

Carol Head Comments – Washington DC IOM report Briefing

March 25, 2015

SLIDE ONE

I'm Carol Head, President of the Solve ME/CFS Initiative.

I'm also an ME/CFS patient; I was quite sick 30 years ago, for many years. I know the deep despair of being very sick, not knowing why you are sick, receiving no help from conventional medicine and being dismissed, and ignored. However, I am one of the very fortunate few who is mostly recovered from this disease. I understand full well that I dodged a bullet.

So I'm proud now to serve the Solve ME/CFS Initiative. It is the longest-standing organization in ME/CFS in the US. Our mission is to "*Make ME/FS understood, diagnosable and treatable.*" I'm proud of our Solve ME/CFS biobank, an asset for **all** qualified researchers in the ME/CFS/SEID community. And I'm proud of the several millions of dollars in ME/CFS research we've funded over the last years.

And a quick thank you to Mary Dimmock for allowing me to use her research and data in my comments

The publication of this IOM report regarding Myalgic Encephalomyelitis/Chronic Fatigue Syndrome is one of the most important days in the history of this illness. With its pre-eminent roster of scientists and experts, rigorous methodology and forthright conclusions, this is the substance we have long needed.

SLIDE TWO

Our organization doesn't purport to represent all patients; no one can do that. We **do** however, use rigorous research and evidence-based data to **obtain additional research funding for ME/CFS/SEID.**

To be clear - We are here today because it is time for our government to increase funding and support for this disease. We believe that the IOM report is a turning point in the history of ME/CFS.

SLIDE THREE

With this slide, I give you a preview of my comments here today:

- What does the IOM report change? Why is it important?
- Some background on ME/CFS, for those who may not be familiar with the disease.
- Why does this disease matter to all of us, not just patients?

- At what levels has NIH funded ME/CFS research?
- What needs to happen now?

SLIDE FOUR

So, what changed six weeks ago when the IOM report was published? After all, for those of us who are patients, this report is like confirming that water is wet. We already knew that water is wet. We already knew that this illness is real. To quote the IOM report: it is a “*serious, chronic, complex, multisystem disease... In its most severe form, this disease can consume the lives of those whom it afflicts.*”

But we patients are **not** the audience for the IOM report. The audience is legislators, doctors, federal officials and private foundations who now see the official stamp of approval that, yes, **ME/CFS/SEID is indeed a serious, debilitating, physical disease.**

We believe that this report is a defining moment for two key reasons.

First, the federal government has now clearly affirmed that this is a serious, physical disease, not a syndrome. For the million Americans who have long suffered with skepticism and lack of care, this is deeply affirming. And for the doctors, nurses and medical researchers, this definitively places this disease in its rightful place.

SLIDE FIVE

And therefore, there now exist no credible barriers to **significantly increasing medical research funding for this disease** that will lead to **treatments and cures**. Federal agencies and private medical research foundations, now have a bright green light to move forward with substantial funding, commensurate with the number of Americans who suffer with this illness. The seriousness of this illness can now only be refuted by those who choose to be ignorant.

SLIDE SIX

And at the same time, what **didn't** change six weeks ago when this report was published?

ME/CFS/SEID continues to be a complex, multi-system disease that is still at the very early stage of medical research and understanding. It can be reasonably debated whether this disease has aspects that involve the immune system, neurological system, genetics with epigenetic effects, viruses, bacteria, brain and spinal cord inflammation, and many other systems.

Rigorous research has been done into ALL those areas, with many compelling and interesting research results, but nothing yet definitive. And very few research dollars have been available to replicate even the most compelling findings.

ME/CFS research is not yet far enough along to be of interest to pharmaceutical industry funders. Therefore, the potential sources of private funding are quite narrow and utterly insufficient to solve this complex disease.

And of course the other thing that has not changed, is that hundreds of thousands of patients continue to suffer. They are in pain, usually without a diagnosis, locked inside bodies and minds that no longer serve them well, almost always without a doctor who can help them, and with zero FDA-approved drugs or therapies.

