Testimony to the CFSAC of the
U.S. Department of Health and Human Services
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Thank you for allowing me the opportunity to present testimony. My testimony today addresses four issues, but they are all tied to one that is most basic: Accountability.

1. Accountability.

There is a stunning disconnect between what we supposedly know from this committee, and what the public knows (including medical professionals).

I have attended all save one or two of the meetings of the CFSCC and the CFSAC. Everything I know about my disease has been presented to this committee at one time or another. Dr. Suhadolnik spoke about the Rnase-L defect. Dr. Ablashi spoke about HHV-6. Dr. Rowe spoke about NMH/POTS. In the course of fifteen years there have been many more scientific presentations – and the presentations were tied to peer-reviewed journal articles.

Yet these researchers could have been shouting into the wind for all the good it has done. At its worst, the CDC and NIH have produced quick little studies enabling them to say "there is no known relationship between CFS and [pick a virus or biomarker]."[1] At its best, the CDC has simply ignored the information.

When the *Science* study by researchers from the Whittemore-Peterson Institute, Cleveland Clinic, and National Cancer Institute first surfaced, Dr. Reeves of CDC responded as he always has: the CDC will end up invalidating the findings. Because that is what he has been doing for twenty years; it is what Stephen Straus did for fifteen years.

It does not matter what testimony scientists have presented to this body; it matters even less the testimony that patients have struggled to bring to the attention of the agencies. There has never been any mechanism by which any of the agencies had to do anything at all relative to the information that came out of these meetings.

Every time CDC addresses the public about this disease, they begin with some version of the following: "Chronic fatigue syndrome (CFS) is an important public health problem. The causes of CFS are unknown and effective prevention strategies remain elusive."[2]

From the CDC's information for patients and caregivers: the same can be found in the "Toolkit for Professionals":

"Diagnosing chronic fatigue syndrome (CFS) can be complicated by a number of factors: 1) there's no diagnostic laboratory test or biomarker for CFS…" [3]

And also from CDC's "Toolkit for professionals:"

> Theoretical and Experimental Tests: **A number of tests, some of which are offered commercially, have no demonstrated value for the diagnosis of CFS.** These tests should not be performed unless required for diagnosis of a suspected exclusionary condition (e.g., MRI to rule out suspected multiple sclerosis) or unless they are part of a

> scientific study. In the latter case, written informed consent of the patient is required. No diagnostic tests for infectious agents, such as Epstein-Barr virus, enteroviruses, retroviruses, human herpesvirus 6, Candida albicans, and Mycoplasma incognita, are diagnostic for CFS and as such should not be used (except to identify an illness that would exclude a CFS diagnosis, such as mononucleosis). In addition, no immunologic tests, including cell profiling tests such as measurements of natural killer cell (NK) number or function, cytokine tests (e.g., interleukin-1, interleukin-6, or interferon), or cell marker tests (e.g., CD25 or CD16), have ever been shown to have value for diagnosing CFS. Other tests that must be regarded as experimental for making the diagnosis of CFS include the tilt table test for NMH, and imaging techniques such as MRI, PET-scan, or SPECT-scan. Reports of a pathway marker for CFS as well as a urine marker for CFS are undergoing further study; however, neither is considered useful for diagnosis at this time.[4]

What is the purpose of having researchers present information to the CFSAC if the CDC is going to deny it has any relationship to CFS? Along with many other patients, I have been diagnosed using many of the tests that the CDC continues to label "experimental," and I have been treated as successfully as possible on the basis of those tests. We are well past the point where these should be still considered "experimental."

Let's contrast the CDC's current position with the article by Fukuda et al establishing the current working research definition for CFS: "In formal studies, cases of the chronic fatigue syndrome and idiopathic chronic fatigue should be subgrouped before analysis or stratified during analysis by the presence or absence of essential variables, which should be routinely established in all studies."[5] An entire section of the Fukuda article was devoted to the importance of establishing subgroups. That was sixteen years ago. Where are the subgroups?

Despite Fukuda's urging, CDC has continued with a "one size fits all" approach to the disease. Either everybody has it, or it doesn't matter. The possibility that there might be patients out there who were positive for any of the above viruses and biomarkers – let alone that there might be patients who were positive for several of them – is not admitted by CDC. Fukuda's mandate to find diagnosable subgroups was completely ignored by CDC – and remains so to this day.

That stands in stark contrast to the numerous presentations and discussions I have heard while attending the CFSCC and CFSAC.

