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- Newsrooms
- Forums
- Digital Edition

- General
- Community
- Products
- Food
- Complications & Care
- Fitness
- Medications
- Monitoring
- Research
- Health Care
- Psychology
- Legal
- Pregnancy
- Celebrities

Welcome to Diabetes Health Forums! This is a discussion board where professionals and patients can hash out pressing problems affecting our community and our health. Join a conversation in one of the rooms on the menu to the left, or start one of your own.

Most Active Forums

- Food** — 14 posts within the last month
- Community** — 11 posts within the last month
- Products** — 10 posts within the last month
- General** — 7 posts within the last month
- Health Care** — 3 posts within the last month
- Complications & Care** — 2 posts within the last month
- Psychology** — 2 posts within the last month
- Medications** — 1 post within the last month
- Fitness** — 1 post within the last month

Recent Posts

From **Positive by example** in the Psychology forum:

jimmysdevoted

When I was openly diagnosed in 2000 as diabetic, I had a long understanding of diabetes. Everyone on my father's side of the family was diabetic. I was 16th generation confirmed.

Anyway I had this great DE. She came in and said you have to consider it's like your eye color and hair color. It's a part of you. But you can let it control you or you can control it. You need glasses right, you need insulin.

Well that was it for me. I accepted it and went about my daily routine. Ok so there were a few things to do during the day that I didn't have before. but it wasn't all that bad. I had to watch my diet.. been doing that all of my life. I had to exercise.. humph.. been doing that all my life.

New to the Forums?
Any Other Questions?

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Art Director **Thos Chapman**
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Bookkeeper **Scott Matthews**
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Diabetes Health Office

P. O. Box 395 • Woodacre, CA 94973
Phone: (415) 488-1141 • (800) 234-1218
Fax: (415) 488-1922

Customer Service

In the United States, (800) 488-8468; from Canada and foreign countries, (818) 487-4524.
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Mission Statement

Diabetes Health is the essential resource for people living with diabetes—both newly diagnosed and experienced—as well as the professionals who care for them. We provide balanced expert news and information on living healthfully with diabetes. Each issue includes cutting-edge editorial coverage of new products, research, treatment options, and meaningful lifestyle issues.

Letters to the Editor

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In This Issue



FEATURES

26 The Starfish Story, Diabetes, and the Poorest Nation in the World

Certified Diabetes Educator, Jean Roemer, collects diabetic supplies and sends them to Malawi, Africa. Although it feels like a drop in the bucket, that's how change happens.

30 Flying on Insulin

Captain Steve Steele lost his pilot's license in 1986 when he was diagnosed with type 1. Today, Canada is the only country in the world to license commercial pilots with diabetes. Captain Steele flies commercial passengers all over the world for Air Canada.

34 Following Dr. Bernstein on Holiday

Al Krause and Ruth Higgins traveled Down Under while trying to keep to Dr. Richard Bernstein's strict low-carb diet. Find out how challenging it can be to stay "on course" while traveling.

36 Sleep Apnea and Diabetes

Here's something to make you sit up and take notice (maybe 100 times a night): 23 percent of type 2s have obstructive sleep apnea (OPA).

COLUMNS

8 Making a Difference

10 Guest Editor

11 My Own Injection

12 Reaching the Finish Line

LIVING WELL

14 Pre-Diabetes

- Should pre-diabetes be treated as aggressively as newly diagnosed cases of diabetes?

15 Type 1

- Silver Linings. The Heintz family includes nine kids—three with type 1. Mom, Cynthia Heintz chronicles how the family and kids have dealt with the trials and tribulations of diabetes.

17 Types 1 & 2

- PAD Affects 1 in 3 People With Diabetes. Peripheral Artery Disease (PAD) afflicts many people with diabetes. Here are some of the risk factors associated with it.
- Eye Exams. Getting your vision checked not only can (literally) improve your outlook on things, it can be a lifesaver when it leads to the early detection of diabetes.

20 Blood & Honey: A Documentary

- A psychologist looks at how some vastly different people have responded to diabetes—and how diabetes affects people's identities.

NEWS

23 AADE Report

- Riva Greenberg recaps this summer's AADE conference in Washington, D.C. including all the hot products from the exhibition hall.

52 Saving on Test Strips

- Many people are not only confused about how to test their blood glucose, they are also paying out-of-pocket for test strips when they don't have to. Marie McCarren offers some great meter tips.



In This Issue

56 Schools and Full-Time Nurses

- When schools try to ax full-time nurses to save money, we need to speak up...here's some inspiration for speaking to your local school board.

FOOD FOR THOUGHT

40 Recipes

- Supplement your Thanksgiving dinner with Eggplant Parmigiana and Pumpkin Cake Rolls. Plus, learn to make a low carb baking mix for use in all kinds of recipes.

42 The Sugar Myth That Won't Die

- John Mantle, MD, argues against the sugar myth, insisting that foods containing sugar don't produce a greater rise in blood sugar than bread, rice, and potatoes if the calories are the same.

44 Going Vegan

- Many people with diabetes are finding that a meatless, dairy-less diet makes controlling their blood sugar vastly easier. Here's why.

RESEARCH

46 Dr. Faustman Continues Working Toward the Cure

- A champion diabetes researcher makes the move to human trials—a crucial step on the road to curing type 1.

TECHNOLOGY TODAY

50 Finding Community in Diabetes Blogs

- The simple act of going online to share the joys and sorrows of living with diabetes can be profoundly rewarding

MARKETPLACE

60 Marketplace

AD DIRECTORY

61 Advertiser Product Directory

CARTOONS

62 A1 Chuckles

Contributors

Malawi Story • Page 26



Jean Roemer is a certified diabetes educator, pediatric nurse practitioner, and a past president of the American Association of Diabetes Educators. After meeting two men from Malawi, Africa,

she began collecting diabetes supplies to send to their country. She has had type 1 for over 40 years and has been interested in international diabetes care for many years.

Flying On Insulin • Page 30



Captain Steve Steele was the first pilot with type 1 diabetes in the world to fly as the captain of a commercial airliner while taking insulin. In June 2006, he transitioned to the Boeing 767, which he flies on international routes around the globe.

Following Dr. Bernstein • Page 34



Ruth Higgins & Al Krause are freelance writers based in Birch Bay, Washington.

Previously, Ruth was a manager in hospital administration, specializing in quality improvement, risk management, and safety. Al worked in advertising and investment public relations. In Birch Bay, they are active in community politics and environmental issues.

Nine Kids • Page 15



Cynthia Heintz lives in Northern California with her husband and large family. Cynthia enjoys advocating for diabetes causes, helping in the schools, and watching her children grow up to

care about and contribute to their community.

Eye Exams • Page 19



Beth Morrow is a freelance author, teacher, and active volunteer for the Central Ohio Diabetes Association in Columbus, OH. She currently serves on the Youth Committee

and is a member of the Camp Leadership Team. She has worked as the Senior Week Program Director for Camp Hamwi, the association's summer residential camp for children with diabetes, for 15 years.

