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October-November 2006

**The Quest for a Secure  
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**We Must Protect Ourselves  
Now More Than Ever**  
A Guest Editorial

*Sites of  
Care*  
*What's Best for You?*

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**2006 IG Living Legislator of the Year: Representative Steve Israel, New York**

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Cover: *Texas Neurology Center in Dallas, Texas*

Correction: In the August-September 2006 article "Is Flu Vaccine for You?," Dr. Marc Riedl was misquoted as saying the following about flu vaccination: "There's less of a chance that it's going to work for someone with autoimmune problems." The correct quote is, "There's less of a chance that it's going to work for someone with immunodeficiency problems."

### About *IG Living*

*IG Living* is the only magazine dedicated to bringing comprehensive healthcare information, immune globulin information, community and reimbursement news, and resources for successful living directly to immune globulin consumers and their healthcare providers.

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# IG Living Legislator of the Year: Rep. Steve Israel

Why do we have politicians? Theoretically, to represent us. Although, once elected, too many seem disinclined to remember us. And, when "us" is a small constituency of chronically ill Medicare beneficiaries who rely on immune globulin therapy, representatives dedicated to our cause are as rare as our diseases.

Hence, our admiration for one jovial congressman from Long Island, New York, Representative Steve Israel. Israel is one of those rare and wonderful politicians who are much better at rolling up their sleeves and digging into a challenge than posing for a camera, and we are grateful he has taken on the challenge of access to intravenous immune globulin (IVIG) for Medicare beneficiaries. In fact, he has done so with such dogged persistence and endearing passion that we felt compelled to honor his work for the immune globulin community in a special way.

So, we are very pleased to announce Rep. Steve Israel as the recipient of IG Living's inaugural Legislator of the Year Award 2006.

Were this a real-time medium, you would surely hear drum rolls and fanfare and many grateful tears being shed, for Israel has embraced the cause with the compassion of someone living through it, despite his initial unfamiliarity with the crisis.

"This is an issue that constituents brought to me," Israel recounted, "and I hear so many different issues during the day and I'm subjected to so many concerns, but this really jarred me, because, honestly, I didn't know much about it before. But when I was told a simple matter of reimbursement increases could literally save a life, I just felt obligated to focus on it. ...I thought it was outrageous that we're balancing budgets on the backs of people who desperately need IVIG therapies. For them, it's life and death; for Washington, it's a budget choice."

The focus of Israel's efforts is a campaign to convince Secretary Michael Leavitt, of the Department of Health and Human Services, to declare a public health emergency. This would allow the Centers for Medicare and Medicaid Services to temporarily increase IVIG reimbursement rates.

Israel and his colleagues sent their first letter to Leavitt in September 2005, with 28 signatures. Their second letter to Leavitt, delivered in June with 58 signatures, was even more powerful: "We continue to receive alarming reports of patients going without therapy, physicians



Rep. Steve Israel accepts award from Patrick M. Schmidt, IG Living publisher and CEO of FFF.

not being able to provide IVIG in their offices and infusion centers, and hospitals having to eliminate IVIG on an outpatient basis," the letter reads. "...While we acknowledge that this issue is very complicated... patients are suffering and dying. Access to IVIG has become a crisis for patients who cannot survive without it."

While awareness has increased, Leavitt still hasn't taken action, and the crisis continues.

"Part of the battle," Israel explained, "is that there is very little understanding among policymakers of this issue. I think it's critical that people who are affected educate their members of Congress. With a war in Iraq and high gas prices and Iran and North Korea developing nuclear weapons, talking with my colleagues about IVIG is sometimes an uphill battle. So we need to continue to work together to demonstrate for my colleagues that this is indeed a life and death issue.

"The ideal solution," Israel continued, "is for the federal government to change its priorities and provide effective reimbursement rates. This issue, like every other issue, is ultimately about money, and if we can give \$2 billion a year in tax cuts to oil executives, we should be able to appropriate funds to subsidize patients who need lifesaving IVIG therapies."

Exactly!

Advocating for improved access to IVIG won't do much for Israel's political career; it probably won't garner him 30 seconds on CNN or even a column or two in the Washington Post (although we can hope!). Nonetheless, Israel's campaign for fair IVIG access and reimbursement will help some critically ill people stay alive, regain their health and return to being productive members of their communities.

"I cannot single-handedly end the war in Iraq," the congressman acknowledged, "but if I can improve access for one person to IVIG therapy, then my day has been worthwhile."

Yes, it has. Congratulations, Congressman Israel, and thank you! ■

For more information and to take action, visit [http://www.igliving.com/web\\_pages/action\\_items.html](http://www.igliving.com/web_pages/action_items.html)

Kit-Bacon Gressitt, Editor



# Triathletes

It was daybreak on a foggy Sunday morning this June, and triathletes from all over Southern California were packing up their gear—bikes, wetsuits, running shorts—and driving to the San Buenaventura State Beach. There, streets were cordoned off, flags were planted along the sand designating start and finish lines, and hundreds of gleaming bike racks had overtaken the parking lot, threatening to outshine the ocean itself. It was the dawn of the Breath of Life Ventura Triathlon.

One family, the LaVignas, had spent the past year organizing this event. It was a labor of love that really started in August 1999, with a mere three participants who initiated the race as a fundraising event in honor of Dina LaVigna, who died in 1997. Dina died from complications related to a primary

immune deficiency disease (PIDD). Dina's husband, Jeff Schmidt, began the Breath of Life Fund in her memory, dedicating the organization to helping those who suffer from PIDD, under the umbrella of the Jeffrey Modell Foundation. Those first three participants, Dina's brother, Grant, and his friends, Mark and Monica Spiro, ran the first triathlon, hoping to raise money for the cause. They raised over \$15,000.

This foggy Sunday morning marked the eighth annual triathlon, registering over 1,000 participants and 250 volunteers. Many of the volunteers were friends of the LaVigna family, participating as a gesture of love, support and friendship. One couple, Alan and Charlie Campbell, who had been there since 8 a.m. the prior day, said they volunteer for this event "because

it's a really good cause—95 percent of all proceeds go to what it's for." This seemed to be the consensus among the volunteers and athletes; they were there because the organization funnels nearly all its proceeds to the cause.

As the sun slowly made its appearance, turning the ocean into a gleaming race-ready aquatic track, a thousand triathletes in black wetsuits and a rainbow of swim caps made their way to the beach, standing in groups of 100, ready to start the race in waves, a metaphoric homage to the ocean and the cycle of life itself. They swam, they biked and then they ran—for other people's lives.

As each wave finished the race, the athletes were greeted with a family-style cookout, hosted and paid for entirely by Dina's parents. Free low-calorie grilled hamburgers and hot dogs, snacks and



## Breath of Life Triathlon Sponsors

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# Try for Life

By Nicole Criona

drinks awaited everyone, athletes and volunteers alike. Dina's father, Gary LaVigna, manned the barbecue along with several other volunteers, gratefully grilling and serving food to the multitude of supportive people.

At a small but meaningful ceremony, local Assemblywoman Audra Strickland presented the organization with a framed Assembly Resolution that recognized the Breath of Life Fund and commended its hard work for the community. It was a poignant moment for the LaVignas. In fact, the entire event was a poignant experience for this family, whose members have dedicated the past eight years to helping others who have the same disease as their daughter, Dina.

The family's many accomplishments include the fund's April 2000 dedication

of the Dina LaVigna Breath of Life Room, aka "The Dina Room," a state-of-the-art infusion clinic at Mt. Sinai Hospital in New York, where Dina received her treatments.

The June race proceeds are earmarked for Dina's alma mater, UCLA, for the UCLA Foundation to renovate and expand the Witherbee Foundation Children's Health Center for outpatient pediatric infusions. The Breath of Life Fund also plans to equip the center with a flat-screen TV, DVDs, books and games.

And it's no surprise that the fund's volunteers will not rest with these successes; they are already planning next year's race. Information can be found at <http://www.triforlife.com>. ■



# We Must Protect Ourselves Now More Than Ever

By Stephanie Feldman Aleong

Florida has dealt a significant blow to the safety of all people who rely on prescription drugs, particularly those patients who need delicate and expensive therapeutics, such as immune globulin: In the 11th hour of the last day of the legislative session in May, both chambers of the Florida Legislature passed HB 371, which significantly weakens Florida's 2003 Prescription Drug Protection Act.

Then, in the last days of June, Governor Jeb Bush signed HB 371 into law, allowing distributors of prescription drugs to avoid their responsibility to provide documentation regarding the source and conduits of prescription drugs, and making it easier for counterfeit prescription drugs to reach your pharmacy shelves.

## From Leader to Laggard

In 2003, Florida was the leader in the nation with its passage of the Prescription Drug Protection Act, which required all distributors of prescription drugs to prepare, authenticate and distribute drug pedigrees, in paper or electronic format, whenever they transacted prescription medication. These pedigrees would document the true origins of drugs and make the distribution of prescription drugs a transparent process that health inspectors could verify. The pedigrees would also provide critical evidence for prosecutors to catch criminals who counterfeit and adulterate prescription drugs that end up on reputable pharmacies' shelves.

Florida's drug protection law was enacted in response to the 17th Statewide Grand Jury of Florida Report, which noted that the legitimate marketplace of drugs in Florida was riddled with counterfeit and adulterated medicine that felons had introduced into the national drug supply through the use of a complex web of shell corporations.

Prescription drugs that eventually found their way to the largest of U.S. drug distributors had passed through hot car trunks, laundry rooms, trailers and numerous hands in South Florida. As noted by the Nevada State Board of Pharmacy, because there is no such thing as a local, regional or statewide drug supply, it was the entire

nation's drug supply that was contaminated by these bad actors.<sup>1</sup> In fact, the book "Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply" reported the rampant proliferation of counterfeit and adulterated drugs in Florida that eventually traveled nationwide.<sup>2</sup>

Florida's pedigree requirement was set to go into effect on July 1, 2006. However, the pharmaceutical industry led an all-out assault on the Prescription Drug Protection Act by encouraging and supporting legislation watering down the pedigree requirement, legislation that eventually became law in the form of HB 371. Now with its enactment, HB 371 eliminates the pedigree requirement as long as drug wholesalers simply "promise" that they buy their medicine from drug manufacturers directly and sell directly to a dispenser, such as your local pharmacist. No documentation of the origin of the drug—including lot number or invoice number—will travel with these pharmaceuticals.

## Is a Promise Enough?

This lack of a traceable number makes it nearly impossible for the drugstore where you buy your medicine to make sure that the wholesaler has in fact bought the drugs directly from the manufacturer. Without an identifying number, this meaningless "promise" merely signifies that at some point a distributor "promised" it purchased a specific unit of a drug from a manufacturer, but, without a pedigree, there is no way for a health inspector or prosecutor to prove that a specific vial of drug was the subject of a fictitious "promise" or a valid one.

Additionally, HB 371 allows distributors to make "intra company transfers" of medicine without providing any pedigrees, which is exactly the type of practice that led to counterfeit medicine being introduced into one of the



Photos by Cap-TurkyVihmaz

nation's largest distributors, Cardinal Health Inc., when one of its employees took kickbacks from a counterfeiter in exchange for purchasing unsafe, adulterated medicine from a previously convicted felon.<sup>3</sup> The drugs Cardinal's employee bought traveled from warehouse to warehouse at Cardinal and into the nation's drug supply because of intra company transfers.

Without the original protections in Florida's 2003 Prescription Drug Protection Act, patients' health once again depends on the honor of an industry that has successfully refused to provide pedigree documentation for over 15 years and that has allowed counterfeit medication to reach our pharmacy shelves.

### Anyone Can Be Affected

Patients have been injured by the counterfeit and adulterated medicines reaching pharmacy shelves. Most notably, on Long Island, New York, a 19-year-old liver transplant recipient, Tim Fagan, was injected with adulterated Epogen that came from Florida.

Tim's mother had purchased the Epogen from her local CVS and had no reason to suspect there was anything wrong with the vial of medicine. Only later, after Tim had suffered painful convulsions and anemia, did the family eventually find out that the Epogen had passed through 12 different locations and unauthorized, unsafe supply channels before landing on their drugstore's shelves.

Tim's struggle spurred Representative Steve Israel, D-N.Y., to introduce federal legislation that would make pedigree papers compulsory, increase penalties for dealing in counterfeit medicine and give the FDA much needed resources to investigate counterfeiting.<sup>4</sup> Sadly, that bill continues to languish in committee in the House since its introduction in May 2005.

There is some hope for patients, however. The federal government is finally about to mandate that many distributors produce pedigree papers. In 1988, Congress enacted the Prescription Drug Marketing Act (PDMA), which required that distributors of prescription drugs provide pedigree papers with each shipment of prescription drugs. One of the reasons counterfeit and adulterated drugs have continued to flourish since 1988 is that industry successfully convinced the FDA to "stay," or put on hold, the pedigree requirement for 18 years. Instead, a mandatory requirement for pedigree papers became an "advisory opinion," because of the political pressure drug companies brought to bear.

Because of all of the recent publicity surrounding, and

prevalence of, counterfeit drugs, the FDA announced in June that it is lifting the stay on the federal pedigree requirement, effective this December.

This should be our happy ending, correct? Even if the state law on pedigrees in Florida is now gutted, we still have the federal pedigree law to protect us. Right? Not exactly.

The federal PDMA has a large exception to its pedigree requirement: It excludes "authorized dealers of record" of a drug, which it defines vaguely as a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. The PDMA does not define "ongoing relationship."<sup>5</sup> Neither does the FDA define that term in the Code of Federal Regulations.

So, bottom line, industry can still skirt the pedigree requirement, unless the FDA constructs a narrow definition of "authorized distributor" and "ongoing relationship." It is my fervent hope and mission to convince the FDA to construct such a definition.

### What Can You Do?

As a group, patients who take costly injectable pharmaceuticals are particularly vulnerable to counterfeiters because of the incredible profit that entices criminals to move unsafe, adulterated and counterfeit versions of these products into the legitimate marketplace. Current federal and state law is not sufficiently strict to stop this practice, although I am hopeful that continued pressure on the FDA to narrow the definition of who can be exempt from the pedigree requirement will result in better regulation.

For now, you should always check the packaging of your drugs to see if there are any discrepancies, and contact your doctor immediately if you experience any abnormal reaction to your medicine. As a type I diabetic and a cancer survivor, I carefully scrutinize every prescription each and every time I open a new vial of medicine or bottle of pills. I know that, until the government takes the right action, careful observation is our best line of defense. ■

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1 Larry Pinson, Pharm.D, Executive Secretary for the Nevada State Board of Pharmacy, Letter to the Governor to Veto HB 371 (May 9, 2006).

2 Katherine Eban, *Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply* (2005).

3 *United States v. Spence, Carlow*, Case No. 3:06-00047, United States District Court for the Middle District of Tennessee.

4 HR 2345 (2005).

5 21 C.F.R. § 203 (2006).

# The Evolution of IVIG Therapy

By Melvin Berger, MD, PhD, and Alberto Martinez, MD

The heroes of immune globulin production are many. They include physicians, scientists, and nurses, but most importantly, the patients who continue to seek new treatments and ask for alternative options.

Since the first practical use of serum immune globulin therapy for primary immune deficiency by Dr. Ogden Bruton in 1951, the use of immune globulins has evolved in the method of manufacture, the formulation and expanded applications for new diseases. Have newer products created these new uses or have new needs driven the creation of new products?

As the United States entered into WWII, the country recognized an untold number of American lives would be lost due to trauma, unless injured soldiers could be stabilized on the battlefield: The leading cause of death in combat was bleeding, which sent soldiers into shock before ever reaching the first medical aid station. However, the battlefield was no place to store fragile, refrigerated blood or whole plasma.

Because necessity is the mother of invention, Dr. Edwin J. Cohn, biochemist and protein scientist, saw the need to individually separate the many proteins in human plasma. Albumin, the chief protein constituent of plasma and one that Dr. Cohn had separated from plasma, could help solve this problem if it could be administered quickly. Albumin allows blood to remain in the blood vessels and is responsible for attracting water, thereby increasing blood volume. In addition to being a lifesaving protein, albumin could be freeze-dried and stored as a powder in the harshest of environments.

Once reconstituted, albumin could keep soldiers alive until they arrived behind the lines to mobile hospitals.

In 1941 the Department of the Navy commissioned Dr. Cohn to develop a large-scale process to separate albumin from human plasma, a process

known as fractionation. Cohn's invention led to the manufacture of more than 2 million units of albumin by approximately five U.S. manufacturers, and saved countless

lives during the war. Plasma fractionation was a major factor in this improvement.