It also stands in contrast to what I know from my own experience. I am one of a subset of CFS patients who has both immune markers and numerous active viruses. I have abnormal Rnase-L; my natural killer cell function is 2%; I have recurring EBV and active HHV-6, HHV-7, cytomegalovirus – and XMRV. We've known about most of this for twelve years, and as a consequence, I have benefitted from treatment with the experimental immune modulator Ampligen. During these 12 years, why has not the CDC investigated the subset to which I clearly belong? Why haven't *other patients* had the opportunity to be tested and treated?

So this is my first and primary question:

Where is the accountability from the federal agencies that report to the CFSAC?

2. Next I need to point out that there is a serious issue that the CFSAC must address, and address soon. That is the creation of a new psychiatric category for DSM-5 called **CSSD**, or **Chronic**

Somatic Symptom Disorder.[6] The head of the committee that created CSSD is Michael Sharpe, a psychiatrist who is part of the Wessely school – a small group of professionals who assert that what appears to be a physical illness in CFS is actually "deconditioning," which has been caused by "inappropriate illness beliefs." The "cure" is for the patient to undergo Cognitive Behavior Therapy (CBT), during which the patient learns she is not physically ill at all, in conjunction with "graded exercise therapy" (GET) to get her back in shape. On the King's College, London, website, one of the examples they give of their success with CBT/GET is a patient who is brought to the clinic in a wheelchair. She must be separated from friends, family, and medics who confirm her "inappropriate illness beliefs." Then, and only then, she can rise out of that chair and walk.

Make no mistake about it, CSSD is designed for Michael Sharpe's own specialty: CBT for CFS.[7] The APA received numerous letters protesting the category during an open comment period that ended April 20. They sent the protests back to the same *committee*, with the *same person presiding*. There will be another opportunity for open comments this summer. The CFSAC must formally address this effort to create a psychiatric category for chronic fatigue syndrome. **At the least, before diagnosing a patient with CSSD, a doctor should be required to check for the symptoms of CFS. If the patient has CFS, then the patient cannot have CSSD.**

3. Dr. Reeves may have left the CDC's section on CFS, but his questionnaires remain. The Reeves questionnaires have created a different definition for CFS. While the CDC insists that the "Fukuda definition" has been used in all recent research, that statement is simply untrue. The Reeves questionnaires do not create a data set that conforms with the Fukuda definition. Therefore **CDC must either acknowledge that we have a new definition, the "Reeves definition," or it needs to disavow those questionnaires entirely**.

4. Direct changes to the charter

We have been asked to comment on changes to the charter for the CFSAC when it is renewed in the fall.

> **(1) The first and most important of these must be some way to hold the agencies accountable for their speech and actions regarding CFS**. It is as if the CDC had continued to refer to GRID long after everyone else had agreed to use AIDS. They seem stuck in the period before any biomedical research had been conducted on what was a mysterious illness in the mid-1980s, but is not such a mysterious illness today. I do not know what the answer is – but there must be some way to require that the agencies take seriously what goes on in these meetings – or why are we bothering at all? **I suggest that the CFSAC not only report to Secretary Sebelius, but also to Senator Tom Harkin, Chair of the Senate Committee on Health, Education, Labor, and Pensions.**
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> **(2) Return to the format of the CFSCC in the 1990s, when the public was permitted a short question-and-answer period after each ex officio presentation.** When the CFSAC first met in 2003, we were told that only the representatives of the public on the committee had any right to address the ex officio members. I had the unpleasant experience, while testifying, of having to ask Dr. Reeves for a clarification of some of his research (the question had actually been asked of me by a public member on the CFSAC.) Dr. Reeves responded, "I don't have to answer to *you*" and turned his back to me! I do not know what language was in the CFSCC that gave me the right to ask a question and have it answered, but I think we deserve to have that right back again. There needs to be a microphone in the middle of the aisle, and at some point people in the

audience who wish to ask questions should be allowed to line up at the microphone. It is a simple courtesy.

(3) Require that patients be permitted **at least 5 minutes of oral testimony**

(4) Make available the records of past CFSAC and CFSCC meetings. The minutes were edited heavily during both the Clinton and Bush administrations, but an unedited aural tape was made of all the meetings, and I was assured it was being preserved. The public should have access to both the printed minutes and the unedited aural tapes.

(5) Return to the format of meeting four times a year. There is already too much to be done to be able to accomplish what is needed in only two meetings a year.

