



The CFIDS Association of America

SOLVECFS

PUTTING YOU AT THE CENTER OF RESEARCH

The Chronicle of the CFIDS Association of America
Winter 2013

One Patient's Story

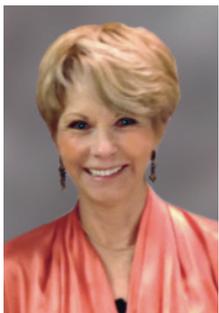
Increased awareness of ME/CFS helps to generate research funding. So it's important for those struggling with ME/CFS to keep sharing their stories.

For ME/CFS sufferers, "coming out" to family and friends about their illness can be a tremendous challenge.

*The CFIDS Association is proud and thankful to work with individuals who are willing to share their story as widely as possible, like **Anna Zapp**...*

Rocky Mountain Highs

My life's dream was to design and sew for famous people. In August 1973, my amazing journey began. John Denver



Zapp

spied my custom made western shirts at the Aspen Mining Days Art Fair. This began a ten-year relationship as I designed and made his stage clothes and later designed for Robert Redford, Willie Nelson, Bonnie Raitt, John Travolta and more.

My career continued to take exciting turns. I sold garments internationally, created custom designs for Neiman-Marcus, Macy's, and others. I collaborated on three patented ergonomic sewing products, built a company, "Sew-Ergo," taught tailoring techniques, and wrote articles for the national magazine "Sew News." I designed embroidery discs and in 2002 I wrote an instructional book; "The Zapp Method of Couture Sewing." I worked tirelessly for a year on the graphic drawings, photography and the necessary sewing. But at the end of each day I was REALLY tired.

During the spring of 2005, I started feeling ill with no energy or appetite, severe, unrelenting pain going down my right leg and an impingement in my left shoulder. I kept getting viruses that wouldn't go away. After shoulder surgery in November '05, I awoke knowing something was terribly wrong. I got worse. I couldn't sleep, eat, or think; I had intense nausea, non-stop migraines, fever, my spine was on fire, arms and hands burning. All the systems in my body seemed to be non-functioning.

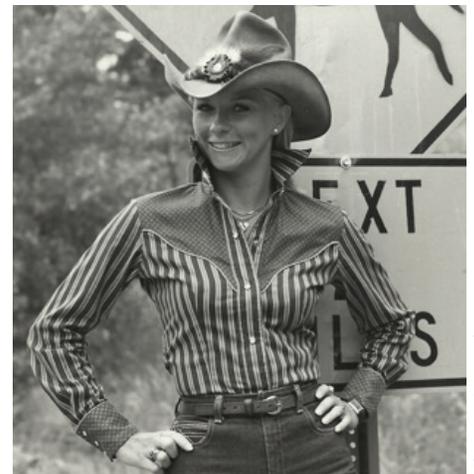


Photo: Pat Holgate

Anna Zapp modeling one of her custom creations.

Late February '06, I had to cancel a speaking engagement. I was terribly sick. My life as I'd known it was over. My weight dropped to 88 lbs. at 5'4". I was disappearing.

I saw 17 different doctors/specialists over the next 5 months, having hundreds of blood tests, cultures and scans. I was given a myriad of meds "to try." Only one doctor mentioned CFS, but only that it "was a waste basket for unknown symptoms." Then one night in fall of 2006, the Nightly News reported on CFS research. "This is what I have!" I told Ray, my husband.

continued on page 7

The CFIDS Association of America Board of Directors

Amy Squires
Alexandria, Virginia
Chairman

Vicki Boies, PsyD
Chicago, Illinois
Vice Chairman

Kevin Frick
San Carlos, California
Treasurer

Lynn Royster, Ph.D.
Dallas, Texas
Secretary

Diane Bean
Bethesda, Maryland

Beth Garfield
Los Angeles, California

Pamela Laird
San Francisco and Occidental,
California

Terry Tyler, M.D.
Owensboro, Kentucky

Christine Williams, M.Ed.
Chevy Chase, Maryland

Professional Staff

Carol Head
President & CEO

Suzanne D. Vernon, Ph.D.
Scientific Director

Kristina P. Hopkins
Chief Financial Officer

Mark A. Stone
Development Director

Leigh A. Reynolds
Engagement Manager

Gloria E. Smith
Office Manager & BioBank Coordinator

Kim A. Almond
Operations & Network Administrator

From the CEO

Friends,

As the year draws to a close, many of us reflect on what we are most thankful for as we look ahead to the new year. I'm deeply gratified by the opportunity to play a leadership role in solving ME/CFS. While it's unacceptable that we are still so far from solving ME/CFS and that we don't yet know why we get sick or why some of us get better, I'm hopeful about the path ahead. The work of the CFIDS Association is to make real the day when ME/CFS is solved. As a patient, I'm dedicated to assertively leading that effort.

