

# IDF ADVOCATE

**IDF NATIONAL CONFERENCE**  
 Save the Date: June 19-21, 2003

## New Health Insurance Assistance Program

In response to the many inquiries we receive from both patients and health care providers, IDF has established a Health Insurance Assistance Program. We know individuals affected by primary immune deficiency diseases face many challenges with regard to health insurance coverage. The IDF Health Insurance Assistance Program is one step in helping individuals and their health care providers meet these challenges. This program includes a reimbursement helpline and a pilot financial assistance program.

### REIMBURSEMENT HELPLINE

Through the reimbursement helpline, individuals and health care providers can seek assistance for insurance problems, including denial of claims for therapy or procedures related to primary immune

deficiency diseases, and for problems related to reimbursement of IGIV.

### PILOT FINANCIAL ASSISTANCE PROGRAM

The second component of the Health Insurance Assistance Program has been made possible through a partnership with Patient Services, Incorporated (PSI). PSI is a non-profit organization with eleven years of experience in assisting individuals with certain chronic illnesses to obtain and maintain affordable health insurance. IDF and PSI have created a pilot program for one year to provide limited financial assistance for insurance premium or coinsurance payments to individuals with primary immune deficiency diseases who meet financial eligibility criteria.



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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 Foundation.

- Alpha Therapeutic Corporation
- Baxter Healthcare Corporation
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# IDF ADVOCATE

THE NATIONAL NEWSLETTER OF THE IMMUNE DEFICIENCY FOUNDATION



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## Lives in the Balance



### A CONTINUING SERIES ON IDF CORE SERVICES

In this issue of the *IDF Advocate*, we present a second article that focuses on IDF's Core Services Programs and how they improve the health and quality of life of people with primary immune deficiencies. This article explains the long-term process of influencing public policy related to primary immune deficiencies, the resulting benefits to patients and their families, and how you can participate.

### Influence: What does it really mean?

Anyone who has seen an episode of the TV series "The West Wing" might well imagine that the work of the federal government is one dramatic and highly politicized conflict after another, with life and death decisions influenced by personal intrigue and charisma, the granting of favors, and unlikely alliances between mortal enemies. "Perhaps those things do happen on occasion," states Jason Bablak, IDF's vice president of public policy and legal affairs, "but in my experience, the policies that guide government activities—and have real impact on people's lives—are created and changed through a long-term process that demands patience and consistency. Primarily, it's a process of talking and listening to people in government agencies—people who are not household names—who will do their best to help you if you ask. Success depends on being available and prepared for that discussion."

## A MESSAGE FROM THE EDITOR

Do you need more information on primary immune deficiency diseases? Are you looking for a knowledgeable professional or support network to share your concerns with? Either way, IDF can help. To request our educational literature for patients and family members, or to ask specific questions, call our toll-free IDF Hotline at 800-296-4433. Our professional staff will answer your questions about primary immune deficiencies and put you in touch with our network of volunteers. Remember—IDF is here to help!

*Elizabeth Lee*

## IDF ADVOCATE

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LIVES IN THE BALANCE, CONTINUED FROM PAGE 1

## Reducing the risks of future IGIV shortages

The recent shortage in immunoglobulin (IGIV) provides an excellent example of how public policy is actually changed. IDF determined that an important factor in the shortage was the lack of new products coming to market, a problem that would eventually undermine all other efforts to alleviate the shortage. What was the problem? In 1997, the United States Food and Drug Administration (FDA) revised its IGIV clinical trials design. The design then being encouraged by the FDA was a barrier to entry into the U.S. market for all but the largest international manufacturers. The endpoints, number of patients, and statistical data requirements resulted in a trial design that was extremely difficult to perform on an “orphan patient community” (such as people with primary immune deficiencies), and discouraged multiple, simultaneous clinical trials.

IDF worked closely with FDA personnel over several years to achieve a balance between their goal of collecting more information and our patients’ continuing need for IGIV. The result was a trial design that provided sufficient safety and efficacy data to answer their safety concerns and posed less of a barrier to new manufacturers. Today, additional companies are preparing to enter the market, helping reduce the risk of future shortages.