The invention of fractionation led to other new opportunities. Due to Cohn's process, the use of purified immune globulin as a medical treatment became possible. The first human immune globulin preparations were administered as intramuscular (IM) injections, and could only be given in small doses. IM immune globulin (IMIG) injections were extremely painful, limiting the quantity of protein that could be administered. Nevertheless, such injections were a life-altering innovation for people suffering from antibody deficiencies, and there was a need for IMIG for these and other disease states.

Overcoming the obstacles to save and improve human life was the challenge of Dr. Ogden Bruton, an Army lieutenant colonel and a practicing pediatrician at Walter Reed Army Medical Center. Recognized as the "Father of Primary Immune Disease," he successfully used IM formulations of immune globulins on Joseph S. Holtner, an 8-year-old boy who presented with congenital agammaglobulinemia. Bruton administered the immune globulin just under the skin, subcutaneous administration. Dr. Charles A. Janeway Jr., a leading immunologist from Harvard School of Medicine, picked up on Bruton's work and established IM dosages of immune globulins as a standard of care for primary immune deficiency diseases (PID) in the United States. Although the quantities of immune globulins that were given at that time were low by today's standards, fewer infections were seen in PID patients, and survival was enhanced. Between 1950 and 1960, with immune globulin injections as the standard therapy, the quality of life improved for PID patients.

With this advancement, new applications for immune globulins were explored using higher doses. However, purification of immune globulin from plasma was still in its early stages and higher doses resulted in a corresponding increase in the rates of adverse events. What was needed was the ability to deliver large quantities of purified protein in an acceptable dosage formulation.

Once again, manufacturing adapted to meet patient and healthcare providers' needs. It wasn't easy, though. The technology and equipment for large-scale operations was not available, and product formulations had to be improved



Photo from National Archive, Washington, D.C.

# A Brief History of Immune Globulin

By Nicole Criona

not only to eliminate harmful side effects, but also to improve the stability of the product. These challenges were overcome in the late 1970s when the first generation of intravenous immune globulins (IVIG) was born. These “first gen” IVIGs gave patients the ability to receive large amounts of immune globulin. As expected, PIDD patients experienced fewer infections. Serendipitously, the ability to give these greater doses also led to the observation that giving IVIG to patients with leukemia and antibody deficiency also increased their platelet counts. This was followed by the observation that high doses of IVIG, given concurrently with aspirin therapy, had lifesaving effects in Kawasaki syndrome, an inflammation of the blood vessels that caused heart attacks and was often fatal in childhood. Thus, the beneficial effects of IVIG on the quality of life were extended to new, previously untreated diseases.

While the first gen IVIGs were a great improvement for patients over the IM formulation, there were still problems. For instance, manufacturers used pepsin, a naturally occurring enzyme, to break apart the protein aggregates. This enzyme decreased the immune globulin activity. To overcome the hurdles of decreased activity caused by the chemical modifications associated with enzymes such as pepsin, second generation IVIG products were introduced in the mid-1980s. These products did not use pepsin but instead added sugars or amino acids to make the products more easily tolerated in large dosages. In addition, one manufacturer lowered the pH of the product to increase the immune globulins’ natural stability. As a result, patients could receive large quantities of IVIG with fewer side effects.

High-dose applications of IVIG introduced in the 1980s marked a new

age for patient care. Unfortunately, two new healthcare catastrophes came right on the heels of this latest improvement: the AIDS and hepatitis C epidemics. Since IVIG is a plasma-derived product, the possibility of virus transmission became a major concern because it was uncertain how the viruses were transmitted and how to test for their presence in IVIG. The introduction of a new generation of products was needed to address a higher standard of safety, thus the third generation of IVIG products was born.

The third gen IVIGs included steps such as solvent-detergent and pasteurization to increase safety by specifically removing or destroying unwanted organisms such as potentially harmful viruses, without compromising the quality of the life-giving protein needed for patient therapy. In the 1990s, the third generation products became the new standard in the United States, and improved patient care has resulted.

Now, in the 21st century, the fourth generation of IVIG products has been born, yielding greater convenience, higher tolerability and improved patient safety.

Leading immunologist, Melvin Berger, MD, PhD, co-author of this article, recently remarked, “We are fortunate that improved treatments for patients with [PIDD] continue to evolve. We have seen each generation of immunoglobulin preparations becoming safer and better tolerated by the patient. Newer products have decreased adverse effects, and allow increased flexibility in dosing, which together improve the quality of life for those whose survival depends on this essential therapy.” ■

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*Melvin Berger, MD, PhD, is Professor of Pediatrics and Pathology, Case Western Reserve University, Ohio. Alberto Martinez, MD, is President and CEO of Talecris Biotherapeutics.*

As early as the 1890s, physicians were experimenting with blood product transfusions on animals, but they were generally unsuccessful because they weren’t yet aware of such things as blood type compatibility.

In 1901, Austrian researcher Karl Landsteiner discovered that blood drawn from certain people, when combined, tended to clump, while others did not. His work led to the discovery of blood types (A, B and O) and blood type compatibility.

It wasn’t until the 1940s that Dr. Edwin Cohn and his associates invented a large-scale method to separate the components of human plasma, called fractionation. This early method used a combination of alcohol, low temperatures and centrifuges to fractionate the plasma into its components, including immunoglobulins.

At first, immune globulin was administered intramuscularly. “It was painful to get,” said Dr. Richard Schiff, MD, PhD, global medical director for immune therapy and critical care at Baxter, an IVIG manufacturer. “However the incidence of severe infections plummeted.”

These early preparations of immunoglobulin needed to be administered into the skin or muscle due to clumps of antibodies resulting from the fractionation process. These clumps, also called aggregates, resulted in serious reactions if administered directly into a vein. This unfortunate experience was recorded by Dr. Janeway in 1946 during the testing of an initial immunoglobulin preparation on himself. After administering the immunoglobulin into his vein, he had to be treated for a serious reaction.

Fortunately, by the 1960s, the Swiss Red Cross began experimenting with preventing clumping of the IgG molecules with a gentle enzyme treatment. As a result, one of the first viable intravenous products was developed.

In 1973, researchers and physicians began the first U.S. clinical trials, testing the efficacy of IVIG. Eventually, the U.S. firm Cutter Biologicals developed an IVIG product in which clumping was prevented by chemical treatment of the IgG molecule. This led to the first U.S. product in 1981, and then companies all over the world were trying to manufacture IVIG.

Concurrently, safety became a grave concern with the recognition of blood-borne viruses. However, the alcohols used in the original immunoglobulin purification process destroy many viruses and patients receiving immunoglobulin during the early years of the HIV epidemic were spared product-related transmission. Other viruses, however, could survive the process and “the 1990s saw an increase in improved protection against viruses,” Dr. Schiff said. “The New York blood bank perfected a process which used a solvent detergent to break open certain viruses and became effective against what are called ‘envelope viruses’ such as West Nile Virus, SARS and HIV.”

The virus-fighting processes have since become a standard part of the process, and today IVIG is considered quite safe.

# Can You Hear Me Now?

By Cheryl Haggard

There have been times when trying to get to the bottom of our medical issues I have felt like a mushroom: Just keep me in the dark and feed me manure. Nonetheless, many of you will agree that clear communications with our team of physicians is key in correct diagnosis and wellness for our rare disorders.

Nothing has made it easier to communicate, and at times more frustrating, than enlisting the help of a cell phone. Cell phone technology has made it virtually impossible for us to miss Very Important Phone Calls from our doctors, nurses and pharmacies. On the other hand, some curse the cell phone as a rude interruption in the conversation of life itself. Which leads me to this question: How did my parents raise me without a cell phone?

Back in the '70s, Mom and Dad took spare change for public phones on their "date nights" in order to call our babysitter to make sure my brother and I had not set the house on fire. Our family survived very nicely with one avocado green rotary phone in the kitchen and a Record-A-Call answering machine in my parents' bedroom (which they still have today).

The cellular and satellite technology since "The Brady Bunch" years now has our personal conversations and information whizzing around in the heavens. We have also created a society in which a missed Very Important Phone Call is an inexcusable 21st century sin.

Cell phones, however convenient, have not eased the torture of waiting for the Very Important Phone Call from the doctor. This waiting is as annoying as being forced to sing "YMCA" at every professional sporting event we attend (golly, the '70s were a blight on eternity's timeline). We despise the tennis-match argument with ourselves: Do I nag them again about the CT scan or do I take another proverbial patience pill and suffer through one more night of impacted sinuses?

Recently, I was eagerly anticipating some lab results from our kids' last blood draw. The tests being run were not the Average Joe immunology workups, and our hopes for a proper diagnosis were swimming in Petri dishes, waiting for the good doctor's analysis. These particular results were going to point us in the right direction for



keeping our kids off operating tables and the insurance company off our backs.

A desperate phone call from my eldest son's teacher broke my worrisome thoughts of potential answers lying in wait in my kids' red corpuscles:

"Can you help chaperone our Discovery Center field trip?" she begged. "One of my moms just canceled and you are on the wait list."

"Sure. I'll be there in a minute." A great force of sucking wind tainted with monumental relief pulled my ear toward the receiver, confirming that I was about to perform my good deed for the day.

"Oh, thank you, Cheryl," she gasped.

"No problem." I retorted. ... What am I thinking? I battled with myself. I am expecting a Very Important Phone Call from our doctor and I can't take a cell phone into a science center! (Please allow a dramatic pause as my thinking process needed a moment.) Oh, I know! (Can you feel my brilliance dripping off this page?) I'll put my phone on vibrate! That'll work!

I briefly explained the urgency of my Very Important Phone Call to my son's teacher, and she kindly conceded my need of a communication device. Frankly, she was grateful for another warm body.

Floating around a sea of "deep in discovery" third-graders, I found myself docked to an exhibit that experimented



Cartoon by Kim Kinnman

with electrical currents. Never mind the colossal bubble-making machine or the 8-foot mutant ant, this electrical “circus” emitted sparks and sparks make fire—cool! However, the Electrode Trampoline Act couldn’t numb my thoughts about my kids’ perplexing plasma cells or the pending Very Important Phone Call.

Note to reader: The science center appeared to be immune deficient, as it was obvious they didn’t include famished phagocytes engulfing mitogens in their molecular puzzle exhibit.

Gosh, I should have heard something by now, I hypothesized, while manipulating some electrical doohickey thing.

“Wow! This really works!” I exclaimed to the confused student standing next to me. “I can feel currents buzzing right through my overalls!” The glazed-over look on her 9-year-old countenance told me that she’d rather be text messaging Mr. Edison himself than engaging in idle conversation with an exasperated 37-year-old matron.

Speaking of text messaging, I wondered if anybody had called.

I groped through my two-sizes-too-big-for-me-but-oh-so-comfy overalls with arms flailing and finally found the booty of my treasure hunt. Much to my chagrin, the cell phone was flashing red at me like a Maine lighthouse, announcing that I had missed a Very Important Phone Call. “How can that be?” I whispered in frustration.

The recorded message confirmed my fear: I had indeed missed a Very Important Phone Call from my kids’ immunologist. And of course, his contact information bounced from my overalls to cyberspace, never to be retrieved.

“I missed a Very Important Phone Call!” I whined to my third-grade buddy.

“You should have put your phone on vibrate,” the 9-year-old Info-Genius snipped.

“But, I did put it on vibrate!” I whimpered.

“Well, maybe you shouldn’t have gotten so close to the exhibit,” she scolded, then turned on her heel and sauntered away, leaving me reeling from being shown up by a pre-pubescent member of Mensa.

Sure enough, it wasn’t the sparkling exhibit, a premature hot flash or the butterflies doing a samba in my stomach that made my overalls go “off,” but my vibrating cell phone with a Very Important Message for the parent of Caleb and Molly Haggard.

Note to self: One must first experience the sensation of a cell phone vibrating in order for it to be effective.

Because the efforts of trying to communicate with our doctor failed miserably and my ego had taken a pretty big blow, I decided to be more than a warm body to my son’s now exhausted teacher. So I did the unthinkable: I turned my cell phone off and merrily went on with chaperoning our science center field trip. I had fun getting sick on the spinning gyroscope and found out how grateful I am for gravity. It also dawned on me that I could survive a couple more hours without hearing the story a Petri dish was trying to tell: My son’s chubby-armed hug and hearty, “Thanks for coming on my field trip, Mom!” told me so.

Which led me to this thought: If my parents survived raising me with one avocado green rotary phone and a Record-A-Call answering system, then I can handle missing one Very Important Phone Call. I don’t remember Mom fretting over any messages while she was chaperoning my kindergarten class at the zoo, and all my present fussing wasn’t going to change the results waiting on our doctor’s desk. Come to think about it, my children are probably more concerned about my becoming Momma shish-kebab if I decide to answer, instead of ignore, a Very Important Phone Call while pumping gas into our SUV.

Note to reader: If I don’t answer when you call, it’s not that my overalls are failing to vibrate, it’s because I am probably jumping on our backyard trampoline with three Very Important People. But if you “leave me a detailed message after the beep,” I promise to “call ya right back!”



# Sites of Care: What's Best for You?

## An Infusion Center With a Heart at Its Core

By Jeff Siegel

*This is the first in a series of articles on sites of care for patients receiving immune globulin therapy. We will explore care in the home, a hospital outpatient clinic and an infusion center. The decision on the best site of care for the individual patient can be affected by multiple factors, including disease state and severity of the disease, the method of IG administration, reimbursement issues, and patient and physician preference. The best way for a patient to be involved in the decision-making process is to understand his or her options, so here we go!*

Lori White, dressed in nurse's scrubs, stands over the shaker machine, a bottle in her hand. Eight of the 10 spots on the machine have bottles in them, and she adds the ninth. The bottles, filled with specific IVIG mixtures, are shaking back and forth, the liquid inside moving in small circles, up and down the sides of the bottle. She checks the dial on the machine and sees the speed is set at 2.

"How long do they need to mix?" she says, repeating the question put to her, but focused on the job at hand. "It depends, but about 15 minutes."

Meanwhile, a couple of her colleagues are checking the dental office-sized chairs—six in one room, 15 in the second, larger room—that will soon be filled with patients. Another colleague is looking through a sheaf of papers. It is only 8:30 in the morning, and the patients won't arrive for another 30 minutes or so, but the nurses who run the infusion center at the Texas Neurology Center in Dallas have already been at work for a couple of hours. For them, though, it is not just a job.

Talk to the men and women who work at the center—and their patients—and it's something else, something

much more important. Each of them uses words like “family” when they talk about what goes on at the center, and that what goes on is about a lot more than practicing medicine.

“I don’t think it’s being immodest to say that we genuinely care about the patients, that we care deeply about each and every one of them,” says White, RN, CRNI, who runs the infusion center. “And I think the patients realize that, and it adds another level of excellence to what we do.”

### A Day in the Life

The Texas Neurology Center takes up three floors of a bank building in Dallas’ Lakewood neighborhood. It has been treating patients since 1993, and its 12 physicians specialize in a variety of neurological areas, from amyotrophic lateral sclerosis (ALS) to multiple sclerosis (MS) to sleep disorders. The infusion center treats about 110 patients a month, mostly adults, who suffer from diseases such as myasthenia gravis, an immune disorder that shows up as muscle weakness; polymyositis, muscle inflammation caused by white blood cells that invade the muscles; and chronic inflammatory demyelinating polyneuropathy, or CIDP, which starts with a numbness in the toes and can lead to muscle weakness in legs and hands.

While the center may sound to some like just another doctor’s office, to the people who come here, it is far more than that.

“I’m just thankful there’s a place like this that I can come to,” says Robert Connell, 78, a retired airplane industry executive who lives in suburban Arlington and drives almost an hour in rush hour traffic to get infusions for his polymyositis. Connell spends three to four hours once a month in the infusion chair, and has been doing so for about two years. “Thanks to these people,” he says, “I can play golf, work in the yard, drive my car. I have no limitations except for my age.”

That’s what the staff loves to hear. They are an experienced group that remembers wearing traditional nurse’s caps. Greg Wood, RN, is the rookie, with 18 years of nursing experience. Even more important, they are something White says is a rarity: “Good infusion nurses are few and far between.”

White started out as an intensive care nurse several decades ago, and moved to infusions at Baylor Medical Center in Dallas (where she still works a couple of days a week). She has, for the most part, seen IVIG from its beginnings to today, and notes that perhaps the biggest change is where infusions are done. Today, it’s an outpatient procedure done in clinics such as hers, hospital outpatient

clinics or in the home, as opposed to the old days of hospital stays and hospital pharmacists.

Karen Courtney, RN, CRNI, has been a nurse for 28 years, working in oncology before White recruited her to work at Texas Neurology in 2001. The biggest difference she has seen, she says, is that infusion is not nearly as threatening to the patients as it has been in the past. “They have more confidence in the procedure,” she says, “and they know we’re going to look after them.”

