The Immune Deficiency Foundation (IDF) is pleased to announce that it has been awarded the grant “Resources to Assist Investigations in Primary Immunodeficiency Diseases” from the National Institutes of Health (NIH). This grant will allow IDF to continue to advance the detection, understanding, diagnosis and treatment of primary immunodeficiency diseases through their program, the United States Immunodeficiency Network, known as USIDNET.

USIDNET is a team of leading immunologists whose purpose is to advance knowledge in the field of primary immunodeficiency diseases (PIDD). USIDNET solicits, develops, evaluates and implements clinical research strategies to advance the detection, understanding, diagnosis and treatment of PIDD. There are three main components: the national patient registry, a cell repository, and educational programs to train new investigators. The patient consented registry is central to USIDNET’s goals to collect, supply and examine longitudinal data about the diagnosis, prognosis and best treatment strategies in PIDD.

“We are pleased to receive this grant that will allow us to continue the important work of USIDNET,” said IDF president and founder Marcia Boyle. “IDF has been administering patient registries for primary immunodeficiencies supported by the NIH since 1992 and we are excited about the potential of the new patient-consented registries to dramatically improve the treatment of patients.”

The Principal Investigator on the grant, Dr. Charlotte Cunningham-Rundles from Mt. Sinai Medical Center added, “We are enormously pleased with the progress of USIDNET and are delighted to be able to both continue and accelerate the work in primary immune deficiency over the next five years. We thank all of our collaborators, friends in industry and government, and especially the patients who continue to inspire us.”

Dr. Cunningham-Rundles is joined by the Co-Investigators Dr. Luigi Notarangelo, Children’s Hospital Boston; Dr. Kathleen Sullivan, Children’s Hospital of Pennsylvania and Dr. Jennifer Puck from the University of California, San Francisco.

This grant is funded by the National Institute of Allergy and Infectious Diseases (NIAID), which is a component of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (DHHS).

For more information on USIDNET, visit www.usidnet.org.

Patients and physicians interested in being involved in the PIDD registry, please call 800.296.4433 or email contact@usidnet.org.
IDF Announces Campaign for National Newborn Screening Standards for SCID

IDF has announced its SCID Newborn Screening Campaign in an enthusiastic response to Health and Human Services (HHS) Secretary, Kathleen Sebelius’ endorsement of the addition of Severe Combined Immunodeficiency (SCID) to the core panel of 29 genetic disorders that are part of HHS’ national Recommended Uniform Screening Panel for newborn children. The campaign’s goal is to urge each of the 50 states and territories to include newborn screening test for SCID as quickly as possible.

On May 21, 2010, Kathleen Sebelius, Secretary of Health and Human Services (HHS) announced the addition of Severe Combined Immunodeficiency (SCID)—commonly known as bubble boy disease—to the core panel of 29 genetic disorders as part of her recommendation to adopt the national Recommended Uniform Screening Panel. The Secretary made her announcement in a letter to Dr. Rodney Howell, Chair of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC). SCID is the first condition nominated by SACHDNC to be added to the core panel of disorders.

SCID is a primary immunodeficiency disease. Affected infants lack T lymphocytes, the white blood cells that help resist infections due to a wide array of viruses, bacteria and fungi. Babies with SCID appear healthy at birth, but without early treatment, most often by bone marrow transplant from a healthy donor, these infants cannot survive.

“Now the hard work begins,” said Marcia Boyle, President and Founder of the Immune Deficiency Foundation. “We look forward to success with the IDF Newborn Screening Campaign. We have fantastic enthusiasm from our volunteers which will make this campaign a success. IDF volunteers are the best!”

The IDF strongly supported and worked tirelessly toward this goal for years by pushing successfully for the SACHDNC to make a recommendation to include SCID on the newborn screening protocols.

For more information, please contact IDF at 800-296-4433, or idf@primaryimmune.org. Or visit the IDF website at www.primaryimmune.org.
Infusions, the Internet and a Couple of Bowling Buddies

by J. Doug Gill

Children and their love of video games, much like the dog-bites-man axiom, is not news. Take one spirited six-year-old; add an active eight-year-old and a gaming console, and the electronic competition could carry on endlessly - or at least until parental intervention stifles the contest.

