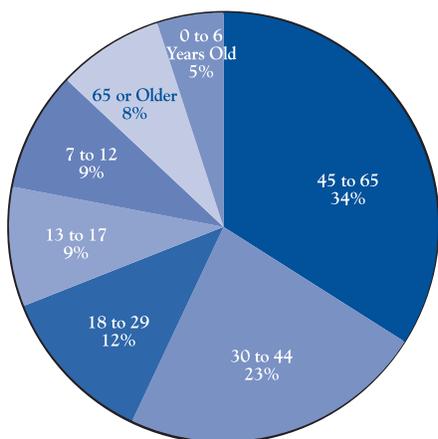
from onset of symptoms to diagnosis, presenting a challenge to the community to increase general awareness about, and greater recognition of, primary immune deficiency diseases.

Treatment

Ninety-one percent of survey participants feel that IGIV controls their primary immune deficiency disease adequately to completely. The most widely cited treatment method is infusions of intravenous immunoglob-

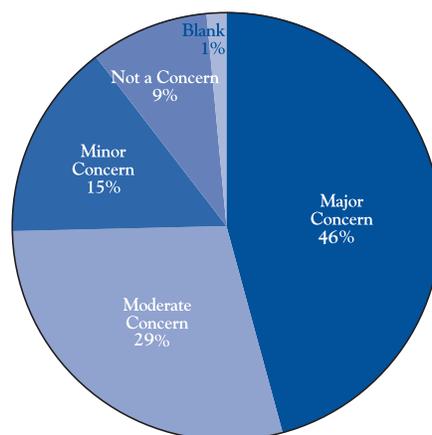
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Current IGIV Users by Age



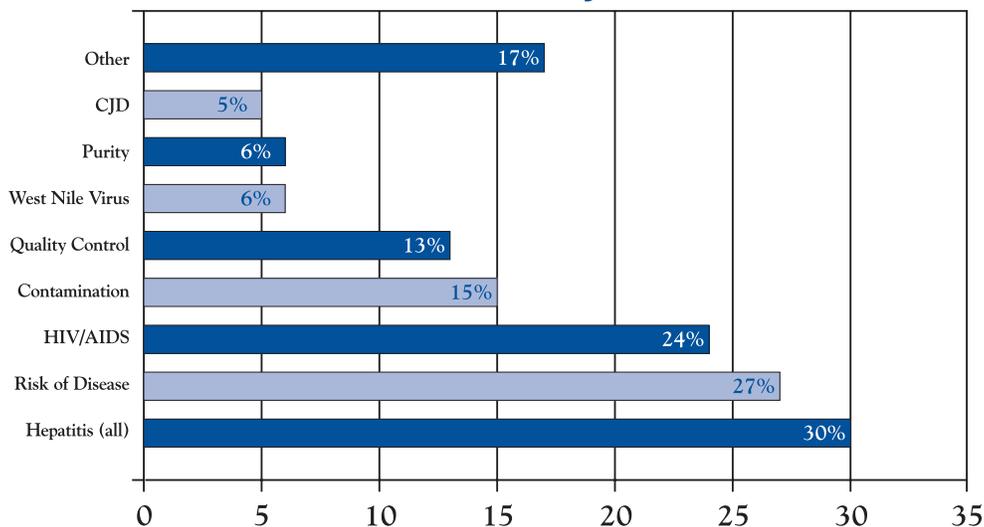
Q2. What is the date of birth of the primary immune deficiency disease patient being treated with IGIV?

Concern about IGIV Safety



Q33. How concerned are you about the safety of the IGIV products the patient infuses?

What is Safety in IGIV?



Q34. When you think of safety in IGIV, what comes to mind?

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ulin (IGIV)—the treatment of 70 percent of primary immune deficient patients surveyed. Seventy-seven percent of those treated with IGIV are over the age of 18. This is a key indicator of the effectiveness of treatment within this population.

When asked which IGIV attributes were most important to them, 75 percent of those surveyed listed product safety as an essential characteristic, stating concerns about theoretical risks associated with viral diseases known to be transmitted by blood such as

hepatitis, HIV/AIDS, and West Nile Virus.

