



# The Solve ME/CFS CHRONICLE

WINTER 2017

## SMCI's Comprehensive Research Program Improves the ME/CFS Ecosystem and Spans Every Phase of the Discovery Process



### THE DISCOVERY PROCESS

Discovery requires not just “bench science,” but also a healthy ecosystem in which research can thrive.

At the Solve ME/CFS Initiative (SMCI), the comprehensive nature of our research program is underscored by **two core components**:

- 1) We initiate and support high-quality research across every phase of the discovery process (as shown above and described on page 4).
- 2) We work to improve the overall ME/CFS ecosystem through the following key functions:

**DEBUNKING** fallacies and misinformation about ME/CFS

**CREATING** opportunities for young investigators

**FACILITATING** patients' participation in research

**ADVOCATING** for effective policies and federal actions

**PUBLICIZING** current scientific and medical developments

**PROMOTING** cross-pollination of ideas through think tanks

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# Why Is Funding ME/CFS Research So Difficult?



Carol Head, President and CEO

Dear Friends,

It's a fresh new year...and once again we look forward to building on 2016's successes as we continue the too-long battle for treatments and a cure for patients with ME/CFS.

As we look to 2017, some of our 2016 work will certainly move forward. We know that the five Ramsay Award Program research projects (discussed in this issue's cover story) will proceed, and we know that our SMCI-Directed Research Studies (detailed on pages 6-7) will yield meaningful results. We will continue our research webinar series, just as we will continue to partner with other research and advocacy organizations.

And at the same time, as we look forward, some matters seem quite uncertain. With the federal administration transition, will National Institutes of Health (NIH) funds be expanded or cut? Will the next director of the Department of Health and Human Services (HHS) continue to support the Chronic Fatigue Syndrome Advisory Committee (CFSAC)? Will the Trans-NIH Working Group continue to build on its progress? Will the Centers for Disease Control and Prevention (CDC) continue its multi-site clinical assessment?

Certainly, come what may, we will continue our relentless, thoughtful, assertive work in both research and advocacy.

**On a different note**, I'm often asked why we, as a private medical research non-profit, repeatedly ask patients and their loved ones for financial donations to support our work. When other disease organizations like ours (e.g., Michael J. Fox Foundation for Parkinson's Research, Susan G. Komen, and the American Heart Association) obtain funds from a wide variety of sources, why don't we?

Certainly, this is top of mind for us! It is painful to ask for funding from those who suffer with this disease and often have extremely limited resources. So let me provide our perspective on this core funding problem our disease faces.

First, by far the primary source of funds for medical research in general is the federal government. Our efforts to obtain those funds for ME/CFS are years long and relentless. It is a long haul, and we have described this at length.

Second, there are unique attributes of our disease that make fundraising, both from individuals and private foundations (e.g. Gates, Ford, and Kaiser), quite difficult:

- **There's a stigma.** Most people simply still do not believe this disease is "real." We can report that our organization has received very few gifts from individuals who have not seen this disease up close and personal. For people who do

## SOLVE ME/CFS INITIATIVE PROFESSIONAL STAFF



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not live with this disease, if the donation choice is between this “weird disease,” which they may not even believe in, or, say, Lupus or MS or cancer—which people know are awful and real—where would you give your dollars?

- **There is little sense of urgency.** This disease has been around for a long time. And it’s not generally fatal (we know the disease can be fatal, but most don’t). As we sometimes say, “ME/CFS is a life sentence, not a death sentence.” Just think of the difference with AIDS in the 1990s, when people were suddenly dying quickly and in significant numbers.
- **The disease is complicated and poorly understood.** Where to start to do research? It can feel overwhelming for potential funders.
- **There is a tendency to give again where individuals and foundations have given before.** So it is a tough bootstrap effort to solicit *initial* gifts.

The other significant source of funds for other diseases is the pharmaceutical industry. Drug companies, as private, for-profit organizations, are responsible primarily to their shareholders. They generally invest in new drugs for diseases when there is a clear “target” for the drug.

With so very little understood about the underlying causes and attributes of ME/CFS, we are years away from a time when pharmaceutical companies are likely to step up. Of course, that time will come. The good news/bad news is that there are a lot of ME/CFS patients. So, at some point, this disease will become an attractive market for pharmaceutical companies—it just hasn’t yet.

Lastly, for individuals, the longstanding tradition of run/walks and other participatory events is difficult when folks don’t really believe in the disease. There doesn’t yet exist a critical mass of people who will put themselves out for this strange, misunderstood disease. The stigma is real. When someone says, “I’m going out to walk for breast cancer on Saturday!” there is much affirmation. Imagine someone saying, “I’m going out to walk for ME/CFS on Saturday!” to blank stares and perhaps even scoffing.

So where does that leave us regarding fundraising to fight for this disease? It’s adding insult to injury that ME/CFS patients carry the additional burden of funding research into this disease. We know that someday this will change. But until it does, please know that we must continue to ask...and we are deeply grateful for every gift. We know that every gift is given with passion and fervent hope. Our responsibility to use each dollar *effectively* lies heavy on my heart.

I end this letter with deep gratitude to the patients whom we serve. We stand when you cannot. We invest in research when you cannot. We advocate when you cannot. We fight when you cannot. Onward into 2017!



Carol

*Each board member is a patient or has a friend or family member affected by this disease.*



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## SMCI's Comprehensive Research Program Improves the ME/CFS Ecosystem and Spans Every Phase of the Discovery Process (cont.)

While our methods of improving the overall ME/CFS research ecosystem are straightforward, allow us to elaborate on the overall discovery process. Dr. Nahle clarifies that this non-linear process can be broken down into six phases:

- 1. Capacity building:** Includes the development of human capital, infrastructure, tools, and resources to drive ME/CFS research forward
- 2. Target discovery:** Encompasses the identification of reliable biomarkers, indicators, or other biological culprits that can be therapeutically targeted or manipulated
- 3. Repurposing opportunities:** The retooling of existing FDA-approved drugs for other uses; when possible, it can bypass several time-consuming steps toward drug approval
- 4. Preclinical research:** Denotes research in the basic sciences using biological specimens (e.g., patient samples, cultured cells, tissues) or model systems (e.g., animal models) to understand the mechanisms and signaling pathways that will have applications in clinical trials; this step is fundamental for targeted therapy design
- 5. Clinical research:** Involves experimentation with human participants done in a clinical or laboratory setting; this includes clinical trials, natural history studies, clinical effectiveness, and outcome research as well as the development and improvement of clinical criteria updates
- 6. Therapeutic discovery:** This is the goal and includes the identification and development of treatments and, eventually, a cure



