

**Obama-Biden Transition Project
Health Care Community Discussion Report**

December 30, 2008

Mary Schweitzer, Host and Moderator

We are a small group of friends within a larger long-term online community of citizens who share one attribute: we are all disabled, significantly ill for a very long time, and we share the maddeningly inept diagnosis of "Chronic Fatigue Syndrome" (CFS).

My name is Mary Schweitzer; I am the moderator. I was a tenured professor of history before I was disabled with this disease in 1994. The members of this committee include Karen Campbell, formerly a paralegal; Pat Fero, formerly a special education teacher; PSB, formerly a scientist with Mitre; Carol O., formerly a teacher; Steven DuPre, formerly a teacher and athlete; Sue C, formerly a sociologist; Rik Carlson, a writer; and Meghan Shannon, formerly a nurse specialist. None of us have been able to work in at least 12 years – Pat Fero and Meghan have been sick the longest: 27 years. Our individual stories are appended.

We ask that

- 1. The U.S. adopt the Canadian Consensus Document for diagnosing and treating ME/CFS, available online at <http://www.mefmaction.net/Portals/0/docs//ME-Overview.pdf>;**
- 2. The U.S. accept the World Health Organization's ICD-10 designation of "CFS" within the chapter on neurology, at G93.3, with M.E.**
- 3. NIH and CDC focus on biomedical research instead of psychosocial;**
- 4. GAO investigate NIH and CDC for the misapplication of funds; and**
- 5. Secretary Daschle take seriously the existing Chronic Fatigue Syndrome Advisory Council to DHHS, along with the 11 recommendations of the CFSAC from 2004 (enclosed)**

Fundamental Inequality in Treatment of ME/CFS at DHHS.

Our primary issue is the **fundamental inequality** in the treatment of patients who have the disease M.E. (Myalgic Encephalomyelitis) and/or have a diagnosis of Chronic Fatigue Syndrome.

We understand the desire to reduce the individual costs of medical care as medical care is extended to all Americans. All of us are convinced that, had we been diagnosed and received treatment earlier (with antivirals or immune boosters, for example), we would never have become permanently disabled. Our disability has cost the nation quite a bit. According to CDC, households with a family member who has "CFS" lose, on average, at least \$20,000 a year. Using the DePaul University estimate of **1 million Americans** (the current CDC estimate is 4-7 million), that would mean **the nation loses \$20 billion in NNP every year, and at least \$6 billion in income tax**

revenues to the federal government, because nothing is being done about ME/CFS. The failure to properly address the problem of “CFS” has been very costly for the nation and the government.¹

We were asked to examine health care in the United States and how best to reform it. Unfortunately, **it matters little whether you have the best health insurance available or none at all, if you have been rendered an invalid by a condition kept invisible by the actions of NIH and CDC.**

Medical doctors and other medical personnel are members of a larger society and culture in the United States. No matter the extent of professional training, popular beliefs and perceptions will subconsciously influence their behavior. In the absence of information about the depth and severity of our illness, popular norms dominate the attitude that greets us when we walk into a doctor’s office or an emergency room.

In a nation where everyone is overworked and hence “a little tired,” where the word “chronic” is associated with such terms as “chronic whiner” and “chronic complainer,” and the word “syndrome” has become code for “fad of the day,” NIH and CDC could not have picked a better way to describe a disease that – quite bluntly – they apparently wish would disappear on its own.

This might have been understandable 25 years ago when a number of cluster outbreaks of the disease occurred in the midst of the AIDS crisis that overwhelmed the medical establishment. Today, however, there are thousands of peer-reviewed research articles into the biological causation of many of the symptoms, and subgroups have been defined through objective testing: biomarkers, SPECT scans, and specific types of stress tests. Almost a decade ago, Anthony Komaroff of Harvard wrote:

In summary, there is now considerable evidence of an underlying biological process in most patients who meet the CDC [Fukuda] case definition of chronic fatigue syndrome. ... [This evidence] is inconsistent with the hypothesis that chronic fatigue syndrome involves symptoms that are only imagined or amplified because of underlying psychiatric distress – symptoms that have no biological basis. It is time to put that hypothesis to rest and to pursue biological clues. ... in our quest to find answers for patients suffering from this syndrome.²

Yet the NIH and CDC have continued to focus on “psychosocial” research, not biomedical. For that matter, the article presenting the CDC’s Fukuda definition clearly

¹ See Jason LA, Richman JA, Rademaker AW, et al. A community-based study of Chronic Fatigue Syndrome. *Arch Intern Med* 159:2129-2137, Oct. 1999, and Reynolds KJ, Vernon SD, Bouchery E, Reeves WC. The economic impact of chronic fatigue syndrome, *Cost Effectiveness and Resource Allocation* 2:4, 2004.