Additionally, while primary immune deficiency patients believe in the life-saving effects of IGIV, they noted a variety of side effects experienced. A majority of primary immune deficiency patients noted a therapy preference due to adverse side effects from specific products.

Since the IGIV shortages in the late 1990's several product enhancements have entered the market. When asked "If your doctor recommended the patient switch to a new FDA approved IGIV product, which of the following would be most important to you in deciding whether to switch?" respondents stated that effectiveness, safety and tolerability were leading considerations.

Although there has not been an industry shortage for several years, 54 percent of respondents reported that they personally had difficulties getting regular IGIV infusions due to shortages. The survey found that nearly 20% of patients who are no longer on therapy ended it because of cost concerns or insurance barriers, not for medically indicated reasons.

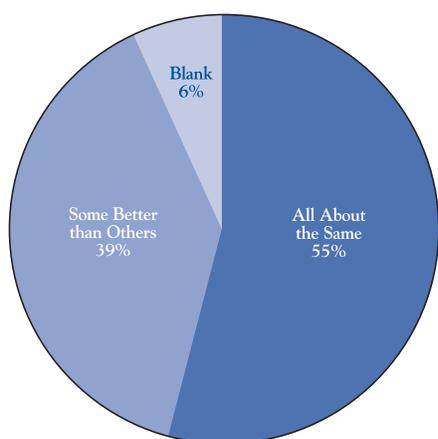
The findings from the survey provide useful information to the Immune Deficiency Foundation in determining patient concerns and needs. This information will help direct the IDF's future programs including patient education, physician education, Capitol Hill

advocacy efforts and continued diligence in addressing the safety and reliability of IGIV product.

This study was funded by an unrestricted educational grant from the Bayer Corporation. It was conducted by the national public opinion research firm of Schulman, Ronca & Bucuvalas, Inc. (SRBI). The survey was authored by John Boyle, Ph.D., a partner at SRBI and a member of the Board of Trustees at the IDF.

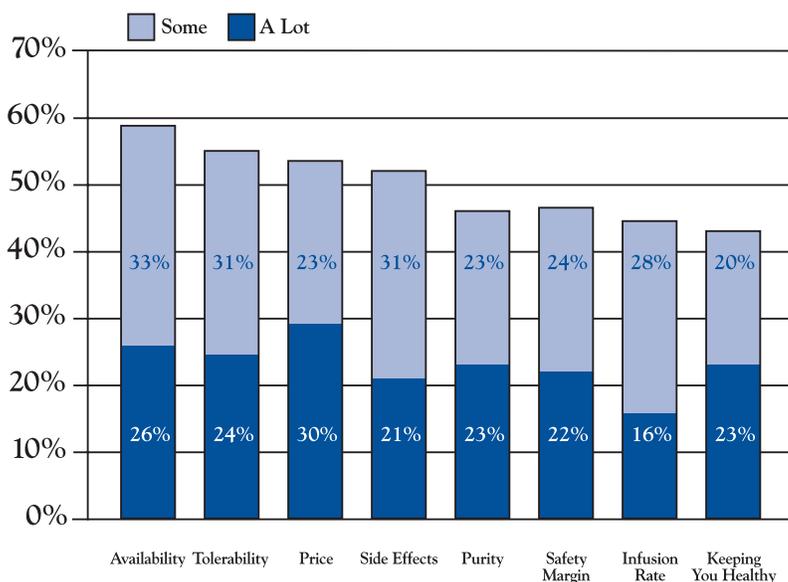
The full findings of the survey will be available at the Breakfast Symposium sponsored by Bayer during the IDF National Conference, and thereafter, on the IDF's new web site at www.primaryimmune.org. We will continue to highlight findings from the survey in upcoming issues of the *IDF Advocate*. Stay tuned... ■

Tolerate IGIV Products Differently



Q41. Does he/she tolerate any IGIV products better than others, or are they all about the same?

Difference Between IGIV Products



Q47. Based on what you know or have heard, how much difference do you feel there is between IGIV products available in the U.S. in terms of?