Report from the AADE • Page 23



At age 50, after living with type 1 diabetes for 32 years, **Riva Greenberg** consulted a diabetes educator for the first time. That experience led her to combine her growing knowledge of diabetes

care with her writing and illustrating talents. Today she is educating and inspiring others to live well with diabetes through her articles, research, and motivational lectures across the country. Visit her web site at www.diabetesstories.com.

Sleep Apnea • Page 36

Sugar & Diabetes • Page 42

Test Strips • Page 52



Marie McCarren is a medical writer who has specialized in diabetes for 15 years. Her books include "ADA Guide to Insulin & Type 2 Diabetes" and "A Field Guide to Type 2 Diabetes." She is

the founder of the Monarchists of Anne Arundel County (MAAC) (we're talking butterflies) and of the Embattled Pedestrians of Arnold (EPA). The EPA has had almost no discernable effect on the safety of local pedestrians.

Recipes • Page 40



Jennifer Eloff was born in South Africa. She moved to North America in her early 20's and now lives in the tropics. She was the world's first (and still the most prolific) author of Splenda-based cookbooks for people coping with diabetes and for low-carbers. A best selling author for 16 years, she wrote seven books, five low-carb and two for traditional diabetes diets. Her books can be ordered from www.low-carb.us

Finding Community • Page 50



Justine Lorelle Blanchard is a senior magazines and writing double major at Drake University in Des Moines, Iowa. For the past three years she has written for and edited her school's publication, *Drake Magazine*, receiving national recognition for her feature writing. Her work has also appeared in *Core Magazine*, *Decorating*, *New Home*, and *Storage*, and she spent last summer interning at *Cookie Magazine* in New York City.

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Nadia Al-Samarrie
 Publisher/Editor-in-Chief

In our next issue, we'll publish our 5th annual Product Reference Guide. It's a comprehensive directory, listing 400 plus products designed for you and your patients. Many readers use this wonderful resource all year long to help them understand the very latest medications and technological innovations available to both healthcare professionals and consumers.

Be sure to sign up for our Free Weekly Email Newsletter, so we can keep you up to date. Go to diabeteshealth.com

November is National Diabetes Awareness month. It's a good time to reflect on your patients' blood glucose successes and have compassion for their less-than-desirable results. Everyone struggles with maintaining good blood sugars. In this issue, you will find everyday heroes committed to reminding other people with diabetes that we are all in this together. Since dialog is what it's all about when dealing with diabetes, I am happy to announce a new section on our popular website, called **Diabetes Health Forums**. It's a place where you can participate in an existing discussion or start a new one of your own. Learn more at www.diabeteshealth.com/forums.

John B. is an active participant in Diabetes Health Forums. He lives in Missouri and was diagnosed with type 1 in 1992. When we asked John why he patiently spends so much time answering people's questions and guiding them to the information they need, he responded, "I want to do good by helping others. I want to work with like-minded people to find ways to improve diabetes care. I want to repay those who helped me and gave me hope by doing the same for others."

Fourteen-year-old Eva H. is another active participant in Diabetes Health Forums. She was diagnosed with type 1 when she was eight years old. Eva started several discussions (or "threads" in today's parlance) because she wants to become a pediatric endocrinologist. She thinks "it's a good idea for teens with diabetes to have a place to go to talk, vent, gripe, or just express success in pumping and with diabetes in general."


Eva's mother, Cynthia, wrote an article in this issue about her nine children, three of whom have type 1. Neither Cynthia nor her husband, Greg, has diabetes, and the three diagnoses were quite a shock. It's gut-wrenching to watch a child cope with something as challenging as diabetes. But Cynthia is an everyday hero. She rolled up her sleeves and became an advocate in the schools for better understanding of diabetes. She taught her children to pick themselves up and go on with life. Cynthia writes, "I think that all of my kids are who they are because of the experiences that have touched them. I like the people that they have become."

This issue of *Diabetes Health* also celebrates the heroes among the patients. Laura Dugan writes in "My Own Injection" about finding out that she had

type 2 at age forty-five. She says she shouldn't have been shocked. Her father had type 1, and other family members suffered from type 2. Her father died at the age of forty-one from a heart attack, but her mother "always insisted that it was partly because he didn't manage his diabetes well." But no one in Laura's family talked openly about diabetes. There was no exchange of information, so Laura had no idea what to do when her own diagnosis came. Thankfully, Laura has since taken control of her health. It's not easy. Diabetes Health Forums can support Laura and help her remember that we are all in this together. Forum participants have shared experiences. They've been frustrated. They've laughed. They've cried. They've carried on.

Kim Higgins, who graces our front cover, is this edition's guest editor. I have known Kim for 18 years and hold her in high regard. As a type 1 herself, Kim has worked tirelessly for diabetes for decades. Here's just a short list of her commitment to making a difference in the diabetes community: She's a CDE; she's current chair of the Diabetes Coalition of California (the volunteer arm of the California Diabetes program under the CDC); she's a faculty member of the Johnson and Johnson Diabetes Institute; she's the immediate past president of the San Francisco Bay Area Association of Diabetes Educators; she's a certified pump trainer; and she's a member of the Sharps Coalition of Alameda County who was instrumental in implementing the new sharps legislation in California. This woman has energy, but it is masked by her laid-back persona!

If you like stories about overcoming odds, don't miss the article about Canadian pilot Steve Steele, who helped pave the way for pilots with diabetes to fly commercial jets in Canada. There's also Jean Roemer, MSN, MN, CRNP, CDE, who gathers diabetic supplies and ships them to Malawi, Africa. Finally, there's Al Krause (diagnosed with type 2 in 2002) and Ruth Higgins, who work hard to stick to Dr. Bernstein's low carb diet while vacationing Down Under.

It's a time to celebrate all of our patients: those who don't give up, those who live by example, and those who help us all live a better life. 



COVER

Our Guest Editor, Kim Higgins, RN, CDE shows off Diabetes Health Forums.

Photo by *Diabetes Health* Art Dept.



Kim Higgins

Guest Editor

Diabetes Educators are Champions

A champion is an ardent defender or supporter of a cause or another person. Someone who fights for a cause

Diabetes care creates its own culture. There is a passion that surrounds the caretakers of the diabetes community. It is the small successes that spark us to find another. Diabetes care creates champions out of all of us and I'd like to mention just a few of the hundreds of diabetes educators I have met.

For many years, "Andy", a nurse from Santa Rosa, California, has taken two weeks of her vacation time and traveled to the Ukraine. She teaches a diabetes class in the local language and brings insulin and supplies she's collected from around Northern California. The insulin is stored in a World War I bunker; 56 degrees Fahrenheit to ensure its freshness over the next year. Parents bring their children by train from as far away as Moscow to obtain the life-giving hormone that will allow their children to continue growing. There is no intensive management or titration. Just life and death. Each child is weighed and their insulin needs for the upcoming year are determined. This amount of insulin is then carefully issued to the parents for use over the next 12 months. Pregnant women arrive, anxious to learn how to safely deliver a healthy child. Glucagon is dispersed to those families with the most fragile children who live on rural farms. These children would die if their seizures could not be abated.