² Komaroff AL. “The Biology of Chronic Fatigue Syndrome.” *Am J Med* 108: 169-161, 2000.

indicated that the next task was to identify subgroups, but the CDC continues to lump more vague conditions under the CFS umbrella.³

Many CFS patients test positive for reactivated viruses [specifically HHV-6 (Variant A), chronic Epstein-Barr, cytomegalovirus, adenoviruses, and enteroviruses]; some have tested positive for mycoplasma; and some test positive for Lyme as well. For these patients, immune, antiviral, and on occasion antibiotic treatment is necessary. But if doctors do not know about these tests, no one will receive the treatments.⁴

It should be no surprise that, **25 years after the first effort by CDC to study the phenomenon of “CFS,” 85 percent of patients today still have no diagnosis (according to CDC).** Of those who have a diagnosis, even fewer have a doctor who understands it. And because this disease is so poorly understood, many who do have a diagnosis of CFS have no symptoms resembling ours.

It is popularly believed that a condition is pretty normal, experienced by everyone at some point in time (fatigue), then having an illness defined by that condition is hardly reason for alarm - hardly reason for urgency - and hardly an excuse for not working. More to the point, **it is no reason to spend money** – a position that makes the insurance lobbyists on K-Street happy, and also pleases those within the government who believe that catering to “entitlements” are a main reason for “high” government spending. **Keeping one million patients hidden from view (because of the extent of our disability) has served political purposes that hopefully will change in the Obama presidency.**

The name "chronic fatigue syndrome," however well-intentioned, subliminally accomplishes this mission. No one takes this disease seriously – no one, except those of us who have been saddled with the diagnosis, and our families.

The CDC has become adept at presenting one position on CFS to patient groups, another to physicians, and yet another to Congress. On the one hand, their own literature states that "CFS is a debilitating and complex disorder". Conversely, they have dismissed outright every biomarker that has been discovered with regard to the cluster outbreak patients of the mid-1980s. Their own “CFS Toolkit for Professionals,” devotes an entire section to "cognitive behavior therapy" (psychotherapy) and another section to “graded exercise.” **The introduction to the CDC Toolkit states, “As yet, there are no diagnostic tests or laboratory markers for CFS, and its pathophysiology is unknown.”**⁵

³ Fukuda K, Straus SE, Hickie I, et al. Chronic Fatigue Syndrome: a comprehensive approach to its definition and study. *Annals Med* 121:953-959, 1994.

⁴ For a recent review of the literature on the relationship between viruses and ME/CFS, see Devanur L.D., Kerr J.R. “Review: Chronic Fatigue Syndrome.” *Journal of Clinical Virology* 37 (2006) 3:139-150.

⁵ See <http://www.cdc.gov/cfs/pdf/Basic_Overview.pdf

For years I would say that yes, "chronic fatigue" is a common experience, but "chronic fatigue syndrome" is an unfortunate name for a very serious medical condition - and then I would describe how bad things are for me. Simple example: Yes, I'm sure you've gone looking for your reading glasses when actually they were on your head. But I doubt that you ever poured an entire pot of coffee into a silverware drawer, absolutely convinced it was a cup (as I have). You may not be able to pull up the right word for something - but it doesn't happen in every single sentence you try to say. You may feel so tired you don't want to have to move - but have you ever lain in bed, looking at a glass of water on the nightstand, unable to move your arm to get the glass of water and quench your thirst? Your eyes may hurt on occasion because you are tired, but do you regularly need to wear sunglasses indoors because light is so painful? Imagine not being able to read a comic strip because you can't remember the first panel by the time you get to the fourth - and imagine it all accompanied by terrible pain. **The disease CDC named "Chronic Fatigue Syndrome" is very, very different from "chronic fatigue."**

