

## Complementary and Alternative Medicine

*Surveying the Options*

**Prepared to Appeal:**  
How Readiness Is  
Next to Healthiness

*Our mission is to support the IG community through education, communication and advocacy*

A community service from FFF Enterprises and NuFACTOR Specialty Pharmacy

Advisory Board

**Erika Lawrence, PhD**

*Assistant Professor, Department of Psychology  
University of Iowa*

**Todd Levine, MD**

*Director, Department of Neurophysiology  
at Good Samaritan Hospital, Phoenix  
Assistant Professor of Clinical Neurology,  
University of Arizona*

**Jim Mathews, RPh, MSA**

*Vice President of Strategic Operations  
at NuFACTOR Specialty Pharmacy*

**Fred Modell**

*Co-founder of the  
Jeffrey Modell Foundation*

**Marc Riedl, MD, MS**

*Assistant Professor, Department of Medicine  
Clinical Immunology and Allergy  
UCLA, David Geffen School of Medicine*

Publisher **Patrick M. Schmidt**

Editor **Amanda M. Traxler**

Assistant Editor **Cheryl Brooks**

Copy Editor and Proofreader **Jackie Logue**

Creative Director **Allan Bean**

Graphic Artists **Allan Bean  
Caroline Carlson**

Contributing Writers

**Ever Fecske**

**Amy Fuller, MPP**

**Lauren Gerstmann, MPH**

**Chris Ground**

**Cheryl L. Haggard**

**Mark T. Haggard**

**Lily Leiva, PhD**

**Chris Lomax, PharmD**

**Kris McFalls**

**Ricardo Sorensen, MD**

**Jim Trageser**

**Amanda M. Traxler**

**Michelle Vogel, MPA**

**Shirley German Vulpe, EdD**

©2008 FFF Enterprises, Inc. All rights reserved.

Please direct editorial, advertising and marketing communications to  
41093 County Center Drive  
Temecula, CA 92591  
Ph: 800-843-7477  
Email: editor@igliving.com  
www.igliving.com

## Features

### 10 Prepared to Appeal: How Readiness Is Next to Healthiness

By Amanda M. Traxler

### 24 Complementary and Alternative Medicine: Surveying the Options

By Lauren Gerstmann, MPH



#### 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.

*IG Living*, published bimonthly, is a community service provided by FFF Enterprises and NuFACTOR, 41093 County Center Drive, Temecula, CA 92591, 800-843-7477 x1362, fax 951-699-9655.

Subscriptions to *IG Living* are free, and readers may subscribe at [www.igliving.com](http://www.igliving.com) or by calling 800-843-7477 x1362.

The opinions expressed in *IG Living* are those of the authors alone and do not represent the opinions, policies or positions of FFF Enterprises, NuFACTOR, the Board of Directors, the *IG Living* Advisory Board or editorial staff. This material is provided for general information only. FFF Enterprises and NuFACTOR do not give medical advice or engage in the practice of medicine. FFF Enterprises and NuFACTOR under no circumstances recommend any particular treatment for any individual and in all cases recommend that individuals consult with a physician before pursuing any course of treatment.

All manuscripts should be submitted in MS Word, in Arial font. Manuscripts should be between 650 and 1,300 words in length, with unjustified margins and without any other formatting. Submission guidelines are available for download from the Contact Us page on [www.igliving.com](http://www.igliving.com). Email manuscripts to [editor@igliving.com](mailto:editor@igliving.com). *IG Living* retains the right to edit submissions. The contents of each submission and their accuracy are the responsibility of the author(s) and must be original work that has not been, nor will be, published elsewhere, without the written permission of *IG Living*. A copyright agreement attesting to this and transferring copyright to FFF Enterprises will be required. Acceptance of advertising for products and services in *IG Living* in no way constitutes endorsement by FFF Enterprises or NuFACTOR. ©2008 FFF Enterprises, Inc.

# Departments

- 4** IGL Editorial  
By Amanda M. Traxler
- 6** *Lifestyle*  
**Whoever Laughs Last,  
Laughs Loudest**  
By Cheryl L. Haggard
- 20** **Counting Her Blessings**  
By Kris McFalls
- 31** **Let's Talk!**  
By Shirley German Vulpe, EdD
- 34** **Rush Hour on the Bay Bridge**  
By Ever Fecske
- 36** **Just a 'Normal' Teenage Life**  
By Jim Trageser
- 42** *Community News*  
**IG Patients Protected Against  
Genetic Discrimination**  
By Amy Fuller, MPP,  
and Michelle Vogel, MPA
- 5** *Research News*  
**Memory B Cells and  
Antibody Function**  
By Ricardo Sorensen, MD,  
and Lily Leiva, PhD
- 32** **IgA Content in IVIG Products**  
By Chris Lomax, PharmD
- 8** *Medical News*  
**Vacillating on Vaccinating?**  
By Chris Ground
- 17** *Inquiring Minds*  
**Ask Kris**
- 38** *Parenting*  
**Adjustments to the  
Game Plan**  
By Mark T. Haggard
- 40** *Product News*  
**Converting the Dose**  
By Amanda M. Traxler
- 43** *Resource Directory*



## Join an IGL Readers Group!

We hear from many, many patient and family member readers who would like to connect with others in their geographic areas—to share their experiences living with chronic diseases or maybe just to have a cup of coffee with folks who understand.

We can help you determine if there's a patient organization support group in your area or help you start an IG Living Readers Group.

To join a group or start one in your own area, visit [www.igliving.com](http://www.igliving.com) and click on IGL Readers Groups.



## Perspective on Our Main Story

I'm pleased that this issue features a story on complementary and alternative medicine (CAM). It's a subject I've been interested in long before immune globulin entered my vernacular. And from what I've heard, quite a few of you have requested an article on this as well. However, I've also had a touch of trepidation about broaching this topic. First, I don't want to condescend to a population that is probably condescended to way too much already (even when it's unintended, such as well-meaning family members or friends who recommend Product XYZ, which always stops their colds right away!!). Second, given all the snake oil out there, I wanted to be sure to soundly survey this subject without increasing anyone's vulnerability to the quacks-extraordinaire who rove the alternative-medicine world.

Recently I read a column that brought the first point home. The author, a nutrition and fitness expert who's also a doctor (whether PhD or MD, I'm not sure), wrote that inflammation is a huge part of arthritis, heart disease, and even fibromyalgia. The best way to deal with inflammation, he continued, is with diet. Further, he contended that a body doesn't develop illness overnight, and that symptoms are signals. Overall, he advocated looking for a cause of illnesses, versus treating symptoms.

Replying to the column, a rheumatoid arthritis patient posted a forceful response, saying that diet had NO effect on her condition, which HAD in fact developed overnight, and that his comments were (surprise) quite condescending. Last, she said that she hoped he never had to experience the type of pain he was now dismissing so casually as having been preventable through diet alone.

I take neither person's side here. I'm not an MD. I know every morning I drink an omega-oil cocktail (whose heinous flavor I mask with juice) for its anti-inflammatory effects—but I also know that, overall, I'm blessed with a sturdy immune system that doesn't seem prone to autoimmune disease. So even though his column may contain "truth" for a certain set of bodies and immune systems (perhaps my own)—I'm certainly not going to claim that it holds

the magic bullet for all.

Along these lines, the intent of our feature is to bring you carefully researched information that you can take to your physician, if you are interested. And yes, we strongly recommend you discuss any of the following modalities with your physician before integrating one into your care.

As to my concerns about quackery, it would be great to be able to trust all purveyors of healthcare products and treatments, but sadly, many charlatans are out there. With that in mind, I wanted to pass along suggestions about how to prudently approach CAM. On the American Cancer Society's website, you can find an article featuring topics such as how to spot fraud and questionable treatments; what questions to ask about CAM; and how to talk to your doctor about these methods. The link to *Guidelines to Using Complementary and Alternative Medicines* follows: [www.cancer.org/docroot/ETO/content/ETO\\_5\\_3x\\_Guidelines\\_For\\_Using\\_Complementary\\_and\\_Alternative\\_Methods.asp](http://www.cancer.org/docroot/ETO/content/ETO_5_3x_Guidelines_For_Using_Complementary_and_Alternative_Methods.asp)

On a closing note, while I don't claim to be a medical expert, I am an avid word lover who relishes finding hidden clues in word meanings. Given that, I'd like to point out a fact that, to me, underscores the importance of this article. On our cover, we feature an image of a man meditating. Etymologically, the "med" of meditating is from the same Indo-European root (med=measure) as that of the word *mederi*, which means "to take care." From *mederi* comes *medical*, as well as *medicinal*. Even *remedy* is from this root. With this in mind, I hope you enjoy this month's feature. As always, please send any feedback my way. 📧

Amanda M. Traxler, Editor

---

Please send your letters to the editor to [editor@igliving.com](mailto:editor@igliving.com).

# Memory B Cells and Antibody Function

By Ricardo Sorensen, MD, and Lily Leiva, PhD

*Editor's Note: This was originally an Ask Kris question that was submitted to Ricardo Sorensen, MD, professor of pediatrics, department chairman at Louisiana State University, and Lily Leiva, PhD, associate professor and director of immunology laboratory at LSU. The first part reflects the original question, "What is the role of memory B cells in the immune system and immune deficiencies?" After answering the initial question, Dr. Sorensen shared more insight on current research, saying, "This is a rapidly evolving field, and I think patients and MDs need to be aware of the potential implication of having low memory B cells."*

## The Role of Memory B Cells

Deficiencies in antibodies that fight common bacteria and viral infections are frequently found in patients who have recurrent or severe infections. These deficiencies are diagnosed by measuring immunoglobulins (IgM, IgG, IgA) and specific antibodies directed against components of commonly used vaccines like tetanus, diphtheria and also pneumococcal vaccines (Pneumovax and Prevnar). We and some other immunologists also measure IgG subclasses, although others express concerns about the value of IgG subclass determinations.

Immunoglobulins and the specific antibodies that are included in each of the immunoglobulins are produced by plasma cells that reside mostly in the bone marrow and intestinal lymphoid tissue. Plasma cells are the most differentiated forms of the B lymphocyte lineage. B cells normally mature from precursor cells without needing any exposure to bacterial antigens to mature.

When B cells encounter bacterial and other proteins and sugars that they recognize as foreign materials, they develop in two directions: Some become plasma cells (immunoglobulin and specific antibodies), and others become memory B cells that recognize the same foreign substances that started the reaction to begin with. These memory B cells have been the subject of intense research in recent years.

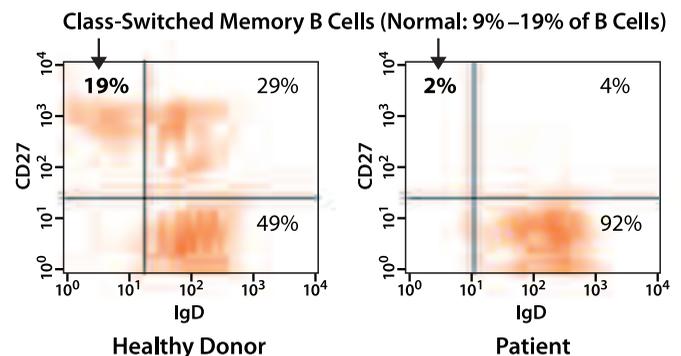
## Clinical Implications of Memory B Cell Testing

For many years, testing of antibody-mediated immunity involved measuring the plasma cell products, immunoglobulins, specific antibodies and, in some cases, measuring the number of mature B cells in circulation. Very low circulating immunoglobulin concentrations plus the absence of circulating mature B cells (CD20 and CD19 surface molecule positive cells) defined a severe immunoglobulin deficiency, agammaglobulinemia. Other forms of immunoglobulin deficiency have normal circulating mature B lymphocytes. This means that when immunoglobulins or specific antibodies are produced normally, something is wrong with the ability of B cells to become antibody-producing cells.

Recently, improved and easier ways to recognize and count several types of memory B cells have become available in immunology research laboratories. Exact definitions of what are normal or abnormal numbers of these various types of memory B cells are still lacking. The influences of age, gender, patient population studied, plus laboratory to laboratory variations still need to be better defined. However, it has become clear that abnormalities in memory B cells are part of this picture for many patients. Patients with low immunoglobulins

may have normal mature B cells, such as in common variable immunodeficiency (CVID), in the more controversial IgG subclass deficiencies, and also in specific antibody deficiencies that have normal immunoglobulins and IgG subclass concentrations. Most remarkably, we have recently identified patients who also appear to have normal specific antibodies to pneumococcal polysaccharides but who continue to be sick. Based on observations made by basic immunologists, we are beginning to understand that some individuals may have immunoglobulins and antibodies as presently measured, but their antibodies do not function properly. While it would be ideal to have assays that measure not only antibody concentrations but also their function, assays that measure function are difficult to perform and not clinically standardized or available for routine testing. The measurement of memory B cells may become a surrogate test for this type of abnormality. Active research in this area is needed to further study the clinical implications of memory B cell abnormalities. If eventually accepted as a marker for deficiencies in antibody-mediated immunity, abnormalities in memory B cells could open the door to treatment for some patients who presently do not fit into any accepted diagnostic and treatment category. ■

## B Cell Subsets



*Dr. Sorensen's current research into memory B cells focuses on a specific subset: class-switched memory B cells (the graphs' upper-left quadrants). In healthy individuals, this type of B cell accounts for 9%–19% of all memory B cells. In some patients, however, as the graph on the right shows, class-switched memory B cells are exceedingly sparse. In the future, being able to assess patients' class-switched memory B cells may help ascertain their clinical prognosis more specifically, for example, by determining whether they will be more prone to respiratory infections.*

# Whoever Laughs Last, Laughs Loudest

By Cheryl L. Haggard



**M**y early morning runs were a good habit. Not only did they allow time for me and our dog, Jax, to exercise, they also helped relieve the stress of raising three PIDD kids. Dealing with insurance, annoying green goo draining from noses, and needle sticks for immune globulin treatments is taxing.

But last December, my life changed forever when, one snowy day, I went from caregiver to patient.

My brother, Kurt, who was visiting from sunny Southern California for the holidays, wanted to jog in the snow. Feeling a recently consumed pound of fudge converting itself to junk in my trunk, I slapped on my bright red running

shoes and proclaimed, "Let the games begin!" Most of the calories were burned laughing as Kurt and I slid across fresh Idaho powder.

Little did I know that our romp through the snow was my final curtain call.

That evening, on a break from dish duty, my mom and I headed to the couch. As I sank into "my spot," I wondered if our house was experiencing a freak electrical storm, as a lightning bolt seemed to be surging through the left side of my body. The few sips of water I managed to get down were easier to swallow than the advice of the assorted men in my house—who, by the way, have never experienced labor pain—to just walk it off.

The next morning I was in the emergency room. The pain had taken over my body and I could not move. An X-ray showed degenerative disc disease, severe scoliosis and three ruptured discs in my lower back. One back surgery later, I write this during my recovery.

"Enough!" you scream. "End this disgusting display of self-pity!"

I know, I know. You're used to reading my "glass half-full" columns. I intentionally attempt to write with a humorous bent, as there is nothing funny about what we all go through with our mysterious diseases, aches and pains.

Rejoice, my faithful! As I've been scratching my way through the fires of hellish suffering, I've taken notes. So hold on to your paper surgical hat and embarrassing backwards hospital gown, because here it comes!

### **Up Your Nose With a Rubber Hose!**

One of my bunko buddies (I'm not ashamed!) and I recently compared our surgical wounds. She bragged about having a tube down her nose to suck up all the gunk from peritonitis, and I boasted about the cool scar that adorned my spine. Our conversation eventually and woefully wended its way into the maze of overwhelming medical bills.

"Can you believe they charged me one hundred bucks every time they changed my nose-drainage-holder-thingamabob?" my friend asked.

"Yeah," I bellyached. "They literally charged me up the wazoo for a suppository."

### **Does This Rod Make Me Look Fat?**

Thirty-something years of running, softball, swimming, golfing, soccer and the sport of birthing humans, and no one caught my crooked spine. I have a hard time believing my 5-foot-3-inch (on a good day) sturdy German-built

frame has been hiding severe scoliosis.

"So, Doctor," I interrupted during my pre-operative visit.

The details and risks of having back surgery were nauseating, so I decided to lighten things up a bit.

"I've never been happy petite," I griped.

"Go on," he said, slightly vexed.

"If I have to get a rod down my back," I asked as if talking about a good bra instead of scoliosis, "can you make me 5 foot 5? I'd even take 5 foot 4."

The surgeon looked at my husband, Mark, and said, "Is she for real?"

Mark answered, "Every inch of her!"

### **Wash, Fluff and Fold**

"Helllllppppp!" I bellowed from under my sheets.

The last time I yelled like that, I was about ready to give birth to Molly. This time, it was the morning after my run with my brother.

"What's wrong, Hon?" Mark gasped as he attempted to get me out of bed.

"Just get me to the shower," I whispered, trying not to inflict pain on my tongue. Every cell in my body was on fire; every step I took felt like shards of glass had penetrated my foot and were heading toward my skull.

"Forget the shower, let's get you to the hospital!" Mark insisted.

"No!" I squeaked. "Just fold me in half and throw me in the shower!"

As the hot water hit my aching skin, I realized that being bent over was the only position I could tolerate. Rubbing my hairy legs, I also realized that I was in dire need of a shave. Well, since I'm down here, I might as well...

"What are you doing?" Mark barked, interrupting my personal hygiene activities.

"It feels good to be in this position, so I decided to shave. I'm sure the ER folks will appreciate my efforts."

As Mark walked away in a huff, I think he muttered: "God forbid she shave for me, but for the ER docs, no problemo!"

As I continue down the uncertain path of being a patient with a debilitating disease, I will note the moments of laughter. A new patient, I am learning to be a good receiver; I certainly have had my share of being a giver raising my PIDD kids.

