I have Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), a disabling and deadly disease that affects 1-2 million Americans and costs the US Economy $17-$24 billion annually. It causes tremendous suffering, and renders many patients homebound or bedbound, sometimes permanently. The hallmarks of ME/CFS are a malfunctioning immune system, leaving patients open to active viral infections and cancer, and a severely impaired ability to produce ATP (energy) at the cellular level, causing myriad symptoms I believe are best described as slow organ failure.

Although the gravity of this disease is clear to the patient community, ME/CFS has been shrouded in mystery and disbelief in the medical community, and research monies are seriously lacking. A mere $14 million per year is allocated by National Institute of Health (NIH) as of FY 2017, an amount that ME/CFS researchers all agree is far too little ($260 million has been the recommended amount that would be impactful). But to date, securing adequate research funding has been a seemingly unsolvable issue - a quagmire of a circular reference as depicted below.
As a former finance executive, I cannot understand the hold-up. Spending $260 million to yield an annual return of $17-24 billion makes fiscal sense (I’m looking at you, Republicans). Oh, and millions of people won’t be disabled anymore – an added benefit. We already have research that substantiates the severity and impact of the illness (but to date, no cause or FDA approved treatments). And we have researchers lined up at top institutions throughout the country, namely Columbia University, Johns Hopkins, and Stanford University, so let’s fund them and solve this!

In an attempt to unravel this mystery, my husband John Piotrowski and I decided to go to the center of this circular reference: The National Institute of Health (NIH). We met with top officials at the main campus of the NIH in Bethesda, MD on March 2, 2017 to discuss what is currently being done with respect to ME/CFS. We wanted to know what can be done to advance research and funding in the future, and through sharing my own experience with the illness, I wanted to provide testimony that this disease is real and very serious, and increasingly quantifiable from a diagnostic perspective.

**List of Attendees**

In attendance were (as pictured, from left to right): Dr. Avi Nath, Clinical Director of the National Institute of Neurological Disease and Stroke; Dr. Francis Collins, Director of the National Institute of Health; Kathryn Fox – Notre Dame Graduate, Former Business Executive, and Patient Advocate for ME/CFS; Dr. Walter Koroshetz, Director of the National Institute of Neurological Disease and Stroke; Dr. Lawrence Tabak, Deputy Director at the National Institute of Health; Dr. Vicky Whittemore, Program Manager of Circuits, Synapses and Cluster at the National Institute of Neurological Disease and Stroke; Dr. Joseph Breen,
Section Chief of Immunoregulation at the National Institute of Allergy and Infectious Disease; and (not pictured) John Piotrowski – Criminal Investigator for the Department of Homeland Security and Husband of Kathryn Fox.

**NIH Perspective**

Dr. Collins kicked off the meeting by offering the support of himself and his team. He indicated that the Trans-NIH ME/CFS Working Group within NIH has been reinvigorated and there is much excitement surrounding the January 2017 issuance of RFA’s for two to three Centers of Excellence and a Data Management Center for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). The result is a $30m NIH investment over a 5-year period, which equates to about $6 million per year, roughly doubling the FY 2017 NIH budget to $14 million from last year’s $7 million.

Collins stated it is rare for the NIH to speak publicly about the need to make specific diseases a priority, and currently ME/CFS is on that list (along with Autism and The Brain Initiative, among others).

The NIH is optimistic that the ME/CFS Centers for Excellence, which will be awarded in September 2017, will serve as thought leaders in this emerging field, will standardize diagnostic criteria and terminology, and will recruit top-tier researchers, all of which will further investment once established. In the meantime, all researchers interested in ME/CFS are encouraged to apply for grants through the NIH’s many other funding mechanisms. Dr. Collins indicated that the composition of the ME/CFS Special Emphasis Panel (SEP), the committee that reviews ME/CFS grant applications, has been revised and the majority of the panel is now comprised of ME/CFS experts, including esteemed ME/CFS clinicians and researchers such as Dr. Ian Lipkin of Columbia University, and Dr. Nancy Klimas of Nova Southeastern University. They are actively working to provide timely feedback and consistency in commentary, and fund any application they deem meritorious. Dr. Whittemore is also engaging subject matter experts in the review process to the extent the application requires specialized knowledge in a particular area. New researchers are especially encouraged to apply!

