

IDF ADVOCATE

THE NATIONAL NEWSLETTER OF THE IMMUNE DEFICIENCY FOUNDATION



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Medicare Bill Provides for In-Home Infusion: Exempts IGIV from Competitive Bidding

Telling your story makes a difference. Gail and Sydney Nelson can speak to this first hand. Syd Nelson's casual conversation during an airline flight five years ago culminated in the inclusion of IGIV home infusions in the 2003 Medicare Bill.

This key provision in the new Medicare law permits patients with primary immune deficiency diseases to receive IGIV infusions at home, in addition to the currently covered settings, such as hospital outpatient departments, infusion clinics and physician offices. The regulations went into effect on January 1, 2004.

IDF advocates Gail and Syd Nelson dedicated years of work with Congressman Jim McCrery (R-LA), for the

inclusion of the IGIV home infusion provision. Five years ago, Syd Nelson took a flight during which he sat next

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**CMS Now Recognizes IGIV
as a Non-generic Biologic**
*Increases reimbursement by more than
91% per gram in hospital outpatient setting*

In January, CMS (Centers of Medicare and Medicaid Services) classified IGIV as a generic drug, resulting in a significant loss for hospitals to administer IGIV. IDF quickly met with key Members of Congress and CMS to change the classification of IGIV to ensure patients have access to this life-saving treatment. As a result, CMS corrected the payment rate for IGIV from \$37.95 to \$72.60 per gram retroactive to January 1, 2004.

Tribute to a Visionary Leader: Thomas L. Moran Departs IDF for New Venture

After seven years leading the Immune Deficiency Foundation, Thomas L. Moran has accepted a position as President and CEO of Primaryimmune Services, Inc. (PSI). PSI is an innovative healthcare subsidiary of IDF. Jonathan Goldsmith, M.D., the IDF Vice President of Medical Affairs, is serving as Interim President of IDF while the IDF Board of Trustees conducts a nationwide executive search for Tom's successor.

With a philosophy that combines social conscience and entrepreneurship, Tom has served successfully as CEO of leading health organizations for more than 20 years – and has served in the human services for 35 years. He came to IDF with a clear vision of growing the organization on all levels, including expanding IDF's role in medical research, providing direct, meaningful services to the patient community and advocating the cause of primary immune deficiency at all levels of government, industry and the medical community.

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Bayer HealthCare
Biological Products Division

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A MESSAGE FROM THE EDITOR

Though we say goodbye to Tom Moran in respect to his leadership of IDF, we are reassured to know that Tom will still be serving our patient community in another capacity. His leadership over the past seven years can undoubtedly be credited for the tremendous growth IDF sustained over this same time period. We've come this far with his smart business tactics, and his vision prepares us for the future. He leaves us with a powerful legacy – the ability to blend sound business practices to this service organization, thereby enabling us to best serve the primary immune deficient community.

Pamela Mooring

IDF ADVOCATE

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Since Tom joined IDF in April 1996, the foundation has increased programmed services from \$380,000 to \$6.3 million, grown its full-time staff from three to fifteen, and increased local programs from fewer than 20 sites to a network of more than 100 volunteers. Tom defined IDF success differently. He says, "At the end of each day, our team – staff and volunteers – wanted to feel that something we accomplished made a real difference in people's lives."

In pursuing this goal, Tom oversaw the launch of numerous forward-looking initiatives and was instrumental in solving crises. Marcia Boyle, IDF Founder, commented on Tom's achievements, "As the IDF founders, who hired Tom, we were fortunate to match a growing organization with someone of Tom's experience and strengths. We created IDF to make a difference for patients, and Tom has helped us do that in many ways."

Moran Led the Way Through the IGIV Shortage

During the IGIV shortage of 1998 to 2001, Tom led the foundation in providing IGIV on a just-in-time basis by establishing Safety Net. Over a period of nearly four years, IDF, in cooperation with manufacturers and FFF Enterprises, distributed almost 2000 kilograms – or 50,000 doses – of IGIV to patients nationwide. Safety Net is still in place today, and will be able to assist patients should the industry ever face a similar crisis.