Unfortunately, CDC has recently moved further from the concept of "CFS" as a serious illness with an unfortunate name. They have created a set of questionnaires that - by their own admission - do not distinguish much between "chronic fatigue SYNDROME" and "chronic fatigue." For an example of the troubling nature of this research, see Tables 2 and 5 in Reeves *et al*, "Chronic Fatigue Syndrome – A clinically empirical approach to its definition and study," Biomed Central 2005, which describes the two-day Wichita hospital stay that has served as the basis of all of CDC's research since 2003. In all, **227 participants were brought into the hospital, but only 58 were ever diagnosed with CFS, and, according to the article, at most, only 16 of those 58 characterized still suffered from CFS at the time of the hospital stay.** Using the questionnaires and re-sorting the participants, Reeves concluded there were **43 patients with CFS** in that Wichita hospital stay. [You must look at the tables to see the actual numbers; they are difficult to find in the text.] **Compare that with Dr. Reeves' reference to "227 patients with CFS" in the same two-day Wichita hospital stay in a conference call to the media and also in a printed press release.** Reeves then published an article claiming that 58 CFS patients in a two-day hospital stay in Wichita showed no signs of Neurally Mediated Hypotension, thereby attempting to refute the Rowe-Calkins study on disautonomia in CFS, published in *JAMA* in 1995. However, **according to the *Biomed Central* article, of the 58 "CFS" patients brought into the hospital, at most only 16 still had CFS at the time of the study. If the *Biomed Central* article is accurate, then both the conference call and the *AJM* articles are incorrect. If the *AJM* article is correct, then the *Biomed Central* article and the press release are incorrect.**⁶

⁶ For the April 2006 conference call when Reeves stated there were 227 patients *with CFS* in the two-day Wichita hospital study, see: <<http://www.cdc.gov/od/oc/media/transcripts/t060420.htm>>. For the written press release from April 2006 that again stated 227 patients with CFS were in that hospital stay, see <<http://www.cdc.gov/media/pressrel/r060420.htm>>. For the article describing the actual two-day hospital study in Wichita (and Reeves has stated there was only one), see Reeves *et al*, "Chronic Fatigue Syndrome – A clinically empirical approach to its definition and study," *BMC Medicine*

Most troubling, the questionnaires that were supposedly vetted by the 2005 *BMC Medicine* study have formed the basis of Reeves “new” institutional definition, and all of his consequent research at CDC. A match of (at best) 16 out of 48 patients seems hardly sufficiently robust upon which to build the entire research program of CDC regarding a disease that impacts one million patients. Dr. Leonard Jason of DePaul tried the questionnaires on his own data set of patients in Chicago from an earlier demographic study and found that they missed the more seriously ill patients (such as the ones in this group) and instead picked up a lot of patients with mild depression. Private institutions benefited financially from the creation of these questionnaires and their distribution; insurance companies will benefit from their use in disability cases. The entire CDC program in CFS, headed by Dr. Reeves, clearly needs to be investigated by GAO.

The result of this unfortunate name (and the new CDC definition of CFS) extends widely. It is exacerbated by the current climate in medical care that tries to rush every patient through in 5-10 minutes, and penalizes medical practitioners for ordering tests that come out negative.

The Situation for Patients with ME/CFS:

1. People with very serious conditions are misdiagnosed, and a misdiagnosis leads to improper treatment, or no treatment at all. Simple example: a patient with Hepatitis C will be misdiagnosed as having CFS and not receive treatment for hepatitis. Conversely, if a patient has CFS because he/she has an immune defect and viruses, "cognitive behavior therapy" (as recommended by CDC) is not going to be much help, and if a patient has encephalitis or myocarditis, graded exercise (as recommended by CDC) can be dangerous.

2. Even well-intentioned and caring family doctors are baffled by patients with a CFS diagnosis who "refuse to get well" - who do not get better, or even get worse. It makes doctors uncomfortable. A patient with a CFS diagnosis can be reasonably expected to have other things go wrong with their bodies – acute appendicitis, for example - but their family doctor may be "burned out" on having to listen to symptoms that he/she cannot fix. The case of acute appendicitis gets dismissed as "yet another one of those symptoms" for this fuzzy thing called CFS - and the problem may not be resolved until the patient is in the hospital with peritonitis [see the personal story of Pat Fero, attached, for an example of such a misdiagnosis]. At best, there is no treatment offered for CFS; at worst, other conditions are ignored because both doctor and patient become used to ignoring any symptom mentioned by a CFS patient. Patients who

2005, 3:19 <<http://www.biomedcentral.com/1741-7015/3/19>>. Finally, for the seminal work in the relationship between dysautonomia and CFS, see I. Bou-Holaigah, P.C. Rowe, J. Kan, H. Calkins. "The relationship between neurally mediated hypotension and the chronic fatigue syndrome," *The Journal of the American Medical Association* 274 (1995), pp. 961-967.

have neither private nor public insurance end up in emergency rooms, where they are treated dismissively if they confess to a diagnosis of “Chronic Fatigue Syndrome.”⁷