I think of William who became ill with this illness in 1986 at age 12 and was diagnosed five years later. He was unable to attend high school, but obtained his GED with the highest score ever recorded in his state. He now 29 years old and is often too ill to prepare or consume meals, speak on the phone or write with a pen. It's quite common that he is housebound for weeks at a time. He is quite sensitive to light and noise, and therefore often lives in sensory deprivation and is in constant pain. It's been 17 years.

William wrote, "I am among the more severely afflicted; those in the lower 25 percent of functioning. Is our country willing to let so many lives like mine be left like detritus on the highway – largely ignored? The loss to the nation, the world, is incalculable."

And there are hundreds of thousands of Williams who suffer intensely, whose once vibrant lives are lived in pain, with loss of ability to be self-sufficient and often with little hope for recovery.

We can and must change that.

SLIDE SEVEN

For those of you who are new to learning about this disease, I pause for a moment to consider: Why has this disease been so poorly supported with federal funding for so long?

First, most people have not believed that it is "real." The most common patient experience is to be told, even by medical professionals, that it's all in your head. Get over it. Buck up. We don't tell people with MS to buck up and get over it. We don't tell people in end-stage cancer to get over it and get on with their lives. We take those diseases seriously. We show compassion for those who suffer with them. And that's what patients who suffer from this disease need and deserve.

SLIDE EIGHT

Second, the **name of the disease** has kept it from being taken for the serious, debilitating disease that it is. It has generally been called "Chronic Fatigue Syndrome." (I can barely stand to utter the words.)

We don't usually describe diseases by a symptom. For example we don't call lung cancer "Chronic Coughing Syndrome."

To quote the IOM report, MC/CFS patients “...are more functionally impaired than those with other disabling illnesses, including Type 2 diabetes mellitus, congestive heart failure, hypertension, depression, multiple sclerosis and end-stage renal disease.” So, having called this serious disease by an inappropriate and, frankly, lightweight, insulting name is one of the factors that has kept doctors, friends, family members, employers from affording it the seriousness that is warranted.

SLIDE NINE

Third, the disease has been poorly defined, which means that diagnosis is difficult. That is not uncommon for a multisystem, complex disease, with symptoms that appear in other illnesses as well, and can be difficult to measure objectively. There is no simple blood test, or genetic test for diagnosis. The newly discovered biomarkers are few and cannot be done routinely in a doctor’s office.

And as it is a genuinely complex disease and therefore can be difficult to diagnose. Doctors face an overwhelming amount of information to absorb, 15 minute appointment slots in their days, filled with both time and financial pressures.

With this new, clear IOM report definition of the disease, diagnosis can become more straightforward.

SLIDE TEN

Fourth, this disease has been incorrectly described as a psychological illness, and still is in many quarters. This mistaken attribution of a physical illness as a psychological illness has often occurred historically when diseases are complex and particularly when the primary sufferers are women.

Certainly, we recognize that psychological illnesses are real and cause extraordinary pain. We do not disparage physiological illnesses.

But it is simply NOT true that ME/CFS is among them. This IOM report clearly puts that long-standing, damaging misconception to rest.

SLIDE ELEVEN

And last, most medical professionals demonstrate little understanding of the illness.

Dr. Lenny Jason has clearly documented that most medical school textbooks and schools do not present meaningful information about the disease, so even new graduates today are either not informed or misinformed. A 2013 meta-analysis of 34 studies reinforced the patient-reported themes of stigma, challenges with getting a diagnosis, skepticism, minimization and misunderstanding on the part of the medical providers.

The IOM report emphasizes the importance of our medical professionals being properly informed about this complex disease.

All five of these core issues were addressed in the rigorous IOM report. **That’s why this report is a seminal moment in the long, painful history of this disease.**

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And we believe that this issue matters to everyone, not just patients and their loved ones.

The ME/CFS/SEID economic burden on our nation is significant. Our government has estimated a \$17 to 24 billion economic burden on our nation, due to lost productivity, indirect and direct costs. The slides that scrolled on the screen moments ago emphasize time and again that what patients want most is to rise from their beds to be productive and their eagerness to work and lift the burden of care from others.

And there are so many who suffer. The IOM report estimates 836,000 to 2.5 million Americans suffer with this illness. The CDC has estimated 1 million Americans. And certainly there are millions upon millions around the world. **This is NOT a rare disease.**

SLIDE 13

Disease	funding (millions)	# of Americans	\$'s spent per patient (column added for this presentation)
HIV/AIDS	\$ 2,978	1,200,000	\$ 2,482
Lupus	\$ 99	350,000	\$ 283
Multiple sclerosis	\$ 102	400,000	\$ 255
Autism	\$ 188	3,500,000	\$ 54
ME/CFS	\$ 5	1,000,000	\$ 5

Source: U.S. Institutes of Health. “Estimates of Funding for Various Research. Condition and Disease Categories (RCDC). NIH, published March 7, 2014.
http://report.nih.gov/categorical_spending.aspx

You see now a chart showing 2014 NIH funding and prevalence for selected diseases. There are four columns, showing the disease, 2014 NIH spending, prevalence and, at the right, spending per patient.

As the chart shows on the bottom line, the 2014 NIH ME/CFS research spending budget totaled \$5 million. And using the conservative CDC figure of 1 million patients, we see that that's \$5 per patient annually.

On a percentage basis per patient, looking at the column on the right, we see that spending on ME/CFS per patient is:

- 2% of spending per patient on Lupus
- 2% of spending per patient on MS
- 9% of of spending per patient on autism

Certainly those are serious medical problems; I don't disparage our government's spending on them. **I simply must illustrate the enormous disparity in spending when compared with ME/CFS.**

SLIDES FOURTEEN, 15, 16, 17, 18, 19, 20, 21, and 22

NIH publishes a list annually showing its spending on various medical challenges and diseases. We see here the 2014 NIH chart showing all 242 diseases, ranked in order by total spending.

Let's take a list of the roster to see where ME/CFS ranks. You see three columns: Rank order 1-242, the disease and the 2014 NIH spending

For example, we see cancer ranked at #7 with \$5.4 annual spending.

Let's take a look down the list for ME/CFS.

As shown on these charts, in 2014 the ME/CFS research budget is 232 out of 242 diseases funded by NIH, at \$5 million per year. **232 out of 242.**

And in actual dollars, the spending on ME/CFS is less than what our government spends on **hay fever.**

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And this low level of 2014 spending is not an anomaly. NIH funding for this disease has averaged roughly \$5.5 million in the 14 years between 1999 and 2013. When we look at the period 1987 to 2012, spending on ME/CFS decreased by 27 percent while total NIH funding **more than doubled.**

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So understanding the economic burden on our nation, the suffering of our citizens, and the new disease validation with the IOM report, what now?

With this new report, there are many actions that can be taken now to do right by patients and their families. **I ask only three:**

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First, provide funding for biomedical research and studies commensurate with the disease burden.

That is, use research dollars to aggressively advance understanding of disease etiology, pathology, diagnostics, treatment, and natural history in patients across the spectrum of disease severity, patient age, race and socioeconomic status.

The math is straightforward based on the chart. Based on disease prevalence, **NIH funding would be roughly \$250 million annually** to be comparable to spending on lupus or multiple sclerosis. The math is straightforward.

We note that researchers are ready. Our research organization and the many other universities, clinics and non-profits who struggle with miniscule research budgets can significantly accelerate the pace of discovery.

By far the primary source of basic research funds in our nation's history has been the federal government. This is its right and proper role – to serve the medical needs of its citizens. That is what the NIH has done with fantastic effectiveness for other diseases.