Andy is a diabetes champion.

Peggy Huang is a graduate of the Presbyterian School of Nursing in Philadelphia and is a certified diabetes educator, par excellence! Peggy developed the award winning Diabetes Center at University of California, San Francisco (UCSF) many years before ADA Certification. She co-founded the Diabetes Teaching Center at UCSF in 1977. Although retired as Program Coordinator, she continues to serve as a program consultant and sees patients for individual counseling.

Peggy was part of the original team to implement the concepts of intensive diabetes self-management in Northern California in 1974. She helped establish several other teaching programs and is a mentor to nurse educators in countries such as Taiwan, Singapore, and Japan, as well as those in the San Francisco Bay Area. From 1978 to 1992 she was the Coordinator and principal instructor for the Diabetes Teaching Center.

Peggy is also an active advocate for educating Asian Americans with diabetes in the Bay Area. She is fluent in Cantonese and Mandarin. After retiring, she continued volunteering and set up a free diabetes clinic for the elderly. The San Francisco Chinese community now has facilities and services that would not have existed

without the passion and commitment of Peggy.

Peggy is a diabetes champion.

Jeanie Hickey, RN, CDE currently puts her passion into the Dogs for Diabetes program. She has donated time, energy and her own hard work to train the dogs to alert on the scent of a person with diabetes becoming hypoglycemic. Jeanie fosters dogs in training, promotes the benefits to those individuals at risk for severe hypoglycemia, participates in identifying recipients of a dog, and helps coordinate training and graduation. She even collects food, buys stuffed dogs to use as fundraisers, and visits any group interested in learning about these amazing dogs.

Jeanie also donates her summer to work at Bearskin Meadows, a diabetes camp in Northern California. The camp understands that diabetes is a condition that affects the entire family of a child with diabetes, including siblings and parents. Bearskin Meadow gives families a uniquely supportive community of peers and adults who truly understand the day-to-day challenges of living with diabetes.

Jeannie is a diabetes champion.

Molly Keane is one of our fallen diabetes heroes. Molly exemplified what a typical diabetes educator is: devoted to helping patients obtain the best control they can. She often took phone calls from patients at night and on weekends. If a patient needed extra care due to illness or pregnancy, she proactively called them and spoke to them daily or more often if that was necessary. In addition to her patient care, she took mentoring new educators on as an important role. She knew this would help even more patients. She did this with compassion, wit, adaptability, and dedication.

Molly died in a tragic accident off the Sonoma coast last February when she tried to save her elderly dog from a rogue wave. Throughout her short life, she touched so many of us. Educators all over the western United States remember how Molly paid such close attention and how she made herself available to so many. She was full of caring and charisma. We are responsible for carrying Molly's work forward. She inspires all of us.

Molly was one of us, an everyday diabetes champion.

We are all champions in the diabetes community. We are passionate. We are there for all the important moments in our patients' lives. Take a moment every day in November, Diabetes Awareness Month, to tell yourself what a great job you're doing and to encourage yourself to make the changes you want to see in the world. **DH**

Peripheral Arterial Disease (PAD) Affects One in Three People with Diabetes

By Dr. Michael Jaff, Medical Director of the Vascular Diagnostic Laboratory at Massachusetts General Hospital, Boston, Mass.

Peripheral arterial disease (PAD), a condition commonly correlated with diabetes, affects at least one in every three diabetics over the age of 50¹ and approximately eight million Americans over the age of 40. Although PAD is common among people with diabetes and senior populations, current data show that public and physician knowledge of the disease is startlingly low, with only 25 percent of the affected population seeking treatment².

People with diabetes are at the greatest risk for developing severe PAD and experiencing complications from the disease because of their difficulty properly processing sugar. As a result, plaque (fatty deposits) accumulates in the arteries, triggering changes in internal blood vessel size and elasticity that cause subsequent circulation problems.

Plaque buildup causes a narrowing and hardening of the arteries and can eventually decrease blood flow to the lower extremities. When blood flow to the legs becomes limited or restricted, the propensity for developing infections, chronic foot ulcers, gangrene, and leg lesions dramatically increases. Not only that, but these foot wounds have difficulty healing. In severe cases, the affected limb is so damaged that amputation is required if other treatments fail. Problems with the feet are one of the most common causes of diabetes-related hospitalizations. In fact, people with diabetes are up to 15 times more likely to endure lower limb amputation than those without diabetes³. Fortunately, new medical devices and drugs are being developed, and in many cases amputation can be avoided or limited.

Although a common indicator of PAD is extreme leg or buttock pain caused by walking or exercising, as many as 40 percent of people with PAD never complain of this symptom⁴ – and those who do commonly mistake the discomfort for aging pains and fail to seek treatment, allowing the condition to worsen. PAD is highly treatable in its early stages, but as the disease remains undiagnosed, the likelihood of complications greatly increases, as does the probability of heart attack or stroke.

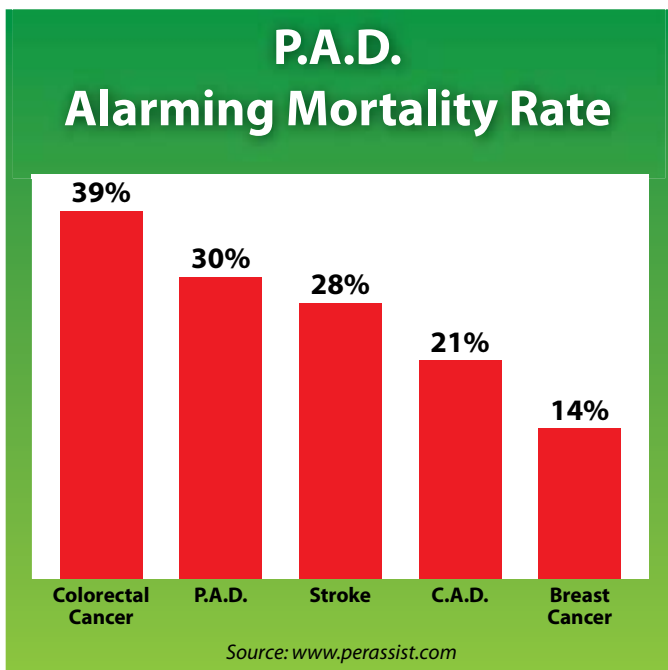
The following are risk factors for PAD:

- Being older than 50 years old (1 in 20 Americans over the age of 50 has PAD)
- Being a current or former smoker (both have an up to four times greater risk of developing PAD)
- Having high blood pressure (high blood pressure increases the likelihood of plaque build-up in the arteries)
- Having a history of heart disease (chances of contracting PAD increase to one in three in patients suffering from heart disease)
- Having high cholesterol (excess cholesterol and fat in the blood contribute to the formation of plaque in the arteries)
- Being African American (African Americans, for reasons not yet fully understood, are twice as likely to have PAD as their Caucasian counterparts)

Individuals who have PAD may also have plaques in the arteries to the brain and heart, which could cause stroke or heart attack, respectively. Early detection and treatment of PAD is essential to improve quality of life and reduce the risk of heart attack, stroke, and amputation among diabetics with the condition.