What is news, however, is not that this video challenge takes place with the competitors hundreds of miles apart, but in the circumstances surrounding the online matches - and in parents that not only support the activity, but also encourage it.

Before their introduction to Skype, a computer software application that gives users the ability to make telephone/video conferencing calls over the Internet, six-year-old Jacob Klipp (of Texas) and eight-year-old Ethan McGrew (from Louisiana) shared one notable characteristic: both boys have common variable immune deficiency disease (CVID).

Now, thanks to two tech-savvy moms who appreciate the positive influence of peer support, Jacob and Ethan can share their infusion treatments - while engaged in a heated game of Bowling.

“I’m a Wii bowling pro,” Ethan tells me during our phone conversation, “I’ve only lost, like, three times in all the years I’ve been playing.”

Ethan’s mother, Denna McGrew, giggles at her son’s boasts, and tells me that Skype conferences and game playing are just part of this unique equation.

“Swine flu,” Denna tells me, recalling the formulation of this distinctive relationship. “Ethan was sick for nine weeks, and I spent most of the time researching the flu and its effect on patients with CVID.”

That research led Denna to Lisa Klipp’s blog, an online journal kept by the family that chronicles her son Jacob’s “journey with CVID.”

After exchanging emails and discussing their sons’ diseases and treatments, the two moms decided to introduce the Skype meeting into the boys’ treatment session.

Not surprisingly, Ethan and his family also have a blog – the adorably named ‘Here I Am Down Here’ - in which young Ethan shares notable tidbits such as, “Yesterday I went to MaMaws. I played in the mud with the water hose.”

Both moms acknowledge that ‘infusion day’ in each household is treated in a special manner – including a feast of one’s favorite fast food – and that the potential for a Skype conversation (and a bowling match) is an added bonus. And both children have learned that their relationship extends beyond electronic gaming.

“I know that I have a friend with the exact same thing that I have,” Ethan tells me, “and it’s fun to talk to him.”

“It’s awesome,” Jacob adds, “that Ethan and I have the same kind of pump.”

In addition to the fun and games it provides, Denna tells me the Skype meetings have also imparted a learning experience. Prior to viewing Jacob’s infusion, the McGrews had no idea of the existence of soft needles, which they promptly started using for Ethan’s treatments.

As beneficial as the Skyping has been to both boys, each mom will happily tell you that the importance of peer support cannot be stressed enough. Electronic gathering spots such as Skype, IDF Friends or IDF Common Ground provide a place where patients and families can share stories and experiences with friends facing the same circumstances.

And not only might such connections lead to friendly competition, but also to an eventual in-person meeting. The McGrews and the Klipps will get together this July, but not via the Internet. Instead, the families are gathering at the Great Wolf Waterpark in Dallas.

“I’m a pro at the water slide,” Ethan excitedly exclaims, “I’m the only one not afraid to go down the tube that’s totally in the dark.”

Sounds like Jacob needs to pack that competitive spirit of his – and a pair of water wings.

Skype Buddies: If you or a member of your family is interested in being a Skype Buddy with someone who lives with primary immunodeficiency, IDF is developing a registry of people interested in connecting with others via Skype – just like Jacob and Ethan. Playing video games together is just one option for Skype Buddies; we are sure members of the PIDD community can develop some great supportive friendships through this internet application. Contact IDF at idf@primaryimmune.org or call 800-296-4433 if you want to sign up.

IDF Social Media: Don’t forget our internet social networking sites for all patients and their families on IDF Friends, www.idffriends.org, and IDF Common Ground, www.idfcommonground.org, our teen and young adult site. These are available 24/7 and you are sure to connect with others who have had similar situations and are able to share experiences and understand.

Peer Support: And of course, IDF has an established peer support program that will give you the opportunity to interact with an IDF peer support volunteer who has had personal experience living with primary immunodeficiency disease. Whether you are a patient, parent or other family member or caregiver you can take comfort in knowing your communications and correspondence will be held in the strictest confidence.

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

An IDF staff member will contact you and get to know you and your needs. Arrangements for a volunteer peer consultant to contact you by phone or e-mail, however you prefer.