### 2016/2017 SMCI RESEARCH DASHBOARD



#### Ramsay Award Program projects awarded through rigorous peer review

<b>TEAM 1</b> Brain inflammation - Diagnostics - Neuroimaging	1	4
<b>TEAM 2</b> B-Cell function - Metabolomics - Rituximab	1	2 3 4
<b>TEAM 3</b> Bioenergetics - Natural Killer cells - Mitochondria	1	2 3
<b>TEAM 4</b> Autoimmunity - genetic screening	1	4
<b>TEAM 5</b> Viral infection - HHV6 - Immunity - Energetics	1	2 3



#### SMCI-Directed Research Studies addressing severe knowledge gaps

<b>Group 1</b> Metabolomics - Bioenergetics (Cornell/Metab/Levine)	1	2
<b>Group 2</b> Immune-senescence - cell cycle energetics (Wash U)	1	2 3
<b>Group 3</b> Dug screening platforms - Therapeutics (MSKCC)	1	2 3 4

#### Collaborative project through our Cathleen J. Gleeson PhD Fund

<b>CJG</b> Diagnostics – Metabolic Imaging (U of Washington)	1	3 4
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BIOBANK

#### Resources in support of studies

- NIH
- University of Vermont
- University of Toronto
- Washington University in St. Louis

Dr. Nahle notes that “By creating environments in which real and durable research and advocacy collaborations develop and flourish, we reframe the discussion so that all voices in ME/CFS can be heard and respected. Through unity and cross-pollination, we are affecting change and deconstructing stubborn medical challenges in ME/CFS.”

We act as agents for change and unity: we meet with government officials and science leaders to advocate for policies and federal action; we author dozens of opinion and technical pieces addressing current ME/CFS affairs across the science, research, and policy landscapes; we debunk fallacies and misinformation through our No Spin Zone; we create opportunity for young investigators through our MeetME Travel Awards; and we bring scientific and current information to our community through webinars and opinion pieces. In addition, we participate in conferences and convene some of the top minds in ME/CFS clinical care and research to collaborate on the key issues facing ME/CFS.

To be specific, SMCI manages the following programs to facilitate research work for all who join us in the fight for a cure, while creating and collaborating on projects that emphasize the role of patients as partners—not subjects:

#### SMCI'S NATIONAL PATIENT REGISTRY

Our new, state-of-the-art national registry for ME/CFS will enable clinical trials, further understanding of the natural history of this disease, and includes built-in options for data sharing and collaboration among patients, researchers, and other disease organizations.

#### SMCI'S BIOBANK

Our biobank is a repository of physical samples from patients to support the work of qualified researchers and accelerate the discovery process. This important aspect of the services we provide also links patients with researchers and facilitates the use of human samples for ME/CFS research. Studies using samples from our biobank have been used in phases 1, 2, and 3 of the discovery process.

#### SMCI'S RESEARCH WEBINAR SERIES

The medical webinars we produce, featuring influencers in science, medicine, and policy, are the go-to source of trusted, up-to-date medical information, current research, and policy development. On-demand video from SMCI's 2016 Webinar Series, moderated by Dr. Zaher Nahle, is offered free of charge on our website at [SolveCFS.org/2016-webinar-series](http://SolveCFS.org/2016-webinar-series).

#### SMCI'S RESEARCH ADVISORY COUNCIL

The SMCI Research Advisory Council (RAC) consists of world-class leaders and provides great depth to our work. The RAC includes foremost experts on ME/CFS like Anthony Komaroff, MD (Harvard); Susan Levine, MD (CFSAC, The Levine Clinic); Jose Montoya, MD (Stanford); Peter Rowe, MD (Johns Hopkins); Cindy Bateman, MD (Bateman Horne Center); and Andreas Kogelnik, PhD, MD (OMI) as well as a number of scientific leaders like Sheila Stewart, PhD (Washington University) and Michel Silvestri (Sweden).

#### SMCI'S RAMSAY AWARD PROGRAM

This program supports and promotes original, bold, quality research work through seed grants. Grant recipients are selected via a peer-review competition with three primary objectives: to **INVEST** in original ideas that could clarify the onset, progression, root causes, and natural history of ME/CFS; to **CREATE** environments to attract, support, and retain talent in the ME/CFS community and help awardees generate relevant data to compete for long-term federal funding; and to **FACILITATE** collaboration and cross-pollination among dedicated researchers through the sharing of resources and access to additional programming and the organization's network.

In 2016, SMCI's Ramsay Award Program supported studies in gut microbiome, autoimmunity, bioenergetics, pathogenic interaction, inflammation, brain imaging, and metabolomics research. Peer-reviewed selection criteria included significance, quality, feasibility, innovation, novelty, and research environment among other factors.

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## SMCI's Comprehensive Research Program Improves the ME/CFS Ecosystem and Spans Every Phase of the Discovery Process (cont.)

SMCI's Ramsay Award Program grant winners selected in 2016 are as follows:

**Research Team 1's study**, entitled "Advanced Non-Invasive Analysis in ME/CFS Diagnosis and Treatment Decisions," will use a **magnetic resonance spectroscopic thermometry** (MRSt) technique to assess absolute temperature across the entire brain, allowing researchers to investigate the **pathophysiology** of ME/CFS (in other words, the functional changes that accompany the disease).

**Research Team 2's study**, entitled "Metabolic Analysis of B-Cell Maturation in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome," theorizes that "a single agent is not responsible and that **chronic changes to the normal functioning** of immune and other body cells caused by **stressors such as infections** more likely underlie this disease."

**Research Team 3's study**, entitled "The Bioenergetic Health Index of NK Cells as a Diagnostic Tool for Chronic Fatigue Syndrome," takes a look at **natural killer (NK) lymphocytes** (a type of white blood cell), a critical first defense against viruses and cancers. NK cell dysfunction is a **pathological hallmark** in myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).

**Research Team 4's study**, entitled "Autoimmune Signature in CFS/ME," **combines in-depth genetic screening** methodologies with the study of **autoimmune factors** regulating a specific type of surface receptors important in cellular signaling and function.

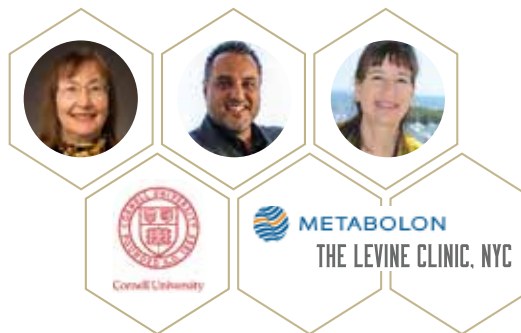
**Research Team 5's study**, entitled "HHV-6 Mediated Mitochondrial Modulation and Its Association to ME/CFS," examines the **role of human herpesvirus 6 (HHV-6)** in the development of ME/CFS.