Dr. Collins explained that what the NIH is looking for with respect to funding ME/CFS research is the use of “latest and greatest technology”, such as thermal imaging scanning, as well as new hypotheses that have not been researched previously (some ideas clearly have not worked in the past). The NIH is very interested in exploring infectious triggers, metabolomics, the microbiome, and genomics as they relate to ME/CFS. Collins provided a copy of the Naviaux 2016 study on metabolomics, *Metabolic Features of Chronic Fatigue Syndrome*¹, noting, “This is (the type of research that) gets the NIH really excited.”

Dr. Collins further noted the NIH is a research institute. They are scientists, not policy makers or lobbyists. They look at the quality of existing research, and make funding decisions based upon the applications they feel are the most meritorious, as described above.

Lastly, in response to the issuance of the February 2017 RFA’s, the team indicated that they have already received interest from several qualified institutions, and Dr. Whittemore is working with the respective candidates to clarify questions surrounding the submission process. They are confident the September 2017 award deadline will be met. When I asked
how the amount was determined, Dr. Koroshetz indicated that this is a “standard amount” that the NIH uses to start a new Center for Excellence. This is meant to be a first step to lay the appropriate infrastructure to grow future investment.

**Patient Perspective**

John and I gave a brief summary of our backgrounds, including how we met in Pittsburgh, PA in the 7th grade and remained friends through the years, eventually marrying in 2006. He is a graduate of Shippensburg University, served 8 years in the United States Army as an officer and Ranger School graduate (deploying to Bosnia and Guantanamo Bay), then joined the Department of Homeland Security as a Special Agent.

I was always a bright kid, in advanced classes since the 2nd grade, earned straight A’s and graduated high school with a 4.2 GPA. I was president of the Biology and German clubs, in the National Honors Society, was Head Majorette, Homecoming Queen, and played flute in the Symphonic Band. I obtained a BA in Accountancy from the University of Notre Dame and was a successful business executive for almost 15 years, working in the San Francisco Bay Area for companies such as PwC, Deloitte, RGP and various tech startups before becoming disabled by ME/CFS in 2009.

I showed many pictures from my life, pre-illness. I was a runner, dancer, world-traveler, surfer, skier, hiker, and motorcyclist with friends all over the world. The images placed me at the top of Diamond Head in Hawaii, in a ‘glacier ball’ fight with friends in Iceland, sailing in Newport, Rhode Island... oh, and clip from the San Jose Mercury News where my marathon relay team, The Fleeting Glimps (comprised of myself and three coworkers), won 2nd Place in the Silicon Valley Marathon Relay. “How,” I proposed, “does a marathon runner’s body flip on a dime from this (aforementioned images), to this (a series of images of me in bed, ill with the disease)? I am mostly bedbound, limited to 1200 steps per day,
and go into anaerobic energy production at 98bpm. It just doesn’t make any sense.” The crowd appeared intrigued.

I continued with some post-illness images, namely before and after selfies from December 2016, taken one day apart, that visually illustrate what an ME/CFS sufferer looks like during a symptom flare. I got choked up as I explained; “I took the first image on Christmas Day. I knew that by getting out of bed, getting dressed, and doing my hair so I could open presents with my family, take a family photo, and eat a nice family dinner... that I would be pushing myself too hard and I would have a flare. So I took the second image one day later. As clinicians, I want you to notice the dead eyes – many ME/CFS patients describe this phenomenon. There is no light reflected in them, they are sunken and hollow. Notice the facial pallor, and the pronounced wrinkles on my neck from dehydration.” I looked at Dr. Nath, who is heading the NIH’s first Intramural Clinical Study on ME/CFS, and said, “You will not see patients on days like this in your clinic, because they cannot get out of bed.”

I then read my prepared statement about how I became ill and what I’ve experienced.