Several symptoms are warning signs and potential indicators of PAD, including:

- Fatigue or cramping in the leg muscles (known as claudication) when walking
- Pain in the legs and/or feet that disturbs sleep
- Wounds on toes, feet, or legs that heal slowly, poorly, or not at all
- Color changes in the skin of the feet (paleness or blueness)



(Continued on page 21)

Blood & Honey: A Documentary

By Jessica Bernstein, Psy.D.

What do an African medicine man, a diabetes researcher, a feminist philosopher, and a Native American psychologist have in common? They are all part of a new documentary in production dealing with the psychological component of living with diabetes.

I was in the middle of doing my dissertation on diabetes when the idea for this documentary hit me. As someone with type 1, I wanted to understand how living with the condition for so many years influenced people's identity development. This question became the topic of my dissertation and led me in surprising directions.

As I delved into the research in this area, I realized that diabetes researchers were focusing primarily on the negative aspects of living with diabetes. Few researchers talked about how people could actually develop in positive ways as a result of dealing with this kind of adversity. I knew from personal experience that it wasn't true that diabetes only had a negative affect. So I turned to literature that discussed the other side of living with illness. Some was written by people who actually had chronic illness, and some was written by people who had explored the issue of suffering.

I discovered two writers who really changed the way I thought about diabetes. They came from completely different backgrounds, but they were actually saying the same thing.

The first person was well-known African medicine man Malidoma Patrice Some', whose book, "The Healing Wisdom of Africa", was assigned to me in graduate school. In Malidoma's tribe, a crisis, such as a diagnosis of diabetes, is seen as an initiation to a new phase of growth. Instead of being seen as a horrible disaster, a diagnosis is perceived as an opportunity to develop greater wisdom.

It Takes a Village

Malidoma feels that in order to successfully make it through a crisis, we have to draw on community and elders. He asserts that people can be elders at any age as long as they have developed a certain level of maturity and wisdom. He views people who have lived with a chronic illness like diabetes for many years as elders.

The other writer who influenced me was philosopher Susan Wendell who has lived with chronic fatigue syndrome for the past 20 years. Dr. Wendell believes that when people with chronic illness spend many years developing wisdom about how to deal with pain and suffering, they become a valuable resource for people with and without

chronic illness. She explains, "We don't talk as much about the experience of illness as we talk about how to get over it, how to stop it, how to prevent it, how to relieve it, how you can be healthy if you really try. We don't look inside the suffering, past the wall of suffering, to see what's behind it. I think there's an enormous body of knowledge out there among people who are suffering that is untapped, and if we could tap into it more, we'd be less afraid, and we'd know more how to cope when it happens to us."

These ideas were amazing to me because they were so different from how we usually view illness. Coming to see myself as someone with wisdom to share was a revelation. Our culture focuses so much on the negative side of illness and suffering. Usually when I tell people that I've lived with diabetes for 36 years, they respond by saying, "I'm so sorry" or "You poor thing." Nobody has ever thought to pick my brain and find out what I've learned about the kinds of issues that are not only at the heart of diabetes, but are also common to us all—uncertainty, loss, change, mortality.


Documenting Diabetes

With these ideas in mind, I began the process of making a documentary about diabetes. I wanted to share the perspectives about illness of people with type 1 and type 2 as well as the thoughts of various psychologists, philosophers, and chronic illness scholars.

The film takes viewers through the journey of three people who have lived with diabetes for 20 or more years. We refer to these individuals as "diabetes elders"—people of all ages who have acquired a wealth of knowledge and experience that can be passed on to others. We hear what it was like in the beginning when they were first diagnosed and then how they progressed through the years. The people with diabetes share not only what they've learned about living with the condition, but also what they've learned about life.

The project has gotten off to an exciting start with our first seven interviews, which include Malidoma Patrice Some' and Susan Wendell. We recently completed our second shoot, and the whole production team was riveted by the interviews.

You Can Help Complete the Film

This project is dependent on tax deductible donations. In order to continue filming, we must raise more funds. If you are willing to help get this film completed, there are many ways you can contribute. You can make a tax deductible donation through www.bloodandhoney.org. 

Jessica Bernstein, Psy.D. is a psychologist and has a private practice in Berkeley, California, with a focus on people with diabetes. She can be contacted at jessica@bloodandhoney.org.



Susan Wendell



Malidoma Patrice Some'

Peripheral Arterial Disease

(Continued from page 17)

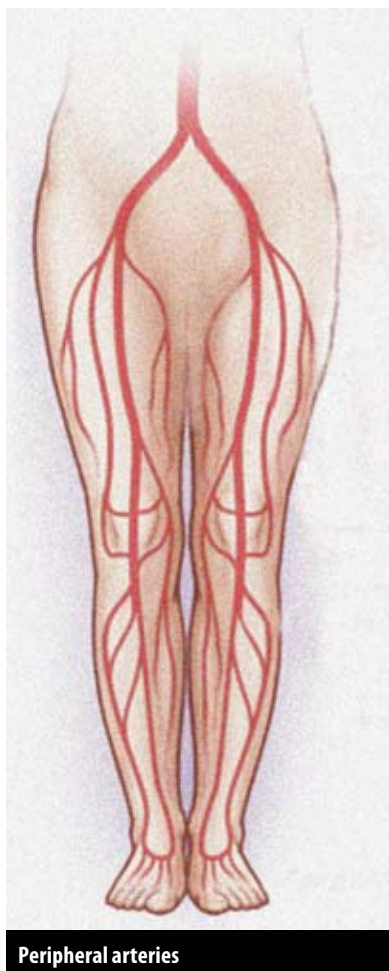
- A lower temperature in one leg compared to the other leg
- Poor nail growth and decreased hair growth on toes and legs

Physicians can quickly and easily test for peripheral arterial disease, which can allow patients to undergo treatment for the condition and arrest its progression. The most common test is the ankle-brachial index (ABI), a noninvasive process that compares the blood pressure in the ankles with the blood pressure in the arms. An ABI can help determine if someone has PAD, but it cannot identify the location and degree of the obstruction in the artery. A Doppler test, which is also noninvasive, can check a specific artery for blockage. The Doppler test uses ultrasound waves to measure blood flow in arteries within the lower extremities.

Once a clogged artery is identified, patients can consider several treatment options with their physician. Angioplasty is a nonsurgical procedure that is used to widen arteries with constricted or blocked blood flow. During the procedure, a catheter with a balloon on its tip is inserted into the narrowed artery and inflated. Once the artery widens, the balloon is deflated and the catheter is withdrawn, often restoring blood flow.