In a similar manner, IDF participates in discussions of the FDA’s blood donor screening guidelines, another potential source of blood product shortages. For example, the agency seeks to reduce the risk that people with variant Creutzfeldt-Jacob disease (the rare and little understood human version of “mad cow disease”) will donate blood; IDF seeks to balance that risk against the well-defined,



From left: U.S. Congressman Jim McCrery, IDF Louisiana volunteer Syd Nelson, IDF vice president Jason Bablak

ongoing need for a steady stream of blood products to keep people with primary immune deficiencies healthy. States Jason Bablak, “The idea that a balance can be achieved between the goals of government agencies, drug manufacturers, insurance companies, and our patients is central to IDF’s public policy initiatives. This balance makes a real difference in people’s lives.”

## Appropriations: Ensuring support for the research we need

The funding of federal agencies, including the National Institutes of Health (NIH) and the FDA, takes place through the creation of “appropriations bills” by congressional committees. IDF goes to the committee hearings to explain what primary immune deficiencies are and why research is important. When the committees include related statements in their appropriations bills, these statements guide the agencies and their activities, resulting in increased attention to primary immune diseases.

In addition, IDF works directly with the different institutes at NIH that have an interest in primary immune deficiencies. One is the National Insti-

tute of Allergy and Infectious Diseases (NIAID), which has announced that it will begin to spend more money on primary immune deficiency research. To oversee distribution of this money—probably between \$2 and \$5 million per year—the Institute will create a national network of research physicians and investigators who will administer the grants. IDF is working with NIAID officials and the medical research community to ensure the best possible outcome from this initiative.

## Improving access to care

Beyond ensuring support for research and the safety and availability of blood products, IDF works to improve access to care for primary immune deficiency patients. Two current initiatives concern Medicare reimbursement, one for home infusion of IGIV, the other for IGIV itself. Medicare currently covers the cost of drugs administered in a hospital or a doctor's office, but not drugs taken at home, including home infusion of IGIV. Thus, as the primary immune deficient population ages and transfers to Medicare, patients may have to change providers and infusion methods. IDF believes that it is completely safe to do infusion at home and may be less expensive as well. Working with Congressman Jim McCrery (see article on page 4), IDF was able to incorporate a study on home infusion safety and cost-effectiveness using the FY 2000 appropriations bill for the Centers for Medicare and Medicaid Services (formerly HCEA). The results of this study will help support the inclusion of a new home infusion benefit for IGIV in the near future.

Regarding reimbursement for IGIV itself, IDF helped to gain a three-year exemption for IGIV and other plasma products, so they are not "bundled" with other products which cost far less to produce and

administer; such bundling would result in reimbursement of only a fraction of the actual costs. This exemption will run out at the end of 2002, and IDF is currently working to establish a permanent exemption for IGIV.

## What can you do to help?

IDF's public policy initiatives are generously supported by our Champions Circle of Support (see inset below). There is also a role for patients and their families. What can you do? First, participate in IDF Capitol Hill Days. These events help improve awareness of primary immune deficiencies and give these diseases a human face. Second, join with us in letter and phone campaigns to advocate for specific causes. We will provide information and instructions. Third, call us to serve as a volunteer. We are building a list of concerned people who will help us in future initiatives, and we hope your name will be on that list. Fourth, if you have established relationships with Congressional or Senatorial representatives, let us know so we can evaluate contacting them on behalf of IDF.

## THE SMALLPOX VACCINATION RISK

The primary immune deficient population may be at risk if smallpox vaccination is resumed in the United States. In response to the potential problems associated with vaccination, IDF has taken the following actions to protect people with fragile immune systems, and normal populations which have complications from the vaccine:

- Organized a Variola Working Group (variola is the medical name for smallpox) of medical and scientific experts
- Proposed a study to determine which, if any, of currently available immunoglobulins have vaccinia (the virus used in the smallpox vaccine) antibodies in them, and opened discussions with fractionators and regulatory authorities
- Developed a research strategy to test IGIV for vaccinia antibodies, and discussed it with NIAID, CDC, FDA, and DHHS.



IDF Medical Director Jonathan Goldsmith, M.D. testified before the FDA's Blood Products Advisory Committee that people with primary immune deficiencies faced special risks under the threat of bioterrorism. An FDA spokesman stated they shared our concerns and were supportive of developing a research agenda. Dr. Goldsmith also presented and proposed strategies to the Advisory Committee on Immunization Practices (CDC's Smallpox Working Group).

## IDF CHAMPIONS CIRCLE OF SUPPORT

### 2002 CORE SERVICES

Services to Individuals and Families  
 IDF Hotline  
 Patient Advocacy  
 IDF Local Volunteer Network  
 Patient Notification System  
 Scholarship Program

### Public Policy

Blood Safety and Availability  
 Access to Quality Health Care  
 Support for Publicly Funded Research

### Medical and Scientific Programs

Consulting Immunologist Program  
 Fellowship Program  
 IDF Research Grant Program  
 Visiting Professor Program

### 2002 CHAMPIONS CIRCLE

Alpha Therapeutic Corporation  
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 ZLB Bioplasma Inc

## Immune Deficiency Foundation Presents 2002 Public Policy Leadership Award to Congressman Jim McCrery



Congressman Jim McCrery and Gail Nelson

On Thursday, April 11, the Immune Deficiency Foundation presented Congressman Jim McCrery (R-LA) with its 2002 Public Policy Leadership Award in a ceremony on Capitol Hill in Washington, D.C.

Congressman McCrery was recognized for his leadership in advancing the Foundation's public policy agenda on Capitol Hill. Congressman McCrery has worked tirelessly to support IDF priorities, including: increasing federal support for primary immune deficiency research at the National Institutes of Health; establishing a primary immune deficiency education program at the Centers for Disease Control and Prevention; and supporting the establishment of a Medicare reimbursement benefit for home infusion of IGIV.

Congressman McCrery was presented with the award by Mrs. Gail Nelson, an active IDF volunteer and constituent of the Congressman's from Shreveport.

The award ceremony was part of IDF's second Capitol Hill Day in Washington, D.C. Over 60 primary immune deficient patients and families participated in the event, making visits to congressional offices in support of the Foundation's public policy priorities.

## New IDF Peer Contact Network

The Immune Deficiency Foundation is pleased to announce it has expanded its network of volunteers throughout the country, with the introduction of "Peer Contacts." This new support network is ready to lend a helping hand to you and your family.

Peer Contact volunteers receive training and materials to provide peer support to other individuals affected by primary immune deficiencies. Nearly one hundred volunteers participated in IDF's inaugural Peer Contact Training Workshop on April 11-13, 2002 in Arlington, Virginia. The two-day workshop, sponsored by an educational grant from Aventis Behring, provided volunteers the opportunity to develop the skills and gain knowledge of the resources necessary to provide effective peer support to others in their communities.

In addition to providing one-on-one support on the phone or via e-mail, Peer Contacts can provide information on



Long-time IDF volunteers welcome new Peer Contacts

local resources, plan educational meetings, increase awareness of primary immune deficiencies, and advocate on behalf of patients in both local and federal public policy arenas.

Most importantly, Peer Contacts are eager to listen to you, and can provide you with educational and community resources to help you overcome the obstacles and challenges associated with living with a chronic illness. Although primary immune deficiencies are rare diseases, you can become part of IDF's large and supportive community. If you would like to get connected with a Peer Contact in your area, please call IDF at 1-800-296-4433.



Carla Pellechia, Pharm. D., Aventis Behring, Medical Affairs, presents information on plasma safety



Attendees at a Peer Contact Training Workshop seminar

## On-Going Regional Activities

The Immune Deficiency Foundation continues to offer peer support and local programming opportunities on a regional basis to individuals and families affected by primary immune deficiency diseases. A team of volunteers throughout the U.S. provides invaluable peer support, coordinates local education programs, and increases awareness of primary immune deficiency diseases in their communities. To learn more about IDF activities in your community, call the IDF office at 1-800-296-4433.

This summer, local IDF activities are being planned in Ohio, Kansas City, Wisconsin, and upstate New York. Invitations will be mailed to individuals in each state. Additional programming for other areas of the country will be scheduled throughout this year... Keep an eye out for IDF in your community!

# Central Venous Access: What You Should Know

Central venous access techniques were developed to make treatment of people with chronic or severe diseases easier. In the case of primary immune deficiency diseases, treatments such as bone marrow transplantation and intravenous gamma globulin therapy have been greatly facilitated by the development of central venous access devices. To insure a long-term access route, the large veins inside the chest, which can tolerate thick and sometimes irritating fluids, are used. These veins are the central veins leading directly into the heart.

Central venous access devices are used widely in medical practice for the delivery of medications, nutrition and blood product support. Tiny babies a few days old, patients who are too ill to take oral feedings, and those requiring reliable administration of antibiotics can benefit from the use of venous access devices.

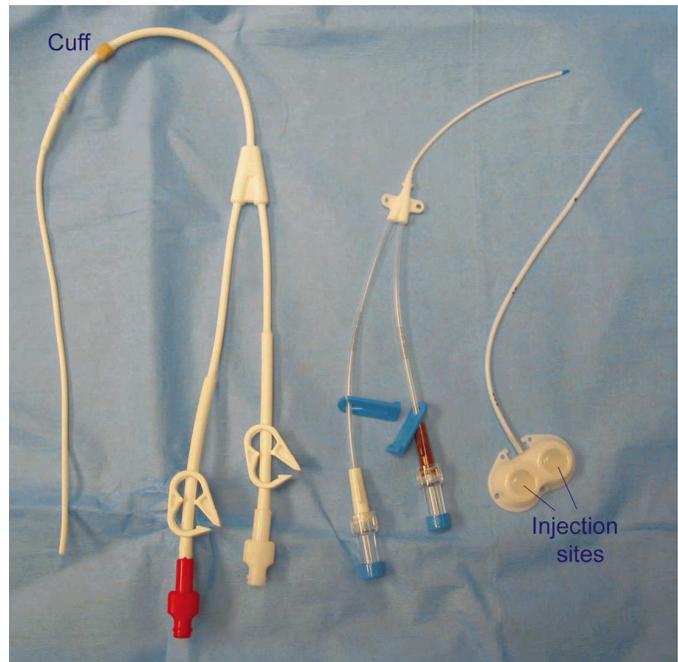
People with primary immune deficiencies may use Broviac, Groshong, or Hickman catheters, or totally implanted devices called ports. Catheters are made of soft silicone silastic tubing and designed to be inserted into a central vein and then tunneled under the skin so that the exit site is far away from the point where the catheter actually

**BENEFITS VERSUS RISKS:**

BENEFITS	RISKS
<ul style="list-style-type: none"><li>• Easy venous access</li><li>• Better tolerance of medications</li></ul>	<ul style="list-style-type: none"><li>• Insertion complications</li><li>• Infection</li><li>• Malfunction</li><li>• Clotting</li></ul>

enters into the vein. The tunnel serves as a barrier to infection, and helps secure the catheter in place. If properly cared for, these catheters can stay in place for years. (See figure.)

Totally implanted devices, known as ports, mediports, or infusaports, are placed completely under the skin so that no part is exposed. They typically consist of a small chamber to which the catheter is attached. The catheter is inserted into a central vein, and the chamber is placed in a pocket just under the skin and secured in place. When needed, a special needle is inserted through the



Central Venous Catheters:

Left: Catheter of Broviac, Hickman or Groshong type. Note cuff, which acts as infection barrier and helps to maintain the catheter in place.

Middle: Non-tunneled central venous catheter, usually inserted in a large vein under the clavicle or in the neck.

Right: Infusaport with the injection/withdrawal chambers at the bottom.

skin and into the chamber, allowing fluid and medicine to be infused through the catheter, and blood to be withdrawn. The needle can remain in position for days at a time, covered by a sterile bandage. Ports can also stay in place for a very long time. (See figure.)

## Risks and possible complications

As with any operation, there are possible risks during the insertion procedure of a catheter or port. These risks include bleeding, injury to the area close to where the catheter is being placed, puncturing an artery, and mistakenly placing the catheter into an artery instead of the vein. However, these risks are very small, and are clearly outweighed in most cases by the significant advantages that the catheters provide.

Long-term risks of catheter and port use include infection and catheter malfunction. If infection occurs, the patient is treated with antibiotics, and frequently the infection can be cured. However, if the infection does not resolve, or it is very severe, the line may need to be removed.

Malfunction is usually a result of clotting in the catheter, at the end of the catheter, or in the vein in which the catheter is inserted. Clotting may require the removal of the catheter and make replacement very challenging. On occasion, a catheter may break or tear, and even more rarely, catheters may break off inside the body.

## Routine care

Most hospitals have protocols to care for central venous devices. Any catheter that enters the skin is covered with a sterile dressing at the exit site at all times. The dressing is changed two to three times per week. Ports, when they are not in use, do not require any dressing since they are under the skin. All venous access devices need to be flushed with a heparin solution to prevent blood clots when they are not being used. Catheters are usually flushed every 24 to 48 hours. Ports are usually flushed every 3 to 4 weeks. Parents readily acquire the knack of caring for catheters and assume this responsibility at home.

## A final note

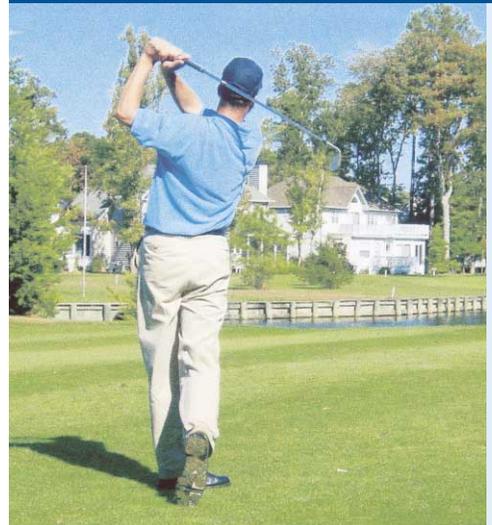
The necessity for long-term indwelling catheters is less when the only need is monthly intravenous gamma globulin infusions in children and adults. Once venous access is solely a matter of performing a venipuncture, the risks of the central venous catheter and the care necessary to prevent clotting or infection probably outweigh the benefit of avoiding a monthly needle stick.

## Summary

The administration of life-saving medications, nutritional support and transfusions can be carried out on a long-term basis through the use of different types of indwelling venous access devices. In small infants, the difficulty of finding and maintaining venous access is avoided. For complicated procedures such as bone marrow transplantation or frequent treatments such as periodic infusions of medications, central venous access may be an extremely helpful technique. As with any medical device, the benefits of using catheters and ports must be weighed against the risks. IDF recommends that you discuss the benefits and risks with your physician prior to making a decision on the use of central venous devices.

To view the complete article on central venous access, visit the IDF Website at [www.primaryimmune.org/](http://www.primaryimmune.org/).

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Nate Burdick tees off

## Golfer Raises Funds for IDF, Youth Programs

Middle Atlantic PGA Junior Golf Director Nate Burdick is a person who is driven to excel and make a difference. Last fall, Nate created a new fundraising event, "100 Holes of Golf for Charity," to support the Immune Deficiency Foundation and the Middle Atlantic PGA Junior Golf Foundation (MAPGA-JGF). At the beautiful River Run Golf Club in Ocean City, Maryland, Nate joined River Run's Head PGA Professional, Bob Baldassari, to play 100 holes, which they completed in seven and a half hours. As a result of that marathon effort, they raised \$15,000, split evenly between IDF and the MAPGA-JGF.

Nate was diagnosed with X-linked Agammaglobulinemia at the age of 11 months, and receives intravenous immunoglobulin replacement every three weeks. Although he has faced significant medical challenges, he has been able to lead a normal and active life, serving as the Junior Golf Director for the MAPGA Section for the past five years. Nate wanted to support the good work of the two charities that meant the most to him, and sought pledges from family, friends, colleagues, and members of IDF and the Middle Atlantic PGA. In fact,

## Recent Developments Affecting IGIV Availability in the United States

The Alpha Therapeutic Corporation is reporting that Venoglobulin S is currently being distributed broadly throughout the United States after resuming full production last fall. Alpha Therapeutic Corporation made improvements to its manufacturing facility in Los Angeles, California to comply with U.S. Food and Drug Administration manufacturing standards. Patients, physicians, and other interested parties can obtain more information by calling Alpha at 800-292-6118 or visiting their website at [www.alphather.com](http://www.alphather.com).

ZLB Bioplasma Inc., based in Glendale, California, was founded in August 2000. ZLB manufactures and distributes IGIV worldwide, including in the United States. Their IGIV, currently sold under the name ZLB IGIV (human) was previously distributed in the U.S. by Novartis Pharmaceuticals Corporation under the trade name Sandoglobulin. ZLB has filed with the U.S. FDA to distribute their IGIV in the United States under the new trade name Carimune. For more information, please contact ZLB at 866-244-2952 or [www.zlb.com](http://www.zlb.com).

Another U.S. brand of IGIV, Panglobulin, distributed by the American Red Cross, is manufactured in the ZLB facility in Bern, Switzerland.

this event would not have happened without the support of the PGA of America: Bob Baldassari allowed Nate to play the River Run course at no charge, and several hundred members of the PGA made generous contributions that benefited both IDF and the MAPGA-JGF. Tom Moran, IDF President, remarked that the philanthropic partnership between the PGA and IDF demonstrates the good that can be accomplished when two organizations work together.

Marcia Boyle, IDF Founder, was pleased to represent IDF at the event. She observed, "Nate's efforts to support these charities is an example of a person taking charge and making a difference. We are honored to be included in his fundraising efforts, which help our mission on behalf of patients with primary immune deficiency diseases. We are most grateful to Nate, to the PGA of America, to the many contributors throughout the PGA, and all of our IDF friends who contributed to this exciting effort." The money raised for IDF will help fund the IDF Annual Research Award program. "Nate's initiative and determination to make this event happen are truly extraordinary and inspiring," says Dick Johns, Executive Director of the Middle Atlantic Section PGA. "He is an outstanding example of what is great about young Americans, the PGA of America, and those individuals challenged with a health condition. Those of us associated with the PGA



Nate Burdick and Marcia Boyle, IDF Founder

GIFTS IN HONOR OF...

- Mark Austin
- Nicholas Barks
- The Brown Foundation
- Harry Kellman for the Eric Marder scholarship fund
- Mary Munson
- Thomas Ryan Smith

GIFTS IN MEMORY OF...

- Gashaku Butoyi for the O'Colmain Wedding
- Andrew Valentine
- Aunt Kitty
- Buddy Webb
- Joseph Dellorso

of America are extremely proud of Nate, his gracious benevolence, and his generous contributions to these most worthy charities." The money raised for the Middle Atlantic PGA Junior Golf Foundation will help subsidize a substantial number of youth golf programs throughout Maryland, Virginia, and Washington, D.C.

On the day of the event, Nate was joined by his parents, Ken and Patricia Burdick, and his cousin, Jeff Rose, who also has X-linked Agammaglobulinemia. The three of them drove more than eight hours from Massachusetts to help. Nate's girlfriend, Melissa Meurer, River Run staff member, Fran Hathaway, and River Run homeowner, Bob Dillon, also provided invaluable assistance to help the event run smoothly and quickly.

Nate plans to make "100 Holes of Golf for Charity" an annual event, and, hopefully, substantially increase the funds raised. IDF will keep its members informed of the date for the next event, which will take place again at River Run Golf Club in October 2002. We strongly urge our membership to participate by making a tax-deductible pledge of any amount. Pledge forms will be sent out this summer, and will be available on the IDF Website at [www.primaryimmune.org](http://www.primaryimmune.org). If you wish to make a donation now, please contact Judy Flagle at IDF at 1-800-296-4433.

For individuals who are associated with the golf industry or the PGA of America, the "100 Holes of Golf for Charity" event could be undertaken in other areas of the country. For more information, please contact Jennifer Bass at IDF at 1-800-296-4433.

# Give to IDF through the Combined Federal Campaign

The Combined Federal Campaign is the only U.S. government authorized solicitation of employees in the federal workplace on behalf of charitable organizations. It is the largest workplace fundraising campaign in the world, with access to over 2.2 million federal employees.

The Immune Deficiency Foundation has been found eligible for inclusion in the 2002 Combined Federal Campaign National List. IDF's information and summary of services will appear in the listing of national and international organizations which is published in each local campaign brochure. These brochures are distributed throughout the United States and overseas. The Combined Federal Campaign identification number for IDF is 9808. We encourage all federal employees to contribute to the Foundation through this method. Also, don't forget to spread the word to your federal associates about this simple and easy method of contributing to IDF.