At \$5 million in research spending and the estimate of national economic impact of \$17 to \$24 billion, the economic cost to our economy is more than 4,000 times our government's current spending on ME/CFS/SEID. **I challenge the OMB or NIH to find a more effective use of incremental federal funds than to support research into ME/CFS.**

But the ME/CFS community does not have a massive lobby. We do not have established budgets of meaningful size on which to build up 5 or 10 percent annual increases. **What we have now is an IOM report, commissioned by our government, that documents the desperate need put up against the miniscule federal budget for this disease.**

Further, when one can stand back from the up-close, personal view of the anguish and despair of individual patients, **this is a fascinating medical research problem.** This is the kind of complex problem that attracts brilliant, inquisitive researchers who thrive on using rigorous science to attack complex problems. There are researchers standing at the ready.

Additionally, there are new informatics technologies systems biology models used in other diseases that can parse through large, complex datasets which reveal insights that are not obvious to us mortals. These extraordinary advances in informatics and other areas of medical research, not available even five years ago, are **ripe** to be applied to this complex illness.

This is a medical problem that can be solved.

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Our second request: Resolve the organizational and institutional barriers within the federal departments. We need a strategic and tactical plan and commitment to solving this disease, across agencies, perhaps even an ME/CFS czar.

One clear immediate change is to change the location of this disease from the Office of Research on Women's Health. This disease must be housed within an NIH Institute with budgets and substantial funding authority, perhaps NIAID (Immunology) or NAIDS (Neurology). This disease needs an institutional home that is appropriate and can advocate for dollars and action.

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And our third request, as called for in the IOM report, accelerate education of our nation's medical professionals. Patients cannot wait.

This means, among other things, updating the CDC's primer. And acting on the IOM report's recommendation to disseminate information about the disease to medical schools and working professionals. This is eminently doable with appropriate funding and a thoughtful implementation plan.

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In conclusion, so many people have suffered for so long without medical help or compassion. Along with a million other Americans and their loved ones, I fervently believe this is the **beginning of the end of this deplorable tragedy that's not worthy of the American people.**

I think of Cheryl, a talented scholar and athlete, who went on to graduate from a prestigious business school. She married and then fell sick, with very sudden onset, with ME/CFS. She is now in her early 40s. She can barely care for herself when her husband travels for business. They have had to abandon their dream of having children together. And brain fog makes it difficult to read or watch TV. When they share time together watching Downton Abbey, they can only do in 10 minute increments. Cheryl also was diagnosed several years ago with non-Hodgkin's lymphoma and endured six rounds of chemo. She is now fully clear of the lymphoma.

When asked if she could choose between having ME/CFS or lymphoma, an awful choice, she does not hesitate in choosing lymphoma. Yes, lymphoma can kill you. But she beat it. But ME/CFS leaves her to live in a painful, hellish twilight which may well continue through the end of her days. The choice was a simple one.

There are thousands upon thousands of Cheryls and Williams. Some are now 80 years old having been sick for 40 years.

In our organization, we talk regularly with these patients; the pathos and misery is heartbreaking.

This definitive IOM report has once and for all declared that we must commit to funding research to eradicate this dreadful disease. Now there can be no excuses.

No excuses from our nation's health agencies that haven't funded research at a level commensurate with the economic burden it places on our nation's economy, or in comparison with other diseases.

And no excuses from anyone—doctors, friends, coworkers or family—who dismiss the devastating suffering of a million or more of our fellow Americans.

Our society's understanding of this disease is where, say, MS or autism was 30 years ago—poorly understood, largely dismissed, with skepticism about the cause.

Just as ME/CFS is now, there was a time when autism and MS were dismissed as “not real.” Remember that? Autism was blamed on cold, non-responsive parenting. Multiple sclerosis on hysteria.

We all now feel remorse for that now unimaginable insensitivity to the suffering of those with autism or MS.

Such has been the inhumane dismissal of those who suffer now with ME/CFS. One day the skepticism about ME/CFS and the poor treatment of those who suffer from it will be equally unimaginable to everyone.

With this highly credible, scholarly IOM report, now is the time to Solve ME/CFS.

Thank you.