3. Nobody really believes that somebody with "CFS" can't work. Everyone's tired. Why should one person who claims to be tired get off work when other people who are tired have to remain? Of course, those of us diagnosed with “CFS” are not just “tired” – we have the level of fatigue that is normally associated with congestive heart failure or leukemia. As Dan Peterson noted in the documentary “I Remember Me,” his CFS patients are as seriously ill as AIDS patients in the last two months of life. The popular perception that we are “just tired” obviously makes it incredibly difficult to receive either public or private disability. Everyone in the Social Security system, from intake workers to the ALJ level, doubts the disabling nature of this illness. Everyone in the private sector, from personal bosses and colleagues to the Human Resources Department and private insurance companies, is skeptical when you say you can't work. People are human; their prejudices influence their behavior. We know that at least one million Americans currently have this disease. Based upon research by the CDC, which historically has downplayed the severity of this disease, we know that at least half of them cannot work at all at any given point in time. That would mean that **500,000 Americans (most of whom have no diagnosis) are completely and utterly incapable of paid work because they have “CFS.” Few receive SSDI; even fewer receive private long-term disability.** The rest must depend upon family members, and if they have none, their situation is desperate. We all have known of patients who have had to live on the street. How many more are there?

4. If you are denied disability, you are also denied medical care. Admittedly, private insurance and Medicare will not pay for testing and treatment for “CFS.” However, there are a number of comorbidities that are recognized by CDC, and (as in the appendicitis example), CFS patients can be expected to have the same general physical problems (such as heart disease and diabetes) and experience the same acute problems (such as a diseased gallbladder or appendix) as the normal population – but if you do not have insurance, it is very difficult to get help.

5. Prejudice against patients "claiming CFS" can infect everyone from family members to neighbors to church groups. During the years that I ran a supportive on-line discussion list (averaging about 500 members at any given point in time), I knew patients who had been cast out by spouses or parents, scolded and disdained by siblings, and even abandoned by their churches.

6. Here we are, a quarter of a century after the set of cluster outbreaks in the 1980s that led to the name "chronic fatigue syndrome" adopted by CDC and NIH, and there simply are no doctors who can treat a patient with the disease. Of the handful who can be considered true experts, who have kept up with thousands of refereed journal articles over the years, I know two who are retiring in 2009. Patients call

⁷ Jason LA, Taylor RR, Stepanek Z, Plioplys, S. Attitudes regarding chronic fatigue syndrome: The importance of a name. *J Health Psych* 6:61-71 (2001).

me, email me, implore me to help them find a doctor. I live in the most populated section of the United States - the Northeast Corridor. I don't know what to tell patients. The only doctors I know who have specialized in this disease have retired, left their practice to focus on research, or closed their practices to newcomers because they are so overwhelmed.

7. Changing the name from Myalgic Encephalomyelitis (as it was known in Canada, Australia, and Britain) and Epidemic Neuromyesthenia (as it was known in the United States – or for that matter, “chronic Epstein-Barr Virus,” the name NIH first gave to the disease, to “chronic fatigue syndrome,” has had international consequences. British psychiatrists picked it up and have successfully convinced British public health (and the “NICE” initiative) that CFS and M.E. are the same thing. But they do not use the same definition for CFS as the U.S. Their definition is entirely psychological, and all they offer for treatment is ten weeks of “cognitive behaviour therapy (CBT)” to convince the patient she isn’t really sick, followed by ten weeks of “graded exercise therapy (GET)” to get her back up to speed. They believe the disease should really be called “neurasthenia” – the nervous disease diagnosed back in the 1800s. M.E. was classified as a neurological illness by WHO in the late 1960s, so British psychiatrists have thus far failed in their efforts to reclassify the disease as a neurosis.

Nevertheless, the consequences of applying the name CFS to a psychiatric diagnosis has been horrendous. Patients who once could get treatment can no longer find a caregiver. Schoolchildren, young adults, and even a vocal critic of the NICE guidelines have been “sectioned” – involuntarily committed to psychiatric hospitals. The result has been greater disability (patients who could walk are reduced to needing a wheelchair) and death, including two recent deaths of young people. Young Sophia Mirza, for example, insisted she could not swallow, but was repeatedly sectioned with a diagnosis of anorexia. She eventually died of dehydration. The autopsy showed significant damage to the basal root ganglia – the same finding as in the death of an adult with M.E. who was autopsied after an automobile accident. Any effort to adopt the “NICE” guidelines from Europe should not be attempted without an investigation into the stark criticism of these guidelines by patient groups in Britain. They save money in the short run – but they cause immense suffering. According to patient advocate Margaret Williams, **“The head of the British Department of Health has stated in writing (in 2008) that he knows of no evidence suggesting anyone has ever returned to work because of CBT [Cognitive Behaviour Therapy] or GET [Graded Exercise Therapy].”** Yet that is all that is offered patients in Britain through the NICE Guidelines – and CDC is beginning to follow suit.