Remember, you are not alone. IDF is here to help.
On March 23, 2010, the Patient Protection and Affordable Care Act became law. As a result, key changes will be made to the health care insurance market to help patients gain access to critical health care services. For those with primary immunodeficiency diseases (PIDD), the new law will provide key support for individuals with chronic and genetic conditions and expanded access to critical drugs, along with other key patient protection provisions. Unfortunately, the legislation did not address several key areas of importance – Medicare physician payment and access to IVIG therapy. IDF will continue to urge Congress to ensure access to all IVIG brands in all sites of care appropriate for primary immunodeficiency patients. Although the health care reform legislation made clear strides to improve patient health care access, IDF will continue to monitor key provisions to ensure that there are no unintended consequences.

Key provisions that improve patient health care access

Support for individuals with chronic conditions

- **Immediately provides $5 B for high risk pools** – Provides $5 billion in immediate federal support for a new program to provide affordable coverage to uninsured Americans with pre-existing conditions to help assure coverage until the new insurance Exchanges are operational.
- **Eliminates pre-existing condition exclusions** – Prohibits insurers from not covering conditions that patients had prior to receiving insurance coverage
- **Addresses rescission of health coverage** – Prohibits insurers from canceling policies for health care coverage based on claims history.
- **Prohibits annual and lifetime insurance coverage limits** – Prohibits insurers from establishing lifetime or unreasonable annual limits on the dollar value of benefits.
- **Minimizes variability in health insurance premiums** – Beginning in 2014, establishes that premiums in the individual and small group markets may vary only by family structure, geography, the actuarial value of the benefit, age (limited to a ratio of 3 to 1), and tobacco use (limited to a ratio of 1.5 to 1).
- **Guarantees availability of coverage** – Beginning in 2014, each health insurance issuer must accept every employer and individual in the State that applies for coverage, permitting annual and special open enrollment periods for those with qualifying lifetime events.
- **Guarantees renewability of coverage** – Beginning in 2014, requires guaranteed renewability of coverage regardless of health status, utilization of health services or any other related factor.
- **Prohibits discrimination against individual participants and beneficiaries based on health status** – Beginning in 2014, no group health plan or insurer offering group or individual coverage may set eligibility rules based on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability – including acts of domestic violence or disability.
- **Patient navigator program.** Reauthorizes demonstration programs to provide patient navigator services within communities to assist patients to overcome barriers to health services. The program facilitates care by assisting individuals with coordinating health services and provider referrals; and, assists community organizations in helping individuals receive better access to care, information on clinical trials, and conducting outreach to health disparity populations.

Access to critical drugs

- **Fills the Medicare Part D “donut hole”** – Closes the coverage gap in the Part D benefit such that, by 2020, beneficiary coinsurance will be 25% for all drug spending in excess of the deductible and below the catastrophic limit.
- **Better presentation of prescription drug benefit and risk information** – Requires the Food and Drug Administration (FDA) to evaluate and determine if the use of drug fact boxes which would clearly communicate drug risks and benefits and support clinician and patient decision making in advertising and other forms of communication for prescription medications is warranted.
- **Qualifying therapeutic discovery project credit.** Creates a two year temporary tax credit subject to an overall cap of $1 billion to encourage investments in new therapies to prevent, diagnose, and treat acute and chronic diseases. The credit would be available for two years.

Additional patient access provisions

- **Provides small business tax credits** – Immediately offers tax credits to small businesses to make employee coverage more affordable. Tax credits of up to 50 percent of premiums will be available to firms that choose to offer coverage.
- **Extends dependent coverage to young adults** – Requires insurers to permit children to stay on family policies until age 26 on policy plan years beginning after September, 23, 2010.
- **Expands Medicaid coverage to 133% of Federal poverty level** – Beginning in 2014, requires expansion of the Medicaid program to 133% of FPL for children ages six to 19.
- **Comprehensive health insurance coverage** – Beginning in 2014, requires health insurance issuers in the small group and individual markets to include coverage which incorporates defined essential benefits, provides a specified actuarial value, and requires all health plans to comply with limitations on allowable cost-sharing.
- **Prohibits excessive waiting periods** – Beginning in 2014, prohibits any waiting periods for group or individual coverage which exceed 90 days.
- **Preserves right to maintain existing coverage** – Beginning in 2014, any individual enrolled in any form of health insurance may maintain their coverage as it existed on the date of enactment.
Missing health care reform provisions