For more information on the studies summarized above, please visit [SolveCFS.org/2016-ramsay-award-program-results/](http://SolveCFS.org/2016-ramsay-award-program-results/) or check out the December issue of *Research 1*<sup>st</sup> in our SMCI publication archive located at [SolveCFS.org/archive](http://SolveCFS.org/archive).

### SMCI-Directed Research Projects

Dr. Zaher Nahle has led the creative scientific work to design and invest aggressively in much-needed projects to further understanding of the pathophysiology of ME/CFS. With a growing number of targeted investments in severe knowledge gaps (such as pathway and biomarker discovery, immuno-senescence and cell-cycle energetics, drug screening and functional genomics, diagnostics and advanced imaging, and metabolomics and big data research), we are creating value across every phase of the discovery process. These are the elements of a growing portfolio of investment in ME/CFS at some of

the most prestigious medical centers and research establishments in the country, including Washington University in St. Louis, the University of Washington, Memorial Sloan Kettering Cancer Center, Cornell University, and Metabolon.



**Pathway and Biomarker Discovery.** Original research in the areas of bioenergetics, metabolomics, and lipidomics using high-throughput technology. Testing completed. Partners in this SMCI-Directed Research Study include Dr. Sue Levine of **The Levine Clinic** in New York, Dr. Maureen Hanson of **Cornell University**, and metabolomics leader **Metabolon**.

- Analysis of same ME/CFS patients characterized for their gut microbiome imbalance using metabolomics and lipidomics methodologies; this is a powerful, integrative approach

- Analysis of well-characterized twins, one with ME/CFS and the other without, to study possible genetic and monogenetic differences in an ideal comparative group
- Analysis of metabolomics profile in patients before and after exercise to characterize the foundation of exertion intolerance in ME/CFS patients in well controlled settings

**Immuno-senescence and cell-cycle analysis in the pathophysiology of ME/CFS.** Characterization of the disturbances in enzymes and cell-cycle regulators that control cell function using specialized senescence laboratories in collaboration with leaders in the field. Partners in this targeted initiative include Dr. Sheila Stewart of **Washington University in St. Louis** and Dr. Masashi Narita of the Narita Group at **Cambridge University**.

- Analysis of the molecular underpinnings of cellular senescence (a fundamental biological process whose pathophysiology manifestations are reminiscent of aging-related senescence and the arrest of cell function), effects on muscle weakening, dysautonomia, and neurological dysfunction

**Drug screening and functional genomics.** Studies aiming to uncover potential drug screening targets in ME/CFS. Partners in this targeted initiative include leading experts at **Memorial Sloan Kettering Cancer Center**, namely Drs. Ralf Garippa, Scott Lowe, and Myles Fennell.

- Uses ME/CFS immune cells and chemical libraries of characterized compounds to identify targets for rapid therapeutic application.
- Objectives include promoting immune cells' ability to kill intruders and bolstering ATP production and bioenergetics health using the power of big data and pharmaceutical-grade technologies.

## A Collaborative Project through Our Cathleen J. Gleeson PhD Fund

This project, funded by our Cathleen J. Gleeson PhD fund, focuses on **diagnostic testing using non-invasive technology** to measure muscle metabolites in ME/CFS patients for diagnostic testing. This project is led by Kevin Conley, PhD, professor of radiology and co-director of the Translational Center for Metabolic Imaging at the University of Washington and David Maughan, PhD, a professor emeritus of molecular physiology & biophysics at the University of Vermont and visiting scholar in radiology at the University of Washington.



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## SMCI's MeetME Travel Awards

This program enables junior scientists and underrepresented groups to attend ME/CFS conferences and build scientific networks by paying their travel expenses for ME/CFS-focused meetings and conferences around the world.

Per Dr. Nahle, "As you can see, we already have many promising programs and studies under our research umbrella. And you have our steadfast commitment to expand on our efforts in 2017, building on our activities of this past year. Previously, I've borrowed the words of President Lincoln in a time of political uncertainty: 'The dogmas of the quiet past are inadequate to the stormy present. The occasion is piled high with difficulty, and we must rise with the occasion.' This has never been more applicable to the here and now in the field of ME/CFS research. That is precisely why we, through our research programming, are shifting the paradigm and altering the status quo." ■

# A Letter from Zaher Nahle, PhD, MPA

Dear Friends,

At the beginning of every new year, with hope and optimism we renew our commitment to solving this complex disease.

This is indeed an extraordinary time for scientific growth and collaboration at SMCI. Numerous programs have been unveiled throughout the year, underscoring durable partnerships with stakeholders and the greater ME/CFS community.

The new Research Advisory Council we convened provides great depth to our work and consists of world-class leaders such as ME/CFS experts Anthony Komaroff, MD (Harvard); Susan Levine, MD (CFSAC, The Levine Clinic); Jose Montoya, MD (Stanford); Peter Rowe, MD (Johns Hopkins); Cindy Bateman, MD (Bateman Horne Center); and Andreas Kogelnik, PhD, MD (Open Medicine Institute) as well as a number of scientific leaders like Sheila Stewart, PhD (Washington University) and Michel Silvestri (Sweden).

The Ramsay Award Program, which awards seed grants in the areas of basic, preclinical, clinical, and epidemiological research, generated international submissions with high-quality, innovative proposals. We expect to see results from these seed grants later this year.

Our MeetME Travel Awards program enables young investigators to attend ME/CFS conferences and build scientific networks.

Our new, state-of-the-art national registry for ME/CFS will facilitate information sharing among organizations, enable clinical trials, and further understanding of the natural history of this disease.

The medical webinars we produce, featuring influencers in science, medicine, and policy, are the go-to source of trusted, up-to-date medical information, current research, and policy development.



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

Our presence and participation at leading scientific conferences, such as the Invest in ME Research Conference and Colloquium, Action for ME CFS/ME Research Collaborative conference's big data session, and IACFS/ME Biennial Conference, has been both fruitful and well received.

And, most importantly, we initiated partnerships with leading medical research centers and industry partners to conduct innovative and targeted investigations through our SMCI-Directed Research Studies, which are explored in detail on pages 6-7.

This is all to change the status quo, create value in the ME/CFS ecosystem, and bring a different perspective to the field. We remain committed to in-depth, basic, and translational research—especially in our areas of priority: bioenergetics, neuroendocrine biology, and immunity/inflammation.

While we are aware of the many challenges still facing the ME/CFS community—from the severe gaps in knowledge to the painful lack of funding—we look to the future, energized and determined to build on our growth and momentum moving forward.

Best,

A handwritten signature in black ink, appearing to be 'Zaher'.