And since my surgery, Mark's learned to give my legs a wonderful shave! ■

# Vacillating on Vaccinating?

Experts concur that lower effectiveness of flu vaccine one year doesn't reduce the importance of vaccination in following years.

By Chris Ground

Thinking of skipping the flu vaccine just because you've heard that last year's vaccine wasn't that effective?

If so, experts will likely take you to task.

According to Dr. Frank S. Virant, who practices at the Northwest Asthma and Allergy Center in Seattle, Wash., chances are slim that last year—which had an overall vaccine effectiveness rate of 44 percent—will repeat itself.

"Some people might be frustrated that they 'got the flu anyway,'" Dr. Virant said, "but they should realize this phenomenon only happens every 15 to 20 years. ...

This is very unlikely to occur again for several years."

Also, last year's vaccine still provided cross-protection benefits. But, according to Luke Noll, director of corporate accounts for vaccines and influenza treatment at FFF Enterprises, those who are unaware of this might still question whether a vaccine is worthwhile.

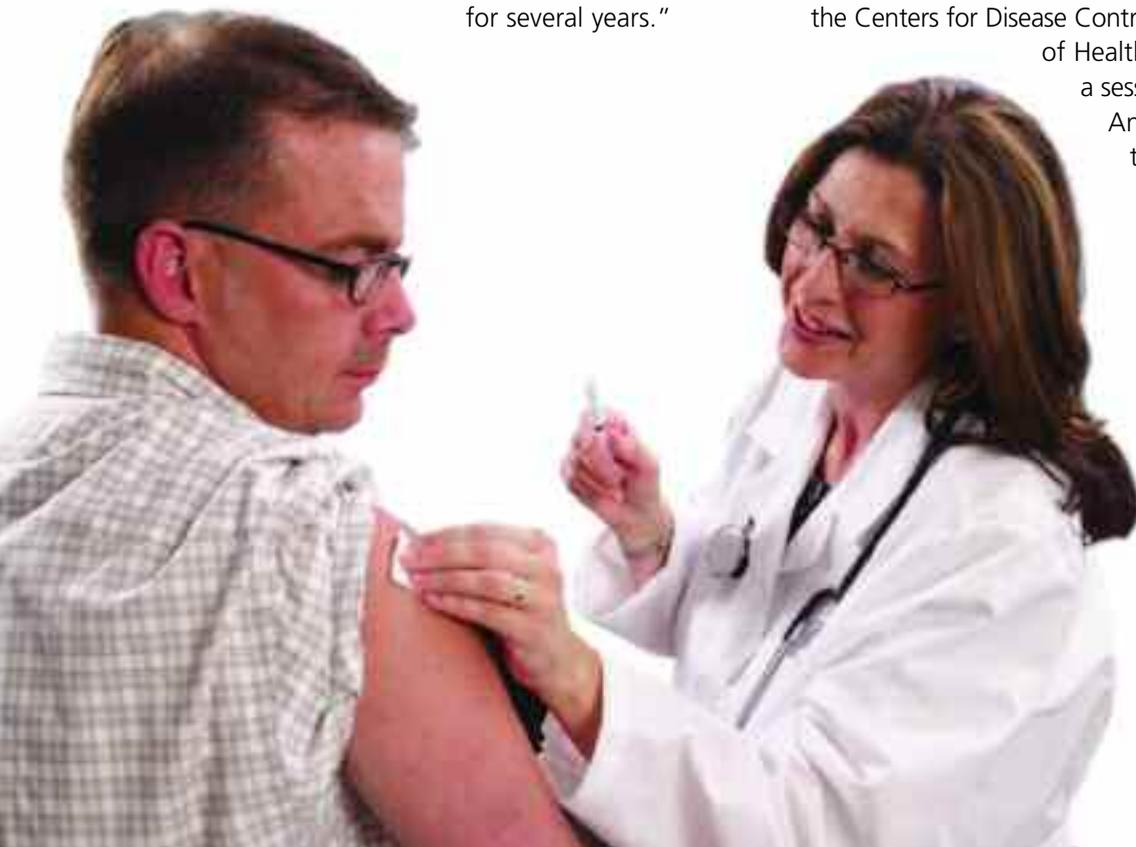
"That will be the primary myth and belief that must be overcome next year," Noll said, referring to the 2008-2009 flu season, which could begin as early as October and continue potentially through May.

Myths are nothing new when it comes to flu vaccines. At the 2008 National Flu Vaccine Summit in May, which was sponsored by the American Medical Association (AMA), the Centers for Disease Control (CDC), and the Department of Health and Human Services (HHS), a session was devoted to the topic.

And yet myths themselves—if they keep people from getting the vaccine—could potentially affect whether a vaccine will work overall.

According to the CDC, one factor that contributes to a flu vaccine's effectiveness is whether vaccination programs are able to successfully vaccinate people before the season starts.

Two other relevant factors are the similarity or "match" between the virus strains in the vaccine and those in circulation, and the age





and health status of the person getting the vaccine—an important consideration for those with immune deficiencies.

In the 2007-2008 flu season, two of the three strains making up the flu vaccine were not good matches for the viruses circulating in the population, and the vaccine was only 44 percent effective overall, according to the CDC.

Last year's vaccine was not effective at all against the B circulating strain. But in terms of the A circulating strain, the vaccine performed better, providing cross-protection benefits against different, but related, viruses, said Noll.

"When you talk about the overall effectiveness of the flu vaccine for the past 16 out of 20 years, it was a good match," Noll stated, referring to the vaccine's 58 percent effectiveness against circulating influenza A viruses.

In a good year, when the vaccine strains and the viruses are well-matched, the vaccine can reduce the chances of getting the flu by 70 percent to 90 percent.

For immune-deficient patients, whether or not to get vaccinated is of special concern.

"Although some patients with primary immune deficiency may not respond well to flu vaccine [poor immune response], it certainly is worth doing in an effort to try to diminish the intensity of disease," explained Dr. Virant.

It's also important that those around patients with immune issues receive the vaccine.

"It's a great idea for family members and close acquaintances to get a flu shot because this is the most likely source of exposure, and again, the immune response of the patient is often not great," Dr. Virant continued.

In terms of what vaccine immune-deficient populations should receive, Dr. Thao N. Tran, an immunologist at the Northwest Asthma and Allergy Center, pointed out that "the CDC recommends the use of inactivated (killed) influenza virus vaccine in patients with weakened immune systems and their family members, rather than the live, attenuated (weakened) influenza virus (LAIV) vaccines. LAIV are the nasal spray influenza vaccines such as FluMist."

For the upcoming 2008-2009 flu season, the flu vaccine will include three new strains, which were chosen based on information gathered in 2007-2008 from 122 national

influenza centers in 94 countries.

According to Noll, the rarity of changing all three strains in one season may have presented a challenge for manufacturers.

"Three new strains add a challenge for manufacturers, primarily because of a lack of experience in working with the new strains," Noll said in May, just after attending the summit.

However, direction was available from manufacturers who had worked with two of the strains in the vaccine for the Southern Hemisphere's current season, which comes months earlier to that region before hitting the Northern Hemisphere.

According to the CDC, healthcare providers should offer vaccination as soon as it's available, ideally by October. However, vaccination should continue throughout the season, as the length of each season varies, and even vaccines given midway through a season are still beneficial.

Myths will never go away, but patients don't have to let them affect their health. Remember, flu vaccination for everyone is a crucial part of staying healthy. ■

### Flu Vaccine Facts for the Immune-Deficient Population

- Lower vaccination effectiveness one year doesn't make getting vaccinated in following years less important
- Vaccination provides cross-protection benefits for related viral strains
- Vaccination can lessen the intensity and course of disease
- Friends and families of those with weakened immune systems should make sure to get vaccinated
- Those with weakened immune systems, as well as family members, should avoid the live, attenuated (weakened) influenza virus (LAIV) vaccines, which include the nasal sprays

# Prepared to

# APPEAL

## How Readiness Is Next to Healthiness

By Amanda M. Traxler

*"Let our advance worrying become advance thinking and planning."*

—Winston Churchill

**W**hen an insurance provider decides not to pay for a doctor-recommended procedure, a denial has occurred. The procedure may have already happened, or you may be at the preauthorization stage. Regardless—payment has been denied. End of story? Not necessarily. Patients have the right to appeal. And patients should flex this right—especially when a doctor's recommended course of treatment is the best course of action.

But that doesn't mean it's going to be easy. Just the thought of an appeal can be stress-inducing, let alone actually doing it. But there are ways to manage the process logically to minimize stress. What helps most is being ready. And for patients in the IG community, this means being prepared for an appeal, even if you aren't currently having access or reimbursement issues. Think best-defense cliché. What, then, is a good offense? To answer that, we must first go to the beginning of the story.

### **First Things First**

If you don't have a current copy of your plan's benefits, call your insurance company and request one. If you do have one, it's still not a bad idea to call to ask if you have the most recent copy. Once you have it, read it. Pay close attention to two things. First, you have to know what your plan says about your condition (this is important, as the medical knowledge on which an insurer bases a denial may be lacking or out of date). Second, you need to know what treatment your plan allows. Without this knowledge, moving forward will be difficult.

*Editor's note: This article was updated on August 16, 2013.*

Once you have taken care of this, the following steps are also necessary for a good offense:

- Start a file now: It's wisest for everyone to already have documents on hand in case treatment is unexpectedly interrupted. This includes lab reports, radiology reports and letters from treating physicians used in requesting authorization for treatment. (Many use a binder for this.)
- Stay in the loop: If your doctor has recently requested preauthorization, an appeal may be happening without your knowledge; ask to be kept in the loop from the get-go. Ask for copies of all tests or lab work done, as well as copies of communication between your doctor and the insurance provider. (Note: Many insurers now have a standard preauthorization form. Find out if yours does by calling or looking on their website. Given varying insurers' requirements and forms, don't expect your doctor to be aware of this.)
- Be armed with medical knowledge: Having relevant medical studies to bolster your case can be vital.

This may sound like a lot to do. And it is. But if a denial happens, and you receive the dreaded letter, you will be ready when it matters most.

### **To the Letter**

A denial letter must include a reason. Knowing this reason is key because this is what your appeal must address. One of the most common reasons is that a procedure or treatment is considered "not medically necessary." On its face, this seems simple enough. But really, the rationale behind it can be nuanced, which these following examples demonstrate.

#### **Example One:**

One man was denied IVIG treatment based on his policy's requirement that a patient with multifocal motor neuropathy (MMN) have anti-GM1 antibodies and positive nerve-conduction block studies. Though the patient did have the positive nerve-conduction tests, he did not have the anti-GM1 antibodies. In appealing the decision, this patient provided documentation that showed it is not uncommon for patients with MMN to not have anti-GM1 antibodies. In addition, he was able to show that treatment with IVIG is a standard of care. As a result, he was able to attain a trial of IVIG to help establish whether it would be a good treatment.

#### **Example Two:**

A similar case illustrates another important note: Maybe you just need a second opinion. In this case, a patient was denied IVIG based on negative nerve-conduction studies and his lack of anti-GM1 antibodies. The denial letter stated that he "...does not meet the medical necessity criteria. There's no indication this member is having anti-GM1 antibodies and conduction block. This information is unavailable despite specific requests from our nurse manager." The patient was referred to another neurologist who was able to find the nerve-conduction blocks. His case was sent for authorization based on the new studies. Further, he also sent documentation showing that anti-GM1 antibodies are not found in many patients with MMN.

#### **Example Three:**

This appeal involves a man who has myasthenia gravis (MG). After a year of IVIG treatment, he was denied reauthorization for IVIG based on a policy of only providing IVIG for MG patients in a myasthenic crisis. Given that his condition had stabilized, he no longer qualified ➤

for treatment. The insurer wanted him to switch to covered maintenance treatments, which include prednisone and Mestinon®. Gathering articles on the use of IVIG in myasthenia gravis patients, as well as physician notes that documented the adverse effects he was having to prednisone and Mestinon—the man wrote an appeal to the independent review board. In his letter, he stated that he felt the insurance company's policy of covering only, in his case, the prednisone and Mestinon was adding to his disability. He also questioned whether that carried a liability issue. Before the case could be reviewed, the insurance company stated that based on the failure of traditional treatment, it would make a single case exception for treatment with IVIG for one more year: "Based on our review of the above information, we are reversing our previous benefit decision and will now allow coverage for continued IVIG therapy for a period of one year. The basis for this determination is that you have been tried on and failed standard therapies and have failed Mestinon for symptomatic therapy."

### How to Track Communication During an Appeal

- Stay within the time frame given for an appeal.
- Keep a log of whom you talk with regarding your appeal and when (both insurance representatives and medical providers). This includes date and time, name of the person you spoke to, his or her title, phone number, and conversation details.
- If employees of the health plan say that they'll call back, make note of this too. If they don't, contact a supervisor. And don't hesitate to escalate the issue to a regional director or manager.<sup>1</sup>
- If a promise is made over the phone, ask for it in writing; if dealing with an HMO, ask that your conversation be recorded.<sup>2</sup>
- Save phone bills that show the calls.<sup>3</sup>
- After each call, send a letter summarizing the conversation and ask to hear back in 30 days.<sup>3</sup>
- Send letters by registered mail.<sup>3</sup> Send your appeal letter and supporting documents all in one packet. Don't be afraid to send a copy to your representative and/or state insurance commissioner.
- This tip comes from the Immune Deficiency Foundation: Save the envelopes of important letters, such as denials that come from the insurance companies. The letters inside are frequently dated a week before the letter actually arrives. If the appeals time frame gets tight, those envelopes are documentation that proves when you actually received notification.

### Other Potential Issues

On a less-complicated note, billing issues or administrative errors (an incorrect diagnostic code or procedural code) may also have caused the denial. In one situation, a doctor used a diagnostic code for a condition for which IVIG was no longer covered. Once the proper diagnostic code was given, the issue was resolved.

Inadequate documentation can also lead to a denial. One woman's denial letter stated that "the diagnosis of chronic sinusitis is not adequately documented." The insurance company had not received records because the infectious disease doctor, the one ordering the IG, had not received them either. The patient, of course, didn't realize this. Neither did the infectious disease doctor. According to this patient, "most

<sup>1</sup> *Research and Appeal a Claim Denial*, [www.healthsymphony.com/healthinsurance.htm](http://www.healthsymphony.com/healthinsurance.htm).

<sup>2</sup> *State of Wisconsin Consumer Guide to Health Care*, <http://dhfs.wisconsin.gov/guide/spec/probins.htm>.

<sup>3</sup> Shomon M, Kline W, M.D. *Your Guide to Thyroid Disease. When Your Insurance Company Won't Pay*, <http://thyroid.about.com/cs/newsresearch/a/insurancepay.htm>.

of the records hadn't gotten to the infectious disease doctor, who was the one ordering the IG." In turn, the insurance company did not have any culture reports, hospitalization records, or records of IV antibiotic use—only a report from a doctor stating that these records existed. She determined this by asking for copies for herself of all the relevant medical records. Once she identified what records were missing, she was able to return to the proper source to obtain them.

As the previous cases show, to appeal successfully, you must address the exact reason given for a denial. And as the previous examples also show, getting to the bottom of that reason can be arduous. However, being prepared will not only help immensely, it also may save precious time. Clichés exist for a reason, and when that reason is your well-being—a good offense is vital. ■

## The Nuts and Bolts of an Appeal

The following is a synopsis of a full-length publication, "Your Guide to the Appeals Process," which was written, produced and copyrighted by the Patient Advocate Foundation. This publication lists the four necessary steps to submit an appeal, as well as sample appeal letters. The complete guide is available for download at [www.patientadvocate.org/requests/publications/Guide-Appeals-Process.pdf](http://www.patientadvocate.org/requests/publications/Guide-Appeals-Process.pdf) or can be requested by patients free of charge by calling 800-532-5274.



### Step 1: Gather Preliminary Information

To begin, start a file to document all correspondence. Keep a record of all letters and a log of all calls, including when and how you received notice of the denial, as well as who notified you. You also need a copy of the denial letter from the insurer as well as copies of the information your doctor submitted and the authorization request. If your requests are ignored, make a record of your attempts to obtain this information.

If you've received a denial for a procedure that has already taken place and there are bills unpaid, you need to find out why. For example, does your insurance company require procedures to be preauthorized? If so, did your doctor's office preauthorize the procedure?

The most important documents you need are your plan document and plan summary. If you do not have current copies, write the administrator to request one. Read your plan to learn what it says about your procedure and the specific reason for denial. If the condition was to be preauthorized, do you or does your doctor have a copy of the authorization or the approval ➤

from the insurance company? If no preauthorization was required, review your plan's specific exclusions. If your treatment is not identified as such, you need to begin your appeal.

If the denial letter does not say whom to contact about your appeal, call your insurer and ask. Ask your insurer for a written copy of the steps you must take to appeal the denial. Also, ask your doctor's staff whom to call to ask for letters or records you might need.

### **Step 2: Understand the Illness and the Insurance**

Support from your treating physician and specialist is critical. You must understand what the doctor wants to do and why. Read any letters your doctor may have submitted to the insurance company. You also need to be familiar with your insurance. If your coverage is through an employer, call the benefits manager and ask to have the coverage explained. A benefits manager might be able to work with you to get the denial overturned.

### **Step 3: Write the Appeal Letters**

Some appeals are handled by the doctor's office, the clinic or the hospital. In this situation, a patient will work with a case manager to oversee the process; make sure to ask for copies of all letters and correspondence to and from the insurer.

In other situations, the patient handles the process. Your appeal packet will include an appeal letter; a letter from your doctor and specialist addressing specifics of the case; pertinent information from the medical records; and articles from peer-reviewed clinical journals that support your case by illustrating medical efficacy.

Your appeal letter, which should be factual and written in a firm but pleasant tone, must express why you think the procedure should be covered. In your letter, include identification (policy number, group number, claim number, or other information used to identify the case); the reason given for the denial; a synopsis of the illness and the treatment; the correct information (in cases where, for example, a wrong diagnostic code was used); why you believe the decision was wrong (specific information based on facts to show that the treatment should be provided); what

you are asking the insurance company to do (typically, this is to reconsider the denial and approve coverage in a timely manner).