- **Does not address Medicare physician payment** — Currently, physicians participating with Medicare face a 21% cut in reimbursement on June 1, 2010 because of a flawed payment formula (i.e., the Sustainable Growth Rate, SGR). For many years, Congress has failed to provide a permanent solution and the lack of a provision to fix Medicare physician payment as part of health care reform is a major shortcoming of the law, potentially compromising access to specialists (especially immunologists) for individuals with PIDD. The threat of drastic funding cuts coupled with the lack of certainty for payment funding may mean that specialists decide to limit treating patients with more complicated disease treatments. IDF supports a long-term, sustainable solution to the Medicare physician payment formula to ensure patient access to care.

- **Does not address access to IVIG** — IDF continues to work with Congress to address the overall access to IVIG for Medicare beneficiaries. During health reform consideration, Senator Kerry and Representative Matsui promoted an amendment to provide access to home infusion for PIDD patients and study the issues related to Medicare payment for IVIG in all care settings. The amendment was not permitted to be offered to health reform because the Congressional Budget Office had not provided an official report on the cost of the amendment. IDF continues to work with Senator Kerry, Representative Matsui and others to obtain the necessary information to eliminate any procedural roadblocks.

Potential unintended consequences

- **Establishes new FDA pathway for the approval of “follow on” biologics** — Provides FDA with the ability to approve generic biologics with the goal of reducing the cost of certain biologics. Includes provisions to ensure a longer time to recoup the development costs for biologics developed for rare diseases. However, the introduction of generic biological products could discourage manufacturers from investing in the necessary research and development of new biologics, especially targeted to small patient populations with rare diseases. Therefore, IDF will monitor the implementation of this section.

- **Expanded participation in 340B program.** Extends the 340B discounts to inpatient drugs and also extends participation to certain children’s hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers. Given the potential for these expansions to disrupt the normal site of care during any product shortages, IDF will continue to monitor the implementation of this section.

- **Pharmaceutical tax** — Imposes an annual fee on pharmaceutical manufacturers and importers of branded prescription drugs (including certain biological products). The aggregate annual fees imposed on covered entities will be $2.5 billion for 2011, $2.8 billion for 2012 and 2013, $3 billion for 2014 through 2016, $4 billion for 2017, $4.1 billion for 2018, and $2.8 billion a year thereafter. The fees will be allocated by reference to each entity’s proportionate share of total branded prescription drug sales during the prior calendar year. Sales of so called “orphan drugs” for rare diseases and conditions are disregarded for purposes of determining fee amount, until such drugs are approved for broad use by the Food and Drug Administration (FDA). Regrettably, the definition used in the law does not recognize IVIG as an “orphan drug” whereas the “orphan drug” definition used by NIH and favored by IDF would have recognize IVIG as an “orphan drug”. Given the impact this additional fee could have on the development of new drugs and biologics of benefit to primary immunodeficiency diseases, IDF will monitor the implementation of this section.

- **Appropriate expansion of Comparative Effectiveness Research** — Establishes a private, nonprofit entity (the Patient-Centered Outcomes Research Institute) governed by a public-private sector board appointed by the Comptroller General to identify priorities for and provide for the conduct of comparative outcomes research. As promoted by IDF and the American Plasma Users Coalition (A-PLUS), the law requires the creation of an expert advisory panel if the entity is examining issues related to a rare disease. Prohibits any findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards to protect against discriminatory coverage decisions by HHS based on age, disability, terminal illness, or an individual’s quality of life preference.

- **Provides adequate access to specialty care** — Ensures that the essential benefits package for the new health plans includes ambulatory patient services and access to emergency care. Also ensures that all physician demonstration projects (including accountable care organizations) include specialists, such as immunologists. Given that the health care reform legislation could have been more explicit regarding access to specialists, IDF will continue to monitor the implementation to ensure that patients with PIDD maintain access to specialists.
Over 50 IDF volunteers, representing states and districts with Members of Congress on committees of jurisdiction over Medicare and health policy, joined with team leaders and IDF staff to climb Capitol Hill on Thursday, April 30 for IDF Advocacy Day 2010. Their mission was to ask their Members of Congress to solve the problems of access to IVIG for Medicare beneficiaries with primary immunodeficiency diseases.