Zaher



# What, Exactly, Is a Biomarker Anyway? And Why Don't We Have One for ME/CFS?

## What is a biomarker?

When is the last time you took your temperature using your thermometer? Temperature is the most commonly used biomarker—one that we all know and trust. We all have a thermometer at home and have used it many times to confirm that our temperature is abnormally high, indicating that we have an infection somewhere in our body. This self-administered biomarker measurement is used to determine whether our kids should stay home from school, we should call the doctor, or we should stay home from work. This is a great biomarker, as it meets all the criteria we seek.

## So, what are those criteria? What makes a good biomarker?

In the example above, the **biomarker** is elevated temperature as **measured by** the home thermometer. The process for testing this biomarker is wonderful for many reasons:

- It's **non-invasive**; putting a tab under the tongue or in the ear is not painful
- It has **little risk of harm**
- It's very **inexpensive**; most everyone has a thermometer at home
- It's **reliable**; we trust the number we see
- It's **easily accessible**; we don't even have to drive anywhere
- **Everyone agrees** that a fever indicates infection; it's **well accepted** in the medical community
- It's **specific**, meaning that it identifies an infection and not something else (like a cataract)

## Why do biomarkers matter so much?

Biomarkers can be important to diagnose, verify, and track the presence of disease; having a great biomarker can even transform an illness.

For instance, the creation of the PSA test for prostate cancer meant that men could be diagnosed much sooner. And the Pap smear, designed to screen for cervical cancer and based on research dating back to the 1920s, has saved thousands of lives. Acute promyelocyte leukemia, once a death sentence, is practically eradicated thanks to identification of its biomarker, fusion oncoproteins (proteins that can turn cells into cancer cells), and, later, successful corrective treatment.



In diabetes, the detection of chronically elevated sugar levels makes diagnosis straightforward. And the discovery of the biomarker responsible for cystic fibrosis, the inherited gene for the CFTR protein, revolutionized that disease. **Biomarkers can be useful for diagnosis and treatment even when the underlying cause of the disease is not understood.**

So, a biomarker for ME/CFS that has all the qualities listed above—it's non-invasive, inexpensive, reliable, accessible, well-accepted, and specific while also having little risk of harm—would transform the diagnosis and treatment of our disease. Just imagine going to your doctor and doing a simple test then having her announce, "Yes, you have ME/CFS." Certainly, that is the very opposite of the experience of most patients now!

## Do we have any biomarkers for ME/CFS now?

Well, yes and no. We don't have any biomarkers that meet all the criteria above. But we do have a few that fall short. They are all either too invasive, too expensive, too potentially harmful, or not well accepted.

Most existing biomarkers for ME/CFS fall, broadly speaking, into established categories such as neurological (e.g., neuroanatomical, neuroendocrine, or neurocognitive), metabolic (e.g., altered regulatory functions

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## What, Exactly, Is a Biomarker Anyway? And Why Don't We Have One for ME/CFS? (cont.)

of key enzymes, suboptimal processing of nutrients), immunological (e.g., altered activities in cytokines, B-cells, or natural killer cells), hemodynamic (e.g., reduced total blood volume, reduced cerebellar perfusion, or cell-free markers like specific microRNAs in blood), or pathological (e.g., microbiome changes, viruses, and pathogens).

Here are some of the difficult biomarkers we have for ME/CFS now:

- **The spinal fluid of severe ME/CFS patients shows elevated levels of autoimmune markers and white blood cells.** But this test fails on most criteria. It is quite invasive, there is risk of harm, it's expensive, and it's not generally accepted. The key positive attribute is that it is **reliable**.
- **MRIs for ME/CFS patients show reduced gray and white matter in the brain.** This biomarker is a bit better than a spinal tap, as it's **non-invasive**, there is **little risk of harm**, and it's **reliable**. However, it's quite expensive, it's not easily accessible, and it isn't clear that the medical community has accepted it.
- **ME/CFS patients' natural killer (NK) cells show reduced functionality.** NK cells act as the first line of defense in the immune system and are a key component of one's blood. This biomarker is one of the earliest uncovered in ME/CFS and has stood the test of time. However, determining the functionality of these cells requires a sophisticated laboratory setup, and data interpretation is not straightforward, requiring special expertise. In addition, other immune-related conditions are also characterized by reduced NK cell function, making this biomarker not unique to ME/CFS.
- **The majority of ME/CFS patients have markedly different "anaerobic thresholds."** This measurement, taken during cardiopulmonary exercise testing (CPET), determines the complex capacity of the whole body for energy production. Common in exercise physiol-



ogy research and athletic performance analysis, this measurement also requires sophisticated equipment and specialized expertise for data interpretation. In the ME/CFS community, it is well known that patients experience post-exertional malaise (PEM) after pushing their energy boundaries.

### Given their importance, what's the fastest path to a meaningful biomarker for ME/CFS? Are we even close?

With steady and focused research, we may be close to identifying biomarkers in the next several years. Of course, understanding the underlying cause of a disease greatly enhances the ease of obtaining a biomarker, and that too is likely years away. At the same time, there are a number of efforts underway with interesting results which may lead to biomarkers, including studies being done by our organization.

The potential biomarkers below have been identified with small sample sizes and must be validated or rejected. Then, those validated must be tested with larger sample sizes for specificity, meaning that we must ensure the tests measure for this disease and this disease only.

- More refined cytokines, which may show distinctive patterns in ME/CFS
- Reproducible results from small molecules as indicators like MicroRNAs
- Mutations, either structural or functional, in an enzyme or receptor of metabolism

In summary, we have a long way to go. Our SMCI-Directed Research Studies and those studies conducted by our recently announced Ramsay Award Program grant recipients will, if successful, continue to move the field toward a biomarker. So, we continue our research. It's clear that someday there **will** be a biomarker for ME/CFS, just as there is for virtually every disease. We simply need to get there faster. ■

# Consensus Needed on ME/CFS Research Case Definitions

By SMCI Board Member Mary Dimmock

**The Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) will be conducting an initiative to establish ME/CFS common data elements (CDEs) to standardize the collection of data across studies and thereby facilitate the comparison of results.**

For a field that has suffered from a lack of standardization, this is an essential step to improving cross-study comparability. But Department of Health and Human Services (HHS) staff members have also stated that as long as researchers use CDEs, it will not matter what research case definition they use.

This is concerning, because requiring that standardized data be collected on the presence or absence of a hallmark symptom, such as post-exertional malaise (PEM), is not the same thing as requiring that patients have these hallmark symptoms in order to be diagnosed with ME/CFS. The critical question to ask is whether CDEs alone will compensate for the continued divergence in what core inclusion and exclusion criteria are required for the selection of ME/CFS research cohorts.

This lack of agreement on patient selection criteria has plagued ME/CFS for decades, confounding research and resulting in inappropriate clinical guidelines that have misled doctors and harmed patients.