Worked with FDA to Revise Clinical Trial Licensure Requirements

Mr. Moran, IDF staff members and leading clinical immunologists formed a close working relationship with the

U.S. Food and Drug Administration (FDA), and in the year 2000 worked cohesively to revise IGIV clinical trial licensure requirements. This, in turn helped manufacturers bring next-generation products to market faster. Previously, trials required extended timeframes and were much more invasive to the patient. Today, effective and safe clinical trials may be performed in less time with fewer patients required in the studies.

Success in streamlining IGIV clinical trial requirements led to new entrants to the U.S. market, notably Grifols and Octapharma. IDF began dialogues with the FDA on other product categories including biotech and recombinant therapies which hold the promise to introduce new methods of treating primary immune deficiency diseases.

Built Professional IDF Staff

Mr. Moran recruited talented staff, enabling IDF to offer a full complement of programs and services to its community. More than two years ago he hired IDF's first medical director, Jonathan Goldsmith, M.D., and created departments for Patient and Family Services, Medical and Scientific Programs, Finance and Administration and Marketing and Communications. The staff has grown to include a patient advocate and genetics counselor, a public policy expert and a volunteer coordinator.

Established National Conference

IDF's First National Conference was held in Baltimore, Maryland in 2001. It was the first event that brought together in one setting more than 1,000 individuals and families managing a primary immune deficiency

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disease. The National Conference afforded patients and family members the opportunity to participate in scientific and life management sessions, while simultaneously creating a forum for sharing personal stories and enjoying the social activities provided.

Building on the First National Conference as a unique venue for shared experiences, a second conference was planned and implemented in 2003, this time bringing approximately 1,300 people to Baltimore's Inner Harbor. By now a regular biennial event, The Third National Conference will be held in Orlando, Florida June 23-25, 2005 and will attract even more individuals and families.

Assembled Research Consortium

In 2003, with Tom's encouragement, IDF assembled an elite group of the world's leading clinical immunologists. Under the banner of US Immunodeficiency Network (USIDNET), the group successfully competed for a five-year, \$12.8 million NIH contract, establishing the first-ever primary immune deficiency disease research consortium. The consortium will continue to develop patient registries, establish a tissue bank for future investigations, mentor promising young investigators, and award multi-year research grants seeking improved detection, treatment and understanding of primary immune deficiency diseases.

Hans Ochs, M.D., Principal Investigator for USIDNET, said "It is a delight to talk about Tom – but I would rather welcome him to join the organization than to see him leave! To be with Tom is not only fun, it guarantees to be with the winning team." *The consortium is being administered by IDF.*

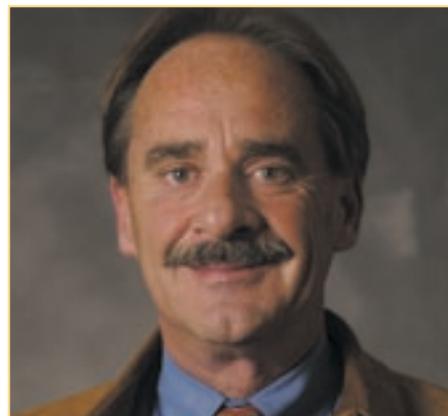
Protected People and Families Affected by Primary Immune Deficiency Diseases

IDF plays an instrumental role in protecting the vulnerable population in times of crisis. During Tom's tenure, the PIDD population faced several threats from the live vaccines for polio, smallpox, and influenza. In each instance Mr. Moran quickly responded by directing IDF to notify the patient population of these potential risks, engaged public health authorities to remain vigilant and encouraged the Medical Advisory Committee (MAC) to publish recommendations.

In March of 2002, an already desperate group of primary immune deficient patients with a potentially fatal disease known as hereditary angioedema (HAE) had lost all hope. Under Tom Moran's astute direction, the Foundation went to work and assembled a coalition that included patients, industry and regulators. According to Anthony J. Castaldo, the head of the US HAE Association, "HAE patients cannot begin to express their gratitude for Tom Moran's vision and efforts. Because of Tom's leadership, a safe and effective treatment for our dreadful disease will soon be available."

Created an Aggressive Public Policy Program

Under Tom's direction, IDF launched an active public policy program encompassing IGIV safety and availability, Medicare eligibility for primary immune deficiency treatments, public health initiatives and increased funding for primary immune deficiency disease research. The annual IDF Day on Capitol Hill events have become fixed features of National



IDF Past President Thomas L. Moran

Conferences and Peer Contact training sessions. Commenting on Tom's efforts, Terry Halper, local volunteer, said, "Tom Moran is a great, supportive strategist. His vision and determination were key to all that IDF has accomplished in both public recognition and the public policy arena. It is hard to imagine how IDF and patients could have ever made this kind of impact without him."