Ninety meetings were held, and 28 of those were with Members of Congress. Several co-sponsors were gained that day, many more have signed on and we are confident that more co-sponsors will be signing on based on the positive accounts of IDF volunteers after their meetings.

IDF Advocacy Day 2010 had a strong start Wednesday evening with encouraging words from one of our advocate champions, Congresswoman Doris Matsui (CA), who joined the group to receive the IDF Public Policy Award. In her remarks, the Congresswoman announced that she would be introducing a new bill based on an amendment filed by Senator Kerry in the Senate. The proposed bill, the Medicare IVIG demonstration project, would allow Medicare beneficiaries with primary immunodeficiency diseases needing IVIG to receive that therapy in the home setting. The bill would also allow for various studies of other government obstacles to care for all patients needing IVIG.

To hear more about IDF Advocacy Day 2010 and find out how you can become involved in these important issues, visit our Advocacy Center at http://www.primaryimmune.org/advocacy_center/advocacy_center.asp. In addition, you can see other photos of the day by visiting IDF’s new FLICKR page: www.flickr.com/photos/idfcommunity.
Did you know that it takes approximately ten donations of plasma to make just one IVIG treatment? Not only that, it takes anywhere from seven to twelve months to take a donation and manufacture it into the finished therapy!

IDF, on behalf of the PIDD community would like to take a moment to thank and acknowledge blood and plasma donors! Without them, the life-saving therapies for individuals with a PIDD would not exist.

Plasma from both plasma donation centers (Source Plasma) and blood donation centers (Recovered Plasma) is used in the production of immunoglobulin therapies (used for intravenous and subcutaneous immunoglobulin therapies). There are several key differences between these two methods of collecting plasma. During the Source Plasma donation process, red blood cells are returned to the donor. Not only does this allow for a larger volume of plasma collected in one visit, it allows for a larger volume of plasma to be collected in totality. This is due to the fact that Source Plasma donors are able to donate every four days whereas blood donors are only able to donate every 56 days, as the body needs more time to generate red blood cells than it does to produce more plasma.

Plasma is the amber colored portion of the blood that remains after red cells, leukocytes and platelets are removed. Plasma consists of water, enzymes, salts, antibodies and other proteins that serve as the starting material for a wide range of plasma-derived therapies.

IDF volunteers regularly visit plasma donation centers nationwide, share their stories and thank the donors for their incredible gift of life-saving plasma. In turn, plasma donors and employees see the importance of the role they play in the lives of persons with a PIDD and the life-saving medications that are produced from plasma. The program provides an overall “sense of good” for donors, patients, and employees to see the important roles they play in this continuous circle of life. Many volunteers have said it’s one of their favorite things to do and a truly moving experience for everyone. If you would like to participate, contact Kathy Antilla at kantilla@primaryimmune.org.
Being a patient with a primary immunodeficiency disease (PIDD) is not an easy task or a light burden. Aside from having increased susceptibility to develop recurrent and severe infections and autoimmune diseases, PIDD patients have to face other problems. The general medical community is not always aware of these rare diseases and assisting PIDD patients is more complex than treating people without PIDDs who are suffering from similar conditions.

In 2007, Gulbu Uzel, M.D., and Steven Holland, M.D., clinicians in the Laboratory of Clinical Infectious Diseases at the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), initiated the NIAID Primary Immune Deficiency (PID) Clinic. Drs. Uzel and Holland have worked with patients with PIDDs for many years. They have studied these rare diseases and understand the specific needs of PIDD patients, which motivated them to establish this specialized clinic.

Two years later, in 2009, Sergio Rosenzweig, M.D., Ph.D., and Harry Malech, M.D., from the Laboratory of Host Defenses at NIAID, joined the project and completed the medical team. Drs. Rosenzweig and Malech share the same interest and passion for working with and for patients with PIDDs.

“The PID Clinic is a very important initiative,” note Kathryn Zoon, Ph.D., and Karyl Barron, M.D., the director and deputy director, respectively, of NIAID’s Division of Intramural Research. “The clinic acts as a gateway for anyone with a known or suspected PIDD and provides comprehensive consultations for patients and their families.”