Your doctor's appeal letter should be addressed to the person at the insurance company who sent the denial letter, or to the medical director at the insurance company.



It should include: 1) important information about your illness; 2) the prescribed treatment plan; and 3) why the treatment is medically necessary. Ask your doctor if there are any medical records that might help your appeal; if so, include these (for example, lab results or certain tests).

Often an insurer will deny a procedure if there's not enough evidence that the procedure can help a specific disease. If this is the case, then submit documentation that the treatment is effective from peer-reviewed medical journals.

This information should be submitted in a packet by registered mail. You should keep copies for yourself, too.

#### **Step 4: Evaluate the Result**

If you receive a letter stating that the denial has been overturned, congratulations! But before you celebrate, you need a copy of the approval letter. Also, be aware of any terms, such as a requirement that a specific practitioner perform a surgery. If the requirements are not acceptable, discuss them with your insurance contact and your doctor; you might want to continue the appeal.

If your appeal was denied, you'll need a copy of the second letter, which must also include a reason (which may be different). If this letter asks for more information, notify your doctor. Another contact may be listed in case you continue your appeal. Again, keep copies of the new packet and submit it by registered mail. If your appeal is again denied, you should request the third denial in writing and notify your doctor. If you believe your insurance company should cover the procedure and are willing to proceed with the appeal, refer to the plan document for the next step.

At this point, some insurers will offer an external review, in which case they send your appeal to a company to review the denial, the appeal, and any new information. The review board, which will make a recommendation to the insurance company about the procedure, typically comprises nurses, attorneys and doctors who specialize in the procedure.

If you have exhausted all levels and are still not satisfied, your remaining alternative may be to pursue the issue in court.

#### **When to Consult an Attorney**

This important question has no easy answer. If you do not understand the appeal process and are unable to get answers from your employer or insurance company, an attorney may be helpful to advise you of your rights and options. If you do seek legal advice, you should select an attorney with experience in healthcare law. Also, you should discuss legal fees upfront, request detailed billing, and determine at what point the attorney will take over the case.

Some patients will completely exhaust the administrative appeal process before involving an attorney. It is very important that you make every effort to have an attorney during the administrative appeal process in the event you wish to pursue the case later in court.

#### **Others to Notify**

In some cases, notifying state and local representatives about insurance issues helps patients. You can send a copy of your denial and appeal letter to your legislators asking for any assistance they can provide. A list of legislators is available by state on the PAF website at [www.npaf.org](http://www.npaf.org). ■

# IG Therapy In Your Home

# with Care



## NuFACTOR Provides:

- Patient Care Coordinators who truly care

*“I not only appreciate the efficient and prompt service, but especially the kindness and caring by each member of the NuFACTOR staff.”*

- Training in all forms of immune globulin administration
- Reliable home delivery of immune globulin
- Individualized services to meet your lifestyle

*“Your company and personnel are a pleasure to work with. Thank you for all you do!”*

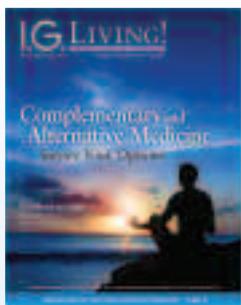
- Peer Support Program™
- 24/7/365 Pharmacist availability for you and your physician
- Arrangement of home infusion nursing services
- Expert claims and reimbursement assistance

*“Service is high quality and the best I have dealt with since I started taking IVIG 13 years ago.”*

- Coordination with your healthcare provider and case manager



NuFACTOR has earned the Joint Commission Gold Seal of Approval



Subscribe to *IG Living* — your community magazine at [www.igliving.com](http://www.igliving.com)

Call us to find out more about NuFACTOR's services: 800-323-6832 • [www.nufactor.com](http://www.nufactor.com)

**NuFACTOR**  
SPECIALTY PHARMACY

NuFACTOR is the specialty pharmacy subsidiary of FFF Enterprises, Inc.

20th Anniversary  
**FFF enterprises**  
Helping Healthcare Care®

# ASK KRIS



Kris McFalls has two adult sons with chronic diseases who are treated with IG. Formerly a physical therapist assistant, Kris is IG Living's full-time patient advocate, and she is eager to find answers to your questions. Email them to [editor@igliving.com](mailto:editor@igliving.com). Your confidential information will not be used for any purpose but communicating with you about your questions.

**Carolyn:** I have multifocal motor neuropathy (MMN) and have been undergoing IG therapy since October. I want to work on my strength and stamina and so would like to start an exercise program. The problem is, I don't know where to start. For example, I'd like to start swimming again (I used to swim with a Masters Swimming Program where I work) but am afraid if I do too much at once I'll set myself back rather than gain strength. Is there any way to know when enough is enough? There seems to be a very fine line between doing some physical activity and doing too much (which causes severely aching muscles). How can I determine where the line is? Right now I'm going backward in terms of strength and stamina and am rarely able to walk the dog. Is there a limit to what is good for me to build my strength in the long run and what is harmful in the long run? I know that for some patients there is such a thing as doing too much, and too much is actually harmful—does the same hold true for MMN patients? Does resting help alleviate the fatigue or does resting in the end create even more fatigue? I'm getting conflicting answers from different doctors.

**Kris:** I directed this question to Matthew D. Hansen, DPT.

**Matthew:** Exercise is an important aspect of treatment for any neuropathy; however, its benefits versus potential detriments can hang in a delicate balance. Fortunately, unlike many other neurological diseases, multifocal motor neuropathy (MMN) is treatable, with many patients who receive early medical treatment experiencing little or no

long-term disabilities. Because every patient's condition is individual, Carolyn should address specific questions regarding her exercise program with healthcare professionals who are more familiar with her case (e.g., primary physician, specialist or physical therapist). Nevertheless, several principles related to MMN may help her to make decisions about her activity level:

- 1) The progression of disuse weakness, due to significantly reduced activity or not exercising at all, can add to the problem of underlying neurological weakness. Exercise is important.
- 2) Recent research suggests that there may be an activity-dependent component of MMN (i.e., physical activity past a certain threshold may temporarily make symptoms worse). It is still unclear how these temporary exacerbations may affect long-term strength gains, but it is generally believed that the effects are transient.
- 3) Muscle soreness/cramping and fasciculations (i.e., involuntary twitching) are common symptoms of MMN that can be aggravated by vigorous activity.

Taking these points into consideration, I would recommend that Carolyn begin a regular exercise program that minimizes any increase in symptoms. Some muscle soreness and fatigue is inevitable, but it should not be debilitating. If her symptoms prevent her from performing her daily routine, or make her extremely uncomfortable when doing so, she is doing too much, and needs ➤

to cut back. Traditionally active people tend to push their exercise program too hard and too fast; patience is the key.

In response to Carolyn's question, rest can help alleviate fatigue, but if she has to rest a full day after exercising, again, she needs to cut back her exercise program to a level that allows her to perform it daily without putting her out of commission. Levels can then be progressed slowly as tolerated. Happily, both swimming and walking can be great activities for MMN; however, Carolyn may need to begin by walking in the pool before swimming, or at least reducing the number of laps that she swims, and she may need to take her dog on extra short walks for the time being. A personal trainer or physical therapist should be able to help monitor the progress of the exercise program, though in my opinion, I would recommend seeing the therapist, who will have a more extensive health background.

**Loyda:** What can I do to increase my potassium intake?

**Kris:** I forwarded your question to our nutrition columnist, Jessica Schulman, PhD, MPH, RD. She provided the following response.

**Jessica:** According to the Institute of Medicine (IOM), the daily reference intake (DRI) for potassium is 4700 milligrams (mg) per day for individuals age 19 and up. Its benefits include lower blood pressure and reduced risk of kidney stones and bone loss. However, the IOM reports that "most American women 31 to 50 years old consume no more than half of the recommended amount of potassium, and men's intake is only moderately higher."

Foods rich in potassium include fresh fruits, vegetables, legumes and some dairy products. The USDA offers a nutrient database of all foods that contain potassium and the number of milligrams ([www.ars.usda.gov/nutrientdata](http://www.ars.usda.gov/nutrientdata)). Be sure to use the same measure, such as 1 cup or 6 ounces, when you are looking up the density of nutrients, so you are comparing apples to apples. Below is a short list of common foods that contain high amounts of potassium.

- Baked potato, plain with skin, 1 medium = 925 mg
- Baked potato, plain without skin, 1 medium = 610 mg
- Yogurt plain, skim milk, 8 oz (1 cup) = 579 mg
- Brussel sprouts, cooked, 1 cup = 504 mg
- Orange juice, raw, 1 cup = 496 mg
- Avocados, raw, all varieties, 1/2 of a medium = 488 mg
- Bananas, raw, 1 large = 487 mg
- Orange juice, includes from concentrate, 1 cup = 473 mg
- Lima beans, large, plain, boiled, 1/2 cup = 475 mg
- Milk, fat-free or skim, 1 cup = 407 mg
- Ensure® and Boost®, 8 oz = 380 mg
- Oranges, raw, all varieties, 1 large = 333 mg
- Seedless raisins, small snack box = 322 mg
- Beans, black, plain, boiled, 1/2 cup = 305 mg
- Lima beans, large, canned, 1/2 cup = 245 mg
- Broccoli, plain, boiled, drained, 1/2 cup = 229 mg

The National Heart Lung and Blood Institute (NHLBI) provides a more extensive list of potassium rich foods ([www.nhlbi.nih.gov/hbp/prevent/factors/supls.htm](http://www.nhlbi.nih.gov/hbp/prevent/factors/supls.htm)). For health-related information by phone, call NHLBI at 301-592-8573.

In healthy individuals, there is little evidence of harm associated with high potassium intake when ingested through regular food sources. However, table salt substitutes contain very high concentrations of potassium chloride. Because potassium is involved in regulating muscle tissue (including the heart, fluid balance and other chemical processes), excess potassium can lead to hyperkalemia, a dangerous state if your body does not process potassium normally. High amounts of potassium can also be harmful to those with disorders of the kidney or people taking certain medications (e.g., enzyme inhibitors, angiotensin II receptor blockers, NSAIDs, etc.). Any medication or nutrient that is consumed in amounts high enough to produce a health effect is also capable of having a side effect. Always consult a physician to determine what diet is best for your health condition.

**Jill:** I have been getting IVIG for about a year now at my doctor's office. At my first infusion, I had a rate-related reaction that started as low- to mid-back cramping and

pain, which then progressed to other symptoms. I was treated with Benadryl and steroids at that appointment. Now, because of other issues, I am premedicated with Solu-Medrol before each infusion. Are back cramps and pain related to the IVIG? Could this be a precursor to aseptic meningitis?

**Kris:** Dr. Richard Schiff responded to your question. Additionally, it is important for you to keep a health diary and infusion log. Record any reactions you have during and after your infusions and record how you feel between treatments. Make sure to take your health diary and infusion log with you to your doctor appointments so you can discuss your concerns.

**Dr. Schiff:** The mechanism by which IVIG causes back pain is not known, but it is not likely to be related to kidney problems and is not related to aseptic meningitis. Back pain, abdominal pain, generalized muscle cramps, nausea and vomiting, and other reactions were very common with the first IVIG preparations. In general, these reactions are much less common now, most likely due to products with fewer aggregates of IgG that can cause inflammation and due to removing some of the additives, such as sugars, which also can cause side effects. Before committing to long-term pretreatment with a steroid, it might be worth discussing with your physician switching to a different IVIG product. Some people tolerate one product better than another, even though we don't know why and it is not consistent.

**Susan:** How much are the medical blood tests for primary immune diseases? And are there different types?

**Kris:** Yes, there are a variety of tests with different costs. There is also the variable of what your insurance actually allows and will pay. Your out-of-pocket costs and/or co-pays are based on what your insurance allows, not what the lab charges. For most people the basic testing starts out the same with a complete blood count (CBC) and differential as well as immune globulin levels. Once those are done, more lab tests can be ordered depending on the patient's

symptoms and family history, in some cases including genetic testing. I don't have figures for lab tests. I can tell you personally my last CBC was charged at \$76, the insurance allowed \$25.78, of which my out-of-pocket cost was \$5.15.

The Jeffrey Modell Foundation has a wonderful chart that explains the stages of immunological testing at [www.info4pi.org/researchlibrary/index.cfm?section=researchlibrary&content=algorithm&CFID=26300466&CFTOKEN=34652952](http://www.info4pi.org/researchlibrary/index.cfm?section=researchlibrary&content=algorithm&CFID=26300466&CFTOKEN=34652952).

**Lisa:** As you suggested, I applied for and was approved for financial assistance from my provider. I was told that the bills for the last two months of 2007 now had a zero balance. I asked why I haven't received a statement showing a zero balance and was told I would not get one. Don't you feel I should have something in writing?

**Kris:** Although it would be nice to have something in writing, I could find no regulations regarding this. If the facility won't give you something, make sure to write down the names of those you spoke with and also the time and date. You can always write your own letter to them stating you spoke with Ms. Doe (give the date and time) and were told you have a zero balance for (give the time frame). You can at that time also request a written response so that you have proof for your files in case there is ever a question in the future. It's always worth a shot.

No matter what happens in this particular case, whenever you talk with anyone regarding bills and insurance, keep a log of whom you spoke with, the date and time. Some insurance companies have a policy of giving only a first name. However, they may have a badge number that can be recorded. Don't be afraid to ask for it. It's not being rude to document, especially when advocating for your health needs. ■

# Counting Her Blessings

By Kris McFalls



Shannon Young is used to the spotlight. So much so, in fact, that the news anchor for Oregon's Channel 10 KTVL—who was diagnosed with dermatomyositis (DM) in January 2003—can't help but consider whether it's affected her health.

"Sometimes I wonder if the business I'm in has anything to do with it, because I spend all day long surrounded by different frequencies," Young said.

This form of myopathy is the most easily recognizable due to its distinctive rash—which Young has had since the beginning.

"The things that set me apart is that my rash is really pronounced, and it has been, and it's never gone away, on my knuckles."

And yet even that didn't ensure a timely diagnosis for Young, whose rheumatologist had been considering lupus before another doctor correctly identified her condition.

"The symptoms are so similar, and they're all so vague across the board," said Young, who also suffered from fatigue, a symptom of both dermatomyositis and lupus.

In September 2002, Young ran a half-marathon. After the event, Young noticed that she was sore and tired, but figured it was due to the race.

But by November and December, walking from the bedroom to the living room was difficult for Young.

One night in a bath, Young noticed that every one of her cuticles was infected.

"I remembered my mom saying years ago that redness and inflammation was infection," Young said, who scheduled an appointment with a dermatologist.

The new doctor finally identified her condition, telling her: "The bad news is, this isn't good. The good news is that this [dermatomyositis] is my hobby, and you're in a good place."

Not that Young was immediately able to appreciate this.

"I was terrified. I was living in Virginia and my whole family was in Oregon or California," Young said. "And I thought, why is this bomb being dropped in my life when my support system is this far away?"

And yet Young didn't lose sight of the positive—the fact that she had a support system.

"I think I've just been blessed in that I've always had ... a really supportive family," Young said. "When I was going through this, everyone was sympathetic."

By that same token, Young also needed time to digest the news without the pressure of how those close to her would handle it.

"I remember my mom, she really wanted to come out and be with me. I didn't want her there. I needed some time to get comfortable with myself," Young said. "I would've spent more time taking care of her reaction than I would have me. It was important to me that she not take that personally."

Her mom, who would later be diagnosed with rheumatoid arthritis (RA), has become more of a bosom buddy than she expected.

"But then my mom got diagnosed with RA, so now she can be empathetic. It's nice that we're both going through similar types of things," Young said.

With treatment about to begin, Young approached her boss.

"I went to my boss and I told him 'I'm going to be on high doses of steroids, and it'll affect my appearance.'"

Her boss kept her on the air. A few observant viewers did reach out to Young, though their comments caught her off guard.

“Mostly people just thought I was pregnant.”

Given that her rash sometimes appears on her face, Young jokes that she’s blessed to work in an industry that values heavy makeup.

“Slather on the foundation, and it’s fine.”

As far as her condition, which she treats with a low dose of prednisone as well as methotrexate, Young considers herself lucky.

“They have not determined positively that I have it in my muscles. One test was negative, one inconclusive. I get tired sometimes. If I haven’t had sun for a while, then I get tired.”

Overall, though, Young’s life has not been narrowed by her condition. If anything, it’s widened.

“I’m not not doing things because of it. I’m doing more things because of it.”

Case in point? The banjo.

“I’ve been in love with Steve Martin since I was 8 years old. My parents got me a banjo at Christmas when I was 15. After I was diagnosed, I really wanted to play the banjo, but I didn’t think I could because my fingers hurt. I thought this is stupid, I either need to get rid of the banjo, or start playing.”

Bare-fingered—because using picks hurt—Young started playing.

(Not well, she contends—but we at *IG Living* think that good music is in the ear of the beholder.)

Another post-diagnosis change: Young also takes time for things that she didn’t before.

“I think the topic of my first myositis talk was about how getting this disease ... was probably one of the best things that ever happened to me. It made me focus on my life and my choices and my health—things I was taking for granted and ignoring. Oftentimes I think I brought this on myself because I have so much to learn from it—getting clear about what I need. It makes you get really clear about taking care of yourself.”

And that means something different for everyone, Young says, as no condition affects people the same way. Young advises others to do their research, but to not ignore their symptoms.

“Pay really close attention to your own body and how you feel. Even though you may share the same disease, your symptoms will be different. Everyone’s case is so different and everyone’s disease manifests differently.”

And for those who find themselves as part of someone’s support system, Young says:

“Follow the lead of the patient, but just make sure they know you’re there.”

Sometimes, even unexpected people will be “there” for Young, who says that random acquaintances occasionally give her cream for her hands.

But Young doesn’t feel beholden to share about her condition, which she almost views as a social litmus test.