Another option in certain arteries such as the iliac is a stenting procedure. In this process, a stent (a wire mesh tube) is inserted into the artery, where it is expanded to act as a “scaffold” to hold the artery open and allow blood flow to resume. The procedure is minimally invasive, as the stent is guided into the restricted artery with a catheter inserted through a small opening in the artery. Drug-eluting stents, which are coated with medicine that is slowly released into the artery, were created to prevent plaque from growing around the stent due to inflammation and forming scar tissue, a process called restenosis. These devices have shown clinical effectiveness in treating coronary artery disease.

An investigational device for PAD with this characteristic is the new Zilver PTX Drug-Eluting Stent (www.zilverptxtrial.com) from Cook Medical. Currently in clinical trial for use in the superficial femoral artery (SFA), the largest artery in the leg, the Zilver stent is coated with paclitaxel, a drug used as an anti-cancer agent and used successfully with coronary stents to reduce the recurrence of narrowing in the coronary



arteries. The Zilver PTX stent was created to reduce arterial reblockage in the nearly 40 percent of patients⁵ who now must endure repeat procedures when arteries re-narrow. The Zilver PTX Trial is currently enrolling patients having PAD in the artery between the groin and knee in clinical trial locations around the world, and it has commercial approval in New Zealand, Singapore, and Hong Kong. Future PAD studies will be conducted to examine the effectiveness of treating obstructions in arteries below the knee to the foot with this technology.

In situations where large sections of an artery are narrowed, arterial bypass is a surgical option. During leg bypass surgery, a vein from another part of the body or a fabricated blood vessel is sewn above and below the clogged area of the artery to detour blood flow around the blockage. Bypass surgery is a largely successful treatment option, but can be risky for patients who suffer from other disorders such as diabetes or high blood pressure.

People who have experienced any of the aforementioned symptoms or are at increased risk for PAD, especially those with diabetes, should speak to their healthcare professional immediately to

schedule testing. Identification and diagnosis of peripheral arterial disease is critical, as early treatment can ultimately save a life. DH

Footnotes

- 1 National Institute of Health Peripheral Arterial Disease Fact Sheet - NIH Publication No. 06-5837 • August 2006
- 2 Becker GJ, et al. “The importance of increasing public and physician awareness of peripheral arterial disease”. *J Vasc Interv Radiol* 2002;13[1]:7–11
- 3 Diabetes Health: “The Double Whammy: When Peripheral Artery Disease Complicates Peripheral Neuropathy” by Linda von Wartburg May 8, 2007
- 4 Hirsch AT, et al. “Peripheral arterial disease, detection, awareness, and treatment in primary care”. *JAMA* • 2001;286:1317-24
- 5 www.zilverptxtrial.com/treatment.html

Byetta Takes a Beating as Feds Question Its Safety; Defender Chides FDA for Bureaucracy and Bad Science



By Patrick Totty

As we go to press in early September, this is the latest update on the Byetta story. For further updates, please visit www.diabeteshealth.com.

Byetta has had a tough past few days. A lawsuit by a Virginia man alleges that the drug caused his life-threatening bout of severe pancreatitis, and there are rumblings from the U.S. Food and Drug Administration that it may force Byetta's makers to attach a "black box" warning to its container and packaging—a stern, highlighted caution about potentially dangerous, even fatal, side effects.

Both events indicate that the glow may be coming off Byetta (exenatide), which has been hailed since its introduction in 2005 as one of the most powerful and effective type 2 diabetes treatments ever developed, thanks to its weight reduction and A1c percentage-lowering capabilities.

But even as some try to make the case that Byetta might be linked to severe pancreatitis that has led to two deaths, the drug's makers and proponents have taken the FDA to task for allegedly misusing statistics and taking an overly cautious approach.

What Has Been Happening

Virginian Victor Deleon's lawsuit against Amylin and Eli Lilly, Byetta's co-marketers, is seeking restitution for damages from pancreatitis he says was brought on by his use of the drug. Deleon, who was hospitalized for pancreatitis last December, alleges that the companies failed to adequately test and monitor Byetta's potential side effects or to state them forcefully enough on the drug's warning labels.

Deleon came down with the disease, a painful inflammation of the pancreas that can lead to internal bleeding and even death, just weeks after the FDA ordered Amylin and Lilly to provide stronger cautions to prescribers and users that Byetta could be a factor in the onset of pancreatitis.

At the time, the FDA was responding to reports that Byetta usage was suspected in the onset of 30 cases of pancreatitis. Even though that number was miniscule when compared to the

number of Byetta users—conservative estimates say 700,000—the form of the disease being reported, hemorrhagic pancreatitis, was more severe than the normal affliction. In hemorrhagic pancreatitis, unlike normal pancreatitis, acute inflammation destroys pancreatic cells and can lead to a patient's death.

On August 18, some time after it had directed Amylin and Lilly to beef up Byetta's warning labels, the FDA announced that it had received news of six more cases of possibly Byetta-related pancreatitis, including two of which the patients had died. As result, the agency indicated that it is considering asking for a "black box" warning label on Byetta that spells out potentially fatal side effects from taking the drug.

Byetta's Defenders Weigh In

Amylin and Lilly weighed in on the controversy on August 26, 2008. In a teleconference with news media, the companies said that since 2006, the prescribing information for Byetta has included information about pancreatitis. "The companies were aware of the pancreatitis cases referenced in the alert, as well as others, and previously reported these cases to the FDA," they said in a press release that preceded the conference.

The co-marketers also pointed to a recent study that said patients with type 2 diabetes run nearly three times the risk of developing pancreatitis as those without diabetes.

David Kliff, publisher of the Chicago-based *Diabetic Investor* newsletter, mounted a blistering attack on the FDA, questioning its statistics and competence in the matter. He cited the FDA's August 18, 2008, statement that there was no indication of causation between acute pancreatitis and Byetta and that the events were "rare and uncommon."

"Has the FDA ever heard of something called a statistically relevant sample size or incidence rate?" Kliff asked in an email update on the controversy to his subscribers. "Do they understand the concept that patients with diabetes are at an increased risk of pancreatitis?"

(Continued on page 28)



The Byetta needle-tip is tiny



Byetta Takes a Beating

(Continued from page 25)

He accused the agency of being “hypersensitive to any possible issue after Rezulin, Avandia, and Vioxx—just to name a few of the agency’s more recent blunders. Rather than fully investigate and follow their mission to use evidence-based medicine, the FDA overreacted.”

He called the agency’s actions “careless” and said that the people who will be hurt the most are diabetes patients and their physicians. “Once again government bureaucrats drop the ball and it lands where it does the most damage. Even if the FDA did the unthinkable and actually issued some sort of statement clearing Byetta, the mercury is already out of the thermometer. They cannot undo the numerous press reports on their action or change public perception.”