Margaret Hastings, RN, who took her nurse’s training in Great Britain, worked as a nurse in the United States and then left the profession about 10 years ago to do marketing for several health-related businesses. Three years ago, she received a call from White, who asked her to come to work at the center. “Our goal is to create the least institutional environment we can,” she says.

Like White, Wood also came to Texas Neurology from Baylor, where he worked in a variety of home healthcare units, which included doing infusions. Wood took his training in Arkansas, after a very short career working in a soft drink bottling plant. A friend told him nursing would be a better job, and Wood had his doubts, but, “it turns out that this job showed me I had strengths I never knew I had,” he says.

### Making Small Talk

On this day, Connell is sitting next to Anthony Grizzaffi, 65, a retired banker, who drives in from a country town called Terrell, about 30 miles east of Dallas. He suffers from CIDP, which means a 4 1/2- to 5 1/2-hour infusion once a month. The two men are waiting for a couple of White’s colleagues, who are wheeling IV stands toward the pair. Their talk turns to Dallas’ pro basketball team, which is in the middle of the playoffs, a vacation trip to Louisiana and Mississippi, and even British politics.

That’s when Hastings, a Briton who has lived in the U.S. for 40 years, comes over and joins the conversation. Later, she says, “The two best things about this job are the patients and that I get to work with my best friends,” motioning to the three other nurses in the room.

There’s that family closeness again. J. Theodore Phillips, MD, PhD, a board-certified neurologist who runs the ➤



center's MS practice, notes that it's not unusual to see patients come from hundreds of miles away, as far as west Texas, New Mexico, Oklahoma and Arkansas.

"I think they enjoy the sense of community," he says, sitting in his research-cluttered office. "It's a time for them to visit, not just with people they like but with people who have similar problems. Of course, they're not alone in this. That's what the doctors and nurses are doing, too."

Another distinction: There appears to be very little of the discord that sometimes goes on between doctors and nurses in other healthcare facilities. Here, each group treats the other with genuine respect and acknowledges that they get along much better than at other practices. "We're extremely pleased with our staff," says Dr. Phillips, "and I think that shows in what happens here."

In fact, sit and listen while patients are undergoing their infusions, and a couple of things become clear. First, there is acceptance of their conditions, and a willingness to do what's necessary to fight it. Scott Wilson, 35, a truck mechanic from north suburban Lewisville, has been having infusions for eight years, once a month for six hours, for his myasthenia gravis. His family makes adjustments; his employer makes adjustments, and has been willing to give Wilson the time off for his IVIG. "This can be very tough," Wilson says, "but it's now more of a pain than anything else. And it's a lot better than

plasmapheresis [his previous treatment]."

Second, it's not easy. Not everyone wants to chat about the process, and some prefer to sit in a corner, away from the others, and read or sleep. Mae Chan, 82, of Dallas, has CIDP, which causes numbness in her legs, and she receives a three-hour infusion every month. "Yes, it was a big adjustment," she says, noting that getting to the center is difficult, since she doesn't drive. "Would I rather be

doing something else? Of course. But if I have to have it done, this is the place I would like to come to. It always looks very nice."

### Helping Themselves

Perhaps the most intriguing thing about the infusion center is that most of the patients are well-versed in both their diseases and their infusions. Says White: "Obviously, the technology has changed and improved our ability to help nurse patients. But what has also changed is that the patients are very much educated. Technology has empowered more of them to take control of their health."

Technology, in this case, is the Internet. Connell can talk about his many tests – he discussed his various CPK results (a blood test that measures creatine phosphokinase levels, a chemical or enzyme in muscles) and his treatments like a physician. Connell credits his knowledge to his research on the Internet, something he felt he needed to do, so he would know what was going on during his visits to doctors and hospitals.

Less helpful, it seems, are the insurance companies that reimburse for immune globulin treatment. Grizzaffi, who credits infusion for restoring his life to most of what it was before he was diagnosed, has had a lengthy correspondence over the past several years with both his carriers and the state agency that regulates health insurers. The catch, he says, is that as soon as the treatment works and he can walk, his insurance won't cover additional treatments—until, that is, he gets bad enough again so that he can't walk.

"That's the frustrating part of the job," says White. "You can see the patients deteriorate in front of your eyes when their insurance changes. I just wish they wouldn't be so difficult in approving [IVIG] use for the patients."

Patient decline is something no one wants to see.

"If it wasn't for this, I'd be in a wheelchair," says Grizzaffi. "I was ready to try anything. So I came in here, and now I'm walking. That's a miracle."

It's also part of why the staff enjoys their jobs and their patients so much. Says Courtney: "It is a team effort, and it is like a family. We know what's going on in their lives, and they know what's going on in ours. It's part of their routine now, and it's part of ours. And we can see the improvement in chronically ill people, which is the most rewarding part of the job. That's what makes us so passionate about our jobs."

Because, in the end, that's what the center is all about. ■



Photos by Can Turkyilmaz



# Hey, Aren't They My Records?

By Lauren Gerstmann, MPH

## Patient Privacy Laws

In 1996, Congress passed the Health Insurance Portability and Accountability Act, commonly referred to as HIPAA. HIPAA was a reaction to the increase in electronic collection and sharing of personal health information. While designed to deal with issues related to payment for medical care, HIPAA has had far-reaching implications for our insurance companies, researchers, fundraisers and (as we all know from the forms we fill out every time we go to the doctor's office) our healthcare providers. The HIPAA Privacy Rule has created a federal standard for protecting the privacy of health information. The Privacy Rule went into effect April 14, 2001, and required affected entities to be in compliance by April 14, 2003.

It is very important to note that HIPAA forms tell us what will be done with our medical records, but they do not ask us how we would like those records to be used. In other words, they appear designed to prevent lawsuits as much as they are to protect patient privacy. HIPAA does give us the right to request that our healthcare providers and plans restrict uses or disclosures of our medical information. For example, you may say that you do not want to be targeted as part of a fundraising campaign or you may say that you do not want to be approached to join a research study. The provider or plan, however, is not obligated to agree to these restrictions.

## Access to Our Records

Federal law allows you to see and obtain a copy of your health records. In most cases, your doctor or hospital is required to provide you with a copy of your health records within 30 days of your request. They may, however, charge you for the copies or for any mailing expenses. You also have the right to make corrections to your medical record: If you and your provider agree that there has been a mistake, the record should be changed within 60 days. Even if your provider does not agree, the disagreement should be noted in your file.

Additionally, up to once a year, you have the right to request a free report that lets you know how your provider is sharing your information. You should receive this report within 60 days of your initial request. ➤

It seemed as though Steve always had an ear infection. His pediatrician, Dr. Doe, was not concerned, because he felt that the ear infection was "one continuous infection that needed to clear up." When Steve's parents switched pediatricians, Dr. Doe did not forward any records. Steve began seeing Dr. Jones, who was not concerned because he had not observed the pattern himself, and he indicated that Steve's parents were overprotective. Finally, Steve's parents found a new pediatrician, Dr. Smith, who did listen to them. Dr. Smith immediately referred Steve to a specialist. By this time, Steve was 2 1/2 years old and had suffered from a chronic ear infection for at least two years. The specialist performed an outpatient surgery on Steve, and he has been pain-free ever since.<sup>1</sup>

We've all been there. As patients or caregivers, we often feel as though we are not part of the healthcare "team." Some physicians will withhold information, not hear information their patients or the patients' caregivers offer them, or even be condescending. Additionally, in this era of increased legislation and malpractice suits, physicians have become so fearful of being sued and of the new privacy laws, that some have assumed a defensive posture in relation to their patients' healthcare records. As healthcare consumers, we are feeling the increased tension between protecting our privacy and protecting our right to access our own medical information.

## Physicians vs. Patients?

Patients with complicated health issues get the best quality of care when their care is coordinated. The coordinating caregiver (this can be a family member, a case manager, a guardian, even the patient him or herself) should have a sense of how the patient is being affected physically and emotionally by his or her illness. Different people may be affected differently by the same illness. An additional complicating factor is that people who suffer from one illness often have “co-morbidities,” other physical ailments as a result of or in addition to their primary illness. Often, however, the coordinating caregiver has no medical experience, which can make it harder to be accepted as an active part of the team.

The American Medical Association (AMA) instructs its member physicians to treat patients and families as part of a collaborative effort, even though “such a partnership does not imply that both partners have identical responsibilities or equal power.” And, they recognize that patients’ “physical, emotional and psychological integrity should be respected and upheld. ... [and that patients’ have] the human capacity to self-govern and choose a course of action from among different alternative options.”

Sometimes, though, it feels as though the coordinator is not being informed and included in care decisions. The relationship with the patient’s healthcare providers may become more adversarial than collaborative.

There is a very funny “Seinfeld” episode (“The Package,” air date Oct. 17, 1996) in which Elaine discovers that her doctor has noted in her chart that she is “difficult.” All of her efforts to prove she is not difficult backfire, and her label follows her from doctor to doctor:

Elaine (looking at her chart): *Difficult?*

Doctor: *Elaine, you shouldn't be reading that. So, tell me about this rash of yours.*

Elaine: *Well it's, it's... You know, I noticed that somebody wrote in my chart that I was difficult in January of '92 and I have to tell you that I remember that appointment exactly. You see this nurse asked me to put a gown on, but it was a mole on my shoulder and I specifically wore a tank top so I wouldn't have to put a gown on. You know they're made of paper.*

Doctor: *Well, that was a long time ago. How about if I just erase it. Now about that rash...*

Elaine: *But it was in pen. You fake erased!*

Doctor: *All right, Miss Benes. This doesn't look too serious. You'll be fine...*

As we groan in laughter, we empathize and hope doctors wouldn't really do that, would they?

According to the AMA: “Notes made in treating a patient are primarily for the physician’s own use and constitute his or her personal property. However, on request of the patient, a physician should provide a copy or a summary of the record to the patient or to another physician, an attorney or other person designated by the patient.”

Even though federal law and the AMA both assert that patients should have access to their records, these notes are still the doctor’s private property. This is true even if the contents of these notes are shared with patients or other providers. So, it is feasible that a doctor may make a personal note that a patient is “difficult.” The lesson here is that you should know what is in your healthcare records, so ask.

## Where Do We Go From Here?

We want doctors to protect our privacy and guard our confidentiality, but we need to ensure that these protections do not become so stringent that we cannot access our own records. With rapidly advancing technology, more and more of our records are kept electronically. This should streamline access to our records and make it much simpler for us and our physicians to coordinate patient care. But, as every doctor has a proprietary interest in his or her notes, and as every service provider interprets the privacy legislation differently, these databases are totally separate. Each office has its own system, making interchange of electronic information no easier than with paper files.

However, this may be about to change. David Brailer, a physician and former software company CEO now at the U.S. Department of Health and Human Services, is trying to build a National Health Information Network. This net-



work would allow all hospitals, doctors, laboratories and claims processors to share data by 2009. Such a system could be a true breakthrough for coordination of care, but it could also have frightening implications for our privacy.

The good news is that Brailer promises that healthcare consumers will be able to access our own records and correct errors. This could be tremendously useful if we are trying to learn more about our health history and play an active role on a patient's healthcare team: It can help us coordinate between multiple physicians and advocate for our loved

ones. The bad news is that we may lose control over how much of our personal data each provider can access. Your dentist may be able to learn that you are being treated for a completely unrelated ailment or your insurance company may learn that you paid out-of-pocket for an HIV test. While we wait to see how Brailer's efforts are realized, it is important that you begin—today—to be an advocate, both medically and legally. Be aware of upcoming legislation that might affect you or your loved one's privacy and access to healthcare records, and vote to protect yourself. And, make sure

that you keep your own records of medical events.

As Steve's parents learned, you can't always trust your records to follow you when you switch physicians. Healthcare is a service we pay for, and you may need to shop around. Whether you are coordinating someone else's care or your own, you are part of the healthcare team. If your healthcare provider does not agree, you have the right to find a new one. ■

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<sup>1</sup> Names have been changed to protect people's privacy.



## For more information...

The U.S. Department of Health and Human Services Agency for Healthcare Research and Quality: <http://www.ahrq.gov/>

United States Congress (search engine for legislation being considered by Congress): <http://thomas.loc.gov/>

State and Local Government on the Net: <http://www.statelocalgov.net/index.cfm>

The American Medical Association: <http://www.ama-assn.org/>  
(specific information on its policies regarding professional ethics can be found at <http://www.ama-assn.org/ama/pub/category/2416.html>)

Foundation of Taxpayer and Consumer Rights: <http://www.consumerwatchdog.org>

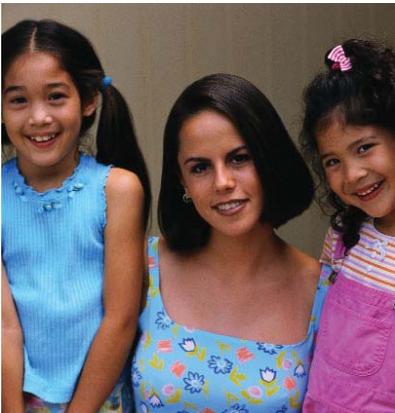
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# The Curse of Looking Good

By Dayna Fladhammer



*Thomas, Kate, and Charlie Fladhammer*

I think my kids are cute. Of course, I'm their mother, so I'm biased. That said, when I look at them, some days I think they look healthy and other days, I can see it in them, this disease. Charlie's eyes might look a little less bright, with circles underneath that are darker than normal. Kate might be a little pale, or Thomas' eczema might be flaring just a bit. People who know them really well can sometimes see it, too. The reality is, though, most of the time, they look like any other child.

This used to be a huge source of frustration for me—that they looked so healthy to the outside world when I thought they looked so sick. Even now, when they feel bad, they usually look good. I'm not complaining, mind you. I'm glad they look healthy, because really, they are relatively healthy now that they are on IVIG, but sometimes, when I'm explaining primary immune deficiency diseases (PIDD) to someone, I feel like the person is looking at me like I'm a liar, with that "they-couldn't-possibly-be-sick-they-look-so-healthy" stare.

It's not just with friends, family and acquaintances; sometimes it's even doctors.

When Kate, our first child diagnosed with PIDD, was in the hospital for the second time in four months, at the tender age of 6 months, I recall the first infectious disease doctor telling me, "She's too fat to be sick." I could have screamed at him. In fact, I may have. Truth be told, I felt stupid and dismissed, and slightly horrified. I had insisted he be dragged in to examine her, and then I was embarrassed. I fought the urge to listen to my own instincts about my child, but ultimately I didn't listen to him—and neither did our pediatricians. Two months later, Kate was diagnosed immune deficient.

The "looks-so-good" factor, I like to call it, is an ongoing

source of conversation with other PIDD parents I know. I fought it with my extended family members, who, while they encouraged me to trust my instincts regarding my children's health, didn't really "get it" until they watched a "20/20" special on ABC about a little boy with severe combined immune deficiency (SCID).

I can remember as though it were yesterday, my mom saying to me, "He looked so healthy." I didn't have to wonder what his parents thought when people said this to them. This little boy, awaiting a bone marrow transplant, born without any immune system at all, looked too healthy to be sick. I wonder if they ever want to ask people, "Oh, really? Can you see his immune system?"

Not all PIDD patients look healthy: Some have horrific rashes; some are exceedingly pale or have significant dark circles under their eyes. Failure to thrive is one of the 10 warning signs of a primary immune deficiency.

I'd venture to guess that many parents whose kids do look sick would love it if they looked healthy, even if just for a day.

As my children have gone through this process from sickness to health and on to maintaining with a chronic illness, I've realized that dealing with how they look is as much of a process as dealing with the illness itself.

Now that we have settled into this routine and this life, when someone comments on how great my kids look or how healthy they seem, I'm grateful. I feel as if I'm doing my job, and their IVIG is working to allow them as normal and healthy a life—and an appearance—as possible.

Earlier this year, my daughter Kate spent 13 days in the hospital. While there, one of her doctors referred to her as "the healthiest-looking sick kid in America." I could not have been more proud. ■

# Can We Talk?

By Ever Fecske

**W**e all have one thing in common: We have, or we know and love someone who has, a chronic disease. Although we each cope with the stress of our situations differently, I find it can help to talk about it.

In fact, I have no problem explaining every dirty detail. It may seem a little crazy to some people, but I want everyone to know about my condition—the checker at the grocery store, the guy I rent videos from, my teachers, my boss—everyone. I find some comfort when people know that one of my medications is making me fat and turning me into a lunatic at times. This way I don't need to make any excuses. I like being an open book. It is how I cope.

On the other end of the spectrum, I know there are those who don't feel comfortable at all talking about their illnesses, but holding in stress is not good for your health. You owe it to yourself and your body to speak up. It may not be the first thing you say in a conversation, but it could be the fourth or fifth.