“It’s kind of a nice tool. If you don’t feel like letting someone into that part of your life, then maybe you don’t feel like letting them into other parts of your life.”

Not that she’s ashamed of it, says Young.

“I’m not afraid of what other people will say.”

Disclosing her condition, Young says, just doesn’t always seem appropriate for every situation.

For example, Young is aware that announcing her condition can potentially make her the center of attention at inopportune times.

When given the chance to host a telethon, whose proceeds were going to support research for myriad conditions—including hers—Young was unsure whether to announce her dermatomyositis.

“I was really torn because I didn’t want to do it without disclosing it, but I didn’t want to make it about me.”

Young instead chose to spend her weekend at an event for The Myositis Association—where she was a featured speaker.

According to Young, she might host a telethon sometime in the future, when she no longer works in TV.

Not that she expects that to be anytime soon.

But who knows?

Perhaps that ol’ banjo calling will become too loud to ignore, and Young will switch career tracks entirely. ■

The Myositis Association will hold its 2008 Annual Conference in Denver from Sept. 18–21, with the final day falling on National Myositis Awareness Day. This year, the conference will focus on the progress made in the field of myositis diagnosis and treatment—highlighting the promise of recent developments.

To learn more or to register, visit [www.3446.sslldomain.com/myositis/template/page.cfm?id=409](http://www.3446.sslldomain.com/myositis/template/page.cfm?id=409)

# Complementary and Alternative Medicine

## *Surveying the Options*

By Lauren Gerstmann, MPH

**H**ippocrates told female patients to chew on willow bark to ease labor pain. If modern patients were to hear that, they might wonder about this seemingly alternative herbal therapy. But today, willow bark extract is used to make aspirin—the most commonly used pain reliever and anti-inflammatory. In 2005, more than one-fifth of U.S. adults reported regular aspirin use, and

almost half of adults over 65 reported aspirin use either every day or every other day.<sup>1</sup>

For centuries, people all over the world have used treatments such as herbal remedies, acupuncture, and mind-body therapies to improve health and ward off disease. Depending on how you define these therapies, somewhere between 9 percent and 65 percent of people in developed countries have tried a complementary or alternative technique.<sup>2</sup> Generally, alternative medicine is care that is used instead of standard medical treatment, while complementary medicine is used in addition to mainstream medical care.

In Western society—which is devoted to a scientific medical model—some of these treatments are considered unproven and risky. Historical skepticism has been changing, however, as scientists, physicians and patients are becoming more interested in more natural treatments. What had been alternative is now becoming mainstream. In 1992, the National Center for Complementary and Alternative Medicine (NCCAM) was created. Part of the National Institutes of Health, the center is devoted to scientific study of treatments that were once considered most unscientific.

NCCAM defines complementary and alternative medicine (CAM) as “a group of diverse medical and healthcare systems, practices, and products that are not presently considered part of conventional medicine.”<sup>3</sup> But, as we examine these practices alongside Western techniques—scrutinizing them scientifically—the boundary between “traditional” and “nontraditional” techniques starts to shift. Massage therapy, acupuncture and nutritional guidance are standard therapies at the Zakim Center for Integrative Therapies<sup>4</sup>—part of Dana-Farber/Harvard Cancer Center—the world’s largest comprehensive cancer center. And the UCLA Collaborative Centers for Integrative Medicine is a network of clinics that treat conditions such as pediatric pain, women’s digestive disorders and integrative oncology.<sup>5</sup> These are just a few of many examples of physicians integrating CAM with traditional (Western) medical treatments.

### What Are the Most Common CAM Therapies?

Given that approximately 800 CAM therapies exist, it is helpful to categorize them. NCCAM’s five categories of therapies are described below.

- Whole body systems are complete sets of theories and practices that act independently of traditional Western medicine. These include homeopathy, naturopathy and traditional Chinese medicine.
- Mind-body medicine seeks to improve the mind’s control over the body. Through techniques such as meditation,



biofeedback and hypnosis, mind-body medicine seeks to improve function and reduce symptoms. Increasingly, mind-body medicine is being integrated into traditional Western therapies for chronic pain syndromes, other chronic illnesses and cancer.

- Biologically based practices seek to improve health and wellness with things found in nature (such as herbs, foods and vitamins). The difference between biologically based CAM and traditional medicine is that the efficacy and safety of biologically based CAM practices have not yet been scientifically established.
- Manipulative and body-based practices actively move the body (for example, the way a chiropractor would ➤

<sup>1</sup> Soni A, Statistical Brief #179: Aspirin Use Among the U.S. Non-institutionalized Population, With and Without Indicators of Heart Disease 2005, Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, July 2007.

<sup>2</sup> Goldrosen MH and Strauss SE. Complementary and Alternative Medicine: Assessing the Evidence for Immunological Benefits, *Nature Reviews Immunology* 4, 912-921 (November 2004) | doi:10.1038/nri1486.

<sup>3</sup> NCCAM website: <http://nccam.nih.gov/health/whatisacam>.

<sup>4</sup> Dana Farber website: [www.dana-farber.org/pat/support/zakim/default.html](http://www.dana-farber.org/pat/support/zakim/default.html).

<sup>5</sup> UCLA Collaborative Centers for Integrative Medicine website: [www.ccim.med.ucla.edu/clinical/index.html](http://www.ccim.med.ucla.edu/clinical/index.html).

## Where Can You Research CAM Therapies?

### NCCAM Hotline

Toll-free: 888-644-6226

International: 301-519-3153

Website: <http://nccam.nih.gov>

The hotline and website both provide an enormous volume of information about CAM therapies and up-to-date research results.

### PubMed

Website: [www.ncbi.nlm.nih.gov/sites/entrez](http://www.ncbi.nlm.nih.gov/sites/entrez)

A government-sponsored website where you can find publications of specific experimental and clinical trials. If you have questions about a specific treatment, PubMed is a great place to investigate. Potential dangers of specific therapies may show up before potential benefits, which can help you to avoid experimenting on yourself with therapies that might cause harm.

extend a joint or a physical therapist would stimulate a muscle) and are frequently combined with other therapies. Osteopaths, relatively holistic practitioners of Western medicine, frequently use manipulation in treating their patients.

- Energy therapies involve the use of energy fields, of which there are two kinds: biofield therapies and bioelectromagnetic-based therapies. Biofield therapies are intended to affect energy fields that purportedly surround and penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy manipulate biofields by applying pressure or manipulating the body by placing the hands in, or through, these fields. Examples include qi jong, reiki and therapeutic touch. Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating-current or direct-current fields. (Please note: This area is especially experimental.)

## What Role Can CAM Play in Promoting Health?

CAM can play a significant role as adjunct therapy for chronic illness. Additionally, some herbal remedies (or nutraceuticals) show promise as therapy for many conditions, and may even have potential to stimulate or support the immune system. (See *Current Nutraceutical Research*, Page 30.) Biofeedback, meditation and hypnosis may mediate the stress of caregiving. These types of CAM also may alter the perception of pain, making it easier to handle. This area—mind-body techniques to boost coping skills and to help with stress or pain management—is one of the least controversial uses of CAM. As Dr. Anne Harrington, medical historian and author of “The Mind-Body Cure” says, “I think it can change [patients’ and caregivers’] relationship to their suffering. And, I do not think that is a small thing.”

It is well documented that stress can reduce the immune response. For example, researchers at Ohio University found that caregivers of Alzheimer patients had four times the level of interleukin-6 (IL-6, a specific protein that is critical to immune response) as their non-caretaking counterparts. Increased IL-6 levels are associated with increased risk for heart disease, arthritis, osteoporosis, type II diabetes and certain cancers. But, is the reverse true? Can reducing stress boost our immune system? Initial data are interesting.

In 2003, researchers from the UCLA Cousins Center for Psychoneuroimmunology found that training adults in tai chi increased their cell-mediated immunity to varicella-zoster virus (which remains in the system after a person has



chickenpox, and can later cause outbreaks of shingles).<sup>6</sup> But many other studies have not shown an impact on the immune system. While mind-body techniques clearly play a role in immune system functioning, that role has not been defined. Research is still in its infancy.<sup>7</sup>

The same is true for the role of mind-body therapies in pain control. In 1981, Donna Wong and Corinne Baker began developing the now ubiquitous Wong-Baker pain management chart, allowing children to use happy, neutral and sad faces to evaluate their pain.<sup>8</sup> Today, it is used with adults and children alike, allowing patients to more accurately describe their pain and to become active participants in pain control. In 2007, pain management advocates introduced a National Pain Care Act into the U.S. House of Representatives to address the barriers to proper treatment by improving coordination of pain research, healthcare practitioner education and public awareness.<sup>9</sup> As patients have become more active in their pain management and advocates have increased awareness of the need for more accessible pain control, the scientific community has turned more attention to CAM therapies.

A 2007 review of CAM therapies for pain management found mixed evidence for the use of acupuncture in fibromyalgia, osteoarthritis and neck pain, as well as mixed evidence for the role of spinal manipulation in lower back pain. The same review, however, found significant evidence that mind-body therapies may play a supportive role in management of pain related to various forms of arthritis.<sup>10</sup> Other studies, not mentioned in the review article, also support the efficacy of mind-body therapies in reducing pain. Results of one intriguing study, published in 2006, suggest that long-term, daily meditation may help calm your brain during sudden pain.<sup>11</sup>

This is not to suggest that meditation alone can control



pain. At this point, research simply indicates that meditation and other mind-body techniques might help one cope with the sensation of pain. Dr. Harrington cautions care in generalizing results. "It is important to appreciate that this hunger for certainty ... does have the effect sometimes of turning mind-body medicine into a field that ... is driven by promises. Or, that promises prematurely because people ➤

<sup>6</sup> Irwin MR, Pike JL, Cole JC, Oxman MN, Effects of a Behavioral Intervention, Tai Chi Chih, on Varicella-Zoster Virus Specific Immunity and Health Functioning in Older Adults, *Psychosomatic Medicine*, 2003 Sep-Oct;65(5):824-30.

<sup>7</sup> Goldrosen MH, and Strauss SE, Complementary and Alternative Medicine: Assessing the Evidence for Immunological Benefits, *Nature Reviews Immunology* 4, 912-921 (November 2004) | doi:10.1038/nri1486.

<sup>8</sup> Wong D. Wong on Web at [www3.us.elsevierhealth.com/WOW/faces.html](http://www3.us.elsevierhealth.com/WOW/faces.html).

<sup>9</sup> Although it has been endorsed by 37 representatives and is supported by more than 100 organizations, it has not yet been scheduled for debate. See GovTrack.us. H.R. 2994—110th Congress (2007): National Pain Care Policy Act of 2007, *GovTrack.us (database of federal legislation)* <[www.govtrack.us/congress/bill.xpd?bill=h110-2994](http://www.govtrack.us/congress/bill.xpd?bill=h110-2994)> (accessed April 25, 2008) and [www.theacpa.org/documents/Pain%20Care%20Act%202007.pdf](http://www.theacpa.org/documents/Pain%20Care%20Act%202007.pdf) and <http://www.painfoundation.org/page.asp?file=action/NPCPA.htm>.

<sup>10</sup> Khatta M, A Complementary Approach to Pain Management. *Topics in Advanced Practice Nursing eJournal*. 2007;7(1) ©2007 Medscape Posted 05/30/2007 at [www.medscape.com/viewarticle/556408\\_print](http://www.medscape.com/viewarticle/556408_print).

<sup>11</sup> Ghitti M, Meditation May Help Brain Handle Pain: Five Months Meditation May Cut Brain's Pain Response, Study Shows. *WebMD Medical News* 8-9-2006 online at [www.webmd.com/news/20060809/meditation-may-help-brain-handle-pain](http://www.webmd.com/news/20060809/meditation-may-help-brain-handle-pain).

## Examples of Treatment Systems<sup>12</sup>

**Ayurveda:** A system of medical practice that developed in India thousands of years ago. It aims to integrate and balance the body, mind and spirit, which is believed to lead to contentment and health and to help prevent illness. A chief aim of ayurvedic practices is to cleanse the body of substances that can cause disease, and this is believed to help re-establish harmony and balance.

**Holistic:** Relating to or concerned with complete systems rather than with the analysis of, treatment of, or dissection into parts. Holistic medicine attempts to treat both the mind and the body, and holistic ecology views humans and the environment as a single system.

**Homeopathy:** A system of medical practice that treats a disease by administering minute doses of a remedy that would produce symptoms similar to those of the disease in healthy persons.

**Integrative Medicine:** Also called integrated medicine, this combines treatments from conventional medicine and CAM.

**Naturopathy:** Avoids drugs and surgery and emphasizes the use of natural agents (such as air, water and herbs) and physical means (such as tissue manipulation and electrotherapy).

**Osteopathy:** Based on the theory that diseases are due chiefly to loss of structural integrity, which can be restored by manipulation of the parts supplemented by therapeutic measures (such as drugs or surgery).

**Psychoneuroimmunology:** A branch of medicine that deals with the influence of emotional states (such as stress) and nervous system activities on immune function in relation to the onset and progression of disease.

are so hungry for certainty that sometimes [the field] is not in a position to provide.”

Prakash Nagarkatti, director of the Center for CAM Research on Autoimmune and Inflammatory Diseases (funded by NCCAM to study the potential applications of nutraceuticals to immunology) urges that patients be informed consumers. Since physicians may be less informed about CAM treatments, it is crucial that people do their own research.

### Concerns About CAM

Unexamined techniques and therapies should not substitute for Western medicine, especially in a medically vulnerable population. In 1979, when Norman Cousins wrote that he had laughed his cancer away,<sup>13</sup> the belief in our ability to heal ourselves by controlling our beliefs and emotions was popularized. But, although his story galvanized awareness of holistic medicine, and helped spur the integration of holistic techniques into traditional biomedical therapies,<sup>14</sup> he may unwittingly have caused many to forsake their traditional cancer treatments with devastating, unintended consequences.

“To the extent that he made it look easy, you just laughed your way back to health, perhaps that put a burden on people. I think that is the thing that people need to appreciate about this whole world is that it is not just a sunny place ... It is complicated, and there are shadows cast by each of these developments. And we kind of expect that with mainstream medicine, but maybe we expect our mind-body medicine to just be about happy things,” Dr. Harrington says.

Complementary medicine and alternative medicine may supplement and even possibly replace traditional medical techniques, but we should not assume that they are inherently any simpler, safer or more proven.

Dr. Nagarkatti cautions, “I think one of the things I would stress [is that] physicians are not aware to what extent the CAM therapies are so popular.” Additionally, patients may be reluctant or embarrassed to disclose their use of CAM. But, this can be dangerous, as in the case of St. John’s wort, an herbal remedy used to treat depression. Clinical trials showed that St. John’s wort did little to treat true depression, but did in fact interact

<sup>12</sup> References from NCCAM and *The Merriam-Webster Dictionary*.

<sup>13</sup> Cousins, Norman: *Anatomy of an Illness as Perceived by the Patient*, Bantam Books, 1981 (copyrighted 1979).

<sup>14</sup> Anne Harrington, interviewed by the author, 4/16/08.

## Examples of Complementary and Alternative Medicine Techniques<sup>15</sup>

**Acupuncture/Acupressure:** Used in China and other Asian countries for thousands of years, acupuncture aims to restore and maintain health through the stimulation of specific points on the body. Few side effects have been noted when it is administered by an experienced practitioner.

**Biofeedback:** The technique of making unconscious or involuntary bodily processes (such as heartbeats or brain waves) perceptible to the senses (such as by the use of an oscilloscope) in order to manipulate them by conscious mental control.

**Massage:** Massage as CAM involves manipulating the muscles and other soft tissues of the body. It does not appear to have side effects if performed by a professional therapist.

**Meditation:** A variety of techniques or practices intended to focus or control attention that may be religious or secular in principle. Mindfulness based stress reduction (MBSR) is a specific (secular) application of meditation designed to reduce stress and improve health and well-being.

**Nutriceuticals:** A class of agents advertised as having nutritional value as well as having an effect on biologic functions.

**Prayer:** Many CAM therapies have a spiritual component, and there is a long history of people praying for their own or others' health. Prayer is probably the most commonly used form of CAM.

**Qi Gong:** A component of traditional Chinese medicine that combines movement, meditation and controlled breathing. The intent is to improve blood flow and the flow of qi, a proposed vital energy that flows throughout the body.

**Reiki:** A therapy in which practitioners seek to transmit a universal energy to a person, either from a distance or by placing their hands on or near that person. The intent is to heal the spirit and thus the body.

**Tai Chi:** A mind-body practice that originated in China as a martial art. A person doing tai chi moves the body slowly and gently, while breathing deeply and meditating. Many practitioners believe that tai chi helps the flow of qi.

**Therapeutic Touch:** A therapy in which practitioners pass their hands over another person's body with the intent to use their own perceived healing energy to identify energy imbalances and promote health.

dangerously with many prescription medications—limiting the efficacy of everything from heart medications and birth control to HIV and cancer therapies. In addition to interacting with other medications, Dr. Nagarkatti worries that unproven herbal remedies might have their own side effects. He specifically mentions ephedra, a dietary supplement used to enhance energy and to stimulate weight loss that has been linked to heart problems and strokes.

Because of these concerns, Dr. Nagarkatti is part of an

effort to introduce CAM awareness into the medical school curriculum. His goal is to foster patient-physician dialogue. If physicians are aware of current CAM research, they could potentially prescribe CAM remedies to great benefit. For example, he mentions the Age-Related Eye Disease Study (AREDS), a clinical trial sponsored by the National Institutes of Health, which found that high levels of antioxidants and zinc significantly reduce the risk of advanced age-related macular degeneration (AMD) and ➤

<sup>15</sup> References from NCCAM, WebMD, and *The Merriam-Webster Dictionary*.