“When I first got sick in 2007, I was working 70-80 hour weeks as a Director of Finance for Fidelity. I had several departments reporting to me, and was also the lead on a multi-million dollar Oracle implementation. I got mononucleosis, strep throat, and a weird ear infection that turned the inside of my ear fluorescent green. I passed out giving a presentation at work in front of a classroom full of my employees. I knew that something was really wrong, and I was right; it’s been downhill since then.
I took a consulting job that would limit me to 40-hour weeks, and did one project, but had to go on disability in 2009. I went to many different doctors who all said nothing was wrong. So I tried a psychologist. She eventually is the one who convinced me to keep seeking a diagnosis: she said, nothing is wrong with you psychologically. Something physical is going on and you need to find out what. So I researched online and found ME, and also a specialty clinic that was able to finally diagnose me in 2011.

But my health, my career, my finances, and all of my friendships were already taken from me. Everything I loved to do. Every skill I thought I had, my entire identity – gone in one fell swoop. I asked my sisters, my parents, and a few friends for help, but nobody came. My family did not believe me, and even my husband did not believe me. We separated for 2 years and I went to live with my parents.

Fortunately, with time and seeing the devastating effects of this illness, John and my parents have come around and become supportive of me. And as more friends are hearing about this from the news, other doctors, and from people they know, I am slowly starting to rebuild a few friendships.

But my daily reality remains this: waking up feeling like I have the flu or mono or both. My muscles are tied so tightly in knots, sometimes it feels like my tendons will snap. I drag myself around the house to feed myself, grab ice packs, and take medication/vitamins. It is a constant storm of migraines, muscle and nerve pain, neurological symptoms, insomnia, IBS, nausea, freezing no matter how warm it is… and most recently tremors. John and I never go anywhere or do anything, we have no life. My body cannot sustain a life.

I am gluten-free, dairy-free, and alcohol-free. I take a million vitamins. I make sure to walk a bit each day and stretch. I eat an organic paleo diet. I think positively, and pray every day. I have tried to retrain myself by going back to school part-time for my masters but have had to drop out 6 times because of my health. I have done everything that has been recommended to me, and I continue to deteriorate. So that is why I am here. I have more than enough tenacity and faith in myself to know that something is seriously wrong. And something seriously needs to be done about it.“

**The Canadian Consensus Criteria**

I quickly shared the Canadian Consensus Criteria (CCC) for ME/CFS, which I knew they were already familiar with. But to date, neither the Center for Disease Control (CDC) nor the NIH can agree on an accurate enough set of diagnostic criteria, which I believe the CCC to be, and this is muddying the waters for researchers and clinicians. I said, “I know you are all familiar with the CCC so I won’t go into much detail here.” They all nodded in agreement. I continued, ”The point I want to make is that I have the majority of these symptoms. If I got a vote, this describes my disease very well.”
General Findings in ME/CFS

I then discussed general findings common in ME/CFS patients that are currently verifiable via labwork and/or clinical observation.
General Findings in ME/CFS

<table>
<thead>
<tr>
<th>Verifiable via Labwork and/or</th>
<th>Clinical Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune Disturbance:</td>
<td>Neurological Disturbance:</td>
</tr>
<tr>
<td>- High TGFβ1</td>
<td>- Non-reactive pupils</td>
</tr>
<tr>
<td>- Low Alpha MSH</td>
<td>- Non-reactive reflexes</td>
</tr>
<tr>
<td>- Low VIP</td>
<td>- Tremors</td>
</tr>
<tr>
<td>- High ECP</td>
<td>- Increased delta wave activity while awake</td>
</tr>
<tr>
<td>- Low NK Function</td>
<td>- Decreased blood flow to brain (SPECT scan)</td>
</tr>
<tr>
<td>Endocrine Disturbance:</td>
<td>Cardiac Disturbance:</td>
</tr>
<tr>
<td>- High T3/T4 ratio; impaired liver conversion of</td>
<td>- Heart murmur</td>
</tr>
<tr>
<td>T4 to T3</td>
<td>- Anaerobic threshold (AT) occurs early</td>
</tr>
<tr>
<td>- Low cortisol</td>
<td>- Syncope</td>
</tr>
<tr>
<td>-</td>
<td>- Orthostatic hypotension (Tilt Table testing)</td>
</tr>
<tr>
<td>Infections (often recurrent):</td>
<td>Vitamin Deficiencies:</td>
</tr>
<tr>
<td>- EBV, HHV-6, CMV</td>
<td>- Low B12</td>
</tr>
<tr>
<td>- CPN, MPN, MP, HHV-8, Shingles</td>
<td>- Low D</td>
</tr>
<tr>
<td>Genetic Mutations:</td>
<td>Renal Disturbance:</td>
</tr>
<tr>
<td>- MTHFR (ex. A1298C)</td>
<td>- Low BUN/Creatinine ratio</td>
</tr>
<tr>
<td>- MCS</td>
<td></td>
</tr>
<tr>
<td>- Mold Sensitivity</td>
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</table>