I have found that talking about my illness and my experiences relieves a lot of stress, a factor that I have to be concerned with, since unresolved stress only further inhibits my body's immune system.

So, how do you know with whom you can talk about your illness? Friends are ideal, but I have found that they don't always know how to deal with sickness. It's up to me to help my friends feel comfortable with my situation. I can set the tone, put them at ease with the illness and help them understand—so they know I am the same person I was before my friends knew about my disease. Then, there is nothing like talking to a compassionate friend!

Something I value even more is being able to talk with others with a condition similar to mine. I feel a sense of community and common understanding, because they live with the disease too. Why is it I feel so much better knowing I am not alone? I don't think it's just the empathy and support I get from my peers, but what I provide in return. By talking about it, by sharing my experiences

with my disease, I not only help myself, but I help others, and that is enough to motivate me.

In the last few weeks I have realized just how important it is to share my story and my experiences. In June, I spoke at a seminar at UCLA. NICE Day, as it was called, was for people with immune deficiencies and neuropathies, and their families, to come together and learn from doctors and peers. I was asked to talk to teens with chronic illnesses. I knew the topic wouldn't be a problem since I was a teen just a few years ago. Nevertheless, the thought of getting up there was frightening. I went around in circles about what I should discuss: school, friends, family, parties, secret crushes? I contemplated all the afflictions I have had over the years, and the issues. Normal teenage issues are tough enough, but throw in an illness, and the dynamics totally change.

So, after stressing about it for a week, I took my own advice and stopped. I would go in there and be honest. I can only talk about the things I know, so that's what I did. I told my story.

When I was 10, I was sick with idiopathic thrombocytopenic purpura (ITP). The easiest way to explain this illness is that my spleen became confused and started eating up all my good platelets so my blood didn't



coagulate. This made me prone to internal bleeding and bruising.

I was young and did my best to understand the severity of my condition, but I was much more interested in being a kid. I wanted to play dress-up and have lemonade stands and go swimming. It was summer, after all, and I wanted to play. But if I went swimming, I had to stay in the shallow end, and I couldn't dive for fear of hitting my head. I could go to my friend's house and play, but I had to wear a bike helmet in the car for the drive. So, not only was I ill inside, I looked different on the outside.

I also had a regular treatment schedule: Every two weeks I had to receive extremely high doses of IVIG in the pediatric infusion center. Other than getting stuck with needles and having to sit still for eight hours, I actually loved going. I had a friend there, Rebecca, who had leukemia. I didn't know what that meant then, but I knew she was fun and pretty, even with a bald head.

I remember she once took her scarf off and let me touch her head. It felt like my lucky rabbit's foot keychain, so soft and smooth. We would just giggle and play and let our medicine run into our veins, and pray that it would fix us. I eventually had to stop treatment because of the strain on my kidneys. I never saw Rebecca again. I don't know what happened to her, but I would like to believe she is well with long, beautiful hair.

Soon after my IVIG treatment ended, I was introduced to a new one: prednisone. Let me tell you, a 10-year-old on steroids is not a pretty sight. Imagine eating 100 chocolate bars and then being put in a box. It was like a cranky sugar high all the time. It drove me nuts, and there were times I felt so guilty because I couldn't control my urges to eat. Little did I know at the time that prednisone and I would have a long on-again, off-again relationship. Between the weight gain and mood swings and strangers' looks of sympathy, I no longer knew where I belonged. And everyone treated me as if I were on my last leg.

The following September, I started the fifth grade. I went back to school looking completely different. Although body image wasn't a huge concern to me as an 11-year-old, I remember feeling insecure. I grew up that summer, and although I was still a child, I had a whole new understanding of life and how fragile it is.

Eight years later, I had my second run-in with prednisone. I had not been feeling like myself for a week or so, and one night I ended up in the hospital with the diagnosis of autoimmune hemolytic anemia, or the ultimate in

dehydration. I was missing one-third of my red blood cells. The exhaustion was intolerable! Even though I ended up on 100 mg of prednisone a day, I gained 25 pounds in the first two weeks, and I was 18 years old and feeling lost, I was determined to live as normal a life as possible. I didn't want to let my illness stop me, and it didn't.

Just two weeks before I was diagnosed, I had been cast as Mary Magdalene in "Jesus Christ Superstar." I desperately wanted to do this show, so after my treatment started, I spent every night in rehearsals—and the hardest part was trying to fit in! I wasn't able to be very active, and the rest of the cast didn't like the special treatment I was receiving. That's when I decided that the only way I was going to get through this was to communicate. So I told them everything: why I ate so much, why my legs hurt, how many pills I took every day, and on and on. In the end, it was one of the greatest experiences of my life. I was a very sick girl, but I proved to myself that I could still perform and make friends—and get well—all at the same time.

Fast forward to now.

I am now diagnosed with common variable immune deficiency and interstitial lung disease. My lungs work at only about 50 percent, so, needless to say, I haven't been singing much. But I will be. I was accepted to Berklee School of Music in Boston, and my only goal is to get there. This is my life and I will thrive. My illness is a part of me and I accept that it goes with me wherever I go. My only choice is to make peace with it and get to know it like a friend.

And, here I am, once again, on prednisone! Bloated, cranky and very hungry! And, although at times I feel unbearably alone, I know I am not. I turn to my support group online, where I can vent as much as I need to. My family is here to listen to me curse and get angry, and laugh about it afterward. And I have the privilege of writing for IG Living, where I can communicate with people who understand me. It's amazing that writing this helps me so much!

So, why don't you try it? If you just can't bring yourself to talk openly about your illness, write to me instead. How do you cope? With whom do you talk? What are your goals for the future? I would like to hear from you, and we can share it here. ■

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Contact Ever at [editor@igliving.com](mailto:editor@igliving.com).

# Improving Immune Defect Diagnosis: How You Can Help!

Immunologist Charlotte Cunningham-Rundles, MD, PhD, has seen the damaging effects of the struggle many patients have obtaining proper diagnoses for their immune deficiency diseases.

"There are more than 100 known immune defects, but the overall clinical presentation, the illnesses that appear, and the immunologic abnormalities present in each are very different," Cunningham-Rundles explained. "While these diseases are believed to be present in all populations, the diagnosis of primary immune deficiency varies considerably from one country to the next, and in the United States, even from one state to the next. We think this results from under-diagnosis and delayed diagnosis, which leads to increased morbidity and higher medical costs; in many cases, the delay results in increased mortality."

In response to this problem, Cunningham-Rundles and some colleagues applied for and received a National Institutes of Health grant to conduct a study called STRIDE, Study Targeting Recognition of Immune Deficiency and Evaluation. The hypothesis of STRIDE is that undiagnosed patients can be identified in large hospital or insurance populations by using a newly devised computer scoring program to evaluate diagnoses associated with immune deficiencies.

"At Mount Sinai Hospital, we used the computer algorithm to find patients who had two or more significant illnesses suggestive of immunodeficiency, without other diagnoses leading to these conditions," Cunningham-Rundles recounted. "When we tested a group of these patients, we verified that immune defects were present in 35 percent. We are continuing our program at this hospital and at affiliated hospitals in the New York area, and we are seeking to extend this to additional hospitals."

The STRIDE study also includes an important outreach program to solicit information directly from patients. One method of doing this is through an electronic survey. The survey will help identify what medical problems are important to patients and what events led to their correct diagnoses.

"We need as many patients as we can possibly reach to take the survey," said Cunningham-Rundles. "Their input is a very important part of our research, which will ultimately help improve evaluation and diagnosis of immune deficiencies."

## **Patients: Please take the STRIDE survey!**

You can access the web-based survey at [www.igliving.com](http://www.igliving.com).

**Physicians:** For more information about implementing the STRIDE algorithm at your hospital, please call 212-659-9268.

# IVIG Infusion Guide: Tips to Make Infusion Days Easier

By Jennifer Richlin, RN, MSN, PNP

If you or your family member receives intravenous immune globulin (IVIG) infusions, you know how the smallest thing can make treatment day difficult for the whole family. Whether the lack of a good connection with your infusion nurse or poor venous access, IVIG days can be dreaded events—but they don't have to be.

What follows are some tips for infusion days to aid in your endeavor to achieve the least traumatic experience possible. These "infusion gems" have led to a positive dialogue between patients, families and the rest of the healthcare team, and, consequently, have made infusions go more smoothly. We hope they do the same for you.

## IV Access

**First things first.** Without adequate IV access, you or your family member will not be receiving the life-changing benefits of IVIG.

Ideally, you have access to an experienced infusion center where the nurses are trained, gentle and proficient. Many patients form a bond with the nurses whom they trust to get their IV access, and that relationship is a blessing. If you are not fortunate to have the best IV nurses in the world, you still can do a few small things to help the process have the greatest chance of success.

## Drink, Drink, Drink!

No, this is not a college fraternity game, but, in fact, adequate hydration is great advice for anyone who needs good IV access. Start drinking water, juice and power drinks the day before an infusion is scheduled. Stay away from coffee or alcohol as they can dehydrate the body. If you or your family member has a fluid limit, consult your healthcare team to determine how much fluid intake is acceptable. Similarly, if you have a heart or kidney condition, but do not have a fluid limit, discuss your hydration plan with your doctor.

**Make it silly.** If you are encouraging a child to drink, try fun, silly straws and fun cups. Popsicles are also a great way to let children have fun while trying to hydrate before an IV start.

## A Less Painful Start

**Numbing creams.** If you or your family member has a fear of needles or a history of difficult IV starts, try using a numbing cream such as EMLA or Ela-Max. Place the cream on three or four sites that have been successful in the past, as the product packaging directs. Most creams work better if they are on for about an hour.

A word of caution about numbing creams: They can make the veins compress and flatten out due to the constriction effects from the active



Photos by Can Turkyilmaz

ingredients, so if you or your family member has very difficult veins, numbing cream may not be a wise option for you.

**Warm and toasty.** If you or your family member has a history of difficult IV starts, ask for a warm pack to apply to the veins before anyone attempts a stick. The warmth causes a reaction called vasodilation, which can make the veins larger and easier to access.

## Infusion Dread

IVIG days can be very scary for children, and it is important to try to make them the least traumatic as possible.

**Sticker charts.** If your child is 2 to 8 years old and receives IVIG, try a sticker chart for each infusion day completed. The child can help ➤

make the chart, and many infusion centers have Child Life Specialists who are equipped with fun paper and cheerful stickers. Your child may enjoy the pride of placing the sticker on the chart each infusion, and at the end of a cycle, perhaps three or four treatments, you could give him or her a special treat. You know your child, and you can work together to find what special treat works best.

**Prizes.** Some infusion centers offer small presents or toys on infusion days. Most families find this works best if the child can choose the gift or receive the prize at the end of the infusion. This gives the child something to look forward to, and the regular routine is comforting.

**Big kids.** If an older offspring or adult or you are the patient, rewards still work. Use infusion time to indulge in a good book or watch a movie you never have time for. Bring a favorite blanket and take a long nap while you get your infusion. Use the time to nurture yourself as the IVIG nurtures your body. You deserve to feel special, because infusion days are stressful for big kids, too!

### Rates of IVIG Infusion

The infusion rates recommended by most IVIG manufacturers comply with a standard of .5 cc per kilogram per hour of infusion (.5 cc/kg/hr). One kilogram equals 2.2 pounds. This rate usually doubles every 15 to 20 minutes, up to a maximum rate of 4 cc/kg/hr. This is important for you to know because an infusion administered too rapidly can increase potential reactions, and it can also increase the chances of a later reaction at the 24-to-36-hour mark.

Remember, the IVIG package insert rates are recommended, and

different institutions may have varied administration protocols. A word of caution: Do not exceed the recommended infusion rates unless specifically ordered to do so by your healthcare provider. It is generally safe to run IVIG at a slower infusion rate than the maximum for your weight.



If you have any questions about your infusion rate, talk with your healthcare team.

### Pre-medication

Most patients receiving IVIG require some form of pre-medication. "Pre-meds" are those medications given half an hour to an hour before infusion for the purpose of limiting any potential side effects.

The following are some, but by no means all, of the possible pre-meds for IVIG.

- Diphenhydramine (Benedryl)
- Acetaminophen (Tylenol)
- Ibuprofen (Motrin)
- Naprosyn (Aleve)
- Prednisone
- Hydrocortisone
- Methylprednisolone (Solumedrol)
- Saline IV

Again, consult your healthcare team if you have any questions about pre-meds.

### Side Effects

There are many predictable side effects from IVIG infusions that are manageable with either pre- or post-mediations—and some can be avoided altogether with proper communications and precautions.

Initially, be sure to alert your healthcare team if you or your family member has been ill, because illness may result in side effects being more pronounced, and this can alter the pre-medications needed. Even if it seems like "just a small cold," let the healthcare team know before starting the infusion.

If there is pain or discomfort at the site during infusion, always alert the infusion nurse immediately. Sometimes a warm or cold compress on the site of infusion can help. If all else fails, you can ask the IV nurse to look for IV access in your arm rather than in your hand, as the larger arm vein can be far less sensitive than the smaller and more delicate hand veins.

If you or your family member is suffering from serious side effects after IVIG infusions, such as migraines, back pain, vomiting or listlessness, there are some possible solutions you can discuss with your healthcare team:

- Slowing down the rate of infusion
- Changing brands of IVIG
- Switching to subcutaneous infusion (under the skin)
- Infusing normal saline fluid after IVIG

### Nothing to Fear but Fear Itself

A few words on fear and anxiety: If your child is receiving the infusion, and you are exhibiting signs of fear and anxiety, it will make your child more concerned than if you remain calm.

This may seem a tall order when your child is experiencing a scary and possibly painful procedure, but they will pick up your energy. If you are unsure of what to do, talk with the healthcare staff, and they can support you and your child. Ask about having a Child Life Specialist work with your child before and during the IV start. Some families create a photo journal or teaching book, so children can read about their infusions the day before they arrive. Encourage your child to ask a lot of questions before the procedure, so he or she understands what will occur. Remind the child that the staff is there to help him or her feel better, and remember to use rewards to help get through the day.

### Subcutaneous Immune Globulin

A quick note about subcutaneous immune globulin (SCIG) infusions: Numbing cream on the site or sites you and your healthcare team have selected can help alleviate the discomfort some patients feel with SCIG infusion. Your physician can prescribe the cream for you. You may choose to stop using the cream for subsequent infusions, if you no longer need it. You should remove the SCIG from the refrigerator one hour before you start the infusion, so it returns to room temperature before you infuse.

During the first 15 to 30 minutes of infusion, a warm pack or cold pack may help with the burning at the site of infusion that some

patients experience. Because the SCIG dose is smaller, the rate of infusion is more flexible than with the IV formulation, so discuss the best rate with your healthcare team. If there is a great deal of itching at the infusion site, also talk with your team about an anti-itching medication such as Benadryl.

### Logging Infusions

It is very important to maintain an infusion log. Your or your family member's infusion log should include the following information for every infusion:

- Date and time of your infusion
- Dose infused
- Immune globulin product name
- Product lot number with expiration date
- Location of infusion site(s)
- Infusion duration
- Any infusion site reactions or side effects

You can find your product lot number sticker on the vial or you can copy down the product name, lot number and expiration date from the vial into your log.

### Ask Questions!

These infusion tips are a way to increase dialogue between you, your family member and the rest of your healthcare team. Undergoing infusions can be a very scary experience, but the more information you have, the better prepared you will be to help fix any problems that arise. Always ask if you are unsure of something, and remember that the members of your healthcare team are there to assist you and your family in achieving a healthier way of life. ■

## Cheat Sheet for IVIG Infusions

- Drink a lot of liquids for one to two days before infusion day, but stay away from coffee and alcohol.
- Ask for numbing cream, if you feel you need it.
- If there are side effects, ask about pre-medication or decreasing the rate of infusion.
- Do not exceed the 4 cc/kg/hour infusion rate, unless directed by your physician.
- Write down any questions and keep a journal to log infusions, pre-medications, lot numbers and any side effects.
- Try to make the best of infusion days, because they will make the patient feel better!

# The Quest for a Secure

**T**he catalyst for a movement to rid counterfeit prescription drugs from the United States supply channel sits in a butter dish in the Fagan family's refrigerator at their home in New York. It is two vials of Epogen, an anemia-fighting drug taken by Tim Fagan, now 20, following a liver transplant in 2002. One vial has a legitimate label for Epogen's strongest dosage (40,000 U/ml), and the other was relabeled (or "uplabeled") by a counterfeiter, from 20,000 to 40,000 U/ml. While Fagan did not die from being injected with the fake drug, his red blood cell level did not rebound as it should have and he had agonizing side effects.

The only detectable difference between the two thumbnail-sized vials is that the counterfeit drug's label had no Celsius degree symbol next to the words "Store at 2 to 8 C." Unless one has a magnifying glass at the ready, the difference is not readily seen.