Positive Actions that can be taken by DHHS:

1. There needs to be a sense of urgency. For 25 years patients have suffered from this illness. It is contagious at some point in its course. Consequently, every year there are more sufferers as the disease (or diseases) spreads unabated. At what point do we ask the CDC to stop conducting population studies and begin to educate the public as to biomarkers, objective testing (not questionnaires), and treatment? The NIH has allocated nothing for the study of CFS in the past two fiscal years. Surely a disease that impacts one million Americans deserves more attention. Finally, despite the insistence of CDC and NIH to the contrary, there have already been deaths from this disease.

2. Change the name. The CDC claims to be waiting for a name chosen by “medical science.” Yet the name “CFS” represents an arbitrary name change from the known diagnosis of epidemic neuromyesthenia in the U.S., and Myalgic encephalomyelitis in the old British Empire (and NIH’s previous name of “chronic mononucleosis”, or “chronic EBV,” for the outbreaks of the 1980s). There is no reason to keep this artificial name, which has dramatically failed to accomplish much that is positive. Better alternatives for a name would be:

(a) to adopt the name that has been in continuous use for 50 years internationally, **Myalgic Encephalomyelitis;**

(b) compromise: adopt the designation in the World Health Organization's current International Classification of Diseases - **"ICD-10", in which "CFS" is classified in G93.3, the code created for Myalgic Encephalomyelitis in the late 1960s. Call the disease ME/CFS,** until people get used to the name M.E. or until a new name emerges from research.

(c) acknowledge the complexity of the illness by giving a name that includes the multiple systems impacted by the disease: neurologic, immune, endocrine, cardio. One example is: **neuroendocrineimmune disorders.** One advantage is that the name leaves room to carve out subgroups that would get their own name - "Tahoe Syndrome" (CEBV, HHV-6, low nK function, Rnase-L defect) could be considered one KIND of neuro-immune-endocrine disorder. Another would be that there are probably other disorders that already could be included under this name, such as fibromyalgia, multiple chemical sensitivities, Lyme Disease, and Gulf War Syndrome.

(d) **create an eponym** - as was done with Lou Gehrig's disease (ALS). Name it "Skye's Disease" for the 14-year-old in upstate New York who committed suicide after her peers laughed at her silly-sounding disease (CFS), or “Casey’s Disease” for the 23-year-old who died of long-term viral myocarditis, after doctors had ignored his symptoms for years because he and his mother both had a diagnosis of CFS.

The group voted for “Myalgic Encephalomyelitis,” with perhaps an interim use of ME/CFS along with the adoption of the Canadian Consensus Document as the standard for treatment. With so many conflicting definitions, the continued use

of “CFS” as the name for this cluster of diseases has become counterproductive, resulting in misdiagnosis, failure to treat, and (as in the case of Casey Fero) deaths.

3. Change the definition. The current definition being used by the CDC is a watered down version of the Holmes and Fukuda definitions, both originally designed to apply to “chronic mononucleosis.” CDC's current questionnaires diagnose a disorder that is much more about "chronic fatigue" than about the serious disease once called "CFS".

Their "international case definition" effectively drops three of the eight identifying symptoms in the CDC's “Fukuda definition” of 1994, although their literature still insists they are using Fukuda. CDC is drifting towards the British psychiatric definition of CFS.

Adopt the definition from the Canadian Consensus Document for ME/CFS⁸ until we learn more about the disease (or diseases). The committee that created this document consisted of clinical practitioners, and about half practice in the United States. All the other definitions created for “chronic fatigue syndrome” were explicitly designed for research. **This is the only definition designed for clinical use, and it offers a means of recognizing the complexity of the condition at the same time it presents options to begin treating it. The pediatric definition created from the Canadian Consensus Document has been adopted as “best practice” by the International Association for CFS/ME.**

4. Change the diagnostic procedure. Make it clear that this is not an easy condition to diagnose, and that the usual 5-10 minute limitation given doctors by insurance companies is simply not adequate. List tests that need to be given to rule out diseases that give similar symptoms: Hepatitis C, congestive heart failure, diabetes, both types of anemia, leukemia, onset of Alzheimers or Parkinson's – these are just some of the illnesses that should be on this list.

Use the Canadian Consensus Document, which was written by clinicians, as a first pass at understanding the complexity and severity of this disease. Make use (as the Consensus Document does) of current published peer-reviewed research into objective biomarkers, testing, and non-psychiatric treatments.