Severe Acute Respiratory Syndrome (SARS) and West Nile Virus:

Risks for Those with Primary Immune Deficiency Diseases



SARS

Background

A new disease, the Severe Acute Respiratory Syndrome (SARS) is under investigation by the Centers for Disease Control and Prevention in the United States and the World Health Organization (WHO). Cases first occurred in China, Vietnam, and Hong Kong as early as last fall. As of late May 2003, over 8,000 cases have been reported worldwide, with 358 cases (293 suspect and 65 probable) reported in the United States. Worldwide about 3% of those with SARS have died. Many others had a mild illness and recovered completely. SARS appears to be transmitted by close contact including contact with coughed secretions either by breathing or touching objects that secretions land on. A coronavirus appears to be the cause of SARS.

Clinical Features

Those affected by SARS have a respiratory illness with fever greater than 100.4 degrees Fahrenheit. Individuals typically have cough, shortness of breath, low blood oxygen levels, and/or an abnormal chest X-ray which may include findings of pneumonia. They may also have muscle aches, headache, and fatigue. These symp-

toms are not specific to SARS and could represent a number of illnesses affecting the lungs. Therefore, to confirm the diagnosis of SARS, individuals with respiratory symptoms must also have traveled to an area of the world with SARS cases within 10 days of the onset of symptoms OR have been in close contact with a person with a respiratory illness who had traveled to a SARS area.

Treatment

Treatment for those with the most severe cases includes supportive care such as the use of life support. Steroids and antiviral agents have also been administered. Their effectiveness is being evaluated.

Risks for the Primary Immune Deficiency Diseases

It is not known if individuals with primary immune deficiency diseases are at an increased risk for SARS. However, a defective immune system could put a person at increased risk. Therefore it may be reasonable for individuals with primary immune deficiencies to wear surgical masks and wash their hands when they go to health care delivery sites such as hospitals and infusion suites where patients potentially affected by SARS might be evaluated and treated.

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West Nile Virus

As summer approaches, it is time to prepare for West Nile Virus. West Nile Virus is spread by mosquitoes and infection with the virus can cause severe and sometimes fatal illness. Older individuals and those with underlying illnesses including immune deficiency seem to be at increased risk for the more severe complications of infection. These clinical signs of infection range from none to fever, nausea, vomiting, flu-like symptoms as well as meningitis and encephalitis (inflammations of the covering of the brain and of the brain itself). It has therefore become important to increase our understanding of the virus and its potential impact on those with primary immune deficiency diseases.

Current Cases

The CDC reports over 4,000 cases of West Nile diseases in the United States during 2002, including 284 deaths. It is likely that all mainland states in the United States will see West Nile Virus activity in 2003. As of May 2003, Alabama, Florida, Georgia, Louisiana, Michigan, Minnesota, Mississippi, North Carolina and Pennsylvania have reported verified cases of avian, animal or mosquito infections of West Nile Virus.

Safety of IGIV

An important question for those with primary immune deficiency diseases is if IGIV could be contaminated with West Nile Virus. The good news is that there appears to be little to no risk for transmission of West Nile Virus through the use of IGIV for several reasons:

- Potential blood and plasma donors with West Nile Virus may be ill with fever and would not be allowed to donate
- There is only a small chance that an infected person would have virus in the blood stream
- Viral inactivation techniques used on all IGIV products including pasteurization and solvent detergent treatment have been shown by manufacturers to inactivate the West Nile Virus.



Reducing the Risk of Exposure

For everyone including those with a primary immune deficiency disease, the best way to avoid the West Nile Virus is to avoid exposure to mosquitoes. Some ways to accomplish this are:

- Reduce time outdoors, especially in the early evening hours
- Wear long pants and long sleeved shirts
- Apply mosquito repellent containing DEET (N,N-diethyl-m-toluamide) to exposed skin areas following the manufacturer's recommendations for dosing frequency, application, and clean-up.

Public health authorities have also undertaken measures to destroy mosquito habitats and to spray insecticides that kill mosquitoes.

There seems to be little risk posed to individuals with primary immune deficiency disease from the West Nile Virus through the use of IGIV therapy. However, individuals face the same risks as the general population if bitten by an infected mosquito. Those with severe signs of infection are treated using supportive measures. There is active research in the area of vaccine development.