When I became ill with ME/CFS in the 1980's, I discovered the CFIDS Association. I recall the deep sense of relief in realizing that I was not alone. Although I've never known why, I experienced years of gradual improvement, never dreaming that I'd have the opportunity to use my leadership experience and entrepreneurial drive to join the fight to solve ME/CFS. I look forward to faster progress along the path toward a cure and am confident in the direction of the Association.

I'm also keenly aware that we can't do this alone. It will take all of us—patients, researchers, funders, government agencies, other ME/CFS organizations—working together to bring safe and effective, approved therapies to market to eradicate this dreadful and debilitating illness.

On the pages that follow, you will read more about how we're working to drive faster and more effective progress. We are committed to our evidence-based, research-driven work. We hope you find strength in knowing we are here, working with you, toward solving ME/CFS. We ask for your support.

Together we can Solve ME/CFS!



Carol Head
President & CEO
CFIDS Association of America
CEO@CFIDS.org



Head

In this issue

Page 1
One Patient's Story

Page 2
From the CEO
Board of Directors & Professional Staff

Page 3
SolveCFS BioBank:
Accelerating the Discovery of Biomarkers

Page 6
Helping Your Voice Be Heard in D.C.

Page 7
Participate in Progress

Page 8
Join Us at SolveCFS.org
Contact Info

SolveCFS BioBank: Accelerating the Discovery of Biomarkers



Vernon

By **Suzanne Vernon**

A biomarker—or biological marker—is an objective way to measure a process occurring in the body.

ME/CFS is likely to have a variety of biomarkers that can be used to identify ME/CFS subtypes, objectively diagnose ME/CFS, determine specific treatment targets and measure response to treatment. However, there are currently no widely recognized

biomarkers which impedes diagnosis and research.

Recognizing the critical importance of finding biomarkers, the CFIDS Association created the SolveCFS BioBank in 2010. With our BioBank, any qualified researcher can apply to access clinical information and biological samples from ME/CFS patients and healthy control participants. Recruitment of participants in research is a time intensive and costly aspect of research. The SolveCFS BioBank puts patients at the center of research and provides important value to the research process. Making samples easy for researchers to

acquire quickly speeds research, both for researchers who are funded by the Association and by others.

We have leveraged the SolveCFS BioBank to attract some of the brightest investigators from the best medical institutions to discover and validate ME/CFS biomarkers. We believe that information gained from researchers who obtain samples from the SolveCFS BioBank will help in the early detection, objective diagnosis and effective treatments and interventions of individuals affected by ME/CFS. Your contributions to the CFIDS Association directly help us move forward this important research.

Below and on the following pages is a sampling of some of the biomarker research being conducted on samples from our SolveCFS BioBank which you help fund.

Discovering Biomarkers on Genes



McGowan

Patrick McGowan, PhD is an Assistant Professor in the Department of Biological Sciences at the **University of Toronto at Scarborough**.

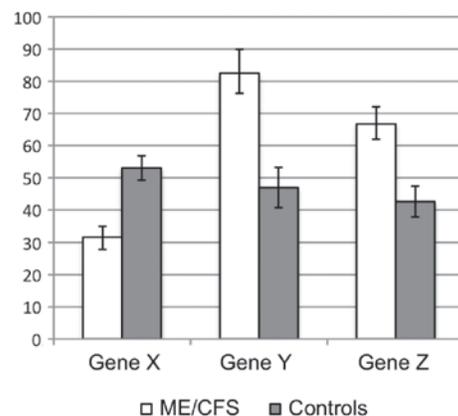
Dr. McGowan is a young investigator new to ME/CFS research and a recipient of our CFIDS Association research grant money. He is one of the first to study epigenetics in ME/CFS. Epigenetics refers to patterns of change in gene expression—not the gene

itself—that occur in response to such things as nutrition, infection and physical and mental trauma, not genetic factors.

“Epigenetics is really a funnel by which the outside environment interacts with the genome,” explains McGowan. This, in turn, influences how cells work (or don’t work.) Already, research shows that epigenetic changes are implicated in numerous diseases, including cancer, asthma and heart disease. And, if Dr. McGowan is right, epigenetics may also play a role in ME/CFS.