Kliff said he considers it “highly unlikely” that the FDA will require a black box warning for Byetta.

Other Woes: A Threat to Byetta LAR and Questions About Weight Loss Effects

Aside from theoretical links between Byetta and pancreatitis, another potential problem for the drug is whether its users can sustain the often significant weight loss many of them enjoy once they begin using it. *The Financial Times of London* quotes an article from Pharmawire, “Amylin’s Byetta: physicians remain skeptical of drug’s real-world benefit,” in which some researchers question the drug’s weight-loss efficacy beyond a year or two.



I am going to continue to use Byetta. It works very well for me and keeps my blood glucose at a good level. I have

been using it for over two years and have not had an A1c of over 5.2 during that time; it is currently 4.9. The risk of pancreatitis seems very small compared to the benefit I get from Byetta.

I took Byetta for about 6-8 months along with 70/30 insulin. I became increasingly sick to my stomach the longer I used the drug. I did lose some weight, but I believe it was because I did not feel all that good while taking Byetta. It also seemed that my food did not go down like it should and that it just sat in my stomach for longer periods of time. I eventually quit taking Byetta and began feeling okay and not so sick to my stomach anymore.

I have been using Byetta now for a year and haven’t had anything except lowered blood sugar and lost about 20 lbs. this stuff is great.

I tried to use Byetta for six months and never was so sick in my life! My whole quality of life was affected by this med. I did lose 10 lbs but it was not worth this type of living which, for me, was non-living. I must add that I had to use chemo

for breast cancer several years before and was not as sick as I was with Byetta!

I was diagnosed with type 2 diabetes in August 2007. After being put on 2 Byetta injections a day, the only side effect was severe nausea for ONLY the first week. I stuck it out and actually Byetta ended up being my LIFE SAVER. Byetta does curb your appetite so you don’t eat as much. So after being on Byetta only 7 months I had a 50 lb weight loss. Exactly one year after a type 2 diabetes diagnosis I am now 64 lbs lighter., take NO MORE Byetta and have a perfect A1c, and no longer am considered as having diabetes. Not that I am saying Byetta takes your diabetes away. It helped me in the weight loss though, and to get my blood sugars back to within a normal range again. THANK YOU TO BYETTA!! It saved my life.

1:20,000 is based on known reported cases. We know that not all cases are reported. For example, digoxin toxicity has been the most common cause of hospitalization, yet only 30 cases a year are reported to the the FDA. That is an extreme case where a toxicity is well known, however, when there is a lot of publicity, as in the present case, the reporting rates will go up (which they probably haven’t yet with Byetta). Even after they go up, comparison of published cases with FDA reports (e.g., Lilly’s Oralflex) as well as FDA’s internal estimates, indicate that 10% or less of cases are reported. That means that the true incidence is not 1 in 20,000, but really more than 1 in 2000. David

Kliff may have knowledge of basic statistics but he clearly has no knowledge of pharmacoepidemiology and reporting rates. I’d also like to know what are the extent of his financial conflicts.

I really felt good on Byetta. My BS dropped and it was a great appetite suppressor. Then a month later I went into the ER because of severe gastral problems.(I thought I was having a heart attack.) Was terrible, would not clear up and I had to go off the only type 2 diabetes drug that worked for me. UGH! Why can’t the drug manufacturers get it right?

I have tried to use Byetta for 2 years. The entire time it made me sick. I had foot surgery in March 2008. The Byetta dosage resulted in increased nausea, and my taste and desire for food decreased. I lost 10 lbs but felt like hell the entire time. I have decided to stop the Byetta because I honestly think it was causing my health to deteriorate and reach a point that I was not going to live. No medication is worth that effect!

Under “What are the odds?” - this is a meaningless exercise without including what the incidence of pancreatitis is in people with type 2 diabetes who are not using exenatide. It is like stating that “2% of people who eat carrots die of stomach cancer.” That sounds pretty serious unless you have the stomach cancer rates of those people who don’t eat carrots (say 2.5%). A little more critical analysis on the author’s part please.



However, other doctors and scientists quoted in the article say that a current study that hints at Byetta's loss of weight-control effectiveness is based on too small a sample. They say it will take more than the three and one-half years the drug has been on the market to ascertain its real usefulness as an agent in long-range weight loss.

Possible Effects on Byetta LAR

The suspicions lodged against Byetta by the FDA may come to bear against its long-term version, Byetta LAR, a once-weekly injection that is now in late-stage FDA-approved trials.

Although Amylin has reported no cases of pancreatitis associated with Byetta LAR, a potential problem with the drug is that its active agent remains in patients' systems long after they have ceased taking it. If that agent were later proven to be a causal factor in the onset of pancreatitis, it would have a dampening effect on the long-term drug's marketability.

What Are the Odds?

If a link can be established between Byetta and pancreatitis, what are your chances of developing the disease if you are currently one of the 700,000 people taking the drug?

Based on 36 cases cited by the FDA, you have a 1 in 19,444 chance of coming down with the affliction. In percentage terms, that's 0.005 percent—5/1,000ths of 1 percent.

(If you use David Kliff's figure of "nearly 800,000" Byetta users, your odds decrease to 1 in 22,222.) [DH](#)

This is absolute nonsense. People on Byetta also get skin cancer, grow old, get divorced, and get fired from their jobs. What you want to know (and what nobody is talking about) is whether type 2 diabetic patients on Byetta are more likely to develop pancreatitis than type 2 patients not taking Byetta. As far as I know, there isn't a shred of evidence to suggest that this is the case.

I have been taking Byetta for about 8 months now. I have had weight loss of about 15 lbs and some nausea. I find that if I inject in my stomach or butt that it's not felt as much. Also, if I inject just before a meal it's not as bad. The longer I wait to eat after an injection, the more chance I have of feeling nausea come on. I also feel bad if I eat a high carb meal, so it makes me eat better. I have never experienced any of the gut problems or pain. I will continue to take Byetta and my Metformin. My ranges are from 90 to 120 and don't go over 135 after eating, and that's a spaghetti dinner! If you're taking Byetta and feeling sick, try injecting it in your butt and eating within 15 min after your injection. Worked for me!!

I have been on Byetta for over a year. The first week, I had some nausea but nothing since. My A1c plummeted from 10 to 5.9 in two months, and I have lost 35 pounds. Byetta's saving my life! If diabetics naturally have a higher incidence of pancreatitis even without Byetta, I feel that the risk of taking Byetta is justified. It's got to be better than kidney

failure, heart disease, losing limbs, etc. What about those risks?

Byetta worked well for me during the 9 months that I used it. I had no nausea or abdominal pain and my A1C dropped to below 6 for the first time since I was diagnosed in 2004... But then, my hair started falling out and the Byetta was the only thing new in my regimen. There's nothing on the package, in the formulary, in the PDR, or on the website that lists hair loss or alopecia as a side effect, but when I Googled Byetta and hair loss, I got lots of hits. I stopped taking Byetta and my hair stopped falling out and has finally started growing back. Fortunately, other meds have kept my A1c in check, but I've gained weight. If Byetta were my only choice, I'd just have to wear a wig, because it works!

