



# Solve ME/CFS Initiative

FORMERLY KNOWN AS THE CFIDS ASSOCIATION OF AMERICA

The SolveCFS Chronicle

Spring 2014

## Same mission. New name. Solve ME/CFS Initiative

We're delighted to announce that **The CFIDS Association of America** has a new name—the **Solve ME/CFS Initiative**. While our name has changed, our mission steadfastly remains the same: ***We will make ME/CFS understood, diagnosable and treatable.***

Why the change? We recognize the many changes in our organization and our illness community since the organization was first named so long ago in 1987. While the name of our illness continues to be controversial, "ME/CFS" better reflects today's understanding. And we believe that the word "initiative" (defined as 'leading action'), expresses our strong commitment to funding ground-breaking research.

Since our organization was founded in 1987, we have been the leading organization focused on this illness. Over the years, we're proud of our remarkable advances regarding this controversial and misunderstood disease.

- Under the 22-year leadership of Kim McCleary, the organization's first CEO, the Association played

an integral part in developing a policy ruling for the Social Security Administration that recognized CFS as a disabling condition.

- We are the leading private funder of ME/CFS research, directly funding \$5.5 million in ground breaking research which has been leveraged into more than \$12 million in additional ME/CFS research.
- We helped expose the misappropriation of \$12.9 million in CDC spending, restoring these funds to ME/CFS research.
- We led the first-ever public awareness campaign for ME/CFS, led lobbying events, organized Congressional briefings and regularly deliver testimony at numerous federal hearings and meetings.

Four years ago, guided by a desire to move into a new era of scientific progress on ME/CFS, the Association made a strategic decision to heighten its focus on **research**. Our thinking was simple—the best way to use our

precious dollars is toward **solving** this despicable disease.

Today, led by President and CEO, Carol Head, the organization continues to drive its mission forward—to fund research *that will make ME/CFS understood, diagnosable and treatable*. We provide more funding for high-quality ME/CFS studies, foster increased collaboration among ME/CFS researchers and push the federal government to make ME/CFS research a higher priority. We are working to leverage our experience, relationships and collective knowledge to propel the ME/CFS research field forward. We are a catalyst for scientific advances that translate into better care for ME/CFS patients. We are accelerating ME/CFS research.

As we continue our efforts to **make ME/CFS widely understood, diagnosable, and treatable**, it is fitting that we have a name that more accurately reflects who we are: **The Solve ME/CFS Initiative**. We trust that you will continue this journey with us as we work towards a day when ME/CFS is no more. ■

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Carol Head  
President & CEO

# From the CEO

Friends,

As spring comes into bloom, I'm filled with a sense of renewal and excitement for the season ahead of us. Not just for the weather outside, but for the season of progress, forward momentum and positive change I see occurring for those of us affected by ME/CFS. I am gratified by the opportunity to play a leadership role in this effort and thrilled to be doing it under the banner of our new organizational name, the **Solve ME/CFS Initiative**.

We are driven by a vision of a world free of ME/CFS. Board, staff and volunteers are working tirelessly to leverage experience, relationships and collective knowledge to propel the ME/CFS research field to the next level so that scientific advances can translate into better care for ME/CFS patients. It is because of your support that we are able to fund high-quality ME/CFS studies, foster increased collaboration among ME/CFS researchers and push the federal government to make ME/CFS a greater priority.

As we continue our efforts to **make ME/CFS widely understood, diagnosable, and treatable** by stimulating participatory, patient centered research, I am 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 and ultimately eradicate this dreadful and debilitating disease.

On the pages that follow, you will read more about the initiative we are taking to foster swifter, 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, to activate and engage a community to participate in research that will accelerate discovery of safe and effective treatments, while expanding funding for treatments and a cure.

As the Solve ME/CFS Initiative relies entirely on the generous donations of patients and their loved ones (we have not received a penny of government funding since 2010), we are especially grateful for your support.

Together we can Solve ME/CFS!



President & CEO

Solve ME/CFS Initiative—New Name. Same Mission.

CEO@SolveCFS.org

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# Research News & Notes

## Brain Inflammation Seen in ME/CFS

The Japanese team led by Drs. Hirohito Kuratsune and Yashuyoshi Watanabe have published a very important paper in the *Journal of Nuclear Medicine*.