The NIAID PID Clinic was established to provide state-of-the-art treatments and regular follow-ups for people with PIDDs. Being situated at NIH, the leading government medical research agency in the United States, clinicians are also able to complement patient care with high quality medical research to better understand the causes of PIDDs and develop better treatments for these diseases.

“Our aim is to develop a partnership between NIH and the patients’ physicians with the common goal of improving disease management and, for some people, providing a definitive disease diagnosis when one is lacking,” says Dr. Uzel.

Once a primary care physician or specialist refers a patient to the PID Clinic, every test and treatment is carefully examined, and each patient receives at least a day, or sometimes two, of diagnostic work-up.

The PID Clinic team also is working to generate interest in PIDD diagnosis, care and treatment among younger physician-scientists. For this reason, they offer second-year clinical fellows doing rotations in infectious diseases the opportunity to participate in helping patients in the PID Clinic.

“PIDD under-diagnosis is still a worldwide problem, and there is a need for more national centers with the capacity to make accurate diagnoses,” says Dr. Rosenzweig. “The NIAID PID Clinic is extending a hand to those with these rare diseases.”

In the future the clinicians hope that more investigators at NIH, including those outside of NIAID, will participate in evaluating patient cases. Although the primary goal is to give patients and families better ways to manage disease, they also hope that the clinic will benefit the scientific community. Some people examined in the PID Clinic who qualify also are offered the opportunity to participate in ongoing clinical studies at NIH.

The PID Clinic is open and accepting patients, on a referral basis, for exams. More information about the clinic may be found on the NIAID Web site at www3.niaid.nih.gov/topics/immuneDeficiency/pidClinic/. As interest from the public increases, the clinic is expected to grow.

“This as an opportunity for people affected by PIDDs to get treatment from clinicians at a leading research institute,” says Dr. Uzel. “The clinic is just one way to open up that door.”

Julie A. Wu, Ph.D., is a Technical Writer-Editor, Contractor for the Office of Communications and Government Relations at the National Institute of Allergy and Infectious Diseases.
CSL Behring Receives FDA Approval of HizentraTM, First 20 Percent Subcutaneous Immunoglobulin Therapy

CSL Behring announced that the U.S. Food and Drug Administration (FDA) has granted marketing approval for HizentraTM, Immune Globulin Subcutaneous (Human), 20% Liquid, for treating patients diagnosed with primary immunodeficiency (PI). A once weekly immunoglobulin (Ig) replacement therapy, Hizentra provides effective protection against infection by maintaining a steady and normal level of immunoglobulin in the body.

Hizentra is the first 20 percent subcutaneous immunoglobulin (SC Ig) approved in the U.S. by the FDA. This high-concentration product is stabilized with L-proline, a naturally occurring amino acid. L-proline allows Hizentra to be stored at room temperature (up to 25°C [77°F]). Because no refrigeration is necessary, Hizentra is ready to use, offering patients and physicians convenience and portability. Hizentra can be safely self-administered by PI patients under a physician’s care.

Hizentra allows patients to use a small, portable pump to self-administer their weekly infusions by injection under the skin (subcutaneous administration).


CSL Behring Receives FDA Approval to Extend Shelf Life for Privigen(R) from 24 to 36 Months

CSL Behring announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) to extend the shelf life for Privigen®, Immune Globulin Intravenous (Human), 10% Liquid, from 24 to 36 months. The approval makes Privigen the first liquid intravenous immunoglobulin (IVIg) in the U.S. that can be stored at room temperature throughout its entire 36-month shelf life.

Privigen is the first and only 10 percent liquid IVIg stabilized with proline, a naturally occurring amino-acid. The product is indicated for primary immunodeficiency (PI), a group of disorders, usually genetic, that result from a malfunction in part or all of the immune system. This condition prevents patients from fighting off infections caused by everyday germs. Privigen is also indicated for the treatment of patients with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Excerpted from CSL Behring News Release April 19, 2010.