The only options are the CDC’s “Toolkit for Professionals,” which insists there are no biomedical tests and there are no treatments (except for SSRIs, Cognitive Behavior Therapy, and Graded Exercise Therapy), and the Canadian Consensus Document, which provides information about biomedical tests and about treatments. The choice should be clear, for the CDC approach has been a dismal failure.

5. Inform doctors about the diagnostic testing available now, and require that at least Medicare pay for them. There are immune markers that are found in subgroups of CFS patients and nobody else. There are viruses that we did not know about 25 years ago, but we know about now. For example, HHV-6 encephalitis now has an ICD-9-CM code 049.8, but neither researchers nor clinicians working with CFS

⁸ A summary of the Canadian Consensus Document is available in pamphlet form at <<http://www.mefmaction.net/Portals/0/docs//ME-Overview.pdf>>. It is too long to append here.

patients seem to know this. Why aren't doctors and researchers testing for this virus and using this diagnosis, when there are American patients who, when tested and treated at their own expense, have been shown to have a positive response?⁹

6. Fund Centers of Excellence where family doctors can send patients suspected of having ME/CFS. Given the complexity of the illness, and the wealth of information that is emerging internationally, it is impractical to ask family doctors to keep abreast of this disease - as they cannot keep abreast of other complex diseases such as cancers. Centers of Excellence can serve to diagnose patients, to offer treatment plans that are either continued at the Center or by the family doctor, to train *new* young specialists, and to perform research into the causes, nature, and treatments to alleviate the suffering experienced by these patients.

7. Fund external and internal research into biomarkers and treatments ASAP. The Whittemore-Peterson Institute for Neuroimmune Diseases in Reno, Nevada, has only been open two years, but it has already produced more hard research than either CDC or NIH in 25 years. The NIH has allocated little if any funding for the disease in the past few years. Annual funding during the Bush administration has been as low as 0 and claimed to be as high as \$12 million, but we can find no evidence of that much money used for research into CFS. CDC's funding is entirely devoted to continually revising a baseline demographic study, and making the diagnostic criteria even more vacuous.

Indeed, the entire story of DHHS's practices with regard to "CFS" (the appearance of research without research, the production of information that contains nothing) can be found in the minutes of the CFSCC and CFSAC.

8. We strongly urge a formal investigation by the GAO into the use of funding by both NIH and CDC with regard to CFS. Several members of this committee have hard evidence into abuse of funding by these two agencies. Patient groups have testified to these abuses at the CFSAC meetings, to no avail. For example, **Pat Fero, president of the Wisconsin CFS/ME Association** (the oldest CFS patient organization in the nation), was given a half hour to speak at the CFSAC in 2006. At that time, she **presented evidence from the CRISP tapes that research presented as "CFS" research was in fact nothing of the sort.** Pat and the WCFSA would be happy to share this extensive research with DHHS. Fero has found that most studies that NIH has funded under the "CFS" umbrella term have nothing to do with CFS at all. The CFSAC's subcommittee on research found that the Congressionally mandated Special Emphasis Panel to allocate funding for CFS research has been largely staffed by researchers who have never worked with CFS (only 17 percent of the members have ever published on the subject). Since the committees operate on consensus, the result has been no funding for CFS research. The funds were diverted to other projects that the committee deemed more important – more important than CFS, one must surmise.

CDC's own research program is at a standstill, yet Dr. William C. Reeves' department at CDC, Emory University, and a consulting firm continue to receive funding. Dr. Reeves styled himself a whistleblower the last time there was a GAO investigation

⁹ See <http://www.cdc.gov/nchs/data/icd9/agendam06.pdf>.

into the misallocation of funding by CDC (the GAO determined in 1999 that indeed the CDC had been misrepresenting its research into CFS), but he is clearly at the center of the current misrepresentation of CDC's CFS program. Just a cursory investigation of the CDC's own website on CFS will expose discrepancies and outright contradictions, particularly when it comes to the two-day Wichita hospital stay in 2003, and a study that was supposed to be conducted in the Atlanta area since then

According to testimony presented by Amy S. (a former grant administrator for the federal government) to the CFSAC in October, 2008, **“Since 2005, the CDC has spent upwards of \$11 million total to begin to study 30 patients and publish three papers.... Of the \$11 million allocated to CFS since 2005, several million are sitting in an account somewhere, apparently waiting for the contractor to bill against it.”**¹⁰

9. Revise the information given by the SSA to intake workers and physicians, and reduce the time it takes to receive disability. As objective markers become approved, advise the SSA immediately. In the meantime, the entire Social Security system should act according to court rulings that state clearly that no one should be denied coverage on the basis of the absence of testing, while the CDC insists there are no tests. And no CFS patient should be denied simply because (as one ALJ actually stated), “I simply don't believe in CFS.”