Brurberg<sup>1</sup> reported that there are 20 different case definitions and that prevalence estimates range from 0.01% to 2.60% and even higher, indicating the magnitude of the problem. Worse, these definitions are sometimes modified in ways that further expand the set of conditions given the “ME/CFS” label. One example is the 2011 PACE trial, which stated it used the Fukuda definition to characterize patients but only required Fukuda’s four symptoms to be present for one week instead of the six months required by Fukuda.

Many groups—including the NIH, the Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM), and a group of 50 disease experts—as well as the Pathways to Prevention (P2P) report have identified the definitional inconsistency and lack of specificity as a priority issue. The research community is increasingly using more selective criteria, such as the Canadian Consensus Criteria and the ME International Consensus Criteria, to select research cohorts.

<sup>1</sup> <http://bmjopen.bmj.com/content/4/2/e003973.full>



Given the recognized lack of specificity of some of the commonly used definitions, the proposal to continue to use **any** research case definition raises significant concerns. Will Fukuda or the 2005 Reeves criteria still be used to select ME/CFS cohorts even though we know they select patients who do not have ME/CFS? Will patients selected with the NICE criteria, currently planned for a large UK study, all have ME/CFS? NICE only requires fatigue, characterized by PEM, yet defines PEM’s worsening of symptoms following exertion as optional. If the IOM criteria is used, will those primary psychological illnesses that manifest as physical complaints be excluded? Will any combination of inclusion and exclusion criteria be accepted as a valid way to identify ME/CFS cohorts?

The use of disparate and non-specific research case definitions is responsible for the muddle we face today. Continuing to use **any** case definition to select ME/CFS patients

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# SMCI Presents at Precision Medicine Worldwide Conference

**One of the key goals of the Solve ME/CFS Initiative is to entice new researchers to study ME/CFS.**

To work toward this goal, SMCI presented an hour-long session on ME/CFS at the Precision Medicine Worldwide Conference (PMWC) in late January. Presenting at PMWC was an investment in the ecosystem of ME/CFS, as we were able to educate the heavy hitters in medical research in order to actively draw new scientists into the field.

PMWC is the original and leading forum for personalized medicine. With over 8,500 attendees, mostly from the biotech and academic research arenas, the conference was one of the largest gatherings of recognized authorities and experts across the healthcare and biotechnology sectors.

SMCI's hour-long session explored why precision medicine is fundamental in solving ME/CFS and clarifying its etiology. The session's title, "ME/CFS: The Mysterious Illness Science Has Yet to Unravel," is a nod to National

Institutes of Health Director Dr. Francis Collins and his statement, "Of the many mysterious human illnesses that science has yet to unravel, ME/CFS has proven to be one of the most challenging."

Chairing the panel was SMCI Chief Scientific Officer and Vice President for Research Dr. Zaher Nahle, while speakers included SMCI Research Advisory Council member Dr. Andreas Kogelnik (Open Medicine Institute), and SMCI President Carol Head. Carol, an ME/CFS

patient herself, was able to both address the patient experience and describe the many research challenges of ME/CFS.

For most attendees, we believe this was their first exposure to this complex and fascinating disease.



*Zaher Nahle, Carol Head, and Andreas Kogelnik*

Scientists, by their nature, are often attracted to new and complex challenges; we hope that by speaking to them directly about ME/CFS at this year's PMWC we've gotten a good number of them to view our disease in a new and intriguing light. ■

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## Consensus Needed on ME/CFS Research Case Definitions

will perpetuate this problem, particularly as new researchers enter the field. While essential, CDEs alone will not solve this problem, as many of the studies will be accessed through published literature and evidence reviews—not through a shared database. But even if all studies were suddenly in a single database built on CDEs, the manmade diversity introduced by including dissimilar and/or unspecified conditions in ME/CFS cohorts will impede

the significant progress that would be possible if patients labeled with ME/CFS actually have ME/CFS.

The NIH and CDC are to be applauded for convening a group of researchers to reach consensus on CDEs. This is an important step. But for the **first step**, the NIH and CDC should work with researchers to reach consensus on which research case definition—or at least what core inclusion and exclusion crite-

ria—will be used going forward.

And, just as importantly, explicit consensus should be reached on what research case definitions will no longer be accepted for the selection of ME/CFS cohorts. Achieving this consensus will accelerate research by helping to ensure that all researchers, including those just entering the field, are studying the same disease. ■



# SMCI Continues Its Work to Drive Federal Action for ME/CFS

## Looking Back at Advocacy in 2016

From the #MillionsMissing protest actions to the highest ranking ME/CFS policy meeting in history to the largest congressional action to date on myalgic encephalomyelitis, 2016 was a landmark year for ME/CFS advocacy. Below are some highlights of the 2016 advocacy work done by the Solve ME/CFS Initiative (SMCI):

- **THE BUDGET BATTLE** In February 2016, the President's budget announcement included a bit of a shock: no funding for the Centers for Disease Control and Prevention's ME/CFS multi-site clinical assessment. SMCI President Carol Head and other advocates from across the country traveled to Washington DC and successfully lobbied to have the \$5.4 million budget reinstated.
- **SENATE COMMITTEE APPROPRIATIONS REPORT** Thanks to successful meetings on Capitol Hill, advocates secured strong language from the Senate Appropriations Committee to both the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), directing these agencies to invest in ME/CFS research, include stakeholders as active participants, and work collaboratively to improve patient care.
- **#MILLIONSMISSING** On May 25 and September 27, #MEAction organized the two largest international actions for ME/CFS ever recorded. With 39 separate protests held around the world, thousands of patient activists made their voices heard. SMCI supported and spoke at protest actions on both days.
- **MEETINGS AT THE TOP OF HHS** Led by #MEAction, SMCI President Carol Head participated in two meetings with Dr. Karen DeSalvo, the assistant secretary for health at the Department of Health and Human Services (HHS). This may have been the highest level government official to meet with ME/CFS patients and advocates.
- **THE MIGHTY FIFTY-FIVE** U.S. Representatives Zoe Lofgren and Anna Eshoo of California led the charge by authoring a letter to NIH Director Dr. Francis Collins, urging him to continue strengthening the NIH's efforts in ME/CFS biomedical research. An unprecedented 55 members of congress cosigned the ME/CFS letter, making it the largest congressional action on ME/CFS in recent memory.
- **MEETING AT THE TOP OF NIH** Carol Head and Dr. Zaher Nahle met with NIH Director Francis Collins in New York for a private conversation regarding ME/CFS.



SMCI Board Member Diane Bean and her daughter Lauren Bean, who suffers from ME/CFS, visit Congresswoman Zoe Lofgren of California along with SMCI President Carol Head and Board Member Mary Dimmock.