Proposed Acquisition of Talecris Biotherapeutics by Grifols

Grifols (GRF.MC) a global healthcare company and leading producer of plasma protein therapies, and Talecris (NASDAQ: TLCR) a U.S.-based biotherapeutics products company, today announced that they have signed a definitive agreement through which Grifols will acquire Talecris for a combination of cash and newly issued Grifols non-voting shares having an aggregate value today of approximately $3.4 billion (€2.8 billion), creating a global leader of life-saving and life enhancing plasma protein therapeutics.

The combination of Grifols and Talecris will create a vertically integrated and diversified international plasma protein therapies company, bringing together complementary geographic footprints and products, as well as increased manufacturing scale. Grifols’ leading global footprint will benefit from Talecris’ strong presence in the United States and Canada. Grifols’ available manufacturing capacity will enable Talecris to increase production in the near term. As a result, the combined company will be better able to meet the needs of more patients with under-diagnosed disease states around the world. In addition, upon completion of the transaction, the combined company will have:

• the ability to derive more protein therapies from every liter of plasma, enhancing access and availability for patients, and optimizing use of collected plasma;
• an established plasma collection operation capable of meeting the combined company’s needs to address increasing patient demand and an accelerated path to improving the cost efficiency of the Talecris plasma platform;
• a broad range of key products addressing a variety of therapeutic areas such as neurology, immunology, pulmonology and hematology, among others;
• an enhanced R&D pipeline of complementary products and new recombinant projects that will drive sustainable growth;
• a well established clinical research program in the U.S.


New High Purity Immunoglobulin Enters Phase III in Europe and the US

Octapharma to Set New Standards in IVIG Development, Focused on Improving Outcomes For Patients and Physicians

Octapharma AG announced the start of the first of a series of Phase III studies for its new 10% high purity intravenous immunoglobulin (IVIG). The study will investigate the efficacy and safety of this novel immunoglobulin in the treatment of primary immune deficiency and, together with results from additional upcoming studies, will support its regulatory filing in Europe and the US.

The development of this pioneering high purity IVIG builds upon Octapharma’s experience in the area of immunoglobulin products. octagam(R), Octapharma’s current leading IVIG (an immune globulin human solution for intravenous administration) is registered in about 60 countries, including the EU and the US.

Mary Beth Bylsma’s enthusiasm is infectious – even when she’s talking about a subject that obviously pains her family: the Stanley Cup playoff loss recently suffered by her husband’s hockey team.

“Well, the off season began a little sooner than we expected,” Mary Beth, wife of Pittsburgh Penguins head coach Dan Bylsma (pronounced biles-muh), tells me, “but now we can turn our attention to some summer activities.”

And while that may conjure visions of lounging by the pool or sprawling on a sandy beach, summer brings an endeavor near and dear to the Bylsma family: more hockey, but this time of year it comes in the form of an instructional camp.

“They love Dan – they get to be on the ice with Dan,” Mary Beth explains. “I teach them about exercise, stretching and injury prevention. I’m not the most popular instructor at camp.”

Mary Beth’s popularity, however, is certainly rising among the immune deficiency community, thanks to a public service announcement she arranged with Fox Sports in Pittsburgh, broadcast between periods of a Penguins’ game this past season.

The spot, focusing on patients with primary immunodeficiencies that have been diagnosed with Selective IgA, was a particularly proud moment for Mary Beth: her 11-year-old son, Bryan, has Selective IgA, one of the more common immune deficiency diseases.

“Dan and I have always been supportive of various charities,” Mary Beth clarifies, “but with such a personal connection to immune deficiency, how could we not get involved?”

Dan, who coached the Penguins to the Stanley Cup championship in 2009, founded Dan Bylsma’s Hockey Camp in 1994, and it gave the former NHL player an opportunity to combine his two passions – teaching hockey and helping children.

In short, the camp is just one of many ways in which the Bylsma family gives back to the community. Another is through the Dan Bylsma Charitable Trust Fund, an organization that assists children with the high cost of participating in youth sports programs.

“Professional athletes in all communities are paid extremely well,” Mary Beth explains, “and they need to give back. And with us being so extremely fortunate to be in a position to help, we feel a particularly special need to do just that.”

The Fox Sports’ feature – which can be seen on the Immune Deficiency Foundation’s YouTube site – had, according to Mary Beth, the effect she was seeking.

“Now that I’m in a place where I can raise public awareness of these diseases,” she explains, “I’m going to do all I can.”