He is using blood samples from the SolveCFS BioBank to look for epigenetic differences. A sneak peek at some of the results in the graph shows that

three genes important for immune function have significantly different epigenetic patterns. Gene X has less methylation while Gene Y and Z have greater percentage of methylation in ME/CFS patients. Dr. McGowan is preparing these results for publication.



SolveCFS BioBank: Accelerating the Discovery of Biomarkers (cont.)

Virus Biomarkers



Delwart

Eric L. Delwart, PhD is a professor of Laboratory Medicine at the University of California San Francisco and Blood Systems

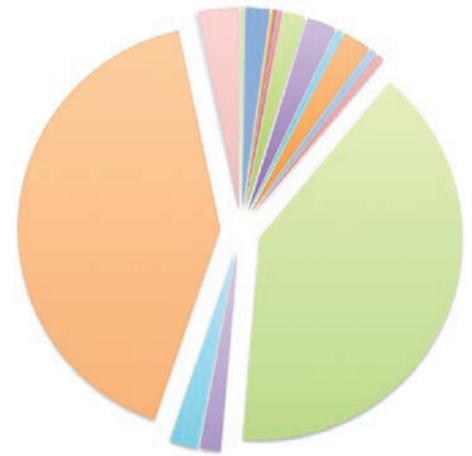
Research Institute. His research focuses on viral discovery from using next generation sequencing technology and associating new viruses with diseases. He wanted to find out if there was a new, previously undiscovered virus associated with ME/CFS.

To look for new viruses in ME/CFS patients, Delwart took plasma samples and treated the samples to concentrate

all possible virus particles. The genetic material from the virus concentrate was sequenced to identify all possible viruses present in the blood of ME/CFS patients. Viruses detected in plasma may indicate an ongoing, active infection.

Viruses from 19 families were identified. No new, novel or highly divergent viruses were identified in the ME/CFS blood samples. Further research is needed to determine if these same viruses are present at similar levels in the blood of healthy controls.

Differences in viruses in ME/CFS patients could be used as “virus profile” biomarkers. It will also be important to apply these powerful next generation sequencing technologies to other types of samples from ME/CFS patients.



Antibodies as Biomarkers



Elledge

Stephen J. Elledge, PhD is a Howard Hughes Medical Institute investigator in the Department of Genetics at Harvard Medical

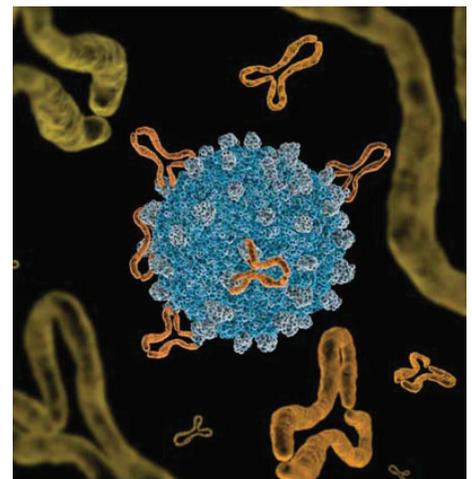
School. He has developed a technology that reveals all the viruses targeted by the antibodies in the blood. Elledge was excited to learn about the SolveCFS BioBank because he

hypothesizes that viruses may cause ME/CFS. He is using blood samples from the SolveCFS BioBank to create an “antibody barcode” that is a history of virus infections in an individual.

Antibodies are substances that our body normally makes in response to an infection. In this image, the virus is the blue object and the antibodies are the “Y” looking objects. Antibodies recognize specific pathogens and as shown in the image, attach and activate a variety of mechanisms to kill and eliminate the pathogen.

This is a new project and Steve estimates it will take about 1 year to

complete the testing and analysis of the 100 samples from ME/CFS patients and 79 samples from healthy controls. We are anxiously awaiting his results.



Autoantibody Biomarkers



Cooperstock

Several lines of evidence suggest ME/CFS may be an autoimmune disorder. Its occurrence in previously healthy indi-

viduals, relatively rapid onset, and persistence over many years, relapsing-remitting course, and its marked female predominance are all clinical features of autoimmune disorders. ME/CFS can be initiated by Epstein Barr virus infection,

an agent known to promote autoimmune processes in lupus and multiple sclerosis. The response to rituximab, a drug that eliminates antibody-producing B cells, also suggests ME/CFS may be an autoimmune disorder.