## Looking Ahead to Advocacy in 2017

SMCI is hitting the ground running. Guided by a new Policy Advocacy Statement, SMCI is committing to leading the charge on a number of major actions, including an ME/CFS Advocacy Week, an educational briefing on Capitol Hill, and a strategic push for the fiscal year 2018 appropriations cycle (10/1/17 – 9/30/18).

The first major advocacy event of 2017 was the annual meeting of the federal Chronic Fatigue Syndrome Advisory Committee (CFSAC) on January 12 and 13. SMCI holds a community liaison representative seat on the committee, and SMCI President Carol Head presented a strong

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## SMCI Continues Its Work to Drive Federal Action for ME/CFS (cont.)

vision of federal agency action on ME/CFS that included bolstering research investments, disability protections, ME/CFS patient equity, and medical education policies.

SMCI plans to support and boost this call for agency action with strong congressional support and advocacy

mobilization. Key patient advocates are currently collaborating on a unified strategy with nationwide coalitions and key organizational partners. Following is a rundown of SMCI’s federal advocacy plans for the first half of 2017:

2017					
JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
CFSAC in-person meeting and presentation	Secure congressional support for Senate and House actions	Draft and send bipartisan appropriations letters	Advocate for ME/CFS to be included as part of Senate confirmation hearings	ME/CFS Advocacy Week to correspond with May 12 International Awareness Day for ME/CFS	Lobby for the creation of a congressional ME/CFS caucus

### New Administration – New Opportunities?

Presidential transitions are turbulent affairs.

Thanks to the 2015 Presidential Transitions Improvements Act, the outgoing administration begins preparing for the incoming administration as early as May with a White House Transition Coordinating Council and an Agency Transition Directors Council.

In terms of ME/CFS advocacy efforts, the new administration presents potential opportunities. Nominees have been announced, and newly cultivated ME/CFS champions in the Senate stand ready to make our community needs part of the conversation. Potential new agency leadership, untainted by misconceptions or stigma about the disease, can lead to new opportunities to start fresh with an administration that has defined itself with a “getting business done” approach. At press time, current National Institutes of Health (NIH) director, and strong supporter of ME/CFS research, Dr. Francis Collins appeared to be a strong contender to remain in his leadership role, which would spell good news for the ME/CFS

community. Dr. Collins has been one of the most effective directors to date in moving the internal processes of the NIH toward progress for ME/CFS.

However, the new administration also presents new challenges. The ME/CFS advocacy community has spent eight years cultivating agency relationships to make progress, and the potential to lose those small gains is very real. Furthermore, the nominee for secretary of the Department of Health and Human Services (HHS), Senator Tom Price, has spurned constituents with ME/CFS who have approached him in the past. SMCI will work actively with the incoming administration to educate and inspire action regarding ME/CFS.

Ultimately, it is not the administration that will dictate the future of ME/CFS, but advocacy. Working with strong coalitions, patient advocates, and congressional champions, SMCI stands ready to spearhead major actions for research investment. And that commitment will not waver. ■

# Determining the Disease Burden of ME/CFS

By SMCI Board Member Mary Dimmock

**Those touched by ME/CFS have long known what the 2015 Institute of Medicine (IOM) report and other recent publications confirmed: ME/CFS causes more debilitation than diseases such as congestive heart failure, multiple sclerosis, and end-stage renal disease. And yet, in spite of this, the IOM reported “remarkably little research funding” for ME/CFS.**

The impact a disease has on patients is called its “disease burden.” The World Health Organization has pioneered a single measure of disease burden, disability-adjusted life years (DALY), which combines the number of years of premature death with the magnitude and number of years of disability caused by a given disease.

Though it may sound cold, this quantifiable measure of pain and suffering allows federal policy makers to compare very different diseases—for instance, the burden of a disease that primarily causes premature death with that of a disease that causes decades of debilitation. DALY also provides a means to evaluate whether public health responses and policies are decreasing a disease’s burden over time. For instance, likely as a result of new treatments the US burden of AIDS fell by 61% between 1990 and 2010.

The National Institutes of Health (NIH) uses disease burden, in addition to scientific opportunity, quality of science, and researcher interest, in deciding where to focus its research. In 2015, the NIH published an analysis<sup>1</sup> of how its funding levels compared to DALY figures for 68 disease areas. A Washington Post article<sup>2</sup> on this analysis by jour-

<sup>1</sup><https://nexus.od.nih.gov/all/2015/06/19/burden-of-disease-and-nih-funding-priorities/>

<sup>2</sup>[https://www.washingtonpost.com/news/wonk/wp/2015/07/17/why-the-diseases-that-cause-the-most-harm-dont-always-get-the-most-research-money/?utm\\_term=.7649893a968b](https://www.washingtonpost.com/news/wonk/wp/2015/07/17/why-the-diseases-that-cause-the-most-harm-dont-always-get-the-most-research-money/?utm_term=.7649893a968b)



Mary Dimmock, SMCI Board Member and ME/CFS Advocate

nalist Carolyn Johnson detailed how diseases with higher disease burden could sometimes have dramatically lower levels of research funding, noting that “in 2010, HIV research received nearly \$3.1 billion in funding, while a deadly lung disease that has more than six times the health toll in the United States got only \$118 million.”

The reasons for these differences are complex and, as was the case with HIV/AIDS, can also include the opportunity to permanently eradicate a disease. But scientists told Johnson the NIH’s analysis also suggested less funding may be provided to diseases “where we blame the victim” or there is less public support.