I have been on Byetta for nearly 30 days and have experienced very little side effects. The positives are better BS, my hunger has significantly been reduced, and I have eliminated two of 6 medications, saving \$140 quarterly. I look forward to testing my A1c in 60 more days. Tomorrow, I move to a 10 mcg injection, hoping the good continues.

I have been using Byetta for a year and have lost about 35 pounds. The nausea was hard to take initially, and now I only have nausea periodically. The weight loss is a blessing and worth feeling nauseated every now and then. I do not believe there is enough information to determine the over-

all safety of the drug. I feel this bears more research and documented results comparable to other drug issues.

I've been on Byetta a year now and it has been well worth any risks there might be! In the last last year or two I've dropped 81 lbs and have lost my sleep apnea - another dangerous co-morbidity for diabetics. I feel a lot better and look a lot better. The Byetta probably has helped me drop a good 50 or the total lost 81 lbs. I only had minor nausea with this at each step (going on the 5mcg a week of nausea, going up to the 10 mcg about 2-3 days). My A1c has dropped from 7.8 to 6.7 and if I'd eat a bit more wisely, I'd probably see it go lower - my problem, not the drug's. I think it's a great help to me, but many people may not be able to use it as we all have slightly different metabolisms and sensitivities. I think it's the best thing to come along in the 10 years since my type 2 diagnosis and plan to continue on until I either lose all of the weight (another 50 lbs is my goal) or lose my symptoms of type 2. I'll take a chance on pancreatitis. I hope that anyone who is really sick on this drug will talk to their doctors, as I would think you'd have some pretty good indication something's wrong. I've had friends with pancreatitis, and they were pretty sick. An early intervention by your doctor could be a real lifesaver. I figure if you are having any problems, question your doctor!

Sugar and Diabetes: The Myth That Won't Die

By Marie McCarren



John Bantle, MD, puts it in real-world terms: "Foods that contain sugar don't produce a greater rise in blood glucose than bread, rice, and potatoes, if the calories are the same. If you add dessert to a meal, increasing the amount of carbohydrate, your blood sugar will be higher. But you'd have the same effect if you had a double helping of mashed potatoes or an extra roll."



Years ago, John Bantle, MD, gave brownies to people with diabetes. Brownies made with real sugar. And their blood glucose levels...did not skyrocket.

Bantle and his colleagues were comparing two meal plans. Both plans had the same amount of carbohydrate. In one, much of the carb was from sugar. In the other, the carb came mainly from starches. Participants ate one meal plan for 28 days and then switched to the other.

Participants' blood glucose levels were essentially the same when they ate the high-sugar meals as when they ate the high-starch meals. Conclusion: Sugar is just another carbohydrate. It's the amount of carb, not the source, that determines blood glucose levels.

That was 15 years ago. Yet today, people who have diabetes still hear, "You can't eat that. It has sugar."

Will the Myth Ever Die?

"Old ideas that are wrong do die," says Bantle, a professor of medicine at the University of Minnesota, Minneapolis. "It just takes them a long time. People spent 60 years drumming it into people with diabetes. It was in all the textbooks. And if your blood sugar is high, intuitively it makes sense that you shouldn't eat sugar."

But starch is a string of glucose molecules. When people know that, they can see that starches will raise blood glucose levels just as sugar will.

"A lot of people who are up-to-date in diabetes consider this old news," says Bantle. "But if you go to the primary care arena, I think they're much less aware. I was talking to some medical students last week, and they thought

sugar was a bad thing. But they're just a product of their culture. As I talk to patients, some people seem to know it, and for others it comes as a surprise."

For years, the American Diabetes Association's Nutrition Recommendations have included their version of "Sugar is just another carb." In the 2008 position statement, the wording is: "Sucrose-containing foods can be substituted for other carbohydrates in the meal plan or, if added to the meal plan, covered with insulin or other glucose-lowering medications. Care should be taken to avoid excess energy intake."

Bantle puts it in real-world terms: "Foods that contain sugar don't produce a greater rise in blood glucose than bread, rice, and potatoes, if the calories are the same. If you add dessert to a meal, increasing the amount of carbohydrate, your blood sugar will be higher. But you'd have the same effect if you had a double helping of mashed potatoes or an extra roll."

Readers, what has been your experience with sugars versus starches? Does your meter tell you that a dinner roll is the same as a piece of cake? [DH](#)

Marie McCarren is the author of *A Field Guide to Type 2 Diabetes* and *ADA Guide to Insulin & Type 2 Diabetes*.

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Dr. Denise Faustman Continues Working Toward the Cure

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Editor's Note: In May 2005, we published an in-depth article discussing the brouhaha that erupted when the New York Times wrote about the JDRF's unwillingness to fund Dr. Faustman's ongoing research. Two medical doctors in the diabetes community and scientific colleagues of Faustman at Harvard Medical School wrote an enraged response to the Times article. After investigating both sides of the story, the Times declined to print the two doctors' letter. The JDRF decided to take matters into its own hands and circulated an e-mail containing the unpublished doctors' letter to JDRF chapters around the country.

Merrill Goozner, director of the Integrity in Science Project for The Center for Science in the Public Interest, was disturbed to see the JDRF go to such great lengths to discredit Faustman. "It is shocking to see that scientists, rather than evaluating something on its merits, would spend so much time attacking the messenger," he said. "You have to wonder, what is their real motivation? You would think that scientists connected with the JDRF would be pursuing every effective cure, not attacking approaches that rival their own."

Diabetes Health is pleased to see that the Iacocca Foundation supports Dr. Faustman's research and that she has made the exciting leap to human trials.

As we go to press in early September, this is the latest update on the Byetta story. As always, visit www.diabeteshealth.com for the latest information.

After it saved the lives of diabetic mice, a drug used to treat tuberculosis and cancer is now being tested in humans at Massachusetts General Hospital as a possible cure for type 1 diabetes.

Denise Faustman, MD, PhD, director of the MGH Immunobiology Laboratory and associate professor of Medicine at Harvard Medical School, proved in 2001 that the drug, Bacillus Calmette-Guérin (BCG), cured mice with end-stage diabetes. She is now leading a Phase I clinical trial in patients that began in February and is expected to take 18 months to complete. BCG is a generic drug with an excellent safety profile in humans. It causes the body to make a natural substance called TNF, which helps regulate the immune system by killing the rogue T-cells that cause diabetes.

BCG has been used safely for nearly 80 years as a tuberculosis vaccine. It is being used in the human trial because it causes a low-grade inflammatory reaction, which in the mouse model of autoimmune diabetes led to the destruction of the abnormal autoimmune cells.