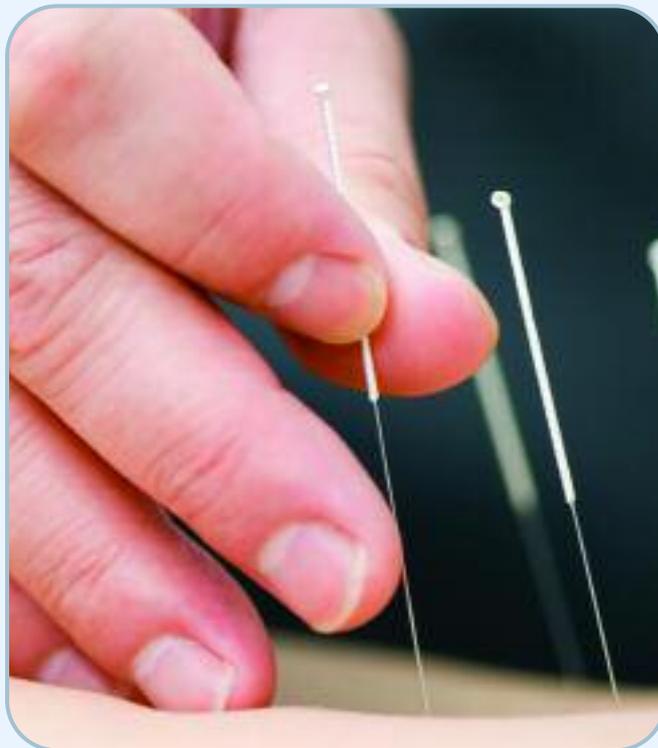
## Current Nutraceutical Research

Prakash Nagarkatti, director of the Center for CAM Research on Autoimmune and Inflammatory Diseases, leads a group that uses animal models to learn how to prevent or arrest inflammation when the immune system breaks down. His lab is specifically looking at resveratrol, a compound in the skin of red grapes, as a possible therapeutic aid in multiple sclerosis. His center is also looking at the anti-inflammatory mechanisms of the herb American ginseng in colitis and the actions of a compound from hemp in treating autoimmune hepatitis. He is very optimistic that with scientific study, these compounds may complement or even replace traditional therapy. “Our goal is, for example, that compounds like resveratrol that we can identify ... might complement the existing treatment modality—so that you could take the existing low dose, but along with the extract, you could potentially feel very well and you might find significant relief from pain and aches.” He adds: “The other possibility is that once we have identified the mechanism ... we could purify the resveratrol in large quantities or we could synthesize the molecules that mimic resveratrol in the lab or in an industrial setting,” making it possible to synthesize a more natural anti-inflammatory that would not carry the same risks or have the same side effects as some of the more commonly used and prescribed anti-inflammatories. But, he cautions that research is still experimental, and patients should consult with their physicians before deciding on any course of treatment.<sup>16</sup>

its associated vision loss.<sup>17</sup> Previously, there had been no treatment. “Lots of nutraceuticals have introduced those ingredients, and it really does help our patients.” Other studies have examined Chinese herbal remedies, and found indications that they can complement treatment of dysmenorrhea (a condition in which young women experience severe pain with menstruation) and may even complement treatment of type II diabetes.<sup>18</sup>

### Where Does All This Leave Us?

Complementary and alternative medicine is not a discrete entity. Rather, it is a patchwork of therapies, techniques and medical models, each of which needs to be individually evaluated. If you are currently using traditional medical therapies, some CAM remedies might complement your care. But, ultimately, you need to do your own research and work with your physician to determine the safest and most effective treatment for *you*. ■



<sup>16</sup> Prakash Nagarkatti, interviewed by the author 4/9/2008.

<sup>17</sup> National Eye Institute: Results of the Age-Related Eye Disease Study online at: [www.nei.nih.gov/amd](http://www.nei.nih.gov/amd).

<sup>18</sup> Zhu X, Proctor M, Bensoussan A, Smith CA, Wu E, Chinese Herbal Medicine for Primary Dysmenorrhea, *Cochrane Database of Systemic Reviews*. 2007; Issue 4. Article No. CD005288.



# Let's Talk!

By Shirley German Vulpe, EdD

If your life depends on immune globulin, this column is for you! It is an opportunity to network and share our experiences, because it behooves us to learn as much as possible about all of the ramifications of our illnesses. This column allows us to learn from one another. If you have a story you'd like to share, please email us at [editor@igliving.com](mailto:editor@igliving.com).

In this column of the "Let's Talk!" series, I interviewed 45-year-old Jordana Denslow. Jordana has multiple sclerosis (MS), an autoimmune neurological disorder. The immune system mistakenly destroys cells that protect nerves, causing sclerosis. This damage results in malfunction of nerves to any and all parts of the body. The cause is unknown, but genes and viral infections play a role in the cause and course of the disease. The disease affects people differently. It can be controlled for years, have periods of remission or be unrelentingly progressive.

**Shirley:** Thank you for the interview. When were you diagnosed with MS?

**Jordana:** About 20 years ago, in my 20s.

**Shirley:** How was the diagnostic process?

**Jordana:** Upsetting, my eyes were acting up. I went to an eye doctor. He said he thought I had a brain tumor and referred me to a neurologist. He ordered an MRI and told me I had MS.

**Shirley:** Any treatment recommended?

**Jordana:** Yes, I gave myself Copaxone shots daily for years. My treatments changed after I had my two children. My son is 22 now and my daughter is 13. My memory is bad so I forget things.

**Shirley:** No problem, what is your treatment now?

**Jordana:** Now for my MS I receive IVIG once a month, for five days, 30 grams a day. I also get IV steroids every other month. Six years ago, daily Copaxone was replaced by weekly Avonex injections. I have a lot of pain associated with the MS and take 20 milligrams of Baclofen for the pain and spasticity. I do not like to take medicines, so I lowered my dose. Motrin sometimes helps pain. I also take medications for migraines, high blood pressure, low thyroid hormones and something to help me sleep.

**Shirley:** What other symptoms of MS do you have?

**Jordana:** I have lost my taste buds; chocolate and coffee are all I taste. Now my family decides the menu and I don't care. I have sensory loss in my fingers and am unaware of hurting myself. I can do most things for myself but have low endurance and tire easily. I have an electric wheelchair that I use for outings. A wonderful group of businessmen got it for me. The problem that bothers me most is my bad memory. It really is a nuisance. Like I can't remember the name of that men's group.

**Shirley:** Have you had any problems receiving or paying for the IVIG?

**Jordana:** My insurance pays for it, but it's a constant battle to arrange for the nurse to get it on time. My other problem is access. Sometimes they have to stick me 14 times. They want me to have a port but I don't

want one. I have been wondering if those subcutaneous IG treatments would work for me?

**Shirley:** Have you checked with your doctor?

**Jordana:** I will.

**Shirley:** What has helped you cope with your illness most?

**Jordana:** God, family support, attitude and a sense of humor. I focus on taking care of today and the positive. I can't change yesterday. I think there is always a bright and/or humorous side to everything. I am a stubborn fighter, even though I wake up in pain and go to bed in pain, less drugs are better. I give everything up to God's strength, wisdom and power, pray a lot, and give thanks for good things I have been given. ■

## Resources

1. Information about multiple sclerosis can be found at [www.mayoclinic.com/health/multiple-sclerosis/DS00188](http://www.mayoclinic.com/health/multiple-sclerosis/DS00188).
2. Online peer support can be found at [www.FriendsWithMS.com](http://www.FriendsWithMS.com) Forum: <http://health.groups.yahoo.com/group/FriendsWithMS>.

# IgA Content in IVIG Products

## What Is the Real Concern Regarding Anaphylactic or Anaphylactoid Reactions?

By Chris Lomax, PharmD

### Introduction

Human intravenous immune globulin (IVIG) products contain a range of antibodies that are purified from pooled batches of plasma from thousands to tens of thousands of donors. In addition to IgG antibodies, which constitute the largest percentage of antibodies, IVIG products also contain various amounts of IgM and IgA antibodies. Of these latter antibodies, IgA has garnered the most attention in terms of the potential for anaphylactic or anaphylactoid reactions. Some IgA deficient patients can experience anaphylactic or anaphylactoid reactions when given IVIG products that contain moderate amounts of IgA. The question is how relevant this concern is for the majority of IgA deficient patients.

### Discussion

Anaphylactic or anaphylactoid reactions can occur in any patient receiving IVIG therapy, although the overall incidence is relatively low.<sup>1</sup> The majority of these reactions are more appropriately described as anaphylactoid in that they are slowly progressing reactions that usually begin with a patient complaining of tightness in the chest, difficulty breathing and accompanied with increases in heart rate and blood pressure. Administration of intravenous antihistamines and corticosteroids will generally reverse the reaction and, in some cases, the IVIG administration can be safely resumed.<sup>1,2</sup> Unlike a true anaphylactic reaction, the administration of epinephrine is often unnecessary.

Selective IgA deficiency is the most common primary immunoglobulin deficiency and occurs in approximately one in 600 individuals in the Western world.<sup>3</sup> Early researchers determined that severe anaphylactoid or anaphylactic reactions to IVIG were most likely to occur only in patients who are severely deficient of IgA (<1.2 mg/dl) and who have anti-IgA antibodies of the IgE type.<sup>4-6</sup> More recently, Horn and co-workers<sup>7</sup> attempted to determine what other factors might be present in those patients who experienced anaphylactoid reactions to IVIG. They found that a correlation existed in those patients who (1) had a complete absence of serum IgA and (2) had an absence of IgA-positive B cells—although they noted that the presence of these markers was not absolute.

IgA antibodies of the IgG type can be present in up to 40 percent of patients with selective IgA deficiency and up to 10 percent of patients with common variable immune deficiency (CVID).<sup>7</sup> The presence of IgA antibodies of the IgG type does not predispose IgA patients to experiencing anaphylactic or anaphylactoid reactions when administered IVIG containing moderate amounts of IgA.<sup>1,6,8</sup>

When Horn and co-workers reviewed the literature for CVID patients with an IgG anti-IgA-associated anaphylactoid reactions, they found only six cases.<sup>2</sup> Because the incidence of these reactions is so rare, there is no clear consensus as to whether or not routine screening for IgA deficiency should be performed before IVIG therapy is begun.<sup>1</sup> Currently available IVIG products, with the exception of Gammagard® S/D, contain moderate levels of IgA (<25-720 mcg/ml). There has never been a study that has demonstrated that IVIG-related side effects increase with increasing levels of IgA in the various brands of IVIG. Therefore, the tolerability of individual IVIG products would appear to be dependent on other factors than IgA content.

*There has never been a study that has demonstrated that IVIG-related side effects increase with increasing levels of IgA in the various brands of IVIG. Therefore, the tolerability of individual IVIG products would appear to be dependent on other factors than IgA content.*

### Treatment of Patients With IgA Deficiency

Although all IVIG manufacturers' package inserts list selective IgA deficiency as a contraindication for their use, IVIG products are frequently prescribed in these patients, as many of them also have IgG subclass deficiencies. In such cases, IVIG has been safely used in a large number of IgA deficient patients. In those IgA deficient patients who experience anaphylactic or anaphylactoid reactions to IVIG products with moderate amounts of IgA, Cunningham-Rundles and co-workers demonstrated that most of those patients could be safely given an IVIG product with low levels of IgA (0.4-2.9 mcg/ml). In their study they administered Gammagard® 5% (immune globulin intravenous [human]) manufactured by Baxter Healthcare to five subjects who had IgA antibodies and had previously experienced severe infusion reactions to IVIG products with moderate levels of IgA (270–720 mcg/ml). These reactions included severe myalgias, shortness of breath and chest pain, fever, severe abdominal pain, and/or hypotension. They followed five

patients for a total of 170 infusions and found only mild to moderate infusion reactions in nine of the 170 infusions (5.3%).

A number of researchers demonstrated similar results when immune globulin was administered subcutaneously.<sup>9-13</sup> They found that patients who experienced anaphylactic or anaphylactoid reactions to IVIG products could tolerate subcutaneously administered immune globulins. There is even evidence to suggest that subcutaneously administered immune globulin therapy may reduce the level of IgA antibodies in the serum—a fact not seen when IgA depleted IVIG is utilized.<sup>12</sup> A third but more complicated option was reported by Salama and co-workers.<sup>14</sup> In this case report, a 40-year-old patient who experienced anaphylaxis with Octagam® (immune globulin intravenous [human]), an IVIG formulation manufactured by Octapharma and containing <100 mcg/ml of IgA, was successfully treated with the same product after it was mixed with freshly separated autologous plasma.

## Conclusions

Many patients with IgA deficiency require IVIG therapy. While most patients, even those with anti-IgA antibodies, will tolerate most IVIG products, alternative options are readily available. The use of low IgA IVIG products or subcutaneously administered immune globulin products can often be safely administered to those patients who experience anaphylactic or anaphylactoid reactions to IVIG products containing moderate amounts of IgA. In fact, anaphylactic and anaphylactoid reactions can occur in any patient receiving IVIG products; clinicians need to be aware of this and be knowledgeable in the treatment of these reactions. ■

*Chris Lomax is the director of pharmacy and nutrition services at Children's Hospital Los Angeles.*

---

## Reference List

1. Orbach H, Katz U, Sherer Y, Shoenfeld Y. Intravenous Immunoglobulin: Adverse Effects and Safe Administration. *Clinical Reviews in Allergy and Immunology*, 2005;29(3):173-84.
2. Horn J, Thon V, Bartonkova D et al. Anti-IgA Antibodies in Common Variable Immunodeficiency (CVID): Diagnostic Workup and Therapeutic Strategy. *Clin Immunol*, 2007 February;122(2):156-62.
3. Hammarstrom L, Vorechovsky I, Webster D. Selective IgA Deficiency (SIgAD) and Common Variable Immunodeficiency (CVID). *Clin Exp Immunol*, 2000 May;120(2):225-31.
4. Burks AW, Sampson HA, Buckley RH. Anaphylactic Reactions After Gamma Globulin Administration in Patients With Hypogammaglobulinemia. Detection of IgE Antibodies to IgA. *N Engl J Med*, 1986 February 27;314(9):560-4.
5. Ferreira A, Garcia Rodriguez MC, Lopez-Trascasa M, Pascual SD, Fontan G. Anti-IgA Antibodies in Selective IgA Deficiency and in Primary Immunodeficient Patients Treated with Gamma-Globulin. *Clin Immunol Immunopathol*, 1988 May;47(2):199-207.
6. De Albuquerque CR, Sato MN, da Silva Duarte AJ. IgG Anti-IgA Subclasses in Common Variable Immunodeficiency and Association With Severe Adverse Reactions to Intravenous Immunoglobulin Therapy. *J Clin Immunol*, 2000 January;20(1):77-82.
7. Cunningham-Rundles C, Zhou Z, Mankarious S, Courter S. Long-term Use of IgA-Depleted Intravenous Immunoglobulin in Immunodeficient Subjects With Anti-IgA Antibodies. *J Clin Immunol*, 1993 July;13(4):272-8.
8. Ferreira A, Garcia Rodriguez MC, Fontan G. Follow-up of Anti-IgA Antibodies in Primary Immunodeficient Patients Treated With Gamma-Globulin. *Vox Sang*, 1989;56(4):218-22.
9. Berger M. Subcutaneous IgG Therapy in Immune Deficiency Diseases. *Immune Deficiency Foundation*, 2008 February;(13).
10. Kirmse J, Weiler CR. Subcutaneous Immunoglobulin (SCIG) Therapy: Review of 51 Patients. *J Allergy Clin Immunol* 117[2], S86. 2006. Ref Type: Abstract
11. Stiehm ER, Casillas AM, Finkelstein JZ et al. Slow Subcutaneous Human Intravenous Immunoglobulin in the Treatment of Antibody Immunodeficiency: Use of an Old Method With a New Product. *J Allergy Clin Immunol*, 1998 June;101(6 Pt 1):848-9.
12. Sundin U, Nava S, Hammarstrom L. Induction of Unresponsiveness Against IgA in IgA-Deficient Patients on Subcutaneous Immunoglobulin Infusion Therapy. *Clin Exp Immunol*, 1998 May;112(2):341-6.
13. Misbah S. Intravenous Immunoglobulin in the Guillain-Barre Syndrome. Products With Low IgA Content May Be Used in Patients With Total IgA Deficiency. *BMJ*, 1996 November 30;313(7069):1400.
14. Salama A, Temmesfeld B, Hippenstiel S, Kalus U, Suttorp N, Kiesewetter H. A New Strategy for the Prevention of IgA Anaphylactic Transfusion Reactions. *Transfusion*, 2004 April;44(4):509-11.

# Rush Hour on the Bay Bridge

By Ever Fecske



**A**s we checked into our room, Jim couldn't stop giggling, and I couldn't stop thinking about what had just happened. I was still in disbelief. Maybe it was some kind of prednisone nightmare?

*I wish, but it wasn't. It was just another part of life when living with a chronic illness. Anyone who lives with one knows that mishaps go along with it. I know I do.*

*And this particular mishap—which occurred on a bridge—would best be described as toilet humor, save for one major problem: It wouldn't have happened if there had been a toilet.*

In the midst of the chaos of life, my boyfriend, Jim, decided that we needed an escape, so he planned a road trip to San Francisco. He rented a Ford Focus for its good gas mileage and booked us three nights at the Hyatt by Fisherman's Wharf.

I was excited to get away for a romantic, relaxing time. But in the back of my mind, I was concerned about the long road trip. The thought of being in a car for six hours not knowing where there might be a restroom shook my nerves.

The drive went well. Singing to the Rent soundtrack almost the whole way, we ate an array of road-trip food: beef jerky, caramel creams, and my favorite—spicy Cheetos!

But the best part was that for the first five hours and 45 minutes I didn't have to use the bathroom. I was so proud of myself as we neared the homestretch.

Once we paid the Bay Bridge toll, all we had to do was cross. After handing over \$4, we entered bumper-to-bumper traffic. It was then that a sudden nervous sensation came over me along with a wave of cold heat. Everything in my body was moving downward.