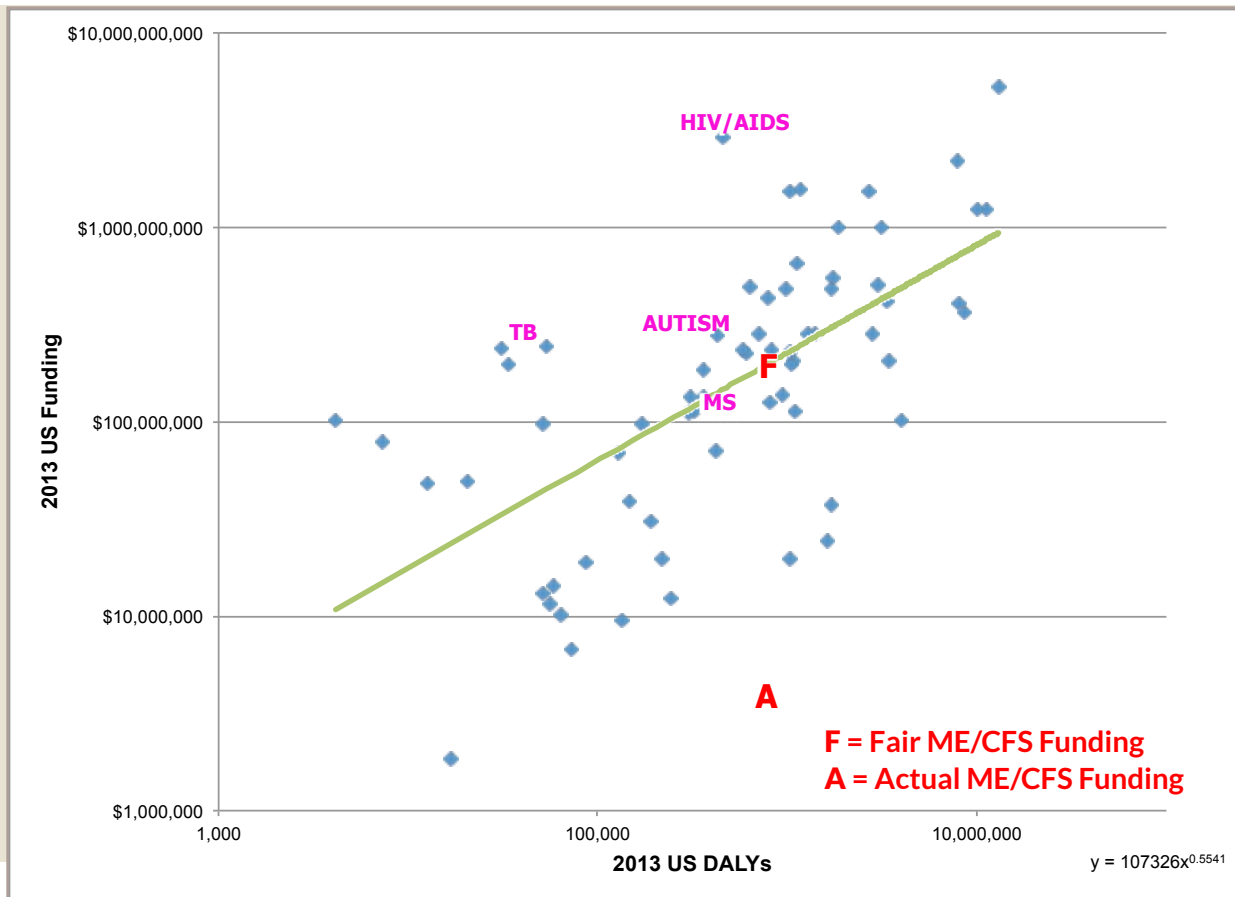
ME/CFS wasn’t included in the 2015 NIH analysis because the US DALY had never been calculated for the disease. To address this gap, Dr. Leonard Jason, Arthur Mirin, and I recently published a paper estimating DALY for ME/CFS and its relation to research funding.

The impact on DALY due to disability was based on reports of decreased quality of life. Given that ME/CFS is underdiagnosed and not effectively tracked in electronic medical records, it’s difficult to directly estimate the impact on DALY from deaths resulting from ME/CFS and its complications. However, several small studies provided reports of increased numbers of premature deaths due to cancer, heart disease, and suicide.

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## Determining the Disease Burden of ME/CFS (cont.)



The resultant DALY was then compared to the NIH’s analysis of funding versus disease burden to estimate the level of NIH funding that would be commensurate with that of these other diseases (Figure 1).

This analysis suggests that NIH funding for ME/CFS would have to increase roughly twenty-five-fold to \$188 million per year (from \$7 million per year) to be commensurate with disease burden.

Our paper describes significant limitations that could impact the accuracy of estimates of DALY and commensurate NIH funding. These include lack of quality research on prevalence, levels of disability, and causes of premature death. Other limitations include missed and mistaken diagnoses of ME/CFS patients and inadequate tracking of ME/CFS in medical and death records. But even considering

these limitations, this analysis demonstrates a remarkable level of underfunding, significant gaps in research, and inadequate clinical care practices.

Dr. Nancy Klimas once noted her HIV/AIDS patients were “hale and hearty thanks to three decades of intense and excellent research and billions of dollars invested,” while her ME/CFS patients “are terribly ill and unable to work or participate in the care of their families.”

As was done with HIV/AIDS, the Department of Health and Human Services has the real opportunity to decrease the terrible burden of ME/CFS by providing commensurate funding and the leadership necessary to address gaps in research, provide for accurate disease tracking, and correct the misperceptions in the medical community that have magnified the burden of an already horrific disease. ■

# PATIENT VOICES

In this recurring section of *The Solve ME/CFS Chronicle*, SMCI will feature the creativity and talent of the ME/CFS community. Every issue you can find the art, writing, or other creations of ME/CFS patients here. To submit an item to Patient Voices, please email Emily Taylor at [ETaylor@SolveCFS.org](mailto:ETaylor@SolveCFS.org).



This quarter, we feature patient advocate Jennifer Brea and her new documentary, *Unrest* (formerly titled *Canary in a Coal Mine*).

*Unrest* poignantly and effectively tells the story of Jen and her husband Omar as they face the challenges and upheavals of a life suddenly redefined by a disability that no one understands. It also demonstrates how ME has affected other patients and their families around the world as well as the physicians and researchers who work with them.

*Unrest* earned a coveted spot at the 2017 Sundance Film Festival, premiering in the documentary competition in late January. Results of the competition were not yet

available at press time. Funding for the film was provided in part by more than 2,500 Kickstarter backers who contributed to the project back in 2013.

“I’m thrilled and honored that this documentary film is launching at Sundance,” said Jen Brea, who directed, produced, and appears in the film.

We at SMCI enormously admire Jen for her vision, passion, and perseverance in creating this important film. We trust this documentary will obtain broad distribution so that many people will come to understand how devastating this disease is.

We applaud you, Jen! ■

# SMCI Answers Reader Questions

In this section of *The Solve ME/CFS Chronicle*, SMCI addresses common questions we receive from those in the ME/CFS community.

## Q: Why does your organization call this disease ME/CFS?

**A:** CFIDS, SEID, ME, CFS—after a while, it all starts to look a bit like alphabet soup. The disease we call myalgic encephalomyelitis (ME), commonly known as chronic fatigue syndrome (CFS), has probably had more name changes than most pop stars. But with all the various names on the table, why has our organization chosen ME/CFS?

As described in the 2015 Institute of Medicine (IOM) report, the name “chronic fatigue syndrome” results in “stigmatization and trivialization and should no longer be used as the name of this illness.” Most every patient agrees that this 1980s name coined by the Centers for Disease Control and Prevention (CDC) fails on multiple levels. It neither describes the disease meaningfully nor captures the seriousness of this disease.

The majority of the patient community prefers the earlier name, “myalgic encephalomyelitis,” which originated in the UK and is actually a highly technical term for inflammation in the brain and central nervous system. But while many patients who suffer from ME/CFS exhibit this symptom, many others do not. And although inflammation is a common symptom, it is not generally thought of to be the cause of the unique array of varying symptoms associated with this disease. So many would argue that while ME connotes seriousness, it does not correctly reflect the key cause or symptom of the disease.