"I am a pharmacist, and most pharmacists I know can't easily make the distinction between real and counterfeits," says Carmen A. Catizone, executive director of the National Association of Boards of Pharmacy (NABP).

Neither can most healthcare consumers. Tim Fagan's parents purchased the Epogen at a local CVS pharmacy. They eventually discovered the counterfeit had made its way through a zigzag chain of distribution from the drug's maker, Amgen, through two of the three major national drug wholesalers to a series of secondary wholesalers in South Florida up to the Fagans' pharmacy in New York. The traditional buying and selling habits of large wholesalers includes buying back product from secondary distributors (discounted from the price at which it originally sold or at increased pricing during shortages). This practice makes the underregulated pharmaceutical supply channel vulnerable to counterfeiters embedded in the gray secondary wholesale market.

What types of drugs are most susceptible to counterfeiting? Not surprising, counterfeiters target widely used and popular drugs, such as Lipitor and Viagra, and

expensive, injectable therapeutics such as Procrit and Epogen, and, yes, immune globulin.

How prevalent is counterfeiting? According to a statement presented to a House of Representatives subcommittee last November, attorney Donald deKieffer noted that in 2003, the World Health Organization and the FDA estimated that counterfeits made up 10 percent of the global medicines market.

In the last four years, following criminal investigations stemming from the Fagans' case and others in states such as Florida and Nevada, strides have been made by both the public and private sector to stop the disturbing crime of pouring adulterated, mislabeled and possibly lethal drugs into the U.S. drug supply.

Unfortunately, like the Fagan evidence that helped spur public awareness of this issue, the toughest federal legislative proposal to secure the safety of the drug supply channel from manufacturer to pharmacy sits on the shelf—in this case, a subcommittee of the U.S. Congress' House Energy and Commerce Committee.

The bill, the Counterfeit Drug Enforcement Act of 2005 (also known as Tim Fagan's Law, HR 2345), was introduced in Congress in May 2005 by Representative Steve Israel, D-N.Y., Fagan's congressman. A companion Senate bill (S. 1978) was introduced by Senator Charles E. Schumer, D-N.Y., in November 2005 and is sitting in the Senate Committee on Health, Education, Labor and Pensions.

Of eight major proposals in Fagan's Law, four of them go even further than current regulation by the FDA under the Prescription Drug Marketing Act (PDMA) enacted in 1988, further than existing state laws, and further than drug wholesalers' self-policing commitments. These proposals are: increasing criminal penalties against counterfeiters (up to life imprisonment if convicted of counterfeiting); mandating that a manufacturer must alert the FDA of a counterfeited drug in two days; giving the FDA recall authority for prescription drugs (currently it can only request, and ultimately sue to require, that private companies recall



# Pharmaceutical Supply Channel

By Angela Macropoulos

product); and requiring a drug pedigree, a record of the chain of custody of a specific unit of medication as it moves through the supply channel from manufacturer to pharmacy. The requirement for a full and contiguous drug pedigree is the bill's linchpin.

This June, the FDA lifted an 18-year stay on the PDMA's pedigree regulations, which will result in implementation of a federal pedigree requirement. However, the federal regulations contain a significant loophole, because they do not require a pedigree from an "authorized distributor of record" of a drug. The PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug.

Katherine Eban, the author of the book "Dangerous Doses," which compellingly chronicles schemes of making and distributing counterfeit drugs in South Florida and ties the tale to Tim Fagan's own bad medicine, says that the authorized distributor loophole is bad because it allows distributors to continue to be able to launder the origin of the drug. "So long as a company is an authorized distributor, there is an assumption that it got it directly from the manufacturer. And the regulation's murky definition of who is an 'authorized distributor' is too permissive," Eban says.

Eban adds that drug manufacturers have been unwilling to disclose who their authorized distributors are, presumably to protect competitive pricing advantages. "The efforts to make the chain more transparent have been stymied," she adds.

Last November, a hearing on counterfeit drugs was held by the U.S. House of Representatives Committee on Government Reform. Among those who testified were Eban and Kevin Fagan, Tim's father, who has become an enthusiastic advocate for this issue. Although the hearing encouraged other congressional representatives to sign on to Tim Fagan's Law, it continues to languish in the House subcommittee.

"It makes no sense," says Eric Turkewitz, a lawyer who

represented the Fagan family in a civil action related to the counterfeit Epogen. "There is nothing partisan in this bill, and it's all for the public's benefit. Where a counterfeited drug could affect millions of lives, who could be against it?"

Eban says that there is some public and political confusion that tangles the effort to preserve the integrity of the supply chain into the argument against importation of cheaper drugs. "Some congressmen take the position that the talk about supply chain safety is a ruse by pharmaceutical companies to prevent drug importation or re-importation," she says.

Catizone of the NABP stresses that, while it is perceived that Canada has a secure supply chain, Canada could obtain drugs from other countries that do not.

Ultimately, while Representative Israel holds that "all politics is personal," when describing how the Fagan family's story has been compelling in articulating his legislative effort, another chestnut, "business is business," continues to hold sway in the battle to eliminate counterfeit drugs.

For example, the Florida Legislature passed a law in 2003 that initially required full pedigrees for 34 of the most commonly counterfeited drugs. The Florida law would have implemented an expansion of the pedigree requirement, effective July 1, for all drugs. Instead, HB 371 was introduced in 2005 to weaken the additional pedigree requirement. It was supported by the Healthcare Distribution Management Association (HDMA), and Governor Jeb Bush signed it into law right before Florida's legislature adjourned this summer.

Martha Harbin, communications director for Safe Drugs Now, a Florida coalition dedicated to the implementation of drug pedigree laws, says that by hiring well-respected lobbying firms within Tallahassee, the HDMA successfully argued against the more rigorous pedigree requirements and in favor of business interests.

Kevin Fagan, who went down to Florida in May to

lobby against passage of HB 371, is not surprised. ➤  
“There are more drug lobbyists than there are members of Congress,” he says.

Harbin says that the Safe Drugs Now coalition is still reeling from its loss. “Government will put more effort in making sure that CDs, DVDs or purses are not counterfeited,” she says.

But there is also political action on the horizon nationwide. For example, in New York, state Assemblywoman Amy Paulin, D-Scarsdale, and state Senator Nick Spano, R-Yonkers, have co-sponsored a bill that requires a full pedigree in electronic format or other emerging technology (A.2957 and S.3278). Wholesalers nationwide have argued previously that they needed time to go from paper to e-pedigrees, but New York’s proposed law, if passed, would force electronic tracking by December 2007. It also increases registration fees for drug wholesalers and manufacturers, and requires that wholesalers post a surety bond of \$100,000 or more.

Paulin says that mandating a surety bond this high will weed out bad apple wholesalers. She is optimistic that the law will pass when legislative session resumes in January. Paulin believes that states should do their part in closing the breaches in the porous drug supply channel. “What the FDA regulations now do is merely to provide a minimum standard. There is no reason in the world why states should not try to take leadership roles on this issue,” she adds.

Not all efforts are political. In 2005, the NABP, a professional association representing the states’ boards of pharmacy, started the Verified-Accredited Wholesale Distributors Program (VAWD). VAWD accredits wholesalers through on-site inspection of their facilities and evaluation of their operating practices. This accreditation process is required in Indiana, and 10 states recognize VAWD in lieu of a state inspection by the individual state pharmacy’s board. The association’s inspectors consist of former employees of the FDA, the Drug Enforcement Agency and the state boards.

“It is intended to fill in the gaps of the federal and state regulatory side,” says Catizone.

In the meantime, the big three drug wholesalers pledged in 2005 not to buy brand-name pharmaceuticals from the secondary market, and CVS agreed that it would not purchase from middlemen who buy from the secondary market.

As for Tim Fagan’s Law, Congressman Israel is undaunted in his effort to establish a national standard for drug supply channel safety. He recognizes that the current Congress and presidential administration do not consider it a priority issue. “My attitude is to fix bayonets and charge. I tend to take on issues that have been relegated to the sidelines,” says Israel.

But it is the personal aspect of this issue that seems to inspire Israel to continue his efforts. “Tim Fagan proved that a single person can catalyze change for millions of Americans,” Israel says. “Any person who is a medical consumer can learn the lesson of Tim Fagan.” ■

## What Can You Do About Counterfeit Drugs?

- Encourage your representative and senator to support the Counterfeit Drug Enforcement Act of 2005 (HR 2345).
- Talk with your healthcare providers about where they buy your drugs.
- Ask your pharmacist if the pharmacy has a policy of not dealing in the secondary wholesale market. Other than the general explanation of side effects given with the dispensed drug, ask if the pharmacist has heard of any other possible side effects.
- Be conscious of new or different side effects from those you’ve had previously or that are disclosed with the drug’s packaging.
- If the drug is ineffective from the start or stops being effective, be suspicious and take it back to the pharmacy.
- Be familiar with your medicine. Examine its shape, color and size.
- Look at the packaging. Is it clear, clean and sealed? Look particularly at the quality and preciseness of the labeling.
- Be sure to keep samples of your medicine for evidence and comparison. Remember, the reason the Fagan family was able to identify the bad Epogen is because they had a good vial to compare it to.
- Most of all, observe your symptoms.
- Check for warnings and announcements from the FDA website and from state pharmacy boards and boards of health. Also explore your pharmacy’s website.
- If you or your doctor suspect a medicine is bad, you or your doctor should submit a report to the FDA on its MedWatch site. Submission forms can be found at <http://www.fda.gov/medwatch/report/consumer/consumer.htm>.

# NICE Day at UCLA

By Dan Bennett

**D**octors, patients, family members and health-care providers gathered at the University of California at Los Angeles one Saturday last June with a goal: to better understand the nature of immune deficiencies, their treatment and the accompanying lifestyle issues, by listening to each other and working together.

The event was the NICE Day at UCLA, sponsored by NuFACTOR, a division of FFF Enterprises, the nation's largest supplier of immune globulin products, and the publisher of this magazine.

The previous year's NICE meeting in Carlsbad, Calif., was successful in educating and enlightening people, and, by the end of the day in Los Angeles—a day filled with informative medical presentations, networking and the sharing of countless heart-tugging personal experiences—it was apparent the UCLA event continued that successful tradition.

The event opened with a presentation by Dr. Talal Chatila, Chief of Pediatric Immunology, Allergy and Rheumatology at UCLA, who talked to the gathering about where immune deficiency treatment has been, and where it is headed.

"Progress is substantial during the last 20 years," Chatila said. "Therapy has moved along, but we still have a long way to go. The growing awareness of immune deficiency disorders is ever increasing," he explained, "and more recognition from the National Institutes of Health and various foundations has at last arrived."

Chatila talked about the warning signs and management of primary immune deficiency, and such ongoing treatment issues as gene therapy. He also discussed the work being done by patient organizations.

"The advocacy area began when patients started taking interest and action," Chatila told the gathering. He encouraged the concept of patients taking on advocating for proper diagnosis and treatment of their diseases.

Next, Dr. Maria Garcia-Lloret, a physician in the Division of Pediatric Immunology, Allergy and Rheumatology at Mattel Children's Hospital at UCLA, talked to the audience



Above: Patient shares her story at NICE Day.

Left: Infusion nurse hugs a young participant.

about intravenous administration of immune globulin.

Garcia-Lloret discussed safety issues, explaining that the last documented case of infection from an IVIG transmission was back in the early '90s and assuring that IG is a very safe product.

However, "costs and availability remain an issue," Garcia-Lloret said. "It's very expensive and we don't think it will get any cheaper, but it's a wonderful drug. I don't know what we would do without it."

Dr. Robert Roberts, one of the conference organizers, then discussed the increasing use of subcutaneous administration of immune globulin. He reviewed the advantages of subcutaneous (SubQ), or under the skin, versus intravenous administration of the product, and addressed such issues as availability and affordability of immune globulin products.

Among the SubQ advantages Roberts listed were no venous access, more consistent IgG levels, and the possibility of self-infusion at home. Disadvantages included the relatively small volume per infusion and requirement of frequent treatments. Overall, though, the presentation included ample evidence of advantages associated with subcutaneous use. ➤



*NICE Day participants gather for a lunch break.*



Dr. Marc Riedl, an assistant professor of medicine for Clinical Immunology and Allergy at the David Geffen School of Medicine at UCLA, talked about the nature of common variable immunodeficiency—what it is and how it is treated. He assured listeners that networking among each other was important.

“For the family members out there, you are not alone,” he said. “There are plenty of people out there who know what you are going through.”

Riedl also addressed subcutaneous administration. “I think SubQ is the way of the future,” he said. “But I don’t think it’s for everybody. You need to talk to your doctor about what’s best for you.”

A lively roundtable discussion followed, allowing patients and family members to ask questions directly of the physician and patient panelists. Many questions concerned the patient-doctor relationship, and how to best improve it through honesty and asking questions.

One patient, Nancy Hoffman, said she used IVIG for nine years, and SubQ for the past year. “It has truly changed my life,” she said. “SubQ has given me my life back in many ways. I wanted control of my care, and this method gave me flexibility.”

Participants also asked questions about insurance and reimbursement, leading to a presentation by Melissa Schweitzer, an associate at Washington Strategic Consulting. Schweitzer discussed Medicare reform and the worsening crises of IVIG supply and reimbursement, problems that are placing patient lives at risk. She encouraged patients to become involved in advocating for a solution.

“You might think one voice doesn’t matter, but it

does,” Schweitzer said. “As a patient, one of the things you can do is become an advocate.”

Following a lunch break, the NICE Day participants divided into small groups for targeted presentations and discussions on such topics as autoimmune problems, neuropathy issues, subcutaneous immune globulin, teens living with chronic diseases, and parents coping with the chronic illnesses of their children.

Rachel Hunt, the director of Child Life/Child Development at the Mattel Children’s Hospital, gave a spirited talk on living with chronic illness. She addressed the various stages of coping with a chronic illness, including shock, denial, confusion and fear.

Hunt then addressed ways of handling things through the years, including sharing feelings, reliance on family members and friends, and becoming involved in the communities of chronic-illness patients and family members.

Young adults Ever Fecske and Keegan McFalls provided an emotional and inspiring talk about how they have dealt with adolescence and immune deficiencies at the same time, agreeing that a thorough understanding of their illnesses helps, as does reliance on and support from peers.

Dayna and Brian Fladhammer, parents of children with chronic illness, discussed their own experiences, sharing that after they came to terms with the fact that life as a family wasn’t going to be as they had originally planned, they were able to manage and even grow stronger as a family.

By the end of the day, attendees expressed gratitude to the presenters, and said they learned much. As one mother who attended both the UCLA event and the 2005 NICE Weekend put it, “I have five children dealing with this, and I’ve come away with a much better understanding of things. It’s helpful to talk to others who know what we go through.” ■

The next NuFACTOR NICE Day is  
November 4, 2006, in Seattle, Wash.  
For more information, call  
Carrie Craig at 800-843-7477.



# Personalized Nutrition: On the Horizon

Jessica Schulman, PhD, MPH, RD

*“Nutritional requirements of individuals differ with age, sex, body type, physiological state (especially pregnancy), genetic makeup, activity and even with the environment, particularly the climate.”*

—Roslyn B. Alfin-Slater, PhD, nutrition authority, and Derrick B. Jelliffe, MD, distinguished pediatrician (1973, *Los Angeles Times*)

The recommended dietary allowances (RDAs) were first published during World War II to provide guidance for nutrition requirements in connection with national defense. Since 1968, the RDAs have served as the benchmark of nutritional adequacy for the public. For individuals with special needs, however, personalized nutrition may prove to be a more effective method for achieving optimal health. How can each of us attain optimal nutrition, given particular genes, age and health challenges? Which nutrients prevent, treat or contribute to disease processes? This article will discuss the current state of research to answer these questions and will explore, with real examples, how individual differences such as chronic disease and genetic makeup impact nutrition status and dietary needs.

## The Daily Reference Intakes

The Food and Nutrition Board and the Institute of Medicine developed dietary reference intakes (DRIs) to provide standard values for nutrient intakes and safe upper levels for ingestion of certain nutrients (refer to Table 1). DRIs are now used broadly in food- and nutrition-related programs in the United States. Although the DRIs updated and replaced the dietary recommendations represented by the RDAs, the term RDA is still used today. The DRIs, and RDAs, address the average daily dietary intake level that is needed to meet the nutrient needs in the majority of healthy individuals. ➤

Table 1

## Dietary Reference Intakes (DRI) Definitions

**Recommended Dietary Allowance (RDA):** the average daily dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

**Adequate Intake (AI):** a recommended intake value based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of healthy people, that are assumed to be adequate—used when an RDA cannot be determined.