In a quiet concerned voice, I turned to Jim and said, "I think I have to go." Jim just looked at me in horror. "You have to go? What do you mean you have to go?"

"I mean I have to GO! I don't know what to do... what should I do? I'm freaking out! OK, OK maybe I don't have to... it's going away. Oh no, it's back!" I hollered as I rocked back and forth, trying to convince my body to wait five more minutes, just five more minutes. The beads of sweat were now breaking out on my forehead.

Jim then informed me half-jokingly, "Well, if you have to go *that* bad, there's a bag in the backseat."

"What? Are you kidding me?" I said in my cold sweat while the traffic on the bridge stood still. "I could never do that, that's ridiculous... OK maybe I will, I think maybe I have to... no, no I can wait... oh god I can't wait... ahhhhhhh!" My body wouldn't listen. Trying to digest World War III, I became blinded by pain. The cramps were only getting worse.

It was then that I began to climb into the backseat to search for the bag. As my body cramped and my mind was clouding, Jim advised me to try to keep my composure.

Composure! I have a watermelon pushing my innards and you want me to be composed?

The squeamish should skip ahead.

I picked up an empty plastic grocery bag on the car floor, but it had a hole in it... GRRR... I picked up another plastic bag full of the trash from the food we had consumed that was now causing all the problems. As my muscles began to shake and my vision blurred, I put all the trash into the bag with the hole in it as quickly as possible. I knew I didn't have much time.

I then pushed all the clutter on the backseat as far to the left side of the seat that I could and proceeded to situate

myself. I looked out the tinted window to make sure no one was looking and began to strip off my clothing as fast as I could. I was committed now to relieving my pain. With my bum hovering over the seat I held the bag under me and... BLLLLLLLLLAAAAAAA... As embarrassing as it might seem—I can't deny it—I felt relief.

Just as I was beginning to clean up I heard a guttural dry heave from the front seat... mixed with laughter. It sounded something like "hhhuuuuuuggggggghhhh... hahahahahahaha." Jim was doing his best to keep his stomach in place and not upheave his snacks. Oh no! I was making my boyfriend physically sick!

This was NOT how I pictured our romantic getaway.

OK, this could have happened to anybody, but because it happened to me, it goes hand in hand with having a chronic illness. Now, you may be thinking "I can't believe she actually told this story." Well believe it, because the incident didn't ruin our trip. Granted, we got to know each other a little better than expected—but we turned the bad into good.

The fact is, the rest of the weekend was great. San Francisco gave us plenty of amazing experiences to revitalize our senses, including buttery crab, Ghirardelli's wafting chocolate, and the ocean's salty breeze. And romance was not lost. I can still taste the raspberry martini and chicken ceasar salad from our fancy candlelight dinner at the Ritz-Carlton. And then there's my favorite memory—walking up the steep hills and seeing the cool houses so unlike those in Southern California.

Now, if I'd dwelled on the negative, the rest of the trip may not have been so great. But unfortunate events happen, and I wasn't about to dwell on this one. If I had, it would have carried over to the next day. And the day after.

The truth is, everybody is handed things in life that they don't particularly love or that are embarrassing. But you have to cope with them, and learning how will strengthen your quality of life.

For me, laughter helps. It's medicine—even when at *my* expense. No wonder, then, the bridge incident was the running joke over the rest of the weekend. It even came up once or twice on the way home, which, you'll be pleased to know, was without incident. ■

# Just a ‘Normal’ Teenage Life

By Jim Trageser

Emily Ernst is starting college this fall, joining millions of others in a milestone rite of passage. But Emily (profiled in *IG Living* in June-July 2006) is not a typical freshman. Nor was she a typical high school senior. Some two years younger than most seniors, she completed four years on the swim team, was first vice president of the Kentucky Latin Club, took advanced placement biology, was editor of the school newspaper, and was a Kentucky Governor’s Scholar.

When you add to her already impressive resumé that Emily has a primary immune deficiency disease—chronic variable immune deficiency (CVID)—and has been self-administering immune globulin for six years, her success might seem, well, remarkable.

But to Emily, it’s just a normal teenage life.

“There’s a school in my area that, if you get accepted after passing entrance exams, you skip one to two grades,” she said by phone from her home in the northern Kentucky suburbs of Cincinnati, Ohio. “So my whole graduating class is 16 years old.”

Emily received immune globulin intravenously (IVIG) since her original diagnosis at 3 and a half, but, she said, it was her switch to subcutaneous treatment (SCIG) that allowed her to succeed academically.

“The IVs were supposed to keep me healthier, but they weren’t,” she explained. “I missed 27 days one year in elementary school. The most days I’ve missed [since starting SCIG] is seven. When I went on the subcutaneous, that’s what allowed me to switch schools and to go directly from fifth to eighth grade.”

If changing to SCIG was relatively easy, Emily’s mother, Carol, an infusion specialist at BioRx, a specialty pharmacy, said getting a diagnosis for Emily was a struggle. Doctors at one point suggested that Emily’s only problem was a crazy mother.

“She was in the hospital for the first time when she was 5 weeks old, for bronchiolitis. By the time she was a year old, I knew there was something wrong with her because she’d had numerous infections.”

When Emily was 2, her sister, Elizabeth, was born.

Carol said Emily’s poor health was made clear by the contrast in the health between the siblings. “Emily was always sick; Elizabeth was never sick.”

Even as a registered nurse, Carol received no satisfactory answers from Emily’s pediatrician about her daughter’s unexplained illnesses. This was in the early 1990s, before the Internet made medical information accessible. Still, Carol and her husband believed something was wrong with Emily’s immune system, based on her recurring infections. But when they took Emily to her regular doctor, he kept saying she was fine.

“They really weren’t doing anything. They kept saying, ‘Well, there’s nothing wrong; she just keeps getting sick.’”

They finally insisted the doctor test Emily’s immune system.

“Basically we demanded that there was something wrong with her immune system. The nurse took Emily from me and said the doctor wanted to see me in private. He proceeded to tell me that I needed counseling, that my actions were possibly making her sick. I thought they were going to call Child Protective Services on me,” Carol recalled. “We switched pediatricians at that point.”

But they were no closer to finding out why she was always getting sick. “By the time she was 3, we changed pediatricians again.”

Their health insurance situation added to their frustration.

“We had an HMO, so we couldn’t take her to a specialist



Emily practices piano while infusing.

Photographs by D.A. Fleischer



without a referral,” Carol said. “The third pediatrician finally listened to me, and sent her to an allergist. But she [the allergist] didn’t think anything was wrong either.”

At that point, Carol was able to access the University of Cincinnati Medical Library, where she began researching Emily’s symptoms. Supported by documentation, she again

raised the issue of an immune disease with Emily’s third pediatrician—and he ordered tests, which confirmed their hunch about the cause of their daughter’s constant illness.

Finally with a diagnosis in hand, they sought proper treatment for Emily, but they were stymied, again by their insurance company.

“They didn’t want to put her on IVIG—they wanted to put her on six months of antibiotics.” But Carol pointed out, “She’d been on antibiotics her whole life” and was still constantly sick.

“We went up the whole chain of the HMO, and finally demanded to see the medical director. They didn’t want to give me an appointment, but I said, ‘He can’t refuse to see me.’ He needed to know she’s not a case number. She’s a thriving, breathing 3-and-a-half-year-old, and there’s a treatment out there for her.”

Though Carol never did meet her HMO’s medical director, Emily had her first infusion two days later.

As Emily began to improve on IVIG treatment, Carol said they nurtured her and her younger sister with the same philosophy.

“From day one, we’ve raised both our girls to believe there’s nothing they can’t do. If there’s something she wants to do, she can do it.”

As for the CVID?

“It’s part of our lives, but it’s not the focus of our lives.”

Still, Emily has bad asthma in addition to her CVID, and despite her success on the swim team, she wasn’t always

able to be active—which Carol thinks contributed to her daughter’s academic success.

“She’s highly intelligent, but I do think a lot of it is because she was an avid reader as a kid because she was sick so much. She’s always been a bright, inquisitive kid, wanting to learn.”

Although Carol and her husband felt isolated during their long struggle for a diagnosis and treatment, Carol said it’s easier today with the Internet. The amount of information available helps, as does the fact that the Internet provides a forum for support groups with others in the same situation. According to Carol, motivation was never a problem. “I think it comes naturally to advocate for your own child. When you see your child is sick, you want to do something.”

For other parents with a chronically sick child, Carol said the first thing to remember is “to just not take ‘no’ for an answer.” And she emphasized confrontation with your doctor or insurance company should be the last resort.

“I really found that old adage that you catch more flies with honey than vinegar to be true. A lot of times, if you just explain things—especially to insurance companies. ... They’re processing claims; they don’t know what you’re going through. A lot of times, if you just say, ‘Give me five minutes to explain,’ they really listen.”

She also said that a proper diagnosis and treatment will often cost less over the long run than quick-fix approaches that don’t work.

“Point out how many times you’re going to the doctor—you’re spending more on antibiotics and tests and hospitalizations than you would if you would just prescribe the IVIG.”

As final advice, Carol counseled that how parents interact with their children can help normalize their lives.

“Raise your kid to be normal,” Carol said. “It saddens me to see the kids think the disease is taking over. Don’t let the kid be defined by the condition.”

As for Emily, while the disease doesn’t define her, you still can’t classify her as normal. After all, instead of worrying about prom and getting a driver’s license, she spent her spring focused on where she’ll attend college in the fall.

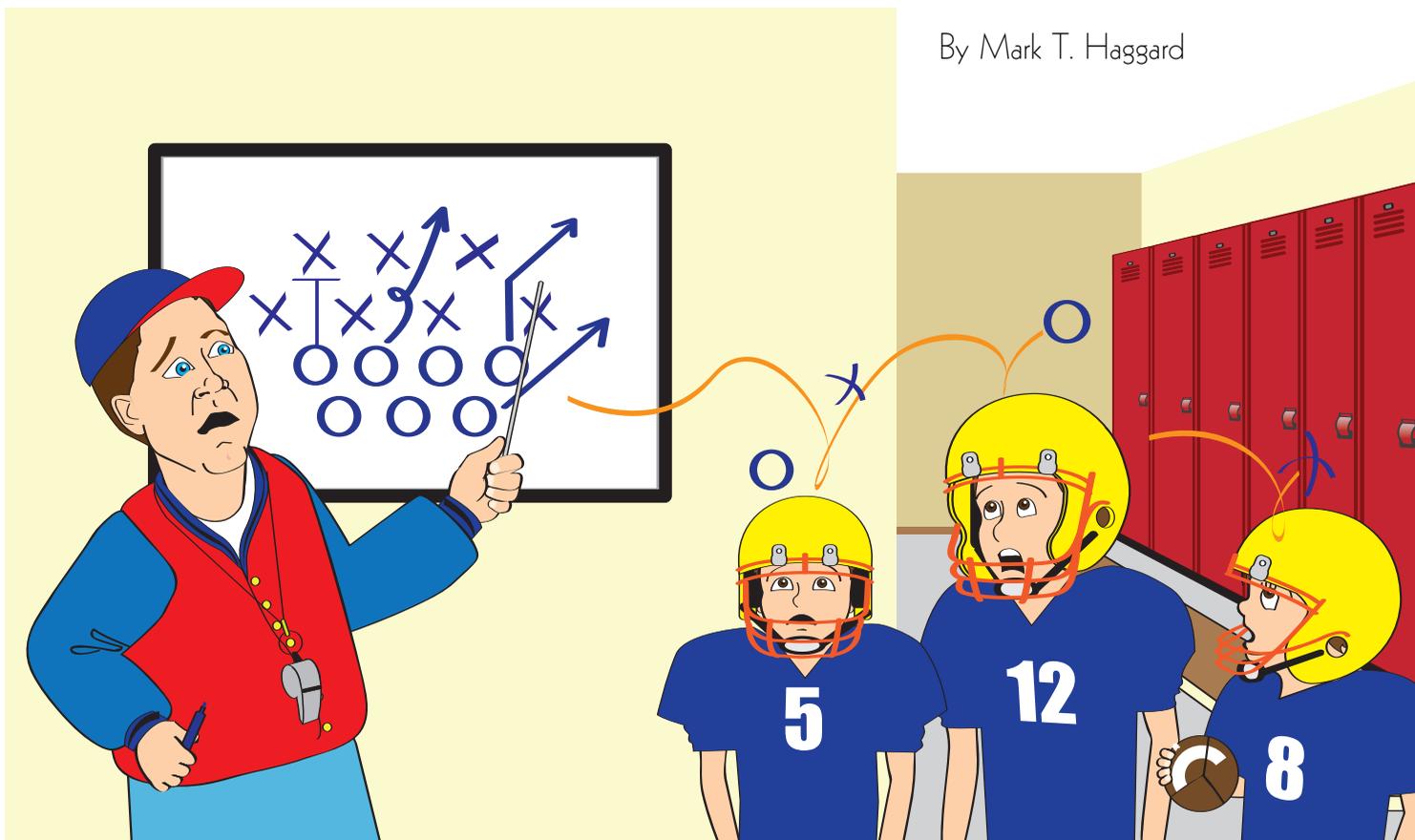
Since then, Emily was accepted to her first choice, Michigan, which she will attend on scholarship. As for what she plans to study, that’s decided too.

“I really want to major in biology,” Emily said. “That’s my favorite class, and has been for a few years. I want to go to medical school; I want to become an immunologist eventually.”

And surely Emily will achieve this challenge, too. ■

# Adjustments to

By Mark T. Haggard



“What did they run?” I ask Greg, one of my assistant coaches. It’s Saturday during the fall, and we’re breaking down film of Middleton High School, our opponent for next Friday’s football game. I keep information on all of our foes. I have notes on one school going back five years. It gives me a good idea of what a team will do in a given situation.

For example, most teams will run 70 percent of the time on first down. Most teams try to pack all 11 players close together—inside the box—on short yardage. For most teams, third down and long yardage is a pass

situation. I can’t stand it when teams do something to the contrary.

For the majority of his tenure at Middleton, Coach Williams has run the wishbone triple option. (For non-football aficionados, this is a running play where the fullback, quarterback or halfback will end up running the ball.) Our game plan: assignment football. I harp on my players all week: “Inside linebackers have dive, ends have quarterback, outside linebackers have pitch! The minute you blow your assignment, they will be in the end zone.”

# the Game Plan



We drill all week, getting players to follow the game plan and focus on their one job: dive, quarterback or pitch.

"Assignment football!" I bark.

Then comes Friday night.

"What is that?" I mutter under my breath as I watch Middleton line up on offense. "What is that?" I call into my headset.

"Double tight end, double wing," Greg calls back.

"They're a wishbone team," I protest.

"Not tonight. That's double tight, double wing."

Sure enough, they're trying to power over the top of us. This isn't assignment football—it's smash-mouth football.

They're doing something to

the contrary. We give up two early touchdowns. Then, we change the game plan. The adjustments work. We win the game.

When a team does something unexpected, it can be tough to adjust. But in some situations, like when the opposing team is immune-system issues, you have no choice. In the Haggard household, that can mean a game plan needs constant modification. Take last spring.

It starts with Caleb acting grumpy and whiny one morning. "Sinus infection," I surmise. "New game plan: Zyrtec and nebulizer before bed. Oh, and no baseball

practice this week." Simple adjustments.

Then Molly sleeps late after being up most of the night. "Sinus infection," I conjecture. "New game plan: Zovirax before her chin breaks out with herpes." Another simple adjustment added to Caleb's adjustments.

"Dad," Calvin complains, "I've got breakouts again." My oldest child has on-and-off issues with eczema. This is an 'on' week. New game plan: Wash with special soap, pat dry, apply mass quantities of lotion afterward. A simple adjustment. Except I now have three irons in the fire instead of one.

"Bronchitis, Mr. Haggard," Rusty announces after listening to my chest. "You have a little crackle in your lungs. Here's an inhaler and an antibiotic; it should clear up in a week."

"Something else to add to the pharmacy we have at home," I quip.

"Just making some adjustments to the game plan," our neighborhood doctor responds. "You should be just fine."

Rusty was right. I got through my bronchitis. Calvin's skin cleared up. We got to Molly's herpes before it could get to her. Caleb required some antibiotics, but he recovered. The adjustments to the game plan worked.

I have charts, graphs, spreadsheets and notes on every opponent that we face during the football season; I know what a team will do in most situations. I wish that I could say the same about the opponent that my kids face year-round. You can't scout this opponent, which challenges each of my kids in different ways. With an MO to continually do something unexpected, few of its plays are ever the same. Yet we keep playing, we keep fighting, we make adjustments to the game plan when necessary in hopes that one day this opponent will be defeated—once and for all. ■

# Converting the Dose

By Amanda M. Traxler

## A Fruity Metaphor

Comparing apples and oranges is usually not considered a good idea.

But for the FDA, such comparisons can be necessary to ensure that dosages for different treatments are equally effective.

Case in point: It seemed to be the veritable apples-and-oranges comparison when the FDA was determining how to convert dosage rates from intravenous immune globulin (IVIG) to subcutaneous immune globulin (SCIG).

Once FDA clinical trials were completed, a conversion rate of 1 to 1.37 was approved.

After that approval, another issue cropped up: Must the 1 to 1.37 dosing conversion ratio be strictly followed when switching from IVIG treatment to SCIG?

It turns out that depending on what criteria are used to compare the efficacy of IVIG versus SCIG, the two can be considered apples to apples after all—which means that a 1-to-1 conversion rate is also efficacious.

Quite a bowl of cherries, isn't it?

## The Patient Perspective

For most patients, conversion ratios are not foremost on their minds.

Such was the case with Jennifer Stenquist, a resident of North Logan, Utah, who had been eagerly awaiting treating her CVID (common variable immune deficiency) via SCIG, which she felt would fit her busy schedule and geographical constraints better than IVIG.

According to Stenquist, when she first asked her doctor about SCIG, it wasn't yet FDA-approved.

"She said, 'No, we're not going to go there. Not yet,' " Stenquist said.