35 Years Serving National Health and Human Services Organizations

Prior to joining IDF in 1996, Mr. Moran was President of the SIDS (Sudden Infant Death Syndrome) Alliance, a national nonprofit health care organization with a mission to promote infant health and survival. Prior to his tenure there, Mr. Moran served in various capacities in local and national United Way organizations, and in community action agencies.

Tom Moran's visionary leadership, combined with his passion for providing for patients, has resulted in tremendous strides in the programs and services for patients, provisions in state and federal regulations and new research initiatives.

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Preparing for the Future of IGIV Therapy

Benefiting from Changes in the Availability of Products



Matt Roth receiving an infusion of IGIV with infusion nurse Barbara Lindenbaum

Background

Recent corporate consolidations and the introduction of new products and new methods of product delivery may affect Immune Globulin, Intravenous (IGIV) use by patients and families with primary immune deficiency diseases. Patients accustomed to receiving a specific product may have to change to a newer version from the same manufacturer or to a product from a different manufacturer due to the introduction and/or discontinuation of some IGIV brands. In addition, safe use of the product in the hospital, infusion suite, or home setting may also be affected by the changes in product availability.

The IGIV Landscape

The first IGIV product was licensed in the United States in 1981 by the firm now known as Bayer Healthcare. Since then, Alpha Therapeutic Corporation, American Red Cross, Aventis Behring, LLC, Baxter Healthcare Corporation, Instituto Grifols and ZLB Bioplasma have also applied for, and received, licenses for their IGIV products. Over the years, some manufacturers have made changes to the production process to incorporate additional viral inactivation or removal procedures and to enhance the acceptability of their IGIV formulation. Laboratory and clinical research studies were performed to document and support the safety, efficacy and tolerability of the new versions of IGIV products.

Corporate Changes

In the last six months there have been even more corporate changes with the acquisition of certain manufacturers by others. The corporate changes include the acquisition of the assets of Alpha Therapeutic Corporation by Instituto Grifols, S.A., based in Barcelona, Spain, and the acquisition of Aventis Behring by ZLB Bioplasma. ZLB Bioplasma is in the process of acquiring Aventis Behring. Carimune NF (ZLB Bioplasma) and Gammar P-IV (Aventis Behring) will remain available in the U.S. for the foreseeable future. Please visit www.ventisbehring.com and www.zlbusa.com for more information as changes in product availability may occur. The recently U.S. licensed Flebogamma will be distributed by Instituto Grifols, and Carimune NF by ZLB. The American Red Cross, Baxter Healthcare, and Bayer will continue their operations unchanged. Characteristics of Grifols' product, Flebogamma, as well as those of other currently available IGIV products, are shown in Table I on page 6, which is similar to the table published in the *IDF Clinical Focus*, October, 2003 issue.

New Products

As mentioned, Grifols has received its U.S. license for Flebogamma. Bayer received a U.S. license and recently released its new product, Gamunex, that will replace Gamimune N, 10%. The characteristics of Gamunex and

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2004 Recommendations for Substituting IGIV Products

Most patients with primary immune deficiency diseases will need to change IGIV products in the current calendar year due to the changes in availability detailed here. The important issues to address are determining the best way to continue to receive IGIV, a life-saving biologic, while minimizing the safety risks associated with changing products.

If you are changing IGIV products and you infuse at home:

- Your physician may require you to receive one to three infusions of the new product in a more controlled medical setting such as a doctor's office, infusion suite, or hospital where reactions, if they occur, can be recognized and treated rapidly, and any changes can be implemented.
- Your physician may suggest the use of medications to reduce the chances of reactions.
- After this "trial" you may be permitted to resume your previous treatment plan.
- If you have been infusing at a faster rate, then slow the rate of infusion to the recommended rate and gradually increase the rate.

If you are changing IGIV products and you infuse in the hospital, a doctor's office, or an infusion suite:

- You may be more thoroughly monitored than in the past. This may include frequent determinations of your pulse, blood pressure and other parameters.
- Your physician may suggest the use of medications to reduce the chances of reactions.
- If you have been infusing at a faster rate, then slow the rate of infusion to the recommended rate. After this "trial" you may be permitted to resume your previous treatment plan.

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Flebogamma are listed in Table I. Octapharma AG, Lachen, Switzerland, has also applied for a U.S. license for its IGIV product, Octagam, and expects licensure in 2004. Other manufacturers are planning clinical research trials for new versions of their IGIV products, which could also be licensed in the near future. As information about these products becomes available, it will be added to the IGIV products characteristics table.

IGIV Administration Location

Based on the IDF's recent survey of patients and families, 40% of those being treated with IGIV receive the infusions at home, 29% in the hospital, 13% in doctor's offices, and 8% in infusion suites. Treatment outside the traditional medical facility setting is generally offered to those who are on a stable dose of the same product for a substantial period of time and experience no adverse events. Under these circumstances, the convenience of at-home administration is carried out with a significant safety margin. Those who self-administer IGIV by the subcutaneous route also administer their treatments at home with a similar large safety margin.

However, a change in product due to choice or necessity may introduce the possibility of reactions to the product that are better managed in a more controlled medical situation. Patients may experience reactions when their product is changed or the rate of administration is altered. The changing landscape of IGIV products will likely result in a change in products for over half of those currently infusing IGIV.

Change is inevitable in medicine. New and improved treatments are continually being investigated and introduced into the practice of medicine. These new treatments may give many patients improved safety and potentially better efficacy. However, the transition to the new treatments may take some adjustment and cause a few short-term changes in treatment routines. Keep in mind that at the end of the transition, you and your family will enjoy the benefits of the new product! ■

Table 1: Characteristics of Available IGIV Products Licensed for Use in the United States - February 2004

BRAND NAME	Polygam S/D		Panglobulin	Gammar-P I.V.	Gammagard S/D		Iveegam EN	Gamunex	Flebogamma 5%	Carimune NF
	5%	10%			5%	10%				
Manufacturer or Distributor	American Red Cross		American Red Cross	Aventis Behring, LLC	Baxter Corporation/BioScience Division		Baxter Corporation/BioScience Division	Bayer HealthCare/Biologic Products Division	Grifols	ZLB Bioplasma, Inc.
Method of Production (Including Viral Inactivation)	Cohn-Oncley fractionation, ultra-filtration, ion-exchange chromatography, solvent detergent treatment		Kistler Nitschmann fractionation, pH 4.0, trace pepsin, nanofiltration	Cohn-Oncley fractionation, ultra-filtration pasteurization at 60° C for 10 hours	Cohn-Oncley fractionation, ultra-filtration, ion-exchange chromatography, solvent detergent treatment		Cold ethanol fractionation, PEG, trypsin treatment	Cohn-Oncley fractionation, caprylate/ chromatography purification, cloth and depth filtration, final container low pH incubation	Cold alcohol fractionation, PEG ion-exchange chromatography, pasteurized at 60C for 10 hours	Kistler Nitschmann fractionation, pH 4.0, trace pepsin, nanofiltration
Form	Lyophilized		Lyophilized	Lyophilized	Lyophilized		Lyophilized	Liquid	Liquid	Lyophilized
Shelf-Life	24 Months		24 Months	24 Months	24 Months		24 Months	36 Months	24 Months	24 Months
Reconstitution Time	<5 minutes at room temperature >20 minutes if cold		Several minutes	<20 minutes	<5 minutes at room temperature >20 minutes if cold		≤10 minutes at room temperature	None (Liquid Solution)	None (Liquid Solution)	Several minutes
Available Concentrations	5%	10%	3 to 12%	5%	5%	10%	5%	10%	5%	3 to 12%
Maximum Recommended Infusion Rate	4 mL/kg/hour	8 mL/kg/hour	>2.5 mL/kg/hour	3.6 mL/kg/hour	4 mL/kg/hour	8 mL/kg/hour	1.8 mL/kg/hour	4.8 mL/kg/hour	6.0 mL/kg/hour	>2.5 mL/kg/hour
Time to Infuse 35 gms ¹	2.5 hours	0.6 hours	<3.3 hours (6% solution)	2.8 hours	2.5 hours	0.6 hours	5.6 hours	1.0 hours	1.6 hours	<3.3 hours (6% Solution)
Sugar Content	20 mg/mL glucose	40 mg/mL glucose	1.67 gm sucrose per gram of protein	50 mg/mL sucrose	20 mg/mL glucose	40 mg/mL glucose	50 mg/mL glucose	None	50 mg/mL D-Sorbitol	1.67 gm sucrose per gram of protein
Sodium Content	8.5 mg/mL sodium chloride	17 mg/mL sodium chloride	<20 mg sodium chloride per gram of protein	5 mg/mL sodium chloride	8.5 mg/mL sodium chloride	17 mg/mL sodium chloride	3 mg/mL sodium chloride	Trace Amounts	<3.2 mEq/L	<20 mg sodium chloride per gram of protein
Osmolarity/Osmolality	636 mOsm/L	1250 mOsm/L	192 - 1074 mOsm/kg	309 mOsm/L	636 mOsm/L	1250 mOsm/L	≥240 mOsm/L	258 mOsm/kg	240-350 mOsm/L	192 - 1074 mOsm/kg
PH	6.4 - 7.2		6.4 - 6.8	6.4 - 7.2	6.4 - 7.2		6.4 - 7.2	4.0 - 4.5	5.0 - 6.0	6.4 - 6.8
IgA Content	< 2.2 µg/mL in a 5% solution		720 µg/mL	<25 µg/mL	< 2.2 µg/mL in a 5% solution		<10 µg/mL	46 µg/mL	<5 µg/mL	720 µg/mL

¹0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL
The time to infuse is based on the maximal infusion rate.

Check product label for storage temperatures, which vary among IGIV brands.

Support BLUE JEANS *for* HEALTHY GENES

IDF introduces an exciting new program to kick off PI Awareness Week. Called *Blue Jeans for Healthy Genes*, this new fundraising program enables you to help support IDF research and patient programs by coordinating a *Blue Jeans for Healthy Genes* program at your workplace. This provides the ideal opportunity to educate those around you about primary immune deficiencies while raising funds for these important endeavors.

Blue Jeans for Healthy Genes Day is a special workday on which your colleagues make a \$5.00 donation or more to IDF in exchange for wearing blue jeans to work on the specified day. This program allows for the IDF to receive 100% of all funds collected and will benefit the patient com-

munity through funding additional research and underwriting existing patient programs.

It's easy to get involved. Call or e-mail IDF to express interest in becoming a *Blue Jeans for Healthy Genes* Coordinator and request an informational packet. This packet includes information about IDF for you to present to your employer. It also contains the details of your responsibilities as a *Blue Jeans for Healthy Genes* Coordinator. Once you decide to participate and have permission from your employer, IDF will provide you with the materials necessary to promote the event and you can start signing up your coworkers!

Additional details about the program and a sample of the materials

in the informational packet will also be available on the IDF web site at: www.primaryimmune.org. So get out your favorite blue jeans and get your colleagues involved in a cause that is important to you. We are looking forward to having you join our fundraising team and hope you will benefit from the experience as well!

Help support IDF while implementing a casual dress day in your workplace. Call or email now: Tracy Namie at 1-800-296-4433 or tn@primaryimmune.org to become a *Blue Jeans for Healthy Genes* Coordinator.

Philanthropy

IDF extends its gratitude to those who generously contribute to the organization, which enables the IDF to fulfill its mission of education, research and advocacy. For more information call 800-296-4433.



Gifts In Memory Of

Anonymous
Florence Arnold
Kathrine Austin
Lane Gottlieb
Ryan Gough
Hannah Green
Evelyn Kessler

Grant Kinnear
Ken Kram
Mary Catherine Myers
Samuel Reding
Dorothy Spalding
Lisa Wright

Gifts In Honor Of

Anonymous
Mark Howard Austin
Amanda Flood
Tara Guetz
Nicholas Sutton
Hannah Rose Willsey

IDF Advocacy at Work for You

Advocacy continued from page 1

to Congressman McCrery. Syd discussed his wife, Gail, and her primary immune deficiency disease. Syd told the Congressman that his wife was able to receive IGIV infusions in their home since her diagnosis. But when she became eligible for Medicare, Gail would have to receive her infusions from a doctor's office or hospital, where she would potentially be exposed to others' infections.

At the same time, over four hundred IDF volunteers campaigned heavily, wrote their representatives and rallied on Capitol Hill. Spurred by his concern and this activity, Congressman McCrery convinced colleagues to fund a study to determine whether home infusion of IGIV for the elderly presented any unique safety risks. The study came to the same conclusion already reached by Congressman McCrery: Medicare's benefits package should be updated to include home infusions of IGIV and that this option would be safe and affordable. Further, this provision would not compromise other patients' access to IGIV.

patients with a diagnosed primary immune deficiency who choose to be infused in their own homes. On December 8, 2003, President Bush signed the Medicare bill into law.

Congressman McCrery and his Legislative Director Jon Traub deserve substantial credit for this inclusion. Patients, family members, and their physicians may send letters of appreciation to the Congressman and his staff for their dedication and commitment to the PIDD community.

The second issue key to the PIDD community is prescription drug costs in the Medicare program. A competitive bidding model introduced by legislators would have limited access to IGIV. Medicare would have allowed coverage for only the least expensive IGIV product. But IDF and its advocates were successful in educating members of Congress on the need for access to all brands of IGIV. They argued that limiting access to different brands would be life threatening to primary immune deficiency patients. Working closely with Chairman Michael

competitive bidding, thereby securing access to all brands of IGIV.

IDF will continue to work closely with Congress regarding any changes in provisions that may adversely affect the primary immune deficiency community before the Bill is enacted in 2006. ■

Benefits of the 2003 Medicare Bill

Home Infusion:

Medicare now covers IGIV in the home, as well as doctor's offices, infusion centers, and hospitals, for patients who have a primary immune deficiency disease.*

Competitive Bidding:

Access to all brands of IGIV is protected under the new Medicare law.

*IDF is working closely with Medicare regarding the coverage of nursing services for the administration of IGIV under the new home health benefit. Presently, patients who have secondary insurance policies may be able to use those benefits to cover the home infusion ancillary services until Medicare makes a final decision on the benefits covered.

Telling your story makes a difference.

Syd Nelson's casual conversation during an airline flight culminated in the inclusion of IGIV home infusions in the 2003 Medicare Bill.

In 2003, Congressman McCrery was finally able to insert language directing Medicare to pay the cost of IGIV for

Bilirakis (R-FL) of the House Energy and Commerce Subcommittee on Health, Congress exempted IGIV from

Thank you letters should be addressed to:

**The Honorable Jim McCrery
U.S. House of Representatives
2104 Rayburn House Office Bldg.
Washington, D.C. 20515**

Local Fundraising Events

How Families are Making a Difference

Usually when a patient is diagnosed with a primary immune deficiency disease, as with many severe diagnoses, family members and friends rally in support. They gather information on the disease and treatments and, in some cases, decide to go a step further by raising funds for research, educational programs and advocacy on the state and federal level.

When families or individuals decide to embark on a fundraising project on behalf of IDF, they are asked to contact the national office. Working in tandem, they can be sure to coordinate key messages and facts and may have the benefit of access to IDF staff and other resources.

In recent months, several families have planned and held special events to raise funds in honor of their children diagnosed with a primary immune deficiency disease.

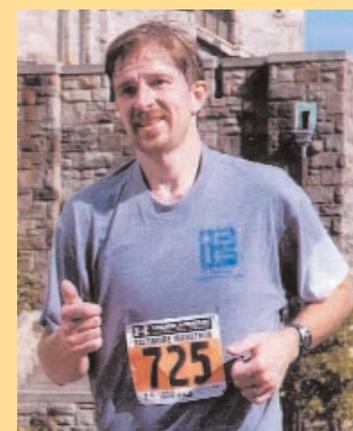
Evelyn Maselli and Terri Lowell held the Third Annual “Spin for the Cure” in five Connecticut locations on October 4, in honor of Evelyn’s daughter, Gabriella. (Pictured top right, with mother Evelyn

Maselli). They secured corporate donations as well as pledges collected by individuals participating in “spinning” – an aerobic activity on exercise bikes, set to music. They raised nearly \$20,000.

Tosha Jo Hennen’s (pictured at right, middle) parents, Andy and Cheryl, and their friends organized a motorcycle rally in Olivia, Minnesota on August 24. Due to the event’s success, bringing in almost \$300, the Hennen’s and friends plan another event this spring.

Mark Flood (right, bottom photo) ran the Baltimore Marathon in honor of his daughter, Amanda. He completed the race October 18 and raised almost \$2,000 in pledges.

All three events generated local media coverage, helping to educate the general population about these diseases. **For more information on how to work with IDF to plan and promote a fundraising event, call 1-800-296-4433. ■**



Recognizing Service and Dedication

Distinguished Layperson Marcia Boyle

Recently, Marcia Boyle was awarded the “Distinguished Layperson Award” by the American Academy of Allergy, Asthma and Immunology (AAAAI). The plaque was presented by (l-r), Burton Zweiman, M.D., FAAAAI, a Past President of AAAAI, and Dean Metcalfe, M.D., FAAAAI, the Immediate Past President of AAAAI.

Marcia Boyle was selected “in recognition of her major contributions, service and dedication on behalf of the patients with immune deficiencies through the establishment of the Immune Deficiency Foundation.”



Raising Awareness and Knowledge

IDF Reaches Scientific and Healthcare Audiences Across the Nation

This spring, IDF representatives for the first time will present at international and national conferences, addressing a wide variety of professional audiences including scientists, physicians, nurses, nurse practitioners and other healthcare professionals. The presenters include the following.

American Academy of Allergy, Asthma and Immunology (AAAAI) March 19-23, 2004 in San Francisco, CA

- John M. Boyle, Ph.D. and Jennifer B. Scharpf, M.P.H.
Title: "Characteristics and Health Outcomes of Patients with Primary Immune Deficiency Diseases in the United States"
Authors: John M. Boyle, Ph.D. and Jennifer B. Scharpf, M.P.H., Schulman, Ronca and Bucavalas, Inc., Rockville, MD and IDF, Towson, MD
- Jonathan Goldsmith, M.D.
(panel introduction and poster session)
Title: "Commercial Immune Globulin, Intravenous (IGIV) Products Contain Anti-Vaccinia Antibodies"
Authors: JC Goldsmith, M.D. and DE Scott, M.D. IDF, Towson, MD, and Center for Biologics Evaluation and Research, US Food and Drug Administration, Bethesda, MD

National Association of Pediatric Nurse Associates and Practitioners (NAPNAP)

March 24-27, 2004 in Dallas, TX

- Debra Sedlak, C.P.N.P.
Title: "Evaluation of Patients with Suspected Primary Immune Deficiency"

Grupo Latinoamericano de Inmunodeficiencias Primarias (LAGID): Tenth Meeting

April 22-24, 2004 in Santiago, Chile

- Jonathan Goldsmith, M.D., with Dr. Eduardo Talesnik and Dr. Carmen Luz Navarrete
Title: *Reunion Corporacion de Padres (Parents' Meeting)*

IDF will also exhibit at AAAAI and NAPNAP. In addition, Dr. Jonathan Goldsmith, IDF Acting President and Vice President of Medical Affairs, will participate in the PPTA (Plasma Protein Therapeutics Association) Roundtable Discussions on Emerging Infectious Diseases in Brussels, Belgium this spring.

2003 IDF Fellowship:

Dr. Nicola Bobey Receives Award for Study of DiGeorge Syndrome



Dr. Nicola Bobey, IDF Fellow

The Immune Deficiency Foundation's Fellowship Program is a national, peer-reviewed competition for clinical researchers. The program encourages the training of future specialists, interested in improving the understanding and treatment of primary immune deficiency diseases. Beginning in the spring of 2004, the timing of the IDF Fellowship Award will be modified to align with the academic calendar of July 1 to June 30.

The 2003 Fellowship has been awarded to Nicola Bobey, M.D., who is currently completing a three-year research fellowship in Pediatric Hematology/Oncology at Cincinnati Children's Hospital Medical Center in Cincinnati, Ohio.

Dr. Bobey's research is focused on the study of the DiGeorge Syndrome (DGS) and is entitled, "Immune Dysfunction in Chromosome 22q11.2 Deletion Syndromes: Thymic Output and Analysis of Compensatory Homeostatic Proliferation." She will study patients with DiGeorge Syndrome (DSG) who also have deletions within chromosome 22q11.2. The purpose of the study is to explore mechanisms for T cell immunodeficiency and autoimmunity in these patients. Dr. Bobey will try to correlate her findings in the laboratory with clinical outcomes in her patients in an effort to better diagnose and potentially treat patients with 22q11.2 deletion.