This is not meant to be an exhaustive list, nor is this intended to diagnose ME/CFS. My hope is that this list will inspire researchers and clinicians to look beyond a standard blood test where ME/CFS is suspected, and clear up any misinformation as to whether this disease lacks verifiable scientific data.

I would also like note that ME/CFS is a serious, biological illness, and is “not a primary psychological disease in etiology”; this is supported by the National Institute of Health, the Institute of Medicine and the ME/CFS research community.

What ME/CFS Does To The Body

My own immune system has gone haywire, most notably my lack of natural killer (NK) cell function. NK cells are responsible for patrolling the body and identifying pathogens and invaders, such as cancer, so the immune system can isolate and destroy them. Without proper functioning of NK cells, a hallmark of ME/CFS, we are at a higher risk than the normal population for suffering from viral infections, and developing cancer. Many ME/CFS patients die decades earlier than the general population of infections and/or organ failure, particularly of cardiac-related events, cancer, and suicide.

Another hallmark of ME/CFS is the inability of our cells to produce enough ATP (energy) to power all of our bodily systems; what little we have is being allocated to supporting our immune system and our brains, both of which can easily require more energy than we have to spare. This causes crippling exhaustion, the symptom referred to, callously in my opinion, as “fatigue”. If we dare get up out of our beds, the amount of energy required to
walk, talk, think, eat, or just generally exist usually depletes the amount of energy we have on hand, causing the symptom referred to as “post-exertional malaise”.

Once our energy is depleted, our cells turn to less-efficient means of energy production, anaerobic energy production, in which the toxin lactic acid is produced as a by-product, saturating our tissues and causing widespread pain. Anyone who has worked out too hard has experienced “the burn” and painful muscle cramps caused by lactic acid buildup. This is a daily reality for ME/CFS sufferers. Compounding the problem is the fact that, unlike a healthy body that can rest overnight and recover from fatigue, it can take an ME/CFS body days, weeks, months, or even years, to refuel depending upon how much energy was depleted. Some patients have even reported going into shock after energy depletion⁸, requiring hospitalization. Add to this Central Nervous System dysfunction, and you have one heck of an illness.

Organizational Challenges

Back to the NIH for one last point... I feel it is important to understand the complexity in researching a multi-systemic disease such as ME/CFS. The NIH is not a monolithic institution; it is comprised of several smaller institutions organized by bodily system (such as NINDS, The National Institute of Neurological Disease and Stroke, or NIAID, the National Institute of Allergy and Infectious Disease, both of whom had representatives at this meeting). Because ME/CFS affects so many systems, it spans almost every institute at the NIH. And as a cause has yet to be identified, confusion exists as to which institute should be responsible for owning it (historically the disease has bounced from NIAID to OD to NINDS, its current resting place).

Dr. Koroshetz and NINDS have graciously stepped up to champion this disease for the time being, as ME/CFS clearly has a neurological component, and Dr. Koroshetz and Dr. Whittemore have done a commendable job this year of creating a budget for the ME/CFS RFA’s out of literally nothing (they were the result of piecing together funds from ten different institutes via the Trans-NIH ME/CFS Working Group). The NIH is looking to future research to illuminate the cause of ME/CFS; at that point they will be better able to identify which institute should own this disease. In the meantime, without a permanent home, and in my opinion, due to the lack of awareness in both the general population and medical community, ME/CFS has not been given the level of funding required to properly research this complex illness. Other multi-systemic diseases such as AIDS and Autism have faced this challenge in the past, both literally requiring an act of Congress to ensure appropriate funding. And that is the next step necessary to mandate funding for ME/CFS as well.