**Tolerable Upper Intake Level (UL):** the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

**Estimated Average Requirement (EAR):** a daily nutrient intake value that is estimated to meet the requirement of half of the healthy individuals in a life stage and gender group—used to assess dietary adequacy and as the basis for the RDA.

*Reprinted with permission from the International Food Information Council Foundation newsletter Food Insight (August 2002) article 'Dietary Reference Intakes: An Update.' Source: Institute of Medicine.*

Yet, because dietary needs are not the same for everyone, recommended quantities for vitamins and minerals will differ for particular individuals and special groups. Acknowledging these differences is relevant for those who live with chronic health conditions, use medications or have additional risk factors. To illustrate why personalized nutrition is so important, we can consider vitamin B12, also known as cobalamin or the building block of blood cells and myelin.

Vitamin B12 deficiency is more widespread than once thought. For the general public, only about 4 percent are deficient in vitamin B12. However, deficiencies in B12 are considerably more prevalent among certain subgroups of the population. For example, up to 20 percent of older adults consume insufficient amounts of vitamin B12 to meet their needs. The DRI does take into account differences for age and gender, but it does not sufficiently address the needs of adults who are over 70 years of age. In other unique groups, such as South Asians, nearly 50 percent of patients demonstrate a deficiency in vitamin B12. Similarly high numbers of B12-deficient individuals were identified in the Framingham Offspring Study (children of the original Framingham Study, which began in 1948, to examine risk factors for heart disease); more than one in three participants were at risk of health problems due to inadequate vitamin B12.

Table 2 provides information about the DRI for vitamin B12, foods that contain vitamin B12, risk factors for B12 deficiency, the most common signs and symptoms of deficiency, and screening methods. Because individuals respond differently to blood nutrient levels, clinical symptoms may be one way to assess whether or not further testing is needed. If individuals are at risk or experience any clinical symptoms, it is advisable to consult with an experienced gastroenterologist, hematologist or neurologist. The use of vitamin B12 to treat any health problem requires supervision.

### Nutrition and Gene Interactions

Just as nutrition influences the expression of genes, such as those that determine eye color, genetic differences may also impact nutrition status and help to explain behavior, such as why some people can't stop at just one scoop of ice cream. Genes may also help us to understand why

some of those same ice-cream indulgers have low cholesterol or why dietary fat is worse for some people than others—even when they consume the same diet.

Years ago, the Framingham Study researchers proposed that differences in serum cholesterol, for example, could not be explained by dietary intake alone. Although diet

Table 2

## Vitamin B12: A Building Block of Myelin and Blood Cells

**Foods rich in B12:** Meats, liver, shellfish and kidney; cheese, milk, eggs and fish; fortified breakfast cereals and energy bars; nutritional yeast.

**\*Recommended Dietary Allowance (RDA) for B12 (µg/d):**

- Children (1-3 y): 0.9; (4-8 y): 1.2; (9-13 y): 1.8
- Males and Females (> 13 y): 2.4; Older adults (> 70 y): 2.4
- Pregnancy: 2.6; Lactation: 2.8

**Common risk factors for B12 deficiency:** Anti-acid therapy, malabsorption and diarrhea, inflammatory bowel disease, gastrointestinal infections and bacterial overgrowth, autoimmune disease, stomach surgery, older age, pregnancy and lactation, nursing infants, surgery, nitrous oxide anesthesia, pernicious anemia, pancreatitis, strict vegetarians, genetic disorders, various medications (see below).

**Medication risk factors that can contribute to B12 deficiency:**

Antacids, proton pump inhibitors (omeprazole, lansoprazole, pantoprazole, rabeprazole), H<sub>2</sub> blockers (cimetidine, famotidine, nizatidine, ranitidine), antibiotics (long-term use), tetracycline, chemotherapy (e.g., methotrexate), metformin, nitrous oxide (anesthesia), phenobarbital and phenytoin, among others.

**Signs and symptoms of B12 deficiency:**

Thrombocytopenia (easy bruising and bleeding), abnormally large red cells, pernicious anemia, nerve damage (neuropathy), gastrointestinal symptoms (diarrhea or constipation), odd sensations (cold, tingling, tightness in the abdomen or chest), leg pain, decreased feeling or reflexes, confusion and mood changes, decreased appetite, weakness, sore tongue, muscle weakness, difficulty walking or ataxia.

**\*\*Screening for B12 deficiency:** Mean corpuscular volume (MCV), serum B12, serum methylmalonic acid, serum homocysteine, testing for intrinsic factor and antibodies against intrinsic factor

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\* RDA is not adequate for treating nutrient deficiencies.

\*\* CBC is not sufficient by itself because nerve damage may predate blood cell disorders. A single B12 level, without other studies, is not definitive.

affects cholesterol level, the study data suggested that genetic factors were more important in explaining variation in serum cholesterol than dietary differences. In general, the physical expression of any trait (i.e., the individual phenotype) is the product of an interaction between an individual set of genes (i.e., the individual's genotype), the effects of the environment (i.e., dietary intake), and some random variation.

### The following equation puts this all together:

Phenotype (trait) = Genes (genotype) + Environment (diet) + Random variation

So, to understand an individual's cholesterol level, the Framingham Study suggested that we need to know about more than what the individual eats; we need to understand each element in this equation. In other words:

Cholesterol level = Genes that affect cholesterol + Ice-cream intake + ???

Today, research supports the finding that differences in dietary fat metabolism can be attributed in part to inherited differences (such as the genetic codes CYP7A1 or A-204C). Genetic variation may therefore account for serum cholesterol levels in a large portion of the population.

### Nutrigenomics: Are We What We eat?

The existence of nutrient-gene interactions also has implications for vitamin and mineral requirements. The emerging field of nutritional genomics, or nutrigenomics, is the study of the interaction between dietary components and an individual's genetic inheritance. Scientists have begun to understand how nutrients interact with genes to alter traits, which means we actually become what we eat. Conversely, nutrigenomics helps us to understand how genes synthesize and break down nutrients. If an individual has a genetic makeup that requires a high amount of one nutrient, and those needs are not met, then health may be compromised even if that individual is meeting the DRI for that nutrient.

For example, 400 µg of folic acid per day is sufficient for most people to stay healthy, but certain individuals may require twice as much (foods rich in folic acid include enriched cereal and whole-grain breads, dark leafy vegetables and fortified ready-to-eat cereals). If a pregnant woman has genes that elevate her need for folic acid, but she follows the DRI for the general population, her children may suffer with neural tube or other vascular defects. A man with the same genotype that gets insufficient amounts of folic acid may suffer with cardiovascular problems. Scientists have identified a specific mutation in a specific gene (methylene tetrahydrofolate reductase [MTHFR], mutation C667T) that may account for this phenomenon.

In these cases, it is clear that one size does not fit all

and that nutrient supplementation is sometimes warranted even for individuals who are meeting the DRI. The specific recommendations will depend on the individual's health status, but in general patients should not exceed the upper level (UL) of safety unless supervised by their physician (refer to DRI Definitions, Table 1). The toxic effects of long-term, unnecessary and excessive vitamins and minerals are well documented.

### Future Directions

Nutrition may prove to be one of the single most important controllable environmental factors that impact health status. However, special groups, such as those living with chronic disease, have unique nutrition needs that are not met by the current guidelines. Therefore, individualized nutrition screening and intervention will continue to be an important part of health promotion and disease management. In the future, methods for identifying genes that affect nutrition needs may allow for further dietary optimization, but there is more to be done. Researchers are working hard to understand nutrient-gene interactions and develop the best practices. They are expected to provide a new vision where genetic information will be used to inform disease risk and nutritional requirements. Through targeted assessment and coordination with the patient's physician, qualified practitioners will be expected to tailor diets to improve health outcomes.

Be that as it may, more research is needed before genetic factors will be used to create personalized diets. Unless a nutrient deficiency is suspected, it is sensible to follow the RDAs and to bear in mind that, to address individual nutrition needs, there may be more to a healthy diet than meets the DRI. ■

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*If you suspect that you may have a nutrition or health problem, consult with a physician specialist and a reputable disease-specific organization. This article was designed for informational purposes only and should not be used for diagnosing or treating health problems. It is not a substitute for professional care.*

### Resources

USDA (Downloadable Tables with the DRIs)

<http://www.nal.usda.gov/fnic/about.shtml>

PDR Health, Vitamin B12

<http://www.pdrhealth.com/>

Nutritional Genomics

<http://nutrigenomics.ucdavis.edu/>

Vitamin B-12 Associated Neurological Diseases

<http://www.emedicine.com/NEURO/topic439.htm>

# Everyone Has a

**M**elissa and Patrick began their lives together in California. There they had three healthy kids. Then they decided to move their family to Michigan in search of a better lifestyle. This included the addition of three more kids.

Today, Melissa and Patrick's six children range from 5 to 16 years of age, and the three youngest all have common variable immune disease (CVID), a primary immune deficiency disease (PIDD). But, despite the health problems, this home is overflowing with love, support and high spirits.

Addison was the first to be diagnosed with CVID.

"She was born a very happy and healthy baby," Melissa explained, but soon after Addison's first set of immunizations, she began to get very sick. By this time, she also had one ear surgery due to infection. (To date, she has had five surgeries.) Melissa had her tested, and, by the time Addison was 7 months old, she had joined the PIDD ranks. Now age 5, Addison has been homebound most of her life, and her friends consist of her brothers and sisters, parents and her prized pup, which she received from the Make-A-Wish Foundation of Michigan in 2004. All Addison wanted was a bulldog, and a bulldog named Ace is exactly what she got—all the way from Russia with love.

Melissa refers to Addison as her "Wild Child." She is fearless and always wants to go first on infusion day. She flushes her own line both before and after her infusion, and then proceeds to flush her two siblings' lines as well.

Addison is the sickest of the three kids. "I like getting IVIG," she says. "It makes me feel better." Plus, when

she receives her IVIG, her nurse, Jan, "always brings me a surprise." Addison says the worst part is, "I get a lot of headaches after my infusion."

Addison does get angry at times. "All I want to do is to go to the beach or to go to Chuck E. Cheese, because I can't go there now because there are too many germs."

Melissa says it is Addison's great spirit that helps her get through.

Makayla, 6 years old, wishes she could be normal.

She was diagnosed with CVID when she was 5. Having CVID makes her feel different from everyone else and even though her friends are nice to her, Makayla says, "Some of them were scared when I wore my mask to school."

Even though Makayla often gets sick following her infusions, she puts a positive spin on it. "The best thing is, my mom makes muffins for every infusion," Makayla says. "IVIG always makes me feel better when it's done."

Later this year, Makayla will

also be granted a wish from the Make-A-Wish Foundation.

"Makayla changes her mind every day... wanting to be a princess, to see Mickey Mouse or to shop at Toys R Us," Melissa explains.

"I would want to go to Disney World," Makayla admits. "We can't go now, because I can't be around a lot of people."

One day, Melissa was driving Makayla to kindergarten and Makayla asked her mom why God makes her and her siblings sick. Melissa was busy fighting back tears when the second question came: "Why doesn't he make us better?"



*Makayla, Elijah and Addison are buddies.*

# Story, and This Is the Letourneaus'

By Carol K. Miletti



*Makayla and Addison with Ace*

"Thank God, I was saved by the bell, literally," Melissa says, "the school bell."

Elijah may be a rock star someday. He plays guitar, is very outgoing and quite the comedian. Melissa says that on infusion day, "we can't shut him up." His outgoing nature may be what helps Elijah, 9, get through his life with CVID.

He was diagnosed at 3 with transient hypogammaglobinemia, and put on prophylactic antibiotics for four years of his life. During those years, Elijah continued to have chronic infections. At 7, he was taken off the drugs. During the next two years, his health declined and he became immune to most antibiotics. Following a 3-month-long ear infection, he was taken to the hospital for a mastoidectomy. The doctors were unable to remove all of the infection, and three days after leaving the hospital, he was back in with an infection that had spread through his entire face and head.

Melissa says, "He looked like he had a basketball on his shoulders."

He was back in surgery to remove more infection, sent home with IV antibiotics, and returned three more times to remove more of the infection. Finally in May 2005, he was diagnosed with CVID.

"Mom and doctors first told me that I had PIDD and had to start IVIG," Elijah recounted. "I said 'I would rather die,' but now, after one and

a half years on IVIG, I don't think it's so bad after all."

And, following his first IVIG infusion, the rock star got out of bed and was dancing and singing.

After undergoing 27 surgeries, Elijah has gotten used to being sick. He does feel angry because he can't do things like play football and other sports. "I can't go to as many places or do things like my older brother and sisters, because I will get sick," Elijah says, but he has a very good understanding of his strengths and limitations.

Elijah is also going to be granted a wish. He can't decide if he wants to meet Jesse James of West Coast Choppers, go to Disney World or have a shopping spree at a video store. Whatever his decision, it's a well-deserved gift.

Melissa worries about the older three children. "It's been equally hard on my healthy kids. ... I've missed out on so much time with them and their school activities."

It is clear that PIDD has had repercussions on all of the family members.

"It's sad," Cathy, 16, says. "We have to be extra careful around them if we get a cold or something so that they don't get sick."

"I can't have any friends over or go places like the beach or on a vacation," Patrick, Jr., 12, bemoans, "because the kids might get sick."

"I don't like it at all," says Mariah, 11. "I hate to see them upset and

sick. I really don't like when they have to get shots in their med-ports. We don't get to have our friends over for sleepovers because they might get my brother and sisters sick."

Melissa felt as though she had done something wrong when her kids were first diagnosed. But, after researching CVID, she learned better. Now she takes it one day at a time, and does not fret over the future. She leans heavily on the kids' teachers, who have been a blessing to the family. The kids think they have the best teachers in the world.

Melissa is also very thankful that they have finally found great doctors. "They really listen to me, and they are so helpful and understanding."

Patrick, the father of this crew of six, a man of few words. He works very hard to make sure that the kids have the best healthcare they can get. Love and support are the gifts he brings to Melissa and the kids.

This family has an undeniably positive spirit. In the words of Melissa, "Anyone who is living with this— never stop fighting!" ■

# Readers Write

## The Joys of SCIG

Sean and I had a chance to look through your magazine during his recent trip to the infusion center. Sean will be 18 in October, and was diagnosed with primary combined immune deficiency at the age of 3. He had secondary symptoms at first, starting at the age of 1, but it was hard to pinpoint exactly what was going on until he got a bit older and his spleen enlarged.

He is doing wonderfully on replacement therapy, and now controls his own treatment with SubQ infusions three times per week. It has freed up our time, compared to the infusions he would get every three weeks via a port-a-cath. He is almost an adult now, and will be going to college next year, so the SubQ treatment came at a very good time for all of us!

P.S. A funny note about our Katie: Sean was correctly diagnosed in February 1992, when I was pregnant with Katie. She grew up watching the infusions from her crib and has no fear of needles. In fact, she and Sean would both hold their arms out at the same time during flu shot season. She wanted to be just like her brother, thinking that everyone got poked with needles on a routine basis!

—John, Renee, Sean and Katie, Minnesota

## IVIG Availability and Collaborative Patient Care

About eight years ago, there was a shortage of IVIG because the FDA had shut down two leading manufacturers. I had two conversations with the FDA about controlling the supply chain for IVIG, because product was getting into the “gray market” at higher prices. It created a similar situation to that we are seeing today: supply allocation problems, with not enough IVIG products to treat everyone.

During that earlier time period, we put together a “Collaborative Care Model” at the hospital where I worked, to address treating patients who would use IVIG as one of their treatment options. It was a multidisciplinary group of physicians (neurologists, rheumatologists, allergists and hematology-oncologists) and pharmacy.

All IVIG patients were contacted about the shortage and were aware of the situation. Patients became part of the Collaborative Care Model and were notified of any issues around supply. All current and new requests for treatment

with IVIG were reviewed by the multidisciplinary team. The goals were to treat as

many patients as possible who needed IVIG with IVIG and not to interrupt current treatments. We discussed other treatment options like WinRHO, plasmapheresis and using steroids, depending on the patient diagnosis. In some instances, there were alternative treatments to IVIG, and we needed to have these discussions to provide care to all patients. We also looked at dosing intervals, and some patients were moved from every four weeks to every six weeks for treatment.

The patients were appreciative of the work the group undertook, and we developed a deeper bond with our patients. We instructed the patients to contact their local politicians, especially around the gray market issue. To this day, I have maintained relationships with some of the patients. Whenever you have a treatment that is determined by human donors, blood and IVIG mainly, there will always be the possibility of a short supply.

Treatment demand for IVIG continues to grow. Developing treatment algorithms is a viable option to make sure that all patients who require IVIG have IVIG when they really need it.

—Fred J. Pane, RPh, North Carolina

## Sharing IG Living

Wow! I just received two issues of IG Living, and I read for two hours straight. I couldn't put it down. Thank you so much for sharing this great resource.