At least one million Americans have “CFS.” According to CDC, at least one-half cannot work at any given point in time. Are there 500,000 patients on SSDI? No. Not even close. Consequently, there must be tremendous pressure against patients with this disease when they apply for disability through a system they paid into their entire working lives.

End the gratuitous penalty by which young people and stay-at-home mothers are not even entitled to federal disability because "they have not worked enough quarters".

Precisely what is a person who is too sick to work supposed to live on during the time it takes to get SSDI – even if the process goes right? Precisely what are they to live on if the process takes years; if they are denied because SSA does not “agree with” the evidence provided by the patient's doctor? Everyone seems so concerned about those who abuse the system – what about the honest and honorable citizens who are suffering daily because you are, in effect, guilty [of insurance fraud] until proven innocent? Many states used to provide interim funds to keep a disabled person or an invalid alive until federal SSDI came through, but most of these programs disappeared years ago.

When you meet patients who have ME/CFS, you'll find they all badly want to be working. It is awful not to be able to work. The accusation that we are deadbeats, con artists, lazy – the accusations hurt greatly when you are trying your best just to survive. We really would rather be working.

¹⁰ See the minutes of the latest CFSAC meeting, October 2008: <<http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac20081028min.html>>. For minutes from the CFSAC meetings since 2003, see: <http://www.hhs.gov/advcomcfs/meetings/index.html>. For the charter reauthorizing the CFSAC in 2008, see <http://www.hhs.gov/advcomcfs/charter/>.

10. Decide whether disability and health insurance companies are going to be regulated locally or federally. If federally [as has been the case since the passage of ERISA], then *regulate them*. Surely the events of the past year have shown that industries that deal in information need to be regulated. **There is a perverse incentive for disability and health insurance companies to cheat the patient as long as no one checks up on their activities.** The insurance companies even have a name for dismissing diseases such as “chronic fatigue syndrome” – they call them “MUS” disorders – “medically unexplained symptoms,” which (even if true, which it is not), should not be synonymous with “imaginary.” Because of ERISA, a patient whose doctor believes he/she is entitled to private disability is restricted to federal court, and no jury. If the patient wins, all he/she is entitled to is the funds that should originally have been granted by the insurance company. The attorney has to be paid out of that meager amount. Consequently, few attorneys will take an ERISA case. Conversely, if the insurance company cheats and gets caught, all it costs is the funds that should have been given in the first place, plus the time of a lawyer on retainer. Court costs and penalties cannot be awarded unless the court finds “a deliberate pattern of intent to deceive.” This would be difficult enough; the practice of requiring a gag order whenever a patient settles out of court makes it even more difficult. The deck is heavily stacked against patients – who, along with their families, have been funding the insurance company all along.¹¹

11. We ask that the transition team look at and take seriously the recommendations made by the Chronic Fatigue Syndrome Advisory Committee to DHHS in 2004 (see attachment). The Secretary of DHHS refused to respond to the report for two years. Finally the Secretary sent down a message stating that the committee had nothing to do with the Secretary (despite the supposedly advisory role). Each agency then used this opportunity either to justify their behavior, or to simply state that the suggestions were beyond their mission. We therefore ask DHHS to review these recommendations once more, and to take seriously the existence of this committee.

Furthermore, we request that the incoming Secretary of DHHS either attend future CFSAC meetings, or at least take seriously the committee’s advisory mission. Previous minutes can be found at the following website:

<<http://www.hhs.gov/advcomcfs/meetings/index.html>>

The minutes are incomplete. For years they were heavily edited. The entire collection of minutes and testimony, dating back to the original CFS-ICC - including written testimony - has supposedly been preserved. At least, that is what we have been promised.

¹¹ For an intriguing new interpretation of ERISA case law, see Yale law professor John H. Langbein’s article, “Trust Law as Regulatory Law: The UNUM/Provident Scandal and Judicial Review of Benefit Denials under ERISA.” *Northwestern U Law Review* 101: 1315, 2007.

“The Fierce Urgency of Now”

President Obama spoke of “the fierce urgency of now.” I cannot imagine anything more urgent than to rescue people who are suffering, and dying, from a disease rendered invisible by the federal government of the United States. The need for care is urgent. The need for research is urgent. Our disease has been allowed to fester untreated in the community for 25 years, causing immeasurable loss to individuals, families, and society at large. On some level this disease is contagious. If nothing else, we need to stop its spread.