This study uses powerful neuroimaging technology to determine if the brain is inflamed in ME/CFS patients. The scientists used a technique to determine if the immune cells of the brain—called microglia and astrocytes—were reacting to something encountered in the brain. The brain images showed that the immune cells were much more “inflamed” in patients and the higher the inflammation, the more severe the patient’s symptoms.

While the results will need to be confirmed in larger studies, it is a very exciting finding; **this is the first time images of this type of brain inflammation have been seen in ME/CFS and provides evidence of the seriousness and debilitating nature of this disease.**

## Two-Day CPET Testing Could Be Used to Diagnose ME/CFS

Our organization was the first to fund investigators at the University of the Pacific to study the effects of cardiopulmonary exercise testing (CPET) done 2 days in a row—known as test:retest—

in ME/CFS patients. Now in a study published in the *Journal of Translational Medicine*, Betsy Keller, PhD and her team at the Department of Exercise & Sport Sciences, Ithaca College have replicated the findings of the University of Pacific. First it is important to understand that CPET testing is used to assess cardiovascular diseases and the abilities of cardiovascular disease patients to repeat a CPET test 24 hours after an initial CPET is well established. Keller showed that on the second CPET test, ME/CFS patients had very different measures (even more abnormal) than the first CPET. **Two CPET tests 24 hours apart could be used to objectively identify the majority of patients with ME/CFS** (versus only 50% with only one CPET test).

Larger studies are needed to begin to standardize CPET for use with ME/CFS. It is also important to conduct research that determines what is causing these disabling physiologic abnormalities in ME/CFS patients.

## ME/CFS Mortality Study

DePaul University’s Center for Community Research is currently **recruiting respondents for a study on myalgic encephalomyelitis (ME) and chronic fatigue syndrome (CFS)**

**mortality.** They are looking to recruit surviving family members, friends, and/or caregivers of individuals who had been diagnosed with ME or CFS and are now deceased.

The intention is to document the experience of these deceased individuals, and the experience of their family and friends, to improve knowledge of ME and CFS and to help those individuals who are currently suffering from the illness. Participants will be asked to complete a confidential online survey and will be given the opportunity to volunteer for an additional in-person or phone interview.

Visit [SolveCFS.org/me-and-cfs-mortality-study](https://SolveCFS.org/me-and-cfs-mortality-study) to learn more. ■

**Want to receive regular research updates?**

Sign up for our FREE monthly e-news, **Research1st**, at [SolveCFS.org/get-involved/newsletters](https://SolveCFS.org/get-involved/newsletters).

## Science Desk

### Breaking Down the Complexity of ME/CFS through Clinical Intuition

In 2012 the CFIDS Association of America—now the Solve ME/CFS Initiative—organized a meeting at the Banbury Center of Cold Spring Harbor Laboratory, “Decoding Clinical Trials to Improve Treatment of ME/CFS.” We invited many of the investigators that over the years have conducted ME/CFS clinical trials and clinical trials in related disease areas; Jose Montoya, Øystein Fluge, Katherine Rowe, Carl-Gerhard Gottfries, Nancy Klimas, Peter Rowe, Italo Biaggioni and about 30 others.

Our meeting objective was to understand the science behind the clinical trials—why some worked and others didn’t—and then to take these lessons learned and apply this knowledge to future clinical trials. It was clear from the many presentations that the complexity of ME/CFS made clinical trials challenging. Many of the trials were small, few went further than Phase II (there are 4 phases in clinical trials) and none were replicated by other clinical researchers. It was interesting however, to see that despite the limitations of these clinical trials, there were hints of some beneficial effect to some of the treatments.

This gave Dr. Elizabeth R. Unger, CDC, a meeting participant, the idea that we should try to capture this clinical intuition (the sense that doctors have

that helps them understand and treat ME/CFS patients.) Dr. Sandra Kweder of the FDA was thinking similarly when she was quoted as saying:

*“...But the key is that a lot of the researchers in this to date have been out there on their own. They’re clinicians who are following a series of patients for decades. And no one’s really been able to tap into the kind of information that they have...”*

ME and CFS Stakeholder  
Teleconference Participant List,  
September 13, 2012

We worked with Biovista, one of our 2011 funded investigators, to develop a platform in order to tap into and capture clinical intuition. Together we developed a web-based survey tool that asked questions focused on three main areas:

1. Efficacy of drugs currently used in the treatment of ME/CFS symptoms.
2. Alternative treatment options (nutritional supplements, fluids, etc.).
3. Treatment strategies: How are symptoms interrelated? Which symptoms are more important to treat first?

About 15 ME/CFS expert clinicians participated in the survey. We are now preparing the results of the survey for publication. Once published, this



Suzanne D. Vernon, Ph.D.  
Scientific Director

To stay on top of progress being made, hear first-hand of advancements to and through the **SolveCFS BioBank & Registry** and get early notifications on ways you can be involved in the research, sign up for our free monthly newsletter at [SolveCFS.org/get-involved/newsletters](http://SolveCFS.org/get-involved/newsletters).

will be useful information for ME/CFS patients to bring to their physicians to share how the ME/CFS experts from around the world are managing and treating their patients.

The knowledge that expert ME/CFS clinicians have gained is invaluable to us as we work to break down the complexity of ME/CFS. By understanding what treatments work and which don't, we learn about the biology that underpins these treatment responses. By capturing this information we are expanding our knowledge base and once again putting ME/CFS into the context of other medical and scientific knowledge. As we strive for a world free of ME/CFS, this is just one of the many ways we are working to accelerate discovery of safe and effective treatments.

## Breaking Down the Complexity of ME/CFS through the Solve CFE BioBank and Registry

“Complex” is a word that is frequently used to describe the ME/CFS disease state. Here are some of the reasons why:

- Many body systems are affected.
- People are sick for varying lengths of time.
- Symptom type and severity vary from person to person.
- A variety of medications are used to treat symptoms.
- The environment that ME/CFS patients live in varies, and that can affect their health.



- Many people experience other “overlapping” conditions in addition to ME/CFS.

ME/CFS is a diagnosis of exclusion, meaning a process of elimination.

A physician must first discern whether a patient has any other overlapping conditions that present in a similar way as ME/CFS, to either eliminate it as a possibility or understand that it is only one piece of the medical puzzle.

Chronic infection with Epstein Barr virus, hepatitis C virus or human immunodeficiency virus has a similar clinical profile to ME/CFS.

Endocrine diseases like diabetes and thyroid disease share symptoms and features with ME/CFS.

Autoimmune diseases like Sjögren's syndrome, PANDAS and celiac disease present with many of the symptoms experienced by ME/CFS patients.

As we gather data about the symptoms and genetics of ME/CFS, we can

increase our knowledge by putting them in the context of these other “medically explained” diseases. When we take this more holistic view, we can begin to explain what is going on in ME/CFS.

One way that research deals with this type of complexity is to break it down so that the most similar people are being studied. The code of our genes can be used to group people who are similar. The genetic similarities can relate to any number of body functions including things like metabolism, immune function or endocrine function and even the types of symptoms that patients experience. Once this complexity is broken down, people with a complex disease like ME/CFS can be grouped based on a more specific genetic profile. Genetic information is helpful to delineate the complexity of ME/CFS and it may also be useful for helping us understand the disease process.

Pharmaceutical companies understand that breaking down this complexity and

facilitating studies with the most consistent groups is important to showing maximum efficacy. A study done by the Tufts Center for the Study of Drug Development in 2010 indicated that 100% of pharmaceutical companies surveyed were using genetic technologies to target specific groups of patients and understand how patients will react to specific treatments.

The SolveCFS BioBank is an important part of this research progress. We simplify the process for investigators by creating a ‘bank’ of research-ready patients and healthy controls where important data that helps group similar patients together has already been collected. As we expand the efficacy and efficiency of the SolveCFS BioBank, we continue to enhance systems that allow us to use patient data to break down the complexity of ME/CFS and move discovery forward at a more rapid pace. When you participate in our BioBank, you become a critical component in our efforts to solve ME/CFS.

## Quantifying the Complexities of ME/CFS

Since the Internet’s earliest days, patients have used online resources to share experiences, learn about diseases and treatments, and become advocates. In recent years we have seen these online communities evolve into centers of patient-driven research. Modern day, patient-driven research has the potential to be used as meaningful evidence as larger sets of data are gathered.

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**Datafication =  
the process of using  
technology to turn  
many aspects of our lives  
into data to help solve  
complex problems.**

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With few researchers and clinicians specializing in ME/CFS, many patients have become experts in ME/CFS specific research by doing their own online study of published literature. In addition, you make important observations about your own condition by living with it every day. With the advent of personal tracking and monitoring devices like the UP, Mio, iBand, and more you can now readily track things like sleep, activity, what you eat, heart rate and more. Smartphones can be used to track and monitor many things using apps or passively using the GPS. This translates to a lot of data; in some cases 24 hours, 7 days a week. These tools allow you to be the researcher, tracking and monitoring the things that are meaningful to you.

And now there are emerging ways for you to incorporate this data with important biological data. We are working on ways to collate all of this information; integrate it with your biological data (e.g., your gut microbiome), share it (if you want to) with others like you, and analyze it so that patterns can emerge.

Currently, there is no other experimental platform that allows for this type of discovery with and by the patients. But

at the CFIDS Association—now the Solve ME/CFS Initiative—we understand that you are critical to effective research. We must actively engage YOU—the patient—in our research efforts if we are to cure ME/CFS sooner rather than later. ■

For more information about the SolveCFS BioBank and to sign up to participate, contact the BioBank Coordinator:

Gloria E. Smith  
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or visit [solvecfs.org/solvecfs-biobank](http://solvecfs.org/solvecfs-biobank).



## Update on Federal Government Activities Regarding ME/CFS

Primarily as a research organization, the Solve ME/CFS Initiative (formerly CFIDS Association of America), is involved in advocacy efforts aimed at improving the research landscape for the early detection, objective diagnosis and effective treatment of ME/CFS. As part of this effort, we work to validate the burden of illness imposed by ME/CFS in agencies where national policy is made and executed. While there is still much work to be done, we are encouraged that ME/CFS is now receiving much attention on a federal level.

Below is a summary of recent Washington D.C. activities.



### Food and Drug Administration (FDA) Draft Guidance for Industry

On March 11, 2014, FDA released a draft guidance for industry entitled “Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.” The purpose of this guidance is to assist companies or organizations in the development of drugs for the treatment of ME/CFS.

All stakeholders had the opportunity to provide comment on the guidance before it was finalized. Guided by our Research Advisory Council, we reviewed the document and provided many specific suggestions to strengthen it.

Most notably, the guidance sets an important precedent as a statement from the FDA that ME/CFS is

an important area of study for drug treatment development and that the absence of approved treatment represents a **significant public health concern**. These, among some other strengths in the guidance, are important points of recognition and legitimacy for the disease and a much-needed statement from this federal agency.

We also provided comment on some shortcomings in the draft guidance document. These included the opportunity to use outcome measures known to be effective for other diseases similar to ME/CFS. We also encouraged the FDA to highlight the opportunity that ME/CFS represents.

We compiled our complete review and submitted it for consideration in the hopes that it would serve to strengthen the guidance document, highlight the opportunities for drug development and help the ME/CFS population. Our

ME/CFS expertise provides significant, direct value in affecting national policy to benefit ME/CFS patients.

To read our complete report to the FDA, go to [solvecfs.org/association-offers-its-feedback-on-the-fda-draft-guidance](http://solvecfs.org/association-offers-its-feedback-on-the-fda-draft-guidance).



### NIH Pathways to Prevention Workshop (P2P)

The goal of the National Institutes of Health (NIH) Pathways to Prevention program, is to identify research gaps in a selected scientific area, identify methodological and scientific weaknesses, suggest research needs, and move the field forward through an unbiased, evidence-based assessment.

It is very significant that among the many diseases vying for precious federal attention, the NIH has designated ME/CFS as one of the few illness to be studied in the P2P program.

At the time of publication, the workshop for ME/CFS was just officially approved and the P2P workshop is anticipated to take place in December 2014. We are currently reviewing the research protocol prior to making any assessment.

Watch our blog to get information as important developments unfold and to know how you can participate.

To read a more detailed breakdown of the process, visit [solvecfs.org/pathways-to-prevention-for-mecfs](http://solvecfs.org/pathways-to-prevention-for-mecfs).



### The Work of the Institute of Medicine (IOM) Continues

On May 5, 2014, the IOM Committee held another public meeting concerning their work on diagnostic criteria for ME/CFS. Like the P2P effort, it is unusual and important that IOM has selected our illness for its focus. This is one more tangible indication that

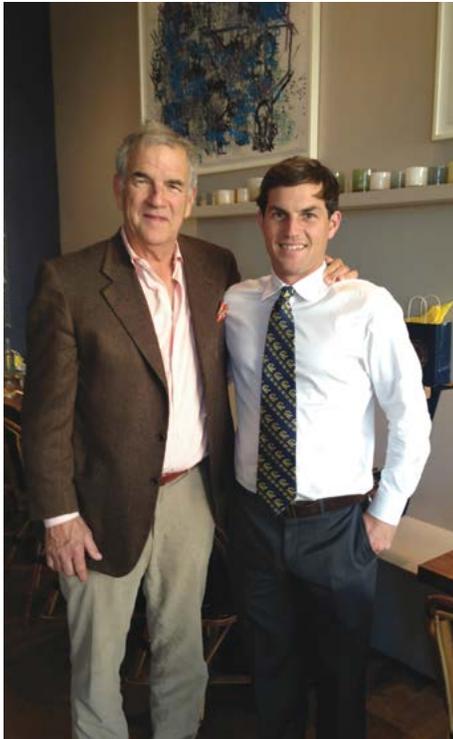
our illness is increasingly prioritized at the federal level.

We were pleased to contribute important information into the IOM process. We created a simple online questionnaire of the committee's two specific questions so that any patient could easily offer their thoughts and insights. We compiled all of the answers into a report and submitted them, unedited, prior to the April 23rd deadline. All told, 143 patients responded. We're proud that so many of our constituent patients stepped up in this way.

We urged the committee to read all the responses saying, "For many, just the effort required to provide their response comes at a great cost in terms of energy spent. They 'spent' their energy reserve on this because of the magnitude of its importance to them personally and to the overall ME/CFS community."

You can read the full survey report on our blog at [solvecfs.org/iom-public-meeting-with-mecfs-committee](http://solvecfs.org/iom-public-meeting-with-mecfs-committee). ■

To stay up to date on all of this activity and more, sign up for the RSS feed or email of our blog at [SolveCFS.org/category/blog](http://SolveCFS.org/category/blog).



Kevin Guibara with his father, Albert

## Kevin Guibara, Refuting the Status Quo

Similar to many patients, I was a normal athletic college student with my life ahead of me when it was completely ruined by a 1–2 month onset of CFS at the age of 21. Growing up, I was perfectly healthy and I enjoyed baseball and soccer. At UC Santa Barbara, prior to my illness, I played rugby and surfed. Seemingly overnight, all of that was gone.

It took me years to reach a self-diagnosis and even more years to get in front of a doctor that provided real treatment options. I was 30% functional with brain fog and fatigue. Early treatments only seemed to make things worse, and I was largely limited to my home; only a couple short excursions per week. Due to lack of activity and the muscular impact of ME/CFS, minor household movement caused a significant injury to my back. I was unable to sleep for 4 days, my nervous system so activated from lying down or sitting. I was convinced that I had sent myself into free fall and that I would not recover.

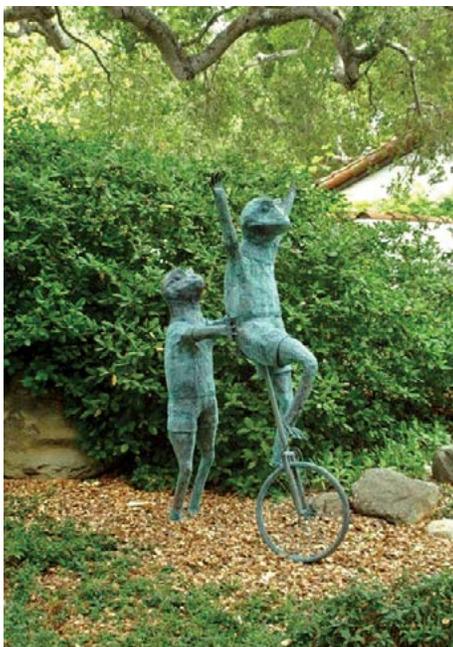
Before this injury, I wanted to protect my body from new treatments and I was paranoid about trying new drugs. But after this injury I cultivated a state of mind in which I believed I could only benefit from venturing into new treatments. The status quo—the state of my health—simply was not acceptable.

I began a fervent search for solutions, taking antibiotics targeted at Lyme

disease, Valtrex, then Valcyte, eventually GC-Maf which allowed me to increase my activity level and improve my post-exertional malaise issue, and most recently hormone supplementation. I have been able to slowly taper off most of the antibiotics and will soon try to taper off from Valcyte.

It has been a long road, but I believe the puzzle pieces exist for a complete recovery for some of us (80–90%), which is where I consider my current functionality. I returned to finish college at UC Berkeley and I am currently able to enjoy life and engage in fun activities again.

I have great faith in the Solve CFS BioBank, the cutting edge research the Solve ME/CFS Initiative is funding, and the tools being developed to create improved, patient-specific solutions for ME/CFS patients. I also believe that through their hard work, we have made significant progress in raising awareness and increasing access to treatment options. I believe that together we will solve ME/CFS. ■



'Helping a Friend' by Albert Guibara

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**Kevin and his father, artist Albert Guibara, will be featured in our spring mailing and on our blog. To learn more about Kevin, visit us at [SolveCFS.org](http://SolveCFS.org). View more of his father's artwork, at [www.Guibara.com](http://www.Guibara.com).**

# Please Join Our Sustainer's Circle

As our new organization's name reflects—**Solve ME/CFS Initiative**—we're out to do exactly that: **Solve ME/CFS**. We know well the devastating toll ME/CFS can take on the lives of patients and we are determined to make the disease widely understood, diagnosable and treatable. Your gifts sustain this organization and help change the research landscape. Together, we are making crucial strides toward a world free from ME/CFS.

**One of the best ways to support the Solve ME/CFS Initiative is through monthly giving. Here's why:**

- Monthly donations provide a steady stream of income we can count on to help fund important research and effectively operate our organization.
- It's an easy way for you to give.
- Your recurring donation ensures the strength of our organization and our ability to make a difference in the lives of people living with ME/CFS.

**And, as a special thanks to monthly givers, the Solve ME/CFS Initiative is pleased to offer:**

- Advance notice of and personal invitations to special events and meetings to help keep you—our most valued supporters—informed about progress in our research program.
- Special recognition in our Annual Report with your permission.
- No longer receiving solicitation appeals for the Annual Fund drive throughout the year. Your monthly donation provides support all year long for our programs so the only time you will be invited to make an additional gift is at year-end.

**Consider pledging your commitment to solve ME/CFS by signing up for the Sustainer's Circle and a monthly gift. Please visit [CollaborateFindSolve.org](http://CollaborateFindSolve.org) or call 704-365-2343 to get your monthly giving account set up today.**

***If you are already enrolled in monthly giving, make sure you have re-activated your account.***

*Because we have recently upgraded our database, you will need to register again for a recurring donation since we do not keep your credit card information on file. And please make note, beginning in July, your statement will read a gift to "Solve ME/CFS Initiative" instead of the CFIDS Association of America.*

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## Shop and Give

Several organizations—like Amazon, iGive and eBay—offer you the opportunity to donate a portion of your purchases to the **Solve ME/CFS Initiative** (formerly CFIDS Association of America). Whether you are shopping for birthdays, anniversaries, baby showers, or just picking up a few things for yourself, your purchase can help fuel our mission to make ME/CFS understood, diagnosable, and treatable.

**Learn more at [solvecfs.org/get-involved/shop-give](https://solvecfs.org/get-involved/shop-give)**

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