David M. Nathan, MD, director of the MGH Diabetes Center, commented on the study, "This is the very first step in what is likely to be a long process in achieving a cure. We first need to determine whether the abnormal autoimmune cells that underlie type 1 diabetes can be knocked out with BCG vaccination, as occurred in the mouse studies." Trial information is available to the public at www.faustmanlab.org.

Dr. Faustman's research is unique because most diabetes research focuses on new treatments involving blood glucose monitoring devices. There is almost no emphasis on disease reversal or cure. "Our goal is to reverse established type 1 diabetes, not simply



"Our goal is to reverse established type 1 diabetes, not simply temporarily halt it or treat its symptoms," says Dr. Faustman. "If we can introduce this inexpensive drug to the market, it will be a tremendous achievement."

—Dr. Denise Faustman

Photo: Massachusetts General Photo Services

temporarily halt it or treat its symptoms," says Dr. Faustman. "If we can introduce this inexpensive drug to the market, it will be a tremendous achievement."

The clinical trial is being supported largely through direct and fundraising support from the Iacocca Foundation and through support from other donors and the Massachusetts General Hospital. The Iacocca Foundation was founded by Lee Iacocca and his family in 1984 to fund innovative approaches to a potential cure for diabetes.

The launch of the clinical trial received press coverage in the U.S. and the U.K. For more information on the MGH Immunobiology Laboratory, go to www.faustmanlab.org.

Response from JDRF

August 6, 2008

Dear Editor,

In regards to your article, "Dr. Denise Faustman Continues Working Toward the Cure," I found the inclusion and focus of your editor's note to be puzzling. While the article focuses on updating Dr. Faustman's research, the note introducing the article focuses on an old, inaccurate, and exaggerated issue

concerning Dr. Faustman from over three years ago.

Since you've decided to bring JDRF into the story, I'd like to set the record straight. Contrary to your assertion, JDRF has never tried to discredit Dr. Faustman or her research. In fact, we have gone to great lengths to avoid public comment on why we did not fund her study, despite a litany of charges and innuendo (though never from Dr. Faustman herself, who has said she respects the process that led to the JDRF's decision). The fact that we are not funding a researcher does not imply that we think any less of his or her work, or harbor

(Continued on page 49)

Denise Faustman

(Continued from page 46)

any ill-will. While we are the largest charitable funder of diabetes research, we fund only one of every four proposals we receive. And it's important to remember, JDRF's research funding decisions are made not by the staff, but by scientists and lay reviewers, which include moms, dads, and others with a personal connection to type 1 diabetes. They are not concerned with starting academic or political squabbles; their singular motivation is to fund research that will deliver cures for themselves or their loved ones.

Regarding the New York Times letter, JDRF circulated this internally in response to staff inquiries—not externally—to make the point that some in the scientific community had a different opinion than was expressed in the Times article. The letter was not an attack on Dr. Faustman, as your editor's note implies, but rather an alternative interpretation of her research findings.

JDRF is committed to finding a cure for millions of people affected by type 1 diabetes and its complications. We've never questioned Dr. Faustman's commitment to the same goal. JDRF and Dr. Faustman have worked together in the past, and we wish her nothing but success with her current trials, which, as you note, have received ample funding from other sources. JDRF itself is currently funding 20+ human clinical trials focusing on reversing the autoimmune process that causes type 1 diabetes. Dredging up old disputes and pointing fingers only provides an unnecessary distraction from the work at hand—finding a cure.

Sincerely,

William Ahearn,
Vice President, Strategic Communications and Information Technology

Editor's response: As always, Diabetes Health appreciates the opportunity to present more than one point of view. We would never dream of "distracting" someone from finding a cure for diabetes. **DH**



The goal of MGH Diabetes Center is to develop and implement innovative therapies that will benefit the lives of people with diabetes and to increase public awareness of this disease and ways to control it. The unique organization of the MGH Diabetes Center, integrating both clinical and research activities, has helped make the Diabetes Center a recognized leader in this field. What is learned in the lab helps to improve patient care; what we learn from patients helps inform our research activities. To make an online donation, visit www.mgh.harvard.edu/diabetes

Nine Kids, Type 1, and Silver Linings

(Continued from page 16)

changing. Eva liked the color screen and the outside colors of the new Animas 2020 (hers is "limelite" green). Ean needed a pump with a large cartridge, and he thought that the Deltec with the FreeStyle meter attached looked like a "Digivice" (think Digimon/Pokemon).

It really makes life interesting that all three kids have chosen a different brand of insulin pump. Different strokes! So, be it Animas, Cozmo, or Minimed, there will be an alert or alarm going off at any given time of the day or night. We just have to figure out whose it is. Kind of like trying to find that annoying little cricket that is deafening until you look for it.

Elliott, Eva, and Ean all have a mini-competition to see who can get the best A1c every three months. They compare insertion sites and the occasional pump bump. All nine kids know how to give glucagon. They all have cell phones ("for emergencies, Eva, not for texting!") just in case.

Amazing People

It isn't a life I would have chosen, but then again, it could be much worse. I have had people say things like "I could never do what you do!" All I can say is, "Nobody asked me." There are reasons we are given what we have to deal

with. Diabetes has shaped the futures of my children and turned me into an advocate. Elliott works in a pharmacy. Eva has definite plans to go to Stanford and become a pediatric endocrinologist. Ean plans to become a research scientist so that he can find a cure for diabetes.

We have met and been associated with some of the most amazing people in the world, from our diabetes camp, Camp McCumber (14 years now!) run by Dr. Logan, to Dr. Sheikhislam and Dr. Prakasam, to the nurses at the PENS team and the amazing distributors who make sure our kids get their supplies when they need them. It's the people we see every day. It's the pediatrician who is willing to pinch hit during a DKA episode. It's the school nurse who is your right hand, eyes, and ears when you can't be there.

Something Good

All of this is something good that has come from something awful. Diabetes is a challenge, to be sure, but it's life as we know it. I think that all of my kids are who they are because of the experiences that have touched them. I like the people that they have become. **DH**

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2. What are your credentials? (Check all that apply.)

- 01 MD
- 02 Endocrinologist
- 03 CDE (Certified Diabetes Educator)
- 04 NP (Nurse Practitioner)

- 05 RN (Registered Nurse)
- 06 RD (Registered Dietitian)
- 07 Pharmacist
- 08 PA (Physician’s Assistant)
- 09 DPM (Podiatrist)
- 99 OTHER

3. What best describes the location where you work? (Check one.)

- 01 Hospital
- 02 Clinic
- 03 Diabetes Clinic
- 04 Medical Group
- 05 Private Practice
- 06 Outpatient Education
- 07 Pharmacy

4. How many diabetes patients do you see per month? (Check one.)

- 05 None
- 01 1 - 25
- 02 26 - 50
- 03 51 - 100
- 04 More than 100

5. Of the diabetes patients you see each month, how many are newly diagnosed? (Check one.)

- 05 None
- 01 1 - 25
- 02 26 - 50
- 03 51 - 100
- 04 More than 100

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October & November 2008

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