Preparing this report has taken us weeks, because we are all quite disabled. An illness that is characterized by massive cognitive dysfunction is difficult for people who used to earn their living with words. Mental activity is as exhausting as physical activity, so we have all needed frequent breaks (in some cases, entire days to rest). One member left her bed at the end of the two weeks to try to edit the completed report (and offered useful suggestions). That will set her back for days. Three members had to drop out of the effort before it was over. But we are speaking for a million Americans – perhaps more importantly, we are speaking for at least 850,000 Americans who have our disease but have no diagnosis. We could not be silent, no matter the personal cost.

As late as the 1960s, patients suffering from Multiple Sclerosis were misdiagnosed as having “hysterical paralysis.” A woman with MS would be told to “shape up” - go back to her role as housewife and mother and take care of the kids. If she could not, it was somehow *her* fault.

A similar pattern of cruelty is being inflicted on patients with ME/CFS in the United States, simply because the NIH/CDC approved research has not caught up with the severity of the disease. It is absurd that patients should be penalized because of an assumption that there is nothing left to learn about the human body - but even that sad period in our nation's medical history can be brought to a close. We already know enough about ME/CFS to stop the inhumanity and begin to appropriately deal with patients and their suffering. All that is lacking is the will.

The need to face this disease squarely and honestly is ***urgent***, and it is urgent ***now***.

Thank you for your time. If any of us can be of assistance, please do not hesitate to ask.

Mary Schweitzer; Karen Campbell, Pat Fero, PSB, Carol O., Sue C, Rik Carlson, Steven DuPre, and Meghan Shannon

Enclosed:

Appendix A: 11 recommendations by the CFSAC to the Secretary of DHHS, 2004.

Appendix B. Personal stories of the members of this group.

**Appendix A:
Recommendations of the
Chronic Fatigue Syndrome Advisory Committee to the
Secretary of the U.S. Department of Health and Human Services, 2004**

Primary Recommendations

In the opinion of the CFSAC, the greatest priority for the DHHS is to substantially increase research efforts and funding. Future research efforts must apply an integrative approach because CFS is characterized by dysregulation of a number of highly integrated body systems, particularly the immune and nervous systems. Forming multidisciplinary research teams would provide a platform to conduct well controlled, methodologically sound, longitudinal studies to clarify the pathophysiology of this syndrome, and to develop effective treatment modalities. Serum and tissue banks for future investigations should be established.

1. We would urge the DHHS to direct the NIH to establish five Centers of Excellence within the United States that would effectively utilize state of the art knowledge concerning the diagnosis, clinical management, treatment and clinical research of persons with CFS. These Centers should be modeled after the existing Centers of Excellence program, with funding in the range of \$1.5 million per center per year for five years.
2. We would urge the DHHS, through the NIH, expedite the issue of an RFA with sufficient set aside funds to attract senior level researchers to engage in the study of CFS. DHHS should fund extramural grants, reviewed by a special emphasis panel knowledgeable in CFS, through RO1, RO3, R21, and Directors Pioneer Award mechanisms.
3. The DHHS should provide funds to develop an international Network of Collaborators that would allow for multidisciplinary CFS-related research using standardized criteria accepted by the international CFS research community. Such a network would pool a large number of patients from around the world, and would require investigators to develop and employ common protocols.
4. DHHS should provide support and funding for an intramural staffed laboratory committed to CFS research.

Secondary Recommendations

5. The DHHS should promote, encourage and fund research directed toward the diagnosis, epidemiology, and treatment of CFS in children and adolescents.
6. The DHHS, through the CDC and NIH, should continue to sponsor, even accelerate, focused workshops in specific areas of CFS and to invite investigators not currently working on CFS who have been identified as having an interest in the illness.

CFSAC Recommendations 2004 (continued)

7. The DHHS should pursue making CFS a topic of training for health care providers, wherever appropriate at regional and national conferences sponsored by the Department.
8. The DHHS should encourage continuing education for Social Security reviewers and adjudicators. The secretary of DHHS should recommend that adjudicators follow the Social Security Policy ruling 99-2P which specifically clarifies policies regarding CFS.
9. The DHHS should increase public education on CFS through a public awareness campaign. Discrimination in health care, education and the workplace should be actively confronted.
10. We would encourage the classification of CFS as a “Nervous System Disease” as worded in the ICD-10 G93.3.
11. The DHHS should consider participation of the Department of Defense, Department of Veteran Affairs, Agency for Healthcare Research and Quality, and the National Institute of Disability and Rehabilitation Research (NIDRR) as ex-officio members of the CFSAC for future deliberations of recommendations.

Respectfully submitted,
David S. Bell, MD, Chairman
Chronic Fatigue Syndrome Advisory Committee
August 23, 2004