## Q: Why doesn't SMCI also work on Fibromyalgia?

**A:** We often get asked why our organization is dedicated solely to ME/CFS rather than also tackling fibromyalgia, a disease from which many ME/CFS patients also suffer.

The reason is simple: while it is useful in some instances to examine diseases with overlapping features, fibromyalgia is a different disease, and we feel that we will have the most impact by focusing on a single disease. Unlike fibromyalgia, ME/CFS currently has zero FDA-approved treatments. So, moving forward, we will remain laser focused on finding treatments and, ultimately, a cure for ME/CFS. ■



The 2015 IOM report proposed a new name: systemic exertion intolerance disorder (SEID). Why don't we use SEID? This name has not caught on, and if we were use it no one would have a clue what we are talking about. While we despise the name chronic fatigue syndrome for trivializing the disease, it unfortunately remains the most familiar name to most people.

ME/CFS is a hybrid term for a community and disease in transition. It combines the older and more broadly recognized “CFS” with the less stigmatized “ME,” which is becoming more commonly used. Many governments and health authorities have recently adopted the term “ME/CFS,” which has evolved to become the most accessible term to meet the needs of the broadest audience. The Solve ME/CFS Initiative adopted this name so that our organization would be accessible and understandable to medical, academic, patient, and government audiences alike.



# Thank You for Standing with Us

Thank you for partnering with us in our mission to solve ME/CFS. Whether you contributed financially, in volunteer time, via acts of advocacy, or with moral support, we are grateful to have you with us in this battle. We fell slightly short of our \$1.6 million fundraising target for 2016; however, together we raised over \$1.5 million—a solid increase over our 2015 budget.

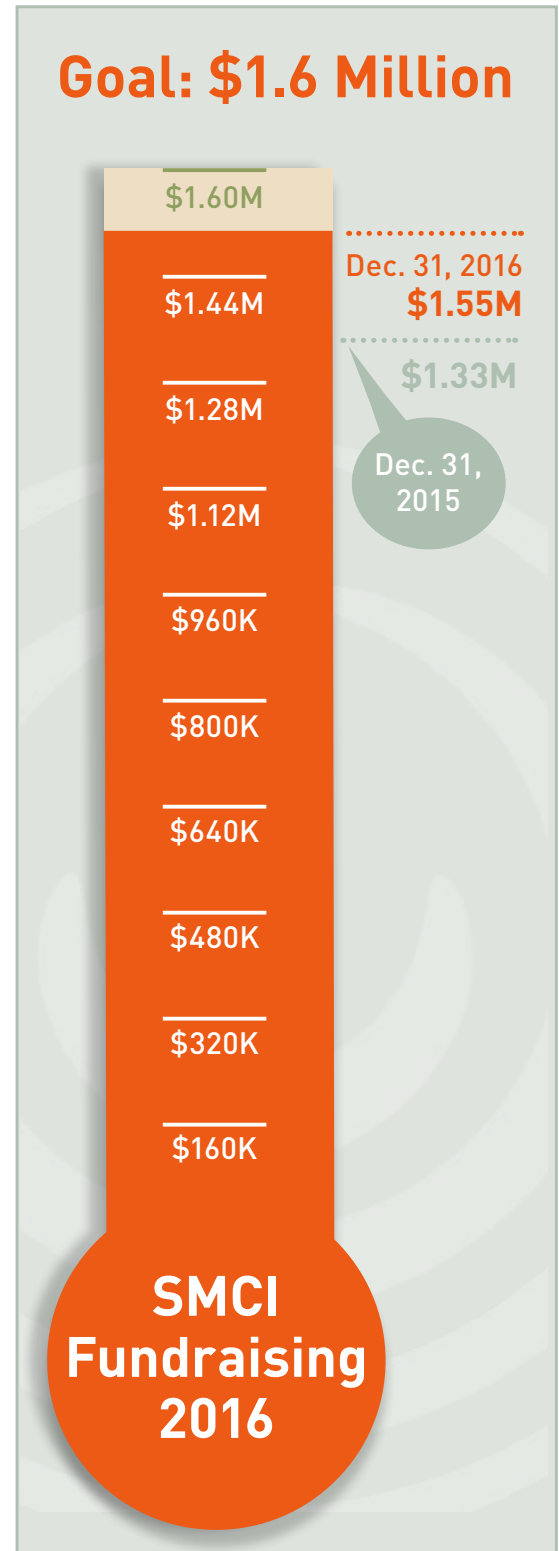
As difficult and challenging as 2016 was, it was also an eventful and productive year. With your support, we

- Launched our SMCI-Directed Research Studies focused on key areas where we believe the answers to ME/CFS will be found
- Awarded five Ramsay Award Program research grants to deserving scientists, again focusing on our key areas of interest
- Began upgrades to our biobank and development of our state-of-the-art patient registry
- Advocated to reinstate CDC funding for our disease
- Met with leaders and key influencers on Capitol Hill to increase awareness for our disease
- Strengthened our working relationship with the National Institutes of Health and pushed for increased spending for ME/CFS

We received over 3,800 donations in 2016. We are so grateful, both for the dollars themselves and for the confidence in our work that your gifts represent. Your contributions fueled our work every step of the way. We look forward to working together for even greater accomplishments in 2017. ■

*As a patient who's contended with the physical and emotional challenges of CFS for more than 25 years, it's gratifying and heartening that the Solve ME/CFS Initiative is there for people like myself, working hard on our behalf with compassion and commitment. Combining sensitivity, integrity, and conscientious professionalism, SMCI provides unique advocacy but also hope, encouragement, and a spirit of camaraderie. My husband and I believe in the Solve ME/CFS Initiative; they have earned our respect and confidence, more than justifying our continued support. I applaud their efforts.*

—Janet Engelhardt



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## Carol Head Named 2017 Health Hero by *O, The Oprah Magazine*

SMCI President Carol Head was honored last month by *O, The Oprah Magazine* as a “2017 Health Hero,” one of fourteen “visionaries who are healing bodies, minds, and communities.”

Although we would have preferred a more substantive piece (and inclusion of “myalgic encephalomyelitis,” or ME, as our disease name), we are touched that Oprah has recognized the importance of featuring this devastating disease. With over **2.4 million paid subscribers**, being featured in *O, The Oprah Magazine* provided much-needed public exposure for our disease.

Carol humbly accepts this honor in the name of the hundreds of advocates who have worked for recognition for this disease and



the millions of patients who continue to suffer, although she maintains that she is no hero. Says Carol, “When we finally understand the devastation of this life-destroying disease—when there’s significant funding to support research and scientists discover a cause and cure for ME—then we’ll have heroes.” ■