This year, Mary Beth will be donating her portion of the Hockey Camp proceeds to the Immune Deficiency Foundation, and plans to begin an awareness push centered on IDF’s highly-successful THINK ZEBRA! campaign.

“IDF has THINK ZEBRA! and the NHL has a referee organization called ‘Zebra Cares’,” Mary Beth adds. “Could a working relationship between the two be any more perfect?”

For now, Mary Beth is thrilled with the results stemming from the Fox Sports/Pittsburgh Penguins/Bylsma family collaboration.

“I heard – through IDF – that someone had responded to the spot that ran during that game,” Mary Beth says proudly. “That’s my success story – that one family or one person reached out after seeing that story, Bryan’s story, about Selective IgA.”

“But I’m far from finished,” she continues, “This is just the beginning of what I hope to accomplish.”
As a national charity, IDF receives contributions from donors all over the country. Most of these gifts come in the form of checks or are made with credit cards. But did you know you could make a generous contribution to IDF by donating your car? Chris and Christine D’Amico of New Jersey did just that!

Christine explains why. “We were in the fortunate position of being able to donate our car and when we found out we could donate the money to IDF, that made it an easy decision. If you are getting a new car, think about it. You will be happy you did when you hear that IDF received a nice check on your behalf to continue the wonderful work they do.”

In addition to cars, you can also donate trucks, RVs, trailers, boats, jet-skis, snowmobiles and motorcycles. And they don’t even have to be running in order to receive a tax deduction!

For more information on donating your car or other vehicle to IDF, please visit our Website at www.primaryimmune.org/donateacar or call 800-296-4433.

The International Patient Organization for Primary Immunodeficiency Diseases (IPOPI) hosted a meeting for Eastern European Countries in Berlin on March 18, 2010. Pictured here are attendees representing twelve countries who attended the meeting to learn about IPOPI and the value of patient organizations. Marcia Boyle, IDF President and Founder, presented a session about the importance of developing a national patient organization.

With Gratitude

Honorary and Memorial Gifts – 3/3/10 to 6/1/10

Gifts in memory of:
Lieselotte Beecher
David Breedlove, Jr.
Brandon Dahley
Delores Y. Goldsmith
Isaiah Howell
Wendi Jones
John Joy
Alex Landry
Eric Marder
Leonard Marks
Christopher Meddaugh
Darlene Roeder
Nancy Thomas Roman
Rachel Roy
Caroline Salvati
Arlan Sprague
Greg Waggoner
Rachael Miller Wenger
Bill Woodruff

Gifts in honor of:
John G. Boyle
Marcia Boyle
Emma Bozarth
Bruce and Frances Chaimowitz
Taylor Dahley
Pam Dail
Tyler & Riley Dietz
Sally & Larry Feniger’s 40th Anniversary
Harrison Green
Sonia Green & Family
Cindi Hennigh
Jacqueline R. Kanovitz
Chris Kluxen
Jaryd Leady
Thomas Marbach
Karen Smith
Jaclyn Solinger’s 12th Birthday
Karen Swedenborg
Thomas R. Tilley

These donations help IDF to improve the diagnosis and treatment of patients with primary immunodeficiency diseases through advocacy, education and research. If you would like to make a donation, please go on our Web site, www.primaryimmune.org and click the “please donate today” picture in the top right corner. You can also contact us in any of the following ways:

Phone: 800.296.4433 or 410.321.6647
E-mail: idf@primaryimmune.org
Mail: IDF, 40 W. Chesapeake Avenue, Suite 308
Towson, MD 21204
Immune Globulin Product Chart Update

New Products Added

The IDF chart Characteristics of Available Immune Globulin Products Licensed for Use in the United States has recently been updated. It includes information on the following brand name products: Gammagard S/D, both 5% and 10%, Gammagard Liquid, Gammaplex, Carimune NF, Hizentra, Privigen, Vivaglobin, Flebogamma 5%, Flebogamma 5% DIF, Octagam, and Gamunex.

The entire chart can be found on the IDF Website at: www.primaryimmune.org/patients_families/prod_safe/ivig_chart.pdf

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For an updated IDF Calendar of events, visit www.primaryimmune.org/idfcalendar.