Michael Cooperstock, MD, MPH, of the **University of Missouri** Health System partnered with Madeleine Cunningham, PhD and David Kem, MD of the **University of Oklahoma** and Armin Alaedini, PhD of **Columbia University** to test blood samples from the SolveCFS BioBank for autoantibodies against antigens in a human neural cell line, several specific human

brain antigens and to mouse brain and dorsal root ganglion tissue. Despite the fact that samples for this study were selected from ME/CFS BioBank participants with brain fog and orthostatic intolerance, the rate of autoantibodies in ME/CFS patients compared to healthy controls was similar. In other words, the types of autoantibodies detected by these investigators appear to be benign and not associated with ME/CFS. And even negative outcomes move us forward as we eliminate causes. There are many more autoantibodies to look at and their search continues.

Biomarker Validation



Houghton

Michael Houghton, PhD discovered the hepatitis C virus and was awarded the 2000 Albert Lasker prize. Houghton is the Canada

Excellence Research Chair in Virology and Professor in the Department of Medical Microbiology & Immunology at the **University of Alberta**. He is using

blood from the SolveCFS BioBank to validate a possible ME/CFS biomarker.

In order for a biomarker to succeed, it must be validated in a large sample set distinct from the one in which the biomarker was discovered. This helps ensure that it is a replicable and robust biomarker. Once the biomarker is validated, it will go through regulatory review and ultimately be approved for clinical use.

Houghton and his team have discovered a biomarker that may have

clinical relevance for ME/CFS. They are now testing 100 ME/CFS and 79 healthy control blood samples to determine if this biomarker can be validated. Importantly, all the samples being tested are coded so Houghton and his team do not know if the sample is from a patient or control. Once testing is complete, we will send them the code for which sample came from patients and which from controls so the analysis can be completed. We have high hopes that the biomarker will be validated.

We know that identifying safe and effective treatments for ME/CFS is going to require a number of key ingredients. **Linking data generated on samples from our SolveCFS BioBank participants is one of the most important and valuable assets we bring to ME/CFS research.** The projects explained here are just the beginning but already they are producing results and speeding progress.

Everyone has a role to play, both those with ME/CFS and healthy people who care about them to act as controls, of any age, are eligible to participate. To get information about enrolling in the SolveCFS BioBank, contact Gloria today at (704) 362-2343 or biobank@cfids.org. ●

Helping Your Voice Be Heard in Washington D.C.

The CFIDS Association is focused on efforts to build awareness and research validating the biological basis for ME/CFS, leading to improved methods of diagnosis and treatment. Your donations have supported our Research Institute without Walls.

An approved therapy cannot be brought to patients in the U.S. without the involvement of federal agencies. It is important to understand the roles of the various offices and agencies within the government who influence this process. We must continually help the staff at these agencies understand the breadth and depth of ME/CFS challenges. The CFIDS Association serves as a bridge to connect them to the patient population.

There are three organizations at the federal level working together on these issues.

The Department of Health and Human Services (HHS) is the government agency that oversees the FDA and the CDC and assists with their shared information and collaborative efforts. The Chronic Fatigue Syndrome Advisory Committee (CFSAC) provides advice and recommendations to the Secretary of HHS through the Assistant Secretary for Health on issues related to ME/CFS.

The Food and Drug Administration (FDA). Simply put, the FDA is the agency within the Department of HHS

responsible for regulating what is safe to put in our bodies. They work closely with drug companies, researchers, and those seeking to develop new medications in a manner proven safe and to be made available to the general public.

Recently, a teleconference with the FDA and ME/CFS stakeholders was held to: “discuss issues of mutual interest and concern including the lack of approved treatment options available for ME/CFS and how treatment development might be facilitated.”

This call was in follow-up to the April 2013, Patient-Focused Drug Development initiative meeting on ME/CFS to more systematically gather patients’ perspectives on their condition and available therapies. The CFIDS Association surveyed more than 1,500 patients on symptoms, impact and treatment. The FDA cited survey data in their September 2013 report, “The Patient Voice” documenting ME/CFS as “...a debilitating disease that can severely affect a patient’s day-to-day functioning and have a devastating impact on a patient’s life.” We’re very proud that the hard work of the CFIDS Association, and other advocacy groups, resulted in this positive step forward. Of all the hundreds of diseases examined by the FDA, ME/CFS was the FIRST disease to be handled in this manner, largely due to our efforts.



The Center for Disease Control and Prevention (CDC) has a similar mission of safety. Among which, is the responsibility to provide the American people with research and information on all forms of disease, infectious or not. The CDC can bring attention and awareness to ME/CFS so that the American public at large can better understand its needs.

Importantly, the CFIDS Association serves on the CFSAC and works to build appropriate relationships with HHS, CDC, FDA, and the National Institutes of Health (NIH) to ensure that the urgency and current underfunding of ME/CFS remains on the federal radar. While we share many advocates’ disappointment about how the Department of HHS has handled ME/CFS, we also see evidence of the department’s recognition that ME/CFS is a real, debilitating and widespread disease. We are a vigilant, informed watchdog on behalf of ME/CFS patients. ●

One Patient's Story (cont. from front page)

He'd read about it in *Newsweek* and had already started the search for a doctor who treated CFS.

Eight years later, I'm still sick. Prior to my illness, I biked, hiked, worked out, went scuba diving and played golf.

Today my life is very narrow. A few times a year I have great days, as if I'm well, but I'm a shadow of who I once was.

I know I'm not in this alone. Hope comes from those around me. My husband, Ray, has saved my life and continues to be by my side. In addition, I have my closest friends and wonderful counselor, along with Bruce Campbell's self-help online group and book, "Managing CFS and FM: A Seven Step Program" to help me know I am not in this alone. Through these people, I've accepted that pacing, rest and not overdoing is the only real medicine, **so far**.

Hope also comes from Suzanne Vernon and the team at the CFIDS Association. I heard Suzanne speak in Denver and could see and feel her commitment, determination, dedication, compassion, and sense of urgency. I am certain that her unrelenting quest for treatment and a cure will come sooner rather than later.

I am confident in the work of the CFIDS Association and believe that together we will solve ME/CFS. In the words of Peyton Manning, "Hurry, hurry!" ●

Participate in Progress

Please join us as we work together to Solve CFS.

Your gifts fuel progress toward improved health, treatments and a cure. You can make a difference in the lives of all of those facing daily struggles with ME/CFS. Please join other ME/CFS patients and their loved ones in making a donation. **Any level of investment advances the path forward.**

We can solve this together.

Your gift:

- Funds research aimed at solving ME/CFS—the Research Institute Without Walls,
- Uses evidence-based research to identify therapies that improve the quality of life for ME/CFS patients until there is a cure,
- Helps the Association act as an informed watchdog with federal agencies.

When you make a direct contribution to the CFIDS Association, everyone in the ME/CFS community benefits. Your generosity enables us to meet our most urgent needs and carry out our Mission to make ME/CFS understood, diagnosable and treatable.

Benefits to you include:

- The opportunity to see the results of your generosity.
- An immediate charitable deduction on your income taxes.

You can make your gift either by going online to
www.CollaborateFindSolve.org
or by sending a check with the envelope provided.

Act by December 31st to have your gift doubled through a generous matching grant from the McGrath Family Foundation.

We are extremely grateful for your support in joining the fight to Solve ME/CFS.

The CFIDS Association of America
PO Box 220398
Charlotte, NC 28222-0398
Resource line: 704-365-2343
Website: www.CFIDS.org
ADDRESS SERVICE REQUESTED

NONPROFIT
ORGANIZATION
US POSTAGE
PAID
CHARLOTTE, NC
PERMIT NO. 2989

8



We are thrilled to announce the launch of our all-new, fully-consolidated website: **SolveCFS.org**

Cleaner, more readable, easier to maneuver... a consolidation of our previous multiple websites into one. You can, for a short time, still access Research1st.org and CFIDS.org but those URLs will soon be redirected to SolveCFS.org so make sure you update your favorites and bookmarks now.

Come visit us soon and tell us what you think!

Contact Info

The CFIDS Association of America
PO Box 220398
Charlotte, NC 28222-0398
Resource line: 704-365-2343
E-mail: cfids@cfids.org

Website: SolveCFS.org

Facebook: www.facebook.com/CFIDSassn

Twitter: [@PlzSolveCFS](https://twitter.com/PlzSolveCFS)

YouTube: www.youtube.com/SolveCFS

Web home for this issue of [SolveCFS](http://SolveCFS.org): <http://solvecfs.org/get-involved/newsletters>

Secure online donation page: www.CollaborateFindSolve.org