For the latest information on SARS and West Nile Virus, visit the CDC's web site at www.cdc.gov. ■

“Happiness Starts Here”

Family honors loved one through gift of hope for finding a cure

When Katharine Austin’s grandson Mark was diagnosed with CD-5/CD-9 primary immune deficiency at age three, she asked herself only one question: “How can I help?” Like many people, Katharine had no knowledge of primary immune deficiency diseases, their symptoms, or treatment options. Instinct told her that public knowledge of these diseases would help lead to advancements in treatment and a cure. Katharine decided the answer to how she could help was by becoming a proactive part of her grandson’s treatment.

From the beginning, Katharine had a special relationship with Mark that

went beyond her role as a grandmother. She served as Mark’s confidant, helping him cope with his illness, school issues, and IGIV treatments. The two shared special time together away from the stresses of primary immune deficiency disease, when they ate fast food and talked about his problems.

As Mark grew older and IGIV treatment became more frequent, Katharine dedicated her time to learning about the disease and helping the family cope with Mark’s illness. When he received his monthly IGIV therapy, Katharine brought dinner for the family and for the nurses who administered

his treatment.

Over the years, Katharine became an advocate for raising awareness about the IDF and generating funds to help researchers find a cure for primary immune deficiency diseases, and for Mark. She spoke with local reporters, urging them to write articles that would help raise awareness for these diseases that kept her grandson home from school for weeks at a time. At church, she encouraged fellow parishioners to give donations to the IDF.

Last spring Katharine unexpectedly passed away. As her final wish she insisted that instead of sending flowers and food to her family, that loved ones donate money to the IDF in her memory. The idea for the legacy fund was born.

Katharine’s family has dedicated May 19 as Katharine & Mark Austin Legacy Fund Day and every year on this day her family will conduct a special fundraising drive to raise money for primary immune deficiency education and awareness.

“Katharine was incredibly passionate about primary immune deficiency diseases. She gave in so many ways to help advance treatments and educate the public about these diseases. Giving to a legacy fund became the most appropriate way to honor her life, her spirit and her gifts to the primary immune deficiency community,” said Autumn Austin, about her mother-in-law’s efforts.

“Katharine kept up to date on the latest medical treatments; she steadfastly believed that raising money to benefit research for a cure was a vital component in helping my son lead a

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normal life,” continued Ms. Austin, “She would be pleased to have her love for Mark honored in this way.”

Mark, who is now 13, and his family further commemorated Katharine’s endless efforts to help the primary immune deficient community by planting a garden in her honor. A polished stone bears a plaque quoting Katharine’s life-long credo: “Happiness Starts Here.”

If you would like to set up a legacy fund in the name of someone you love to benefit the primary immune deficiency community, please contact the IDF.



Second National Conference

The Immune Deficiency Foundation will host its **Second National Conference** in Baltimore, Maryland on June 19-21, 2003. We have reached our goal and more than 1,000 individuals affected by primary immune deficiency diseases, leading clinical immunologists, nursing professionals, and government and industry representatives have registered to attend the three-day conference. Event highlights will be posted on the IDF web site in the weeks following the conference.

IDF would like to acknowledge the generous sponsorship of our industry partners:

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Specific Event Sponsorships

American Red Cross	Breakfast Symposium, June 21
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Bayer Corporation	IDF Extravaganza at Pier 6 Breakfast Symposium, June 20
Dean Family Foundation	Scholarships
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First Union/Wachovia Bank	Continental Breakfast, June 20 & 21
Grifols	Opening Reception Youth Program Coffee Breaks
Infusion Systems, Inc.	Scholarships
ZLB Bioplasma Inc.	Registration Bags Breakfast Symposium, June 21

Philanthropy

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N A T I O N A L
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IDF ADVOCATE

Mark your Calendars

IDF National Conference 2005

IDF is planning to hold its Third National Conference June 23-25, 2005 in Orlando, Florida.

Local Programs

The Immune Deficiency Foundation is planning educational and support meetings this summer in the following communities. For more information on the meetings, call the IDF at 800-296-4433.

Madison, Wisconsin
July 12, 2003

Cheshire, Connecticut
July 13, 2003

Albuquerque, New Mexico
August 9, 2003

Cleveland, Ohio
August 9, 2003

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The Champions Circle consists of organizations committed to supporting IDF at the highest level. The Circle provides vital resources to fulfill the vision, mission, and core services of the Immune Deficiency Foundation.

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