Once it was FDA-approved, Stenquist switched, but she was unaware of dosage-conversion issues.

"I know that in their office it was probably just a matter of doing a little bit of math or going by body weight," Stenquist said. "They said 'Don't worry about it, we'll figure it out and let the pharmacy know.' "

On IVIG, Stenquist's dose was 40 grams every four weeks. Now, she takes 63 mL weekly of Vivaglobin, manufactured by CSL Behring. Given that 10 mL of Vivaglobin equals 1.6 grams of IVIG, Stenquist's weekly Vivaglobin dose translates into approximately 10 grams. Multiplied by four weeks, that's about 40 grams per month—which means her doctor has used a 1-to-1 ratio. And to great success, it seems.

"It's been wonderful," Stenquist said.

## The Package Insert

Because there wasn't any previous data on SCIG, says Annette Zampelli, ARNP and medical science liaison for CSL Behring, the FDA was in uncharted territory when it came to approving SCIG dosing.

To compensate, says Zampelli, a mathematical equation was used that covered the range from peak—the highest immune globulin serum level after treatment—to trough—the lowest immune globulin level before a patient's next treatment. This is referred to as the area "under the curve."

"We had to be at least as efficacious as IVIG as far as the area under the curve; that's where that specific dosing piece comes into play," said Patty Riley, RN, BAN, CRNI, and medical science liaison for CSL Behring.

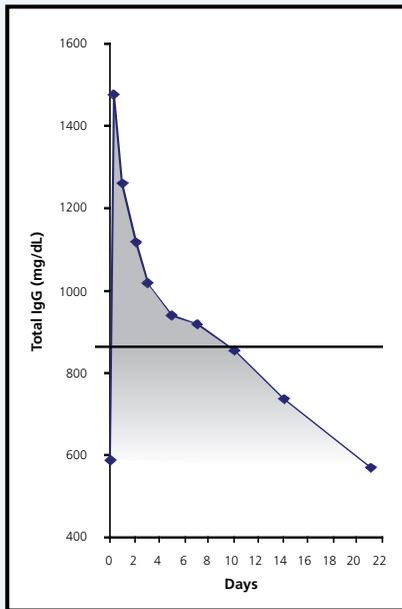
"CSL Behring was required to demonstrate noninferiority in pharmacokinetics," Riley said.

For the layperson, pharmacokinetics is just a big word for an even bigger phrase. It refers to the mathematical study of the extent and rate of absorption, distribution, metabolism and excretion of drugs in the human body.

With SCIG, there had to be a "high enough level initially so the patient would be protected," Zampelli said, as "there is a decrease in the bioavailability of immune globulin given subcutaneously versus intravenously."

To account for that decrease and to accomplish the overall range, a ratio of 1 to 1.37 was approved.

"Multiply the person's [IVIG] dose every four weeks by 1.37 to arrive at the area called 'under the curve' ... That's how the FDA approved it," Zampelli said.



**From Peak to Trough**  
Area 'under the curve' refers to the range from peak—the highest immune globulin serum level after treatment—to trough—the lowest immune globulin level before a patient's next treatment.

A critical element of the approval ratio is peak levels; accounting for them is what necessitates the 1-to-1.37 ratio.

However, in Europe—where SCIG was already on the market—CSL Behring was able to do a study that went by trough levels alone.

"In Europe, there were other SCIG products on the market that we had the ability to compare it to," Riley said. "In the European trial, they looked primarily at the trough. They weren't held to the noninferiority area under the curve for the IgG trough."

According to Zampelli, a 1-to-1 ratio was found to be safe and effective in the European study.

"They were able to show that the serious bacterial infection rate was identical at 1 to 1 as it was at 1 to 1.37."

### Trough to Trough

Branson Worthen, a Syracuse, Utah, resident who has CVID, knows about serum levels, troughs and peaks.

"They're [serum levels] a lot more stable than when I was on the IV. When I was on the IV, it would peak and it would go back down, and then I would get sick toward the end of the three weeks," Worthen said.

On IVIG, Worthen's dose was 17.5 grams every three weeks of IVIG (or about 24 grams every four weeks). Now, he takes 40 mL weekly of Vivaglobin. Given that 10 mL of Vivaglobin equals 1.6 grams of IVIG, Worthen's weekly Vivaglobin dose translates into approximately 6.4 grams. Multiplied by four weeks, that's about 25.6 grams per month, which is nearly a 1-to-1 ratio.

In his case, at least anecdotally, his more consistent trough levels seem to be translating into more consistent health.

In that regard, his doctor has done what Riley described as a physician's prerogative.

"Physicians always have the opportunity to look at the package insert; however, there is supportive evidence to dose at 1 to 1, so physicians have the ability to, from their clinical expertise, prescribe what they are comfortable with," Riley said. "It's their expertise and the response of the patient in how they [doctors] will manage the overall picture. The package insert is a guide; it tells you what was done, this is the data that was collected."

### Decisions, Decisions

For doctors, it's clear that a decision must be made if switching patients to SCIG treatment: namely, what dosage conversion will be used. For patients, though, other things must be considered even before dosage conversion that are usually of an entirely different nature—one that's very subjective. The choice to infuse subcutaneously or intravenously is personal and should be discussed with a physician.

As *IG Living* has highlighted before, many find IVIG infusions to be their preferred method. Their reasons include:

- Desire for the social interaction and camaraderie at IVIG infusion appointments
- Discomfort with increased frequency of treatments
- Greater comfort with a traditional healthcare setting rather than homecare
- Desire for healthcare professional involvement rather than relying on self-administered treatment
- Extreme discomfort with needles

Though Worthen is happy with SCIG, he can still relate to having some apprehensions, especially when he first made the change.

"The only thing that I had a problem with was sticking myself," Worthen said. "And I kinda missed the nurse coming over."

But overall, he's pleased with SCIG.

"I really like the freedom it gives me," Worthen said. "Last time I did it, I went to a social activity, and it was really convenient."

With due consideration to each patient's unique circumstances and proper evaluative discussion with one's doctor, the right treatment can be found for every patient. ■

# IG Patients Protected Against Genetic Discrimination

By Amy Fuller, MPP, and Michelle Vogel, MPA

On May 21, President Bush signed the Genetic Information Nondiscrimination Act, popularly known as GINA, into law. The enactment of GINA, which prohibits health insurers and employers from discriminating against individuals based on their genetic information, has been hailed as a major victory for civil rights, healthcare providers, patients and—most of all—the American public, who will finally be able to take advantage of advances in genetic testing without fear that any information will be used against them. The bill's enactment is also a victory for the more than 500 healthcare and patient advocacy organizations, civil rights groups, industry representatives and employers that officially support the legislation.

In 1995, when Congresswoman Louise Slaughter (D-NY), who holds a Bachelor of Science degree in Microbiology and a Master of Science degree in Public Health from the University of Kentucky, first introduced a version of the bill during the 104th Congress, genetic testing was a new field: Around that time, more than 100 genetic tests were available, compared with the more than 1,200 genetic tests available today that can diagnose thousands of health conditions. In general, clinicians use genetic tests to identify changes in chromosomes, genes or proteins. The results of these tests can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.

Doctors can use the information gained from genetic tests to personalize the course of treatment and to warn patients of their predisposition to health problems. Patients can use this information to take proactive steps to reduce the risks to their health. By giving doctors and patients the information they need to best manage the patient's health, genetic testing has the potential to lower the overall cost of healthcare, as well as improve the quality of life for patients and their families.

The information gained from these tests is invaluable for many members of the IG community who have disorders such as primary immune deficiencies. Genetic tests for primary immune deficiencies give doctors the ability to properly diagnose patients—reducing the amount of time patients have to suffer through uncertainty about their diagnosis and treatment, leading to better health outcomes.

For example, one type of primary immune deficiency that can be detected in newborn screening and treated immediately is severe combined immune deficiency (SCID), or “bubble boy disease.” If the newborn is screened at birth and determined to be a SCID baby, a physician can successfully perform a bone-marrow or stem-cell transplant within the first months of the baby's birth. If the procedure is successful, the baby will live a near-normal life. Without the bone-marrow or stem-cell

transplant, the infant will die before 2 years of age because of severe and chronic infections that the body cannot fight without a functioning immune system.

Given the apparent genetic link to many diseases that respond to IG therapy, the importance of genetic testing to the IG community is likely to grow. The promise that genetic testing portends for the IG community is what inspired several organizations and businesses to officially support GINA, including the Alliance for Plasma Therapies, A-T Children's Project, Baxter Healthcare Corporation, FFF Enterprises, *IG Living*, The Myositis Association, Neuropathy Action Foundation, The Neuropathy Association, Octapharma USA, Platelet Disorder Support Association, and Talecris Biotherapeutics.

As quickly as consumers and healthcare professionals noted the promises of genetic testing, however, they noted the inherent dangers. Because genetic tests can show a predisposition for developing conditions that may be costly to treat or may interfere with their ability to work, patients fear that the information gleaned from genetic tests may be used against them by insurance companies or by employers. In Congresswoman Slaughter's introductory remarks on the House floor when she reintroduced GINA during the 105th Congress in 1997, she noted that “polls and studies demonstrate clearly how much the American people fear genetic discrimination by health insurers. This anxiety is so strong that many people are forgoing genetic testing—even when they have a clear family history of genetic illness and a positive test could lead them to take advantage of effective preventive medicine.”

Unfortunately, consumer concerns about losing health benefits or having to pay more for coverage as a result of information found by genetic testing are well-founded. History has also shown us that in the interest of reducing healthcare costs, employers are apt to misuse this information in their decisions to either deny otherwise qualified candidates a job or to fire otherwise capable employees. According to the Council for Responsible Genetics, an organization founded in 1983 to foster public debate about the social, ethical and environmental implications of genetic technologies: “In as many as 500 cases, individuals and family members have been barred from employment or lost their health and life insurance based on an apparent or perceived genetic abnormality.”

The passage of this landmark law promises to be a positive turning point in the use of genetic testing to improve healthcare. Under GINA's protections, health insurers and employers will not be able to use genetic information against people, leaving Americans free to seek answers about their healthcare concerns, without fear of penalties. ■

# Resource Directory

For a more comprehensive list of resources, visit the Resources page at [www.igliving.com](http://www.igliving.com).

## Ataxia Telangiectasia (A-T)

### Websites

- A-T Children's Project: [www.atcp.org](http://www.atcp.org)
- NINDS A-T Information Page: [www.ninds.nih.gov/disorders/a\\_t/a-t.htm](http://www.ninds.nih.gov/disorders/a_t/a-t.htm)

## Chronic Inflammatory Demyelinating Polyneuropathy (CIPD)

### Websites

- GBS/CIDP Foundation International: [www.gbs-cidp.org](http://www.gbs-cidp.org)
- National Institute of Neurological Disorders and Stroke (NINDS) Chronic Inflammatory Demyelinating Polyneuropathy (CIPD) Information Page [www.ninds.nih.gov/disorders/cidp](http://www.ninds.nih.gov/disorders/cidp)
- Neurology Muscular Dystrophy and Neuropathy Institute Illustration of a damaged myelin sheath on a nerve: [www.beverlyhillsneurology.com/cidp](http://www.beverlyhillsneurology.com/cidp)

### Online Peer Support Links

- The Neuropathy Association: [www.neuropathy.org](http://www.neuropathy.org)
- Barbara's CIDP/GBS Site (This is a personal website) [www.geocities.com/HotSprings/Falls/3420](http://www.geocities.com/HotSprings/Falls/3420)

## Evans Syndrome

### Websites

- Evans Syndrome Research and Support Group: [www.evanssyndrome.org](http://www.evanssyndrome.org)
- Office of Rare Diseases (catalog of online resources) <http://rarediseases.info.nih.gov/asp/diseases/diseaseinfo.asp?ID=6389>

## Guillain-Barré Syndrome (GBS)

### Websites and Chat Rooms

- The GBS/CIDP Foundation International, [www.gbs-cidp.org](http://www.gbs-cidp.org), has 23,000 members in 160 chapters on five continents. 610-667-0131
- The GBS/CIDP Foundation International Discussion Forums provide the opportunity to talk to other GBS patients and learn more about ways to manage the illness: [www.gbs-cidp.org/forums](http://www.gbs-cidp.org/forums).
- Miller Fisher Syndrome, considered to be a variant of GBS, is explained on the National Institute of Neurological Disorders and Stroke, NINDS Miller Fisher Syndrome Information Page: [www.ninds.nih.gov/disorders/miller\\_fisher/miller\\_fisher.htm](http://www.ninds.nih.gov/disorders/miller_fisher/miller_fisher.htm).

### Online Pamphlets

- The National Institute of Neurological Disorders and Stroke has a GBS Fact Sheet at [www.ninds.nih.gov/disorders/gbs/detail\\_gbs.htm](http://www.ninds.nih.gov/disorders/gbs/detail_gbs.htm).
- 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).
- The National Institute of Neurological Disorders and Stroke has an information page about CIDP: [www.ninds.nih.gov/disorders/cidp/cidp.htm](http://www.ninds.nih.gov/disorders/cidp/cidp.htm).

### Online Peer Support

- GBS & CIDP Discussion Forum – UK Bulletin Board – For Ireland and England [www.gbs.org.uk/cgi-bin/ikonboard3/ikonboard.cgi](http://www.gbs.org.uk/cgi-bin/ikonboard3/ikonboard.cgi)
- GBS Support Group and Chat Room, UK [www.jsmarcussen.com/gbs/uk/chat.htm](http://www.jsmarcussen.com/gbs/uk/chat.htm)

- GBS Foundation Discussion Forums: [www.guillain-barre.com/forums](http://www.guillain-barre.com/forums)
- Yahoo Support Group Discussion Board [http://health.groups.yahoo.com/group/GBS\\_CIDP](http://health.groups.yahoo.com/group/GBS_CIDP)

### Books and Articles

- "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).
- "Bed Number Ten," by Sue Baier, provides a view of long-term care through the eyes of a patient totally paralyzed with GBS.
- "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).
- "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.

## ITP (Idiopathic Thrombocytopenic Purpura)

### Websites

- ITP Support Association, UK: [www.itpsupport.org.uk](http://www.itpsupport.org.uk)
- Platelet Disorder Support Association: [www.pdsa.org](http://www.pdsa.org)
- National Heart, Lung and Blood Institute [www.nhlbi.nih.gov/health/dci/Diseases/Itip/ITP\\_Whats.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Itip/ITP_Whats.html)

### Online References

- Idiopathic thrombocytopenic purpura [www.mayoclinic.com/health/idiopathic-thrombocytopenic-purpura/DS00844](http://www.mayoclinic.com/health/idiopathic-thrombocytopenic-purpura/DS00844)
- Idiopathic Thrombocytopenic Purpura: Michael A. Silverman, MD [www.emedicine.com/EMERG/topic282.htm](http://www.emedicine.com/EMERG/topic282.htm)
- Immune Thrombocytopenia: Current Understanding and Future Research, Robert S. Mocharnuk, MD [www.medscape.com/viewarticle/459249](http://www.medscape.com/viewarticle/459249)
- ITP: Idiopathic Thrombocytopenic Purpura: <http://familydoctor.org/113.xml>

## Kawasaki Disease

### Websites

- Kawasaki Disease Foundation: [www.kdfoundation.org](http://www.kdfoundation.org)  
PO Box 45 • Boxford, MA 01921  
Tel: 978-356-2070 • Fax: 978-356-2079 • Email: [info@kdfoundation.org](mailto:info@kdfoundation.org)
- Kids Health discusses Kawasaki disease [www.kidshealth.org/parent/medical/heart/kawasaki.html](http://www.kidshealth.org/parent/medical/heart/kawasaki.html).
- Overview from the American Heart Association focuses on how the disease affects the heart [www.americanheart.org/presenter.jhtml?identifier=4634](http://www.americanheart.org/presenter.jhtml?identifier=4634)

## Mitochondrial Disease

### Websites

- United Mitochondrial Disease Foundation promotes research and education for the diagnosis, treatment and cure of mitochondrial disorders and provides support to affected individuals and families. [www.umdf.org](http://www.umdf.org)

# Resource Directory

- The Cleveland Clinic website provides many articles when searched by the topic, "mitochondrial disease." [www.clevelandclinic.org/health](http://www.clevelandclinic.org/health)
- The National Institute of Neurological Disorders and Stroke provides an informative Mitochondrial Myopathies Information Page. [www.ninds.nih.gov/disorders/mitochondrial\\_myopathy/mitochondrial\\_myopathy.htm](http://www.ninds.nih.gov/disorders/mitochondrial_myopathy/mitochondrial_myopathy.htm)

- Bette's Myasthenia Gravis Support: <http://health.groups.yahoo.com/group/bettesmyastheniagravisupport>
- Maddy's MG Support: <http://health.groups.yahoo.com/group/maddysmgsupport>
- Autoimmune Information Network Inc.: [www.aininc.org](http://www.aininc.org)  
PO Box 4121 • Brick, NJ 08723 • 877-246-4900 • Email: [autoimmunehelp@aol.com](mailto:autoimmunehelp@aol.com)

## Multifocal Motor Neuropathy (MMN)

### Websites

- National Institute of Neurological Disorders and Strokes (NINDS) provides a Multifocal Motor Neuropathy Information Page: [www.ninds.nih.gov/disorders/multifocal\\_neuropathy/multifocal\\_neuropathy.htm](http://www.ninds.nih.gov/disorders/multifocal_neuropathy/multifocal_neuropathy.htm)
- Multifocal Motor Neuropathy Center at Johns Hopkins Department of Neurology [www.neuro.jhmi.edu/MMN/index.html](http://www.neuro.jhmi.edu/MMN/index.html)
- The Neuromuscular Center at Washington University in St. Louis, Mo. Neuromuscular Home Page [www.neuro.wustl.edu/neuromuscular](http://www.neuro.wustl.edu/neuromuscular)
- The Neuropathy Association is dedicated to helping those with conditions affecting peripheral nerves. [www.neuropathy.org](http://www.neuropathy.org)

## Multiple Sclerosis (MS)

### Websites and Chat Rooms

- The mission of the National Multiple Sclerosis Society is to end the devastating effects of MS. [www.nationalmssociety.org/](http://www.nationalmssociety.org/)
- 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. [www.mult-sclerosis.org/index.html](http://www.mult-sclerosis.org/index.html)
- Multiple Sclerosis Foundation works for a brighter tomorrow for those affected by MS. [www.msfacts.org](http://www.msfacts.org)
- Multiple Sclerosis Association of America seeks to enrich the quality of life for individuals with multiple sclerosis. [www.msaa.com](http://www.msaa.com)
- MSWorld's Chat and Message Board features patients helping patients. [www.msworld.org](http://www.msworld.org)

### Online Peer Support

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

## Myasthenia Gravis (MG)

### Websites and Chat Rooms

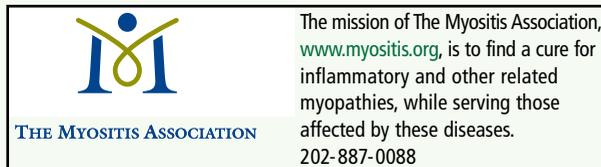
- The Myasthenia Gravis Foundation of America (MGFA) is the only national volunteer health agency dedicated solely to the fight against (MG). [www.myasthenia.org](http://www.myasthenia.org)
- Myasthenia Gravis Fact Sheet prepared by National Institute of Neurological Disorders and Strokes. [www.ninds.nih.gov/disorders/myasthenia\\_gravis/myasthenia\\_gravis.htm]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

### Online Peer Support

- MGFA's Forum: <http://health.groups.yahoo.com/group/MGnet>

## Myositis

### Websites



- 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>
- 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>
- Johns Hopkins Myositis Center is a new patient treatment center that brings the expertise of rheumatologists and neurologists into a single clinic for patients with inflammatory (autoimmune) and toxic (drug induced) muscle conditions. [www.hopkinsmedicine.org/rheumatology/clinics/myositis\\_center.html](http://www.hopkinsmedicine.org/rheumatology/clinics/myositis_center.html)

### Online Peer Support

- Juvenile Myositis Family Support Network: [www.curejm.com/family\\_support/index.htm](http://www.curejm.com/family_support/index.htm)
- Myositis Association Community Forum: [www.myositis.org](http://www.myositis.org)
- Myositis Support Group: [www.myositisupportgroup.org](http://www.myositisupportgroup.org)
- Myositis Support Group UK: [www.myositis.org.uk](http://www.myositis.org.uk)
- Yahoo Myositis Support Group Discussion Board: <http://health.groups.yahoo.com/group/OurMyositis>
- The California Myositis Symposium held in 2005 was captured on DVD. It contains information about polymyositis, dermatomyositis and inclusion body myositis, including doctors' discussions and detailed slides and explanations of muscle biopsies, skin rash, and tools used to diagnose these diseases. Other presentations offer valuable lessons in maintaining a positive attitude, exercises for physical therapy and innovative tools to aid in everyday activities. The DVD is available at no charge by sending an email to [Richard.Gay@socal.rr.com](mailto:Richard.Gay@socal.rr.com).

### Books and Articles

- "Coping With a Myositis Disease," by James R. Kilpatrick, is written by myositis patients telling their personal stories.
- "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.
- "Living With Myositis," edited by Jenny Fenton, is an accessible, realistic and sympathetic guide to facts, feelings and future hopes.
- "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.
- "Myositis and You: A Guide to Juvenile Dermatomyositis for Patients, Families, and

Healthcare Providers,” an indispensable resource for families of children with myositis and their healthcare teams, is available at [www.myositis.org](http://www.myositis.org).

- “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.

## Pemphigus and Pemphigoid

### Websites

- The International Pemphigus and Pemphigoid Foundation provides information and support to people living with the autoimmune diseases. [www.pemphigus.org](http://www.pemphigus.org)
- Information from the National Institutes of Health: [www.niams.nih.gov/hi/topics/pemphigus/pemphigus.htm](http://www.niams.nih.gov/hi/topics/pemphigus/pemphigus.htm)  
[www.nlm.nih.gov/medlineplus/ency/article/000882.htm](http://www.nlm.nih.gov/medlineplus/ency/article/000882.htm)
- Rare disease report: <http://rarediseases.about.com/od/rarediseases/p/pemphigus05.htm>

## Peripheral Neuropathy (PN)

### Websites



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

- To learn about PN, how it is classified, the symptoms, causes and treatments, see the Peripheral Neuropathy Fact Sheet available at [www.ninds.nih.gov/disorders/peripheralneuropathy/peripheralneuropathy.htm](http://www.ninds.nih.gov/disorders/peripheralneuropathy/peripheralneuropathy.htm).
- The Neuropathy Action Foundation, at [www.neuropathyaction.org](http://www.neuropathyaction.org), educates, empowers and informs patients and physicians about neuropathy.

### 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

- Calgary Neuropathy Support Group: [www.calgarypnrs.org](http://www.calgarypnrs.org)
- 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>

### Books and Articles

- “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.
- “Medifocus Guide to Peripheral Neuropathy,” is a guide to current and relevant PN research, organized into categories for easy reading.
- “Numb Toes and Aching Soles,” by John Senneff, discusses the symptoms, causes, tests, treatments and coping strategies for peripheral neuropathy.
- “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.

- “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.
- “Peripheral Neuropathy: When the Numbness, Weakness, and Pain Won’t Stop” by Dr. Norman Latov, MD, PhD, published 2007, Weill Medical College, Cornell University, provides practical information on all the neuropathies, causes and treatments.

## Primary Immune Deficiency Disease (PIDD)

### Websites and Chat Rooms



The Immune Deficiency Foundation (IDF), [www.primaryimmune.org](http://www.primaryimmune.org), is dedicated to improving the diagnosis and treatment of PIDD through research and education. 800-296-4433

**Jeffrey Modell Foundation**

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.
  - The Michigan Immunodeficiency Foundation, [www.midf.org](http://www.midf.org), seeks to improve the quality of life for Michigan residents affected by PIDD.
  - 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 PIDD patients.
  - To connect to a PIDD message board, go to [www.info4pi.org](http://www.info4pi.org).
  - To chat with peers on IDF’s Forum, go to [www.primaryimmune.org/forums/forum\\_intro.htm](http://www.primaryimmune.org/forums/forum_intro.htm).
  - Chat with parents of children affected by primary immune deficiency at <http://health.groups.yahoo.com/group/PedPID>.
  - Chat with peers with PIDD 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: [www.nepin.org](http://www.nepin.org)
  - Baxter’s website, [www.immunedisease.com](http://www.immunedisease.com), offers in-depth information on immunology, PIDD and treatment with intravenous immune globulin. Click on “European” to see SCIG information.
  - Rainbow Allergy-Immunology, [www.rainbowbabies.org/immunology](http://www.rainbowbabies.org/immunology), provides comprehensive diagnostic, therapeutic and consultative services for children and adults with immunologic diseases. For patient information about subcutaneous IG therapy: [www.rainbowbabies.org/subcu](http://www.rainbowbabies.org/subcu).
- ### Online Pamphlets and Education
- 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 [www3.niaid.nih.gov/healthscience/healthtopics/immuneSystem/PDF/theImmuneSystem.pdf](http://www3.niaid.nih.gov/healthscience/healthtopics/immuneSystem/PDF/theImmuneSystem.pdf)

# Resource Directory

- “NIAID Initiative Addresses Primary Immune Deficiency Diseases by National Institute of Allergy and Infectious Diseases” is located at <http://www3.niaid.nih.gov/news/newsreleases/2003/pirc.htm>
- The “Immunodeficiency in Pediatrics” program (PREP®) audio series is a new pediatrician education program that can be obtained by contacting the American Academy of Pediatrics at 866-843-2271 or visiting [www.prepaudio.org](http://www.prepaudio.org).

## Online Peer Support

- Chat with parents of children affected by PIDD <http://health.groups.yahoo.com/group/PedPID/>
- Chat with peers with PIDD: <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)
- Rhode Island peer group <http://health.groups.yahoo.com/group/RhodelslandPID/>

## Books and Articles

- “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.

## Scleroderma

### Websites

- Johns Hopkins Medicine Scleroderma Center: [scleroderma.jhmi.edu](http://scleroderma.jhmi.edu)
- Scleroderma Research Foundation: [www.srfcure.org](http://www.srfcure.org)
- Scleroderma Foundation: [www.scleroderma.org](http://www.scleroderma.org)

### Online Peer Support

- Educating instead of medicating CureZone.com <http://curezone.com/forums/f.asp?f=404>
- International Scleroderma Network: [www.sclero.org/support/forums/a-to-z.html](http://www.sclero.org/support/forums/a-to-z.html)

## Stiff-Person Syndrome (SPS)

### Websites

- American Autoimmune Related Diseases Association Inc., [www.aarda.org](http://www.aarda.org), is the only national organization dedicated to addressing the problem of autoimmunity. 800-598-4668 [aarda@aarda.org](mailto:aarda@aarda.org)
- Autoimmune Information Network Inc., [www.aininc.org](http://www.aininc.org), helps patients and family cope with the disabling effects of autoimmune diseases. 732-262-0450 [autoimmunehelp@aol.com](mailto:autoimmunehelp@aol.com)
- National Association for Rare Disorders (NORD), [www.rarediseases.org](http://www.rarediseases.org), promote awareness of rare diseases and the need for research. 800-999-6673 [orphan@rarediseases.org](mailto:orphan@rarediseases.org)
- National Institute of Neurological Disorders and Stroke (NINDS), [www.ninds.nih.gov](http://www.ninds.nih.gov), offers treatment, diagnosis and research information for rare diseases. 800-352-9424 [braininfo@ninds.nih.gov](mailto:braininfo@ninds.nih.gov)
- Mayo Clinic — Stiff-Person Syndrome: Can it be treated? [www.mayoclinic.com/health/stiff-person-syndrome/AN01377](http://www.mayoclinic.com/health/stiff-person-syndrome/AN01377)
- Diagnosed with SPS in 1994, Debra Kemery recounts her experience and offers practical information about coping with the disease at [www.stiffman.org](http://www.stiffman.org).

### Books and Articles

- “A Flower Grows in Stone: The Diary of a Life in Progress,” a firsthand account of her struggle with Stiff-Person/Moersch Woltman Syndrome, is written by

first-time author Anisah Hassan. Available from Llumina Press, Ingram, and Baker & Taylor, [www.llumina.com](http://www.llumina.com).

## General Resources

### Product Information

- Influenza and the influenza vaccine [www.cdc.gov/flu](http://www.cdc.gov/flu) or call 800-CDC-INFO (800-232-4636)
- IVIG Carimune NF [www.carimune.com](http://www.carimune.com)
- IVIG Flebogamma [www.grifolsusa.com/pdfs/flebo\\_14Jun05.pdf](http://www.grifolsusa.com/pdfs/flebo_14Jun05.pdf)
- IVIG Gammagard Liquid [www.gammagardliquid.com](http://www.gammagardliquid.com)
- IVIG Gammagard S/D [www.immunedisease.com/US/therapies/gammagard/index.html](http://www.immunedisease.com/US/therapies/gammagard/index.html)
- IVIG Gamunex [www.gamunex.com](http://www.gamunex.com)
- IVIG Octagam [www.octapharma.com/corporate/03\\_products\\_and\\_therapeutic\\_areas/01\\_immunoglobulin\\_product\\_line/03\\_octagam.php](http://www.octapharma.com/corporate/03_products_and_therapeutic_areas/01_immunoglobulin_product_line/03_octagam.php)
- SCIG (subcutaneous immune globulin) Vivaglobin [www.vivaglobin.com](http://www.vivaglobin.com)

### Other Organizations

- Alliance for Plasma Therapies is a unified, powerful voice of patient organizations, healthcare providers and industry to advocate for fair access to plasma therapies. [www.plasmaalliance.org](http://www.plasmaalliance.org)
- For suggestions on how to deal with the medical and emotional impact of caring for an ill child, go to [www.kidshealth.org/parent/system/ill/seriously\\_ill.html](http://www.kidshealth.org/parent/system/ill/seriously_ill.html).
- 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).
- 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



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

- 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.
- For a pediatrician’s guide to your child’s health and safety, visit [www.keepkidshealthy.com](http://www.keepkidshealthy.com).
- 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.
- 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
- Band-Aides and Blackboards, [www.lehman.cuny.edu/faculty/jfleitas/bandaides](http://www.lehman.cuny.edu/faculty/jfleitas/bandaides), started by a nurse working on her dissertation, focuses on children with chronic illness.
- American Chronic Pain Association (ACPA) was founded in 1980 to provide resources for people coping with chronic pain. [www.theacpa.org](http://www.theacpa.org)

### Education and Disability Resources

- Continuation of Health Coverage—Consolidated Omnibus Budget Reconciliation Act (COBRA): [www.dol.gov/dol/topic/health-plans/cobra.htm](http://www.dol.gov/dol/topic/health-plans/cobra.htm)

- Social Security: [www.ssa.gov/disability](http://www.ssa.gov/disability)
- California State Disability Insurance (SDI): [www.edd.ca.gov](http://www.edd.ca.gov) (Please note that each state has a different disability program.)
- IDEA 2004 Resources: [www.ed.gov/policy/speced/guid/idea/idea2004.html](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.
- The National Disabilities Rights Network: [www.ndrn.org](http://www.ndrn.org). This website offers a search tool to find resources in your state to assist with school rights and advocacy.
- U.S. Department of Education Website: [www.ed.gov](http://www.ed.gov). This website, a U.S. federal government website, offers a parents section that has a subsection titled "My Child's Special Needs" that can be most helpful.
- U.S. Department of Health and Human Services, Office of Civil Rights, [www.hhs.gov/ocr/504.html](http://www.hhs.gov/ocr/504.html), spells out your rights under Section 504 of the Rehabilitation Act.
- Wrightslaw: [www.wrightslaw.com](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.
- The Americans with Disabilities Act of 1990  
Provides protection for people with disabilities from certain types of discrimination and requires employers to provide some accommodations of the disability. For more information, visit [www.usdoj.gov/crt/ada/adahom1.htm](http://www.usdoj.gov/crt/ada/adahom1.htm).

## Additional Reading

- "Anatomy of an Illness," by Norman Cousins, is a best-seller 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.
- "A Parent's Guide to Special Education: Insider Advice on How to Navigate the System and Help Your Child Succeed," by Linda Wilmshurst and Alan W. Brue, is available on Amazon.com.
- "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.
- "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 [www.thelegalcenter.org/thelegalcenter-cgi-bin/shop?item=15](http://www.thelegalcenter.org/thelegalcenter-cgi-bin/shop?item=15).
- "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.
- "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.
- "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.
- "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.
- "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.
- "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.
- "YOU the Smart Patient: An Insider's Handbook for Getting the Best Treatment,"

by Michael F. Roizen, MD, and Mehmet C. Oz, MD, with the Joint Commission on Accreditation of Healthcare Organizations, shows you how to tackle such healthcare decisions as picking the best doctors and hospitals for you, knowing when to get a second opinion, and more.

## IG Manufacturer Websites

- Baxter: [www.baxter.com](http://www.baxter.com)
- CSL Behring: [www.cslbehring.com](http://www.cslbehring.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)

## Pump and Infusion Sets Websites

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

## Medical Research Studies

- Check out the official website for the National Institutes of Health patient recruitment program. This site provides summaries and criteria for studies as well as the ability to search for studies being conducted for a specific disease or disorder. <http://clinicalstudies.info.nih.gov>
- This website provides a wealth of information about clinical trials and volunteer participation. It gives you the ability to specify the disorder you are interested in, the location of the study, and the medication names or research protocols. [www.centerwatch.com](http://www.centerwatch.com)
- This site has a registration form to request that you be notified about recruitment for future studies. [www.clinicaltrials.com](http://www.clinicaltrials.com)
- WebMD has a service that matches volunteers with trials. There is an online questionnaire to complete and you will be notified via email of upcoming studies that match the criteria of your questionnaire. You can also search for specific studies. [www.webmd.com](http://www.webmd.com)

## Food Allergies

- Allergic Disorders: Promoting Best Practice [www.theallergyreport.com/reportindex.html](http://www.theallergyreport.com/reportindex.html)
- American Partnership for Eosinophilic Disorders: [www.apfed.org](http://www.apfed.org)
- National Institutes of Health, National Institute of Allergy and Infectious Diseases (2004). Food Allergy: An Overview (NIH Publication No. 04-5518). [www.niaid.nih.gov/publications/pdf/foodallergy.pdf](http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf)
- Food Allergy and Anaphylaxis Network: 800-929-4040 [www.foodallergy.org](http://www.foodallergy.org)
- World Allergy Organization: [www.worldallergy.org](http://www.worldallergy.org)
- Sicherer, S.H. (2006). "The Complete Peanut Allergy Handbook: Understanding and Managing Your Child's Food Allergies," Johns Hopkins Press.

## Reading Just for Kids

- "Germs Make Me Sick," by Melvin Berger, explains with colorful illustrations how your body fights germs.
- "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.
- "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 [www.immunedisease.com/US](http://www.immunedisease.com/US).
- "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).

---

*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!*



# Uncertain it will arrive on time ?



Life is uncertain.  
Your flu vaccine doesn't have to be.

YOU PICK THE QUANTITY . YOU PICK THE DATE . WE DELIVER

 **MyFluVaccine** | (800) 843-7477 | [www.MyFluVaccine.com](http://www.MyFluVaccine.com)

Brought to you by FFF Enterprises, Inc., the nation's largest and most trusted distributor of flu vaccine and critical-care biopharmaceuticals.

IG Living  
41093 County Center Drive  
Temecula, CA 92591-9815

PRSR STD  
US POSTAGE PAID  
ESCONDIDO, CA  
PERMIT NO. 390