Recommendations

Multi-systemic diseases like ME/CFS have all faced the circular reference quagmire plaguing ME/CFS, as described above. Patient advocates have been successful in breaking this cycle in the past by lobbying Congress to set aside federally mandated funds for the disease, as was done successfully with Autism and AIDS. Which brings me to my recommendations.

1) Mandate Federal Funds for ME/CFS

I recommend that all ME/CFS advocacy groups and allies focus on lobbying Congress to push for federally mandated funds for ME/CFS. When complex and multi-systemic
diseases have baffled the medical profession in the past, in order to encourage quality research, it has taken an act of Congress in order to mandate federal funds to be reserved for that disease (i.e. Autism and AIDS). That is what, I believe, is required in this case, as well.

Relevant facts for Congressional discussion:

Through an investment in ME/CFS research of $260 million, the United States economy stands to gain $17-$24 billion ANNUALLY¹.

This could even be a conservative estimate of the disease burden. This disease strikes predominantly in the 30-40 year age range; precisely when a person is hitting their peak performance financially and career-wise. I fell ill at the age of 32, and was disabled by 34. Every year I am unable to work, the US Economy loses $66k. Assuming 1 million Americans are living with ME/CFS, in similar circumstances to my own, this would equate to $66 billion in losses annually.

Share your own story and statistics!

*(Please refer to the Autism Legislation as a guide for moving forward with ME/CFS at a Congressional level.)*

2) Educate. Educate. Educate.

We need to educate our Congressman on the impact of this disease so they feel comfortable enough discussing and passing legislation to dedicate federal monies for ME/CFS research. We need to educate our doctors regarding the symptoms we experience and ways they can help treat us. And we need to educate our families and friends so that they understand what this disease is, and how to help us.

A wise former boss once told me, “Don’t come to me with problems. Come to me with solutions.” And that is what I am advocating here. Create fliers, pamphlets. Summarize the research that is out there on ME/CFS (from medical journals, PubMed, etc.). Create an ME/CFS “mission statement” – how would you describe the disease in one sentence to someone who asks? Create brochures we can give to our congressmen, doctors, or take to the hospital with us. If they do not know yet about our disease, explain it to them. Summarize treatment protocols that are currently being used at the ME/CFS clinics. Instead of berating the medical community, arm them with facts. If you were in your doctors shoes, what treatment would you recommend and why? Give presentations at your alma mater for prospective researchers. (The NIH has committed to giving more presentations on ME/CFS at medical conferences they attend). Take your own before and after selfies and post them online #doilooksick? Or just print out the Canadian Consensus Criteria above and use that to for educational purposes.

This is what I have attempted to do in this article, and in the presentation I gave at the NIH. I know this is not easy. It took me three weeks to compile all the data for my NIH presentation (followed by a one week crash), and about another week to write this summary (and another crash). But if you are reading this, you have evidence this approach can work.
Yes, this should not be the responsibility of a disabled patient population. But the reality is, without the funds required, ME/CFS research is advancing at a snail’s pace.

Conclusion

In the business world, I was a problem solver. I was the person called in to restructure business processes, streamline inefficiencies, create effective policies and procedures, and implement new information systems. And ironically, or perhaps fittingly, now I’ve been handed the most complicated problem of my life. I am hoping through sharing my story and continuing to advocate for the 1-2 million Americans who are suffering from ME/CFS, who are alone in their beds, abandoned, and disbelieved, hopefully I can somehow serve in moving the bar forward for us all. But I cannot do it alone. We need more problem solvers - researchers, patients, advocates, clinicians, policy makers and politicians - to step forward. Together, I am confident we can solve this insidious disease.

P.S. For kind souls who wish to help...

- Donations can be made either to SolveCFS.org or MEAction.net.
- Amazon customers can log on to smile.amazon.com and select “Solve ME/CFS” as your charity of choice; for every purchase you make, Amazon will make a donation to ME/CFS.
- Call your Congressman! Tell them you support federally mandated funds for ME/CFS research.
- Take Action! MEAction.net has specific actions you can take, such as signing petitions, volunteering, or supporting us via social media.
- **Watch the film Unrest!** The 2017 Sundance Award-Winning film by Jennifer Brea, Unrest, a documentary film about ME/CFS, will premiere on PBS in 2018.
- Please send up a prayer for ME/CFS patients.

Sources: