



## Solve ME/CFS Initiative



**Myalgic  
Encephalomyelitis/  
Chronic Fatigue Syndrome**



**DERAILS FUTURES**

**DESTROYS LIVES**

**STEALS INDEPENDENCE**



**Annual Report  
Fiscal Year  
2016-2017**

# Slow and Steady Progress

Dear Friends,

While I'm so proud of the work our organization accomplished in the recent eighteen months, at the same time, I'm chagrined by the slow pace of progress toward solving this disease. So much remains to be done! And we know that those who suffer with this disease have already waited much too long.

When I think in the **"glass half full"** mindset at the end of our fiscal year, June 30, I'm proud that SMCI played an important role on several fronts:

- › Funding and conducting multiple rigorous ME/CFS research projects, building the most comprehensive research program in the ME/CFS field
- › Working effectively with the NIH and CDC to move progress forward (albeit frustratingly slowly!)
- › Pushing forward effective congressional advocacy
- › Increasing public awareness of this misunderstood disease

This annual report describes a selection of those victories.

Yet on most days, I continue to see the **"glass as half empty"**. **There is so much more that must be done to bring relief for the pain and anguish of so many with ME/CFS.** We have a long way to go to achieve an appropriate level of federal research funding. To change the public's perception of this disease. To educate medical professionals. And to find biomarkers, treatments, and a cure. Our mission *"to make ME/CFS widely understood, diagnosable, and treatable"* is far from being realized.

I'm so proud of our highly capable, hard-working staff, and our volunteer board, each of whom has a deep stake in this disease, and our thousands of generous donors.

Yes, I'm proud of our role in this fight to Solve ME/CFS...and know how much further we must go. **Together** we move forward.

Onward!



Carol Head  
President and CEO  
Solve ME/CFS Initiative



Carol Head, President and  
CEO

# Building for Research

Dear Friends,

This is a remarkable time in the history of ME/CFS and our efforts to advance the field on multiple fronts are paying off—the momentum is building in the ME/CFS space.

Over the past year, we have advanced a diversified science and discovery agenda through an array of SMCI-initiated projects into the priority areas of bioenergetics, neuroendocrine biology, and inflammation and immunity. We have durable partnerships with leading research centers and are investing in original research, addressing knowledge gaps, and advancing clinical application in ME/CFS. **Some of this work includes ongoing projects in:**

- › **Pathways and Biomarker Discovery** with Cornell University, Metabolon, Sue Levine Clinic
- › **Drug Screening and Therapeutic Exploration** with Memorial Sloan Kettering Cancer Center in New York City
- › **Cell-cycle Energetics and Immuno-senescence Studies in the Pathophysiology of ME/CFS** with Washington University in St. Louis, MO and University of Cambridge in the UK
- › **Cardiopulmonary and Neuropathy Abnormalities in ME/CFS** with Brigham and Women's Hospital in Boston

Moreover, through our Ramsay Awards in basic, clinical, translational, and epidemiological research, we are advancing the most promising ideas to solve this complex disease all over the world. Projects addressing a slew of important topics are being investigated, including the gut microbiome, autoimmunity, bioenergetics, pathogenic interaction, inflammation, brain imaging, and metabolomics. The inaugural grant cycle for the Ramsay Award program selected 5 pilot proposals through a competitive process representing diverse research teams from 6 universities in 4 countries, spread across 3 continents.

We are also thrilled to report that our National ME/CFS Patient Registry entered its final developmental push in 2017 and the launch is anticipated in early 2018. The registry will enable clinical trials, further understanding of the natural history of the disease, and incorporate common data elements, Electronic Health Records and other capabilities to enhance data sharing and collaboration among patients, researchers, and other disease organizations.

Our work is comprehensive and organized around the pillars of purposeful and robust research into the multifactorial aspects of the disease, the incorporation of advanced technological instruments and tools, meaningful collaboration among stakeholders, the advancement of medical education, and steadfast advocacy for equitable funding and stronger policies for ME/CFS.



*Zaher Nahle, PhD, MPA, Chief Scientific Officer and Vice President for Research*

A stylized, handwritten signature in black ink, consisting of a large 'Z' followed by a series of loops and a final horizontal stroke.

*Zaher Nahle, PhD, MPA  
Chief Scientific Officer and Vice President for Research  
Solve ME/CFS Initiative*

# Thank You

We thank our donors—thousands of patients, family members and friends—for their generous support of SMCI in Fiscal Year 2016-2017. Each gift helped to make our work possible—funding researchers and fostering innovation, collaboration and discovery. **We couldn't do our work without you.** At SMCI, we will not rest until ME/CFS is understood, diagnosable, and treatable. You have our heartfelt thanks.

We'd also like to give a special deep thanks to the hardworking team at the national legal firm McDermott Will & Emery LLP, and our generous board of directors.

McDermott  
Will & Emery

# 2016 Year in Review

## PART 1: JANUARY – JUNE 2016

By decision of our board, the accounting year for SMCI has transitioned from a calendar year to a fiscal year ending June 30. Our first fiscal year with this new timing is Fiscal Year 16-17, from July 1, 2016 to June 30, 2017. This change brings the organization in line with common practice for non-profit organizations, who often receive the majority of their funding from individual donors in the final months of the calendar year. This annual report includes audited financials from that new fiscal year, and also includes organization activities for the transition period, January 1 to June 30, 2016.

### Research to understand the fundamentals regarding ME/CFS

- › Results from SMCI funded program at Biovista Inc. identified two FDA approved drugs with potential applicability for ME/CFS
- › SMCI biobank provided samples to NIH research projects
- › SMCI received a grant from the Robert Wood Johnson Foundation White Label PEER (Platform for Engaging Everyone Responsibly) program.
- › SMCI participated in the Invest ME Conference in London
- › SMCI created the new Research Advisory Council
- › The inaugural Ramsay Award program request for applications (RFAs) was launched

### Advocacy to obtain additional federal support for ME/CFS

- › Vice President for Research, Dr. Zaher Nahle, was selected to serve on CDC working group
- › SMCI registered concerns over NIH intramural study design

- › SMCI released Chronic Fatigue Syndrome Advisory Committee (CFSAC) report card to grade each agency's response to formal recommendations
- › SMCI joined letter to Agency for Healthcare Research and Quality (AHRQ) regarding concerns over the PACE trial
- › President and CEO, Carol Head, met with heads of the NIH and members of congress and submits testimony to Appropriations subcommittee on ME/CFS

### Gaining public awareness and community engagement

- › SMCI helped promote May 12th, International ME/CFS Awareness day
- › SMCI conducted a readership survey to improve content and delivery of publications for the ME/CFS community
- › SMCI hosted webinars with Dr. Sue Levine, Dr. Avindra Nath, and Dr. Jarred Younger
- › SMCI president Carol Head, members of the board, and supporters from across the country participated in #MillionsMissing day of action and awareness for ME/CFS

# Fiscal Year 2016–2017 in Review

## PART 2: JULY 2016–JUNE 2017

### Research to understand the fundamentals regarding ME/CFS

- › Dr. Nahle presented in Newcastle, UK at the CFS/ME Research Collaborative Annual Science Conference
- › With financial support from SMCI, Dr. Peter Rowe of Johns Hopkins University published the results of his ME/CFS research on neuromuscular strain
- › SMCI launched the new “meetME” travel awards program, providing travel expenses for ME/CFS researchers to participate in meetings and conferences and the first award went to Fane Menash of University College London
- › SMCI hosted the first collaborative research meeting for ME/CFS with government agencies and members of the board of directors in Washington DC
- › SMCI launched its first “directed research” initiative with Drs. Maureen Hanson and Susan Levine focusing on pathways to biomarkers
- › SMCI participated in **seven of ten grant applications to the NIH** funding opportunity announcement for ME/CFS
- › SMCI funded **5 international Ramsay Award Program research projects**
- › SMCI launched the Cathleen J. Gleeson fund in collaborative partnership with the University of Washington to study improved diagnostic testing for ME/CFS
- › The second SMCI-Directed Research Initiative with Drs. Sheila Stewart and Massahi Narita study began work exploring immuno-senescence and cell-cycle analysis in ME/CFS
- › Epigenetic function study, funded by SMCI at the University of Toronto, was published
- › Dr. Dane Cook published his study “Neural consequences of post-exertional malaise” with funding from SMCI
- › Dr. Nahle presented in London at the 2017 Invest in ME Research International Conference
- › SMCI Directed Research **study partnership with Metabolon yielded key data for publication**
- › Dr. Nahle attended key meetings with the Genetic Alliance and secures partnership for new **PEER ME/CFS national patient registry**
- › Dr. Nahle traveled to Washington DC to advise NIH researchers on their new intramural study

### Advocacy to obtain additional federal support for ME/CFS

- › SMCI joined the coalition to successfully pass the 21st Century Cures Act
- › Dr. Nahle participated in CDC Technical Development Working Group and Common Data Elements Working Group
- › SMCI participated in #Millions-Missing actions in San Francisco, Chicago, and Sacramento
- › Carol Head, with other ME/CFS advocates, met with Acting Assistant Secretary for Health, Dr. Karen DeSalvo of the US Department of Health and Human Services
- › Carol Head also attended the National Institute of Neurological Disorders and Stroke (NINDS) Non-profit forum in Washington DC
- › SMCI supported the Federal Disability Integration Act with over 600 other organizations to improve the choice and care for those disabled by ME/CFS

- › SMCI joined the Research!America Alliance—the largest lobbying coalition for biomedical research
- › SMCI executed the largest ME/CFS Capitol Hill storm to-date with **81 congressional meetings, with over 50 advocates in a single day**
- › SMCI helped restore ME/CFS funding in the federal budget by leading a series of 30 meetings in Washington DC
- › SMCI joined with over 50 ME/CFS organizations and advocates to oppose the inclusion of cognitive behavioral therapy (CBT) and graded exercise therapy (GET) recommendations on the CDC website for ME/CFS
- › In partnership with many advocates, SMCI helped secure 55 members of Congress as co-signers for a letter to NIH Director Francis Collins regarding ME/CFS
- › SMCI mobilized thousands of messages to congress as part of ME/CFS Advocacy Week, culminating in a **Capitol Hill briefing on ME/CFS with Senator Ed Markey**
- › Dr. Nahle presented on ME/CFS to the Rare Disease Legislative Advocates lunch series
- › President Carol Head made a forceful presentation at CFSAC (the Federal Chronic Fatigue Advisory Committee meeting of the Dept. of Health and Human Services) regarding the disappointing federal response to ME/CFS

## Gaining public awareness & community engagement

- › SMCI obtained the highest possible rating, 4-stars, from Charity Navigator
- › SMCI participated in global recognition of Severe ME Day on August 8th
- › SMCI hosted 8 educational webinars for patients, health providers, and researchers
- › SMCI, with the support of an anonymous donor, created a 15-second advertisement to raise awareness of ME/CFS that played for **3 months in Times Square**
- › Dr. Zaher Nahle and Carol Head participated at the Faster Cures conference in New York
- › Carol Head, President and CEO of SMCI, named a **2017 “Health Hero” by O, the Oprah magazine**
- › Dr. Nahle brought ME/CFS to UCLA's Metabolomics and Bioenergetics conference
- › SMCI chaired two panels at the **Precision Medicine Worldwide Conference** in Silicon Valley and Duke University
- › SMCI collaborated to ensure the publication of the first Pediatric Primer for young people with ME/CFS, authored by Dr. Peter Rowe
- › Carol Head participated in UCLA's clinical and translational science conference at UCLA
- › Emily Taylor, Director of Advocacy and Public Relations, gave a guest lecture at USC on medical sociology, using ME/CFS as a case study for the importance of disease definitions
- › Facilitated a partnership with the Brain Donor Project to secure additional donations to key neurological tissue and spinal fluid research





# Independent Auditor's Report

Board of Directors  
Solve ME/CFS Initiative  
Los Angeles, California

We have audited the accompanying financial statements of Solve ME/CFS Initiative (Organization), a nonprofit organization, which comprise the statement of financial position as of June 30, 2017, and the related statements of activities, functional expenses, and cash flows for the year then ended, and the related notes to the financial statements.

## Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

## Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

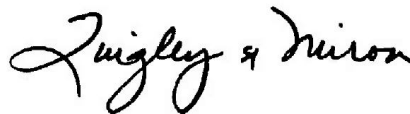
An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of

material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

## Opinion

**In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Solve ME/CFS Initiative as of June 30, 2017, and the changes in its net assets and cash flows for the year then ended, in accordance with accounting principles generally accepted in the United States of America.**



Quigley & Miron  
Los Angeles, California  
November 1, 2017



# Solve ME/CFS Initiative Statements of Financial Position

July 1, 2016—June 30, 2017

## ASSETS

Cash	\$ 835,728
Investments—Notes 3 and 4	16,825
Prepaid expenses and other assets	22,582
Property and equipment, net—Note 5	4,392
<b>Total Assets</b>	<b>\$ 879,527</b>

## LIABILITIES AND NET ASSETS

### LIABILITIES

Accounts payable	\$ 79,000
Accrued liabilities	43,279
<b>Total Liabilities</b>	<b>\$ 122,279</b>

### NET ASSETS

Unrestricted	\$ 640,781
Temporarily restricted—Note 7	110,867
Permanently restricted—Note 8	5,600
<b>Total Net Assets</b>	<b>\$ 757,248</b>
<b>Total Liabilities and Net Assets</b>	<b>\$ 879,527</b>



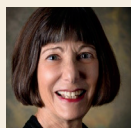
# Solve ME/CFS Initiative Statement of Activities

July 1, 2016—June 30, 2017

	Unrestricted	Temporarily Unrestricted	Permanently Unrestricted	Total
<b>SUPPORT AND REVENUES</b>				
Contributions and grants	\$ 1,349,866	\$ 409,057	\$ 200	\$ 1,759,123
Interest and other income	37,056	-	-	37,056
Gain on investments	923	1,071	-	1,994
<b>Total Support and Revenues Before Reclassifications</b>	<b>1,564,104</b>	<b>410,128</b>	<b>200</b>	<b>1,974,432</b>
Reclassifications				
Net assets released from restrictions	368,197	(368,197)		
<b>Total Support and Revenue After Reclassifications</b>	<b>1,932,301</b>	<b>41,931</b>	<b>200</b>	<b>1,974,432</b>
<b>EXPENSES</b>				
Program services	1,657,084	-	-	1,657,084
Management and general	312,890	-	-	312,890
Fundraising and development	132,052	-	-	132,052
<b>Total Expenses</b>	<b>2,102,026</b>	<b>-</b>	<b>-</b>	<b>2,102,026</b>
<b>CHANGE IN NET ASSETS</b>	(169,725)	41,931	200	(127,594)
<b>NET ASSETS</b> , Beginning of Year	810,506	68,936	5,400	884,842
<b>NET ASSETS</b> , End of Year	<b>\$ 640,781</b>	<b>\$ 110,867</b>	<b>\$ 5,600</b>	<b>\$ 757,248</b>

# Solve ME/CFS Initiative Board of Directors\*

All members of the Solve ME/CFS Initiative Board of Directors have a personal relationship with the disease. They are either patients themselves or have a family member who suffers from it.



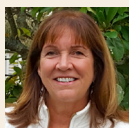
**Vicki Boies, PsyD**  
Chicago, IL  
*Chair*



**Steve Curry**  
Edina, MN



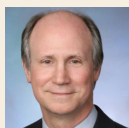
**John Nicols**  
Atherton, CA  
*Vice Chair*



**Mary Dimmock**  
Waterford, CT



**Beth Garfield**  
Los Angeles, CA  
*Treasurer*



**Bill Hassler**  
Washington, DC



**Aaron Paas**  
New York, NY  
*Secretary*



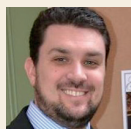
**Carol Head**  
Los Angeles, CA



**Mike Atherton**  
Arlington, VA



**Sue Perpich**  
Minneapolis, MN



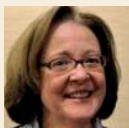
**Brett Balzer**  
Chicago, IL



**Rick Sprout**  
Washington, DC



**Diane Bean, Esq.**  
Bethesda, MD



**Christine Williams, M.Ed.**  
Chevy Chase, MD

# SMCI Research Advisory Council

**Anthony Komaroff, MD**  
Professor, Harvard Medical School

**Susan Levine, MD**  
Former Chair, CFSAC, Medical Office of Susan Levine

**Jose Montoya, MD**  
Professor, Stanford University

**Sheila Stewart, PhD**  
Associate Professor of Cell Biology and Medicine,  
WashU in St Louis

**Natalie Block, MD, MPA**  
Internal Medicine Specialist, Mount Auburn Teaching  
Hospital, HMS Affiliate

**Daan Archer, MBA**  
VP for Technology & Strategy Context Labs and MIT  
Media Lab (Amsterdam)

**Tarek Absi, MD**  
Cardiothoracic surgeon, Vanderbilt University and  
UVA Hospital Assistant Professor

**Peter Rowe, MD**  
Professor, Johns Hopkins Medical Center

**Michel Silvestri, PhD**  
Head of Clinical Laboratory for Gotland region/  
Policy maker (Sweden)

**Maureen Hanson, PhD**  
Cornell University

## AD HOC MEMBERS

**Zeina Nahleh, MD, FACP**  
Director, Maroone Cancer Center

**Cindy Bateman, MD**  
Medical Director, Bateman Horne Center

**Andy Kogelnik, MD, PhD**  
Founder, Open Medicine Institute

**John Nicols, Eng., MBA**  
CEO Codexis

**Morgan Fairchild**  
Medical Research Advocate



# Solve ME/CFS Initiative

The **Solve ME/CFS Initiative** (SMCI) is a non-profit disease organization that works to accelerate the discovery of safe and effective treatments, strives for an aggressive expansion of funding for research that will lead to a cure and seeks to engage the entire ME/CFS community in research.

## OUR VISION:

A WORLD FREE OF ME/CFS.

## OUR MISSION:

MAKE ME/CFS UNDERSTOOD,  
DIAGNOSABLE, AND TREATABLE

**What is ME/CFS:** Myalgic encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS) is a complex and debilitating chronic disease with a serious impact on quality of life. The disease affects up to 2.5 million Americans and an estimated 20 million people worldwide.

## Professional Staff

Carol Head  
*President and CEO*

Zaher Nahle, PhD, MPA  
*Chief Scientific Officer and  
Vice President for Research*

Carolyn Mayo  
*Director of Development*

Emily Taylor  
*Director of Advocacy and  
Public Relations*

Mamie-Louise Anderson  
*Administrative and  
Development Coordinator*

Diana Sagini  
*Development Coordinator*

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