The Tips for the School Nurse page and the Modifications suggestions for kids with PIDD will be very helpful for us. It is a struggle to inform the school about what is “normal” for a child like mine. They do not seem to understand, because she is the only student in our small rural area with this disorder.

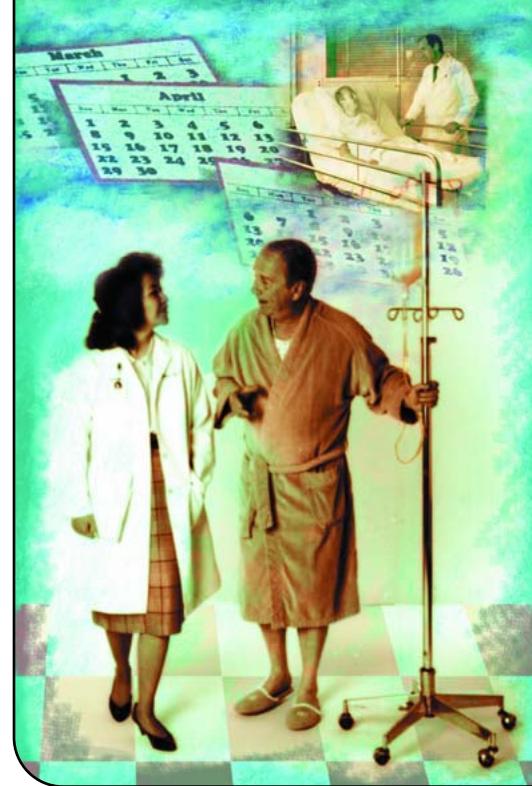
I plan to share this magazine with several of my daughter's doctors. I think other patients would benefit from your publication as well. Thanks again, and keep up the great work.

—Cindy, mother of an 8-year-old with PIDD



# Intravenous Immunoglobulin Treatment for Improving Muscle Strength

By Kristian Borg, MD, PhD



**P**ost-Polio Syndrome, described as weakness and atrophy in skeletal muscles, occurs when there is a failure in capacity of a nerve cell body to maintain large motor units. The large motor units are supported when the capacity for re-innervation is greater than denervation. Eventually this mechanism reaches an upper limit leading to muscle weakness. The cause of the denervation is unknown at the moment.

An ongoing inflammatory process in the central nervous systems of post-polio patients has been described in some studies, but has not been found in other studies.

Our study in 2002 found an increase of cytokine production in the central nervous system of post-polio patients.

We know that:

- Cytokine levels are greater when there is an inflammation.
- Cytokine levels are higher in people with multiple sclerosis (MS), a known neuroinflammatory disorder.
- The level of the increase in the post-polio patients was almost the same as in the MS patients.

We checked older studies to see what work had been done:

- Dinsmore reported an effect of prednisone in high doses and the effect eroded as the doses were lowered.
- Ann Bailey, MD, at Warm Springs, Georgia, in the early 80s, treated 80 patients with the oral vaccination, and 50 of those patients reported a positive effect on their symptoms.\*

Due to her results and to the pattern of the cytokine increase, we began an open, uncontrolled study using intravenous immunoglobulin (IVIG) in 16 post-polio patients.

We were able to down modulate the cytokines, but what is the gain for the patient? We next developed a multi-center placebo-controlled study, double-blinded

in 135 post-polio patients. (In the former study, we used 90 grams of IVIG; 30 grams daily for 3 days.) In this study, we used 30 grams for 3 days, repeated twice. We noted an increase of muscle strength of 4.3% in the post-polio patients. In the placebo group, muscle strength was decreased by 5.7%. This was statistically significant. The natural course of decrease in strength was 5.7% in one-half year.

The benefit: Post-polio patients selected for the study had an increase in cytokine levels, indicating inflammation in the central nervous system. The inflammation was down-modulated by the intravenous immunoglobulin (IVIG) and down-modulated inflammation led to increased muscle strength and should result in a better quality of life. ■

\* Using oral polio vaccine to treat PPS is not an accepted practice.

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# Let's Talk!

By Shirley German Vulpe, EdD



In this fourth column of the "Let's Talk!" series, I interviewed Tina Morgan, who established the Canadian Immunodeficiencies Patient Organization (CIPO) in 1996.

I first met Tina at about the same time, when I was in Canada visiting my family, shortly after my diagnosis with a primary immune deficiency disease. I searched for information about my condition and heard about the first meeting of the CIPO. So off I went to see what I could learn. Since that time, I have kept in touch with Tina via the CIPO chat line. It has been apparent that the organization has thrived and expanded, and Tina is still at the helm.

**Shirley:** Tina, can you tell me a little bit about your illness?

**Tina:** Sure. I had my first pneumonia before I was 1 month old, and throughout my childhood I had multiple respiratory infections and recurrent diarrhea. When I was 16, the diarrhea was so severe my weight dropped to under 80 pounds, and I was admitted to the hospital. They were sure I had an eating disorder!

However, blood tests revealed that I had an IgA deficiency, and low IgG and IgM. Yes, I know now that means I had a mild form of CVID, but no one told me that. Maybe they didn't know what to make of it at that time. I was treated for many years after that with antibiotics, and they were able to control the infections, but things got more severe when I hit my 30s, and [the antibiotics] didn't work all the time. One episode I had went from flu to respiratory infection to sepsis in less than 24 hours. I spent some time in the ICU, but luckily I survived!

After that episode, I insisted on seeing an immunologist. Blood tests again revealed a shortage of IgA, IgG and IgM, but my IgG was now

around 2, where it had been 4.5 those many years earlier. I was also told I had common variable immune deficiency at that time. Now I really started to search for information! I wanted to learn, not blindly trust. Nothing was available locally.

Luckily I discovered IPOPI, the International Patient Organization for Primary Immune Deficiencies. I emailed them and they sent information to me. This helped me decide to go on IG therapy. I am also hopeful about the possibility of SubQ administration of IG helping me.

**Shirley:** Well, I sure hope you find a solution. What led you to establish the Canadian Immunodeficiencies Patient Organization?

**Tina:** It started with my search for information, the realization that there was nothing currently readily available in Canada, and the help that other patient organizations provided me. The catalyst was an international crisis in availability of blood products. The first organization to help me was IPOPI. The information they sent me, combined with attending their conference in Rhodes, Greece, 10 years

ago, made me realize just how helpful a patient organization could be. I also received a great deal of help from the Immune Deficiency Foundation. I met the then-president of the foundation, Tom Moran, in Greece, and he invited me up to a meeting of IDF chapters, and I received a great deal of literature.

Then there was the blood shortage of 1998. Many patients in Canada were not able to receive their IG. One patient I was regularly corresponding with died after 6 months of not getting appropriate treatment. I got upset with the Canadian blood policies. People who needed blood products to live were not receiving them and people who could live without the blood products were receiving them! Something needed to be done. So I started the organization from my kitchen.

**Shirley:** Awesome! Did you continue to receive help from the Immune Deficiency Foundation?

**Tina:** Yes, they continued to supply unlimited literature, and sent physicians from the visiting professor program to provide physician and patient education to Canada. Tom called

primary mission of CIPO?

**Tina:** To pull everyone involved with primary immune deficiencies together as a group and to improve the diagnosis and treatment of these disorders. This includes patients, families, medical and pharmaceutical professionals, as well as organizations such as Canadian Blood Services.

**Shirley:** A tall order, indeed. How do you do it?

**Tina:** Well, so far, we remain an entirely volunteer organization. We have no paid staff and continue to operate out of our kitchens. People think we are a big organization

because the money we do get goes to fund projects and activities of the organization. We stretch a buck a long way.

**Shirley:** I know CIPO has achieved a great deal. Can you tell me more about these accomplishments?

**Tina:** Well, let's see. We now have established six chapters. We work with the Canadian Blood Services (CBS) as part of their National Liaison Committee to offer input into decisions made about blood products and the way CBS operates. We have developed a central database of patients, and a directory of

physicians and clinics at hospitals presently diagnosing and treating PIDD in Canada...We have an Annual General Meeting every year and a number of regional conferences. Attendance has gone up every year. Over 100 people attended our last meeting. Currently we are educating patients about SubQ administration of IG, as it will likely be licensed by year's end. Our patient support chat room is very active, and we are expanding all programs for patients, families and professionals! ■

### For More Information



Canadian  
Immunodeficiencies  
Patient Organization  
[www.cipo.ca](http://www.cipo.ca)  
877-262-CIPO

Immune Deficiency Foundation (IDF)  
[www.primaryimmune.org](http://www.primaryimmune.org)  
800-296-4433

International Patient Organization  
for Primary Immunodeficiencies (IPOPI)  
[www.ipopi.org](http://www.ipopi.org)

## ...Guillain-Barré Syndrome (GBS)

### Websites and Chat Rooms

1. The GBS/CIDP Foundation International, [www.gbsfi.com](http://www.gbsfi.com), has 23,000 members in 160 chapters on five continents. 610-667-0131
2. The GBS Foundation Discussion Forums provide the opportunity to talk to other GBS patients and learn more about ways to manage the illness: [www.guillain-barre.com/forums/](http://www.guillain-barre.com/forums/).

### Online Pamphlets

1. A GBS Fact Sheet is found on the National Institute of Neurological Disorders and Stroke website: [www.ninds.nih.gov/disorders/gbs/detail\\_gbs.htm](http://www.ninds.nih.gov/disorders/gbs/detail_gbs.htm).
2. The Mayo Clinic has an overview of Guillain-Barré syndrome at [www.mayoclinic.com/health/guillain-barre-syndrome/DS00413](http://www.mayoclinic.com/health/guillain-barre-syndrome/DS00413).
3. The National Institute of Neurological Disorders and Stroke has an information page about CIDP: <http://www.ninds.nih.gov/disorders/cidp/cidp.htm>

### Online Peer Support Links

1. GBS & CIDP Discussion Forum—UK Bulletin Board—For Ireland and England: <http://www.gbs.org.uk/cgi-bin/ikonboard3/ikonboard.cgi>
2. GBS Support group—UK Chat room—requires registration: <http://www.jsmarcussen.com/gbs/uk/chat.htm>
3. GBS Foundation Discussion Forums [www.guillain-barre.com/forums](http://www.guillain-barre.com/forums)
4. Yahoo Support Group Discussion Board: [http://health.groups.yahoo.com/group/GBS\\_CIDP/](http://health.groups.yahoo.com/group/GBS_CIDP/)

## ...Multiple Sclerosis (MS)

### Websites and Chat Rooms

1. The mission of the National Multiple Sclerosis Society is to end the devastating effects of MS. <http://www.nationalmssociety.org/>.
2. All About Multiple Sclerosis provides accurate and comprehensive medical information about MS written in plain English by people living with the disease and its symptoms: <http://www.mult-sclerosis.org/index.html>.
3. Multiple Sclerosis Foundation works for a brighter tomorrow for those affected by MS: <http://www.msfacts.org/>.
4. Multiple Sclerosis Association of America seeks to enrich the quality of life for individuals with multiple sclerosis: <http://www.msa.com/>.
5. MSWorld's Chat & Message Board features patients helping patients: <http://www.msworld.org/>.

### Online Peer Support Groups

1. Friends with MS website: <http://friendswithms.com/> forum: <http://health.groups.yahoo.com/group/FriendsWithMS/>.
2. My MSViews: website: <http://www.mymviews.org> forum: [http://health.groups.yahoo.com/group/MSViews\\_Multiple\\_Sclerosis/](http://health.groups.yahoo.com/group/MSViews_Multiple_Sclerosis/).
3. MS Support Group: <http://health.groups.yahoo.com/group/mscured/>.
4. The MS Carousel—A Place to Meet With People Who Understand MS! <http://health.groups.yahoo.com/group/themscarousel/>.

## ...Myasthenia Gravis

### Websites and Chat Rooms

1. The Myasthenia Gravis Foundation of America (MGFA) is the only national volunteer health agency dedicated solely to the fight against myasthenia gravis: <http://www.myasthenia.org/>.
2. Myasthenia Gravis Fact Sheet prepared by National Institute of Neurological Disorders and Strokes: [http://www.ninds.nih.gov/disorders/myasthenia\\_gravis/detail\\_myasthenia\\_gravis.htm](http://www.ninds.nih.gov/disorders/myasthenia_gravis/detail_myasthenia_gravis.htm).
3. Mayo Clinic's overview of myasthenia gravis: <http://www.mayoclinic.com/health/myasthenia-gravis/DS00375>.

### Online Peer Support Groups

1. MGFA's Forum: <http://health.groups.yahoo.com/group/MGnet/>.
2. Bette's Myasthenia Gravis Support: <http://health.groups.yahoo.com/group/bettesmyastheniagravisupport/>.
3. Maddy's MG Support: <http://health.groups.yahoo.com/group/maddysmgsupport/>.
4. Yahoo Support Group for Myasthenia Gravis (30 & under): <http://health.groups.yahoo.com/group/myastheniagravis30andunder/>.

## ...Myositis

### Websites

1.   
**THE MYOSITIS ASSOCIATION**  
The mission of The Myositis Association, [www.myositis.org](http://www.myositis.org), is to find a cure for inflammatory and other related myopathies, while serving those affected by these diseases. 202-887-0088

2. International Myositis Assessment and Clinical Studies Group is a coalition of healthcare providers and researchers with global approaches to improved treatments and understanding of myositis: <https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=home.main>.
3. The Cure JM Foundation was created specifically to find a cure for Juvenile Myositis (JM), while also providing support and information for families affected by JM. <http://curejm.com>

### Online Peer Support Links

1. Juvenile Myositis Family Support Network: [http://www.curejm.com/family\\_support/index.htm](http://www.curejm.com/family_support/index.htm)
2. Myositis Association Community Forum: [www.myositis.org](http://www.myositis.org)
3. Myositis Support Group UK: <http://www.myositis.org.uk/>
4. Yahoo Myositis Support Group Discussion Board: <http://health.groups.yahoo.com/group/OurMyositis/>

# Wanted to Know About...

## ...Peripheral Neuropathy (PN)

### Websites

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The Neuropathy Association, [www.neuropathy.org](http://www.neuropathy.org), is devoted exclusively to all types of neuropathy, which affects upwards of 20 million Americans. The Association's mission is to increase public awareness of the nature and extent of PN, facilitate information exchanges about the disease, advocate the need for early intervention and support research into the causes and treatment of neuropathies. 212-692-0662
- The National Institute of Neurological Disorders and Stroke has diverse topics about PN on its website at [www.ninds.nih.gov/disorders/stroke/](http://www.ninds.nih.gov/disorders/stroke/).
- To learn about PN, how it is classified, the symptoms, causes and treatments, see the Peripheral Neuropathy Fact Sheet available at <http://www.ninds.nih.gov/disorders/peripheralneuropathy/peripheralneuropathy.htm>.

### Support Groups

Click on the Member Services tab of the website, [www.neuropathy.org](http://www.neuropathy.org), for listings of support groups across the nation.

### Online Peer Support Links

- Calgary Neuropathy Support Group: <http://www.calgarypnrs.org/index.htm>
- MSN Support Group: Discussion Board: <http://groups.msn.com/PNPARTNERS>
- The Neuropathy Association Bulletin Board: [www.neuropathy.org](http://www.neuropathy.org)
- Yahoo Neuropathy Support Group Discussion Board: <http://health.groups.yahoo.com/group/neuropathy/>
- Yahoo Support Group—Australia Discussion Board: <http://au.groups.yahoo.com/group/LifeWithPN/>

## ...Primary Immune Deficiency Disease (PID)

### Websites and Chat Rooms

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**IMMUNE DEFICIENCY FOUNDATION**

The Immune Deficiency Foundation (IDF), [www.primaryimmune.org](http://www.primaryimmune.org), is dedicated to improving the diagnosis and treatment of PID through research and education. 800-296-4433
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The Jeffrey Modell Foundation, [www.info4pi.org](http://www.info4pi.org), is dedicated to early and precise diagnosis, meaningful treatments and, ultimately, cures for primary immunodeficiency. 212-819-0200
- The National Institute of Child Health and Human Development (NICHD), [www.nichd.nih.gov/](http://www.nichd.nih.gov/), is part of the National Institutes of Health. Go to the "Health Information and Media" tab on the website and do a search under "primary immunodeficiency."