Dr. Bobey obtained her M.D. at the University of Calgary in Alberta, Canada, where she embarked on the path of clinical research. She has been involved in several projects since that time. After medical school, she completed her Pediatric Residency at Alberta Children's Hospital in June, 2001.

Dr. Bobey has been appointed a Research Fellow in the division of Pediatric Hematology/Oncology at Stanford

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University working in the laboratory of Dr. David Lewis, Associate Professor of Pediatrics, Division of Immunology and Transplantation Biology. She is also currently progressing towards achieving her Master's Degree in Epidemiology and Biostatistics at the University of Cincinnati in the program of Environmental Health. She is the author of three publications, two of which focus on clinical hematology/oncology and a third that explores the genetics of primary immunodeficiency. Dr. Bobey has a strong interest in primary immunodeficiency, as evident by her previous involvement in the Immunodeficiency Clinic at Cincinnati Children's Medical Center. ■

Moran continued from page 3

Dr. Richard Barr, Chairman of the IDF Board of Trustees, said in reflection, "Tom Moran was the architect and catalyst of the phenomenal growth that IDF has experienced over the past seven years. His uniqueness remains his sensitivity and commitment to each and every immune deficient patient. We wish him well in his new endeavors at PSI."

The remainder of the IDF executive team remains intact, with the exception of Paul Pinciaro, Ph.D., who joins Tom Moran at PSI.

PSI is a complete solution for the clinical development and direct-to-patient distribution of therapeutics for rare diseases. It provides services to patients and their treaters, patient advocacy groups, and therapeutics manufacturers. ■

IDF SERVES A WIDENING COMMUNITY

Spanish-Language Version of the IDF "Patient and Family Handbook" Now Available



IDF has long recognized that primary immune deficiency diseases affect people worldwide. With that in mind, and coupled with a strong mission to educate patients and their families, IDF translated the Patient and Family Handbook into Spanish. The translated text is now available on the web site at: www.primaryimmune.org, by accessing "Publications," then "The Patient and Family Handbook."

A copy can be mailed from IDF if anyone has difficulty downloading the handbook. Simply call IDF to request one. A printed version will be available later this year.

Several people were instrumental in developing this project. Key among them were the following.

- Joseph Church, M.D., Division of Clinical Immunology and Allergy at Children's Hospital of Los Angeles in Los Angeles, CA, initiated the Spanish translation.
- Evelyn Cederbaum, president of ESTRANSLATE, of Santa Monica, CA provided translation services.
- Baxter Healthcare Corporation provided an unrestricted educational grant to IDF to fund the project.

Also available in Spanish is the primer, "Nuestro Sistema Immunologico," (Our Immune System). The Patient and Family Handbook is also available in French on the IDF web site.

IDF Family Retreats 2004

Register Now!

IDF will host four Regional Family Retreats in 2004, offering patients and their families the rare opportunity to attend both scientific and life management skills workshops to hear directly from the experts. Social and networking activities are planned during the weekends as well as a youth program of fun and educational activities. Check your mail for a brochure or call IDF at 1-800-296-4433 for more information. The brochure is also available online at www.primaryimmune.org.



- **Woodloch Resort**
Hawley, PA
March 26-28, 2004
- **Garrett Creek Ranch**
Paradise, TX
September 10-12, 2004
- **Sunriver Resort**
Bend, OR
June 11-13, 2004
- **Simpsonwood Conference Center**
Norcross, GA
October 22-24, 2004

IDF ADVOCATE

Mark your Calendars

IDF Regional Family Retreats 2004

Please see Page 11 for more information.

- Hawley, PA, March 26-28
- Paradise, TX, September 10-12
- Bend, OR, June 11-13
- Norcross, GA, October 22-24

IDF Local Patient Meetings 2004

IDF plans educational and support meetings in local communities throughout the year. For more information call IDF at 800-296-4433.

- Minneapolis, MN, April 24
- Salt Lake City, UT, May 3

PI Awareness Week: April 19-25, 2004

Help raise awareness and funds. See page 7 for more information.

IDF National Conference 2005

The Third IDF National Conference will be held June 23-25, 2005 in Orlando, Florida.

Combined Federated Campaign #9808

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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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