- The American Academy of Allergy, Asthma & Immunology, [www.aaaai.org](http://www.aaaai.org), has a helpful Q&A section on its website, with resources and tips for those with various immune deficiencies.
- Baxter's website, [www.immunedisease.com](http://www.immunedisease.com), offers in-depth information on immunology, PID and treatment with intravenous immune globulin.
- The Michigan Immunodeficiency Foundation, [www.midf.org](http://www.midf.org), seeks to improve the quality of life for Michigan residents affected by PID.
- The International Patient Organization for Primary Immunodeficiencies (IPOPI), [www.ipopi.org](http://www.ipopi.org), promotes the worldwide improvement in the care and treatment of PID patients.
- To connect to a PID message board, go to [www.info4pi.org](http://www.info4pi.org).
- To chat with peers on IDF's Forum, go to [www.primaryimmune.org](http://www.primaryimmune.org).
- Chat with parents of children affected by primary immune deficiency at <http://health.groups.yahoo.com/group/PedPID/>.
- Chat with peers with PID at <http://health.groups.yahoo.com/group/PIDsupport/>.
- A group of family and friends of patients with primary immune deficiencies maintains a nonprofit network in the New England area: <http://www.nepin.org/>.

### Online Pamphlets

- Go to the National Institute of Allergy and Infectious Diseases site at [www.niaid.nih.gov/](http://www.niaid.nih.gov/) and search for "primary immune deficiency."
- "Understanding the Immune System: How It Works," by the U.S. Department of Health and Human Services, is found at [www.niaid.nih.gov/publications/immune/the\\_immune\\_system.pdf](http://www.niaid.nih.gov/publications/immune/the_immune_system.pdf).
- "NIAID Initiative Addresses Primary Immune Deficiency Diseases by National Institute of Allergy and Infectious Diseases" is located at [www3.niaid.nih.gov/news/newsreleases/2003/pirc.htm](http://www3.niaid.nih.gov/news/newsreleases/2003/pirc.htm).

### Online Peer Support Links

- Chat with parents of children affected by PID <http://health.groups.yahoo.com/group/PedPID/>
- Chat with peers with PID <http://health.groups.yahoo.com/group/PIDsupport/>
- Immune Deficiency Foundation Forum [www.primaryimmune.org/forums/forum\\_intro.htm](http://www.primaryimmune.org/forums/forum_intro.htm)
- Jeffrey Modell Foundation Message Board [www.info4pi.org](http://www.info4pi.org)

## ...General Resources

### Product Information

- To learn more about Vivaglobin—the subcutaneous immune globulin (SCIG) go to: [www.vivaglobin.com](http://www.vivaglobin.com).
- For more information about the 10% IVIG solution Gammagard Liquid, go to [www.gammagardliquid.com](http://www.gammagardliquid.com).
- Learn about IVIG treatment with Gamunex at [www.gamunex.com](http://www.gamunex.com).

### Other Organizations

- For suggestions on how to deal with the medical and emotional impact of caring for an ill child, go to [www.kidshhealth.org/parent/system/ill/seriously\\_ill.html](http://www.kidshhealth.org/parent/system/ill/seriously_ill.html). ➤

2. The National Committee for Quality Assurance provides free access to detailed report cards on health plans, clinical performance, member satisfaction, access to care and overall quality on its Health Plan Report Cards Online at [www.ncqa.org](http://www.ncqa.org).
3. The nonprofit Patient Advocate Foundation, [www.patientadvocate.org](http://www.patientadvocate.org), seeks to assure patient access to care, maintenance of employment and financial stability. 800-532-5274

4.  The nonprofit Patient Services Incorporated, [www.uneedpsi.org](http://www.uneedpsi.org), specializes in health insurance premium, pharmacy co-payment and co-payment waiver assistance for people with chronic illnesses. 800-366-7741

5. WebMD, [www.webmd.com](http://www.webmd.com), is a handy medical reference that helps consumers take an active role in managing their health by providing objective healthcare and lifestyle information.
6. For a pediatrician's guide to your child's health and safety, visit [www.keepkidshealthy.com](http://www.keepkidshealthy.com).
7. The National Organization for Rare Diseases, at [www.rarediseases.org](http://www.rarediseases.org), provides links to numerous other organizations that have disease-specific support groups and virtual communities for patients and caregivers.
8. American Autoimmune Related Diseases Association (AARDA) [www.aarda.org](http://www.aarda.org) brings national focus to autoimmunity through research, education and patient services. 800-598-4668
9. Band-Aides and Blackboards: <http://www.lehman.cuny.edu/faculty/jfleitas/bandaides/>, started by a nurse working on her dissertation, focuses on children with chronic illness.

### Education and Disability Resources

1. Continuation of Health Coverage—Consolidated Omnibus Budget Reconciliation Act (COBRA) <http://www.dol.gov/dol/topic/health-plans/cobra.htm>
2. Social Security: [www.ssa.gov/disability/](http://www.ssa.gov/disability/)
3. California State Disability Insurance (SDI): [www.edd.ca.gov](http://www.edd.ca.gov) (Please note that each state has a different disability program.)
4. IDEA 2004 Resources <http://www.ed.gov/policy/speced/guid/idea/idea2004.html>  
News and information on the Individuals with Disabilities Education Improvement Act of 2004 (IDEA), the nation's law that works to improve results for infants, toddlers, children and youth with disabilities.
5. The National Disabilities Rights Network: [www.ndrm.org](http://www.ndrm.org). This website offers a search tool to find resources in your state to assist with school rights and advocacy.
6. U.S. Department of Education: [www.ed.gov](http://www.ed.gov) offers a Parents section that has a subsection titled "My Child's Special Needs."
7. U.S. Department of Health and Human Services, Office of Civil Rights: <http://www.hhs.gov/ocr/504.html> spells out your rights under Section 504 of the Rehabilitation Act.
8. Wrightslaw: <http://www.wrightslaw.com/>. Parents, educators, advocates, and attorneys come to Wrightslaw for accurate, reliable information about special education law and advocacy for children with disabilities.

### Books and Articles

1. "21st Century Complete Medical Guide to Primary Immune Deficiency, Severe Combined Immunodeficiency (SCID), Chronic Granulomatous Disease (CGD), for Patients and Physicians," by PM Medical Health News, contains federal government clinical data and practical information for patients and physicians.
2. "A Handbook for Care Givers," by Helen Rummelsburg, gives an account of caring for her husband and offers helpful hints for patients and caregivers. Available at the GBS website bookstore at [www.gbsfi.com](http://www.gbsfi.com).
3. "Anatomy of an Illness," by Norman Cousins, is a bestseller about overcoming illness and the triumph of the human spirit. The premise is that the human mind is capable of promoting the body's capacity for combating illness and healing itself even when faced with a seemingly hopeless medical predicament.
4. "A Parent's Guide to Special Education: Insider Advice on How to Navigate the System and Help Your Child Succeed," by Linda Wilmschurst and Alan W. Brue, is available on Amazon.com.
5. "Bed Number Ten," by Sue Baier, provides a view of long-term care through the eyes of a patient totally paralyzed with GBS.
6. "Caring for a Child With GBS," by Patricia Schardt, is a short guide written by a mother of a child with CIDP. Available at the GBS website bookstore at [www.gbsfi.com](http://www.gbsfi.com).
7. "The Confused Consumer's Guide to Choosing a Health Care Plan: Everything You Need to Know," by Martin Gottlieb, helps consumers through the confusing maze of choosing a healthcare plan.
8. "Coping With a Myositis Disease," by James R. Kilpatrick, is written by myositis patients telling their personal stories.
9. "The Everyday Guide to Special Education Law," by Randy Chapman, Esq., makes the law accessible to parents so they can be more effective advocates for their children. Available at <http://www.thelegalcenter.org/thelegalcenter-cgi-bin/shop?item=15>
10. "If You're Having a Crummy Day, Brush Off the Crumbs!," by Mims Cushing, is a how-to book that offers more than 75 ways to help people get through the days when neuropathy (or other ailments) is particularly difficult.
11. "Inclusion-Body Myositis and Myopathies," by Valerie Askanas (Editor), Georges Serratrice (Editor) and W. King Engel (Editor), is devoted to discussing the two forms of inclusion-body myositis.
12. "Living Creatively With Chronic Illness: Developing Skills for Transcending the Loss, Pain and Frustration," by Eugenia G. Wheeler, is a self-help book specifically designed to help the chronically ill, their families, friends, counselors, medical personnel and the clergy.
13. "Living With Myositis," edited by Jenny Fenton, is an accessible, realistic and sympathetic guide to facts, feelings and future hopes.
14. "Managing Pain Before It Manages You," by Dr. Margaret A. Caudill, is a wellspring of wisdom and practical approaches that can help transform your life and your pain.
15. "Medifocus Guide to Peripheral Neuropathy," is a guide to current and relevant PN research, organized into categories for easy reading.
16. "Myositis—A Medical Dictionary, Bibliography, and Annotated Research Guide to Internet References," by ICON Health Publications, is a three-in-one reference book: a complete dictionary of terms relating to myositis, a list of bibliographic citations about the disorder and a guide to Internet resources.

# You Ever Wanted to Know continued...

17. "No Laughing Matter," by Joseph Heller (the best-selling author of *Catch-22*), who teamed up with Speed Vogel, his best friend, to describe Heller's battle with and triumph over GBS.
18. "Not Dead Yet: a Long Strange Trip From Doctor to Patient and Back Again," by Dr. Robert Buckman, an oncologist and comic writer, is a witty account of his life as a doctor and autoimmune disease survivor.
19. "Numb Toes and Aching Soles," by John Senneff, discusses the symptoms, causes, tests, treatments and coping strategies for peripheral neuropathy.
20. "Numb Toes and Other Woes," by John Senneff, is the second in a series of three books. It focuses on clinical findings and treatment strategies for PN.
21. "Nutrients for Neuropathy," by John Senneff, the third in the Numb Toes series, is focused exclusively on nutrient supplementation as a means for managing PN.
22. "The Official Patient's Sourcebook on Inclusion Body Myositis," by James N. Parker (Editor) and Philip M. Parker (Editor), is a reference manual for self-directed patient research.
23. "Pride and the Daily Marathon," by Jonathan Cole, describes how Ian Waterman was suddenly struck down at work by a rare neurological illness that deprived him of all sensation below the neck, and how he reclaimed a life of full mobility.
24. "Pronoia Is the Antidote for Paranoia," by Rob Breznsy, explores the best way to attract the blessings that the world is conspiring to give us.
25. "When You're Ill or Incapacitated" comprises one-half the booklet it shares with "When You're the Caregiver," both written by James E. Miller, suggesting 12 things to remember or do in each role.

## IG Manufacturer Websites

Baxter: [www.baxter.com](http://www.baxter.com)  
Grifols: [www.grifolsusa.com](http://www.grifolsusa.com)  
Octapharma: [www.octapharma.com](http://www.octapharma.com)  
Talecris: [www.talecris.com](http://www.talecris.com)  
ZLB Behring: [www.zlbbehring.com](http://www.zlbbehring.com)

## Pump and Needle Websites

Intra Pump Infusion Systems: [www.intrapump.com](http://www.intrapump.com)  
Repro Med Systems, Inc: [www.repro-med.com](http://www.repro-med.com)  
Graseby Marcal Medical: [www.marcalmedical.com](http://www.marcalmedical.com)  
Norfolk Medical: [www.norfolkmedical.com](http://www.norfolkmedical.com)

## ...Nutrition

For help contacting medical professionals who understand the links between nutrition and medicine, consult one of the following links.

1. American Board of Physician Nutrition Specialists: <http://www.ipnec.org>
2. American Dietetic Association: <http://www.eatright.org>
3. American Gastroenterological Association: <http://www.gastro.org>
4. North American Society for Pediatric Gastroenterology Hepatology and Nutrition: <http://www.naspgn.org/>

## ...Resources Just for Kids

1. "Germs Make Me Sick," by Melvin Berger, explains with colorful illustrations how your body fights germs.

2. "Little Tree: A Story for Children With Serious Medical Illness," by Joyce C. Mills, is a comforting fable for young children facing serious life challenges.
3. "This Is My IVIG Book," written from a 3-year-old's perspective about his infusions, comes with a kit for other children to create their own personalized book. Free from Baxter at <http://www.immunedisease.com/US/>.
4. "Our Immune System," enables children who are immune deficient and their families to explore together the immune system. Available from the Immune Deficiency Foundation at [www.primaryimmune.org](http://www.primaryimmune.org).

## ...Scholarships

### Immune Deficiency Foundation Scholarship

This award is available to individuals diagnosed with a primary immune deficiency disease. <http://www.primaryimmune.org/services/scholarship.htm>  
800-296-4433

### The ELA Scholarship

This scholarship provides financial assistance to women with physical disabilities who are enrolled in a graduate program in a college or university in the United States. <http://www.ela.org/scholarships/scholarships.html> 626-398-8840

### Bank of America Abilities Scholarship Program

These scholarships are awarded to students with disabilities who have a career interest in finance, business or computer systems. [http://www.scholarshipprograms.org/bada/bada\\_2005\\_ins.htm](http://www.scholarshipprograms.org/bada/bada_2005_ins.htm) 864-268-3363

### Foundation for Exceptional Children

The Stanley E. Jackson Award for Gifted/Talented Students is awarded to students with a disability. <http://yesican.cec.sped.org/scholarship/index.html>  
800-224-6830

### Joyce Walsh Junior Scholarship for the Handicapped

This scholarship is awarded to disabled instrumentalists or vocalist members of National Federation of Music Clubs. <http://www.mfmc.net/scholarships.html>  
317-638-4003

### Panasonic Young Soloists Award

This award is given to vocalists or instrumentalists under age 25 who are permanently disabled and interested in studying music. [http://www.panasonic.com/corp\\_cont/celebrating.asp](http://www.panasonic.com/corp_cont/celebrating.asp) 202-628-2800

### Horatio Alger Association Scholarship Program

The Horatio Alger Association provides financial assistance to students who have exhibited integrity and perseverance in overcoming personal adversity and who aspire to pursue higher education. <http://www.horatioalger.com>  
703-684-9444

### Central Intelligence Agency: Undergraduate Program

The CIA Summer Internship Program is open to undergraduate students, particularly minorities and people with disabilities, who have completed one or two years of college-level academic study. <http://www.cia.gov/employment/student.html>  
800-368-3886

### Through the Looking Glass

This nonprofit offers college scholarships for individuals with parents with disabilities. [www.lookingglass.org](http://www.lookingglass.org) 800-644-2666

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*Have something to add to these pages? Please send your suggestions for additions to the IG Living Resource Directory to [editor@igliving.com](mailto:editor@igliving.com). In this case, more is indeed better!*

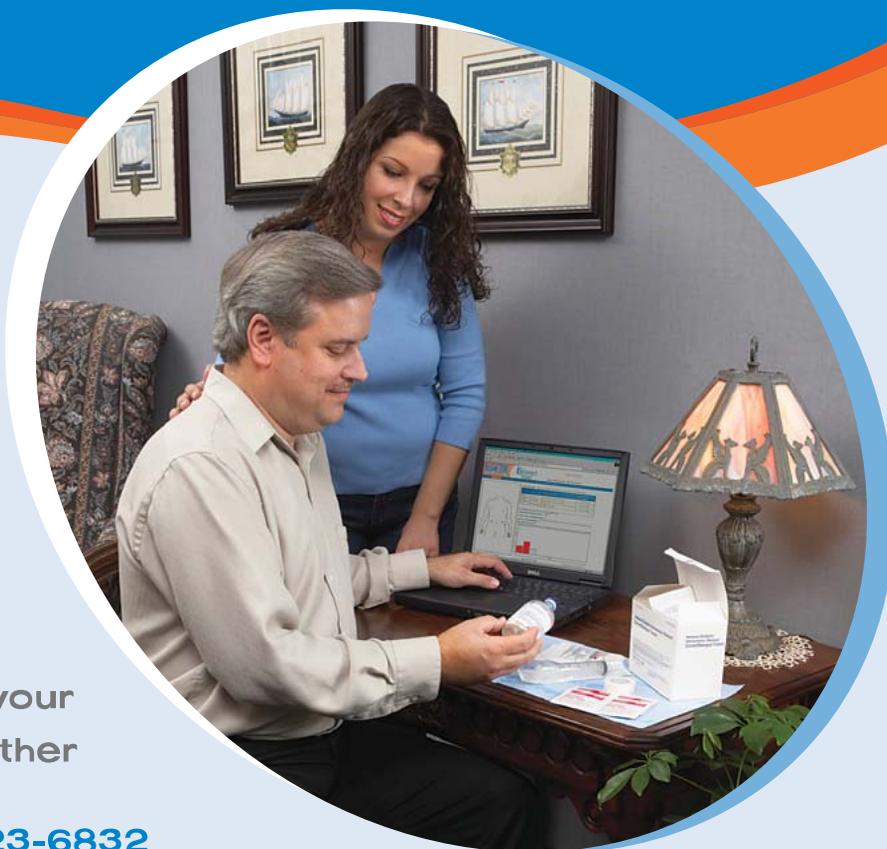
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