(6) For over a decade, the Committee as a whole as known that ***at least* 800,000 adult Americans have this condition and do not have a diagnosis. At what point are we going to do something about that?**

(7) Research by Leonard Jason and others has suggested that teenagers fall ill with this disease at a rate about half that of adults. But the age range for adults is much longer than it is for teenagers. That would suggest that while the incidence in adolescence is half of what it is in adults, the prevalence may be much higher. **The CDC has no program for children and adolescents. These are the most vulnerable of all patients. The IACFS/ME has a clinical definition for children and adolescents, but CDC has refused to admit its existence.** Because of the enormous ignorance about the disease in the public arena – yet anther disconnect - schoolchildren who have a diagnosis have been taken from their parents and placed in foster care. And what happens to schoolchildren who are every bit as sick, but have no diagnosis? Again I ask, **at what point are we going to do something about this?** The charter must include language directing the agencies to address the needs of children and adolescents with this disease.

(8) The CFSAC should hold at least one state-of-the-science meeting a year. This would require funding, but since CDC apparently believes that we do not know anything about how to diagnose or treat a disease that impacts at least one million Americans, it's about time we made a start.

(9) NIH spending on CFS must be comparable to the estimate of at least one million adults with the disease, and the agency must be accountable for where the funds are spent. It is a good sign that the NCI has been involved in research on XMRV, but in the meantime, the dollars spent on researching CFS and its subgroups have been miniscule. At most, NIH has spent $6 per patient per year – and most of that money has gone to projects (such as pain clinics) that have little or nothing to do with CFS at all. The Congressionally mandated CFS study group for allocating research funds at NIH is a sham; the majority of the members know nothing about the disease,[8] and therefore research projects directly addressing CFS are seldom approved.

I wish to thank the Committee again for the opportunity to offer testimony.

Mary M. Schweitzer, Ph.D.

Endnotes:

[1] As a recent example, see the effort to discredit research on NMH/POTS in Jones JF, Nicholson A, Nisenbaum R, Papanicolaou DA, Solomon L, Boneva R, Heim C, Reeves WC. Orthostatic instability in a population-based study of chronic fatigue syndrome: *American Journal of Medicine* 118:1415.e19-1415.e28, 2005.

[2] This particular quote came from "Early adverse experience and risk for chronic fatigue syndrome: results from a population-based study," Heim C, Wagner D, Maloney E, Papanicolaou DA, Solomon L, Jones JF, Unger ER, Reeves WC. *Archives of General Psychiatry* 63:1258-1266, 2006.

[3] http://www.cdc.gov/cfs/cfsdiagnosis.htm - accessed 26 April 2010.

[4] http://www.cdc.gov/cfs/cfsdiagnosisHCP.htm - accessed 26 April 2010.

[5] Fukuda et al, "The Chronic Fatigue Syndrome: A Comprehensive Approach to its Definition and Study." *Annals of Internal Medicine*, Vol. 121, December 15, 1994, pp. 953-959.

[6] See essay on CSSD: http://slightlyalive.blogspot.com/2010/04/my-letter-to-apa-on-cssd.html as well as the APA's website on the proposed category: http://www.dsm5.org/ProposedRevisions/Pages/proposedrevision.aspx?rid=368

[7] Psychiatrist Michael Sharpe was an early proponent (and continues to be) for cognitive behaviour therapy (CBT) and graded exercise therapy (GET) as cures for CFS. "Chronic fatigue syndromes are not new. Victorian physicians diagnosed them as neurasthenia … Cognitive behaviour therapy … emphasises consistency in activity management and the gradual attainment of behavioural targets. Taken together this evidence suggests that it is important to differentiate between the needs of the patient with acute fatigue and the patient with a chronic fatigue state; rest may be indicated for the former, but a gradual increase in activity should be at the heart of the treatment plans for the latter." Michael Sharpe and Simon Wessely, "Editorial: Putting the rest cure to rest – again: Rest has no place in treating chronic fatigue." *British Medical Journal* 316 (14 March 1998) 796-800. It would be disingenuous to suggest that Sharpe's interest in creating the category of CSSD is unrelated to his professional commitment to the psycholization of CFS and its treatment. For other samples of Sharpe's view of CFS, see M Sharpe, KE Hawton, S Simkin, C Surawy, A Hackmann, I Klimes, T Peto, D Warrell, V Seagroatt. "Cognitive behaviour therapy for the chronic fatigue syndrome: a randomised controlled trial." *British Medical Journal* 312 (1996) 22–26. S Wessely, C Nimnuan, M Sharpe. "Functional somatic syndromes: one or many" *Lancet* 1999:354:936 939; P Davison, M Sharpe, D Wade, C Bass. "'Wheelchair' Patients with Nonorganic Disease: A Psychological Inquiry." *Journal of Psychosomatic Research* 47 (1999) 1:99-103.

[8] According to the research subcommittee of the CFSAC, during the Bush administration only 17% of the members of the Congressionally mandated CFS study group that is supposed to examine potential research projects for NIH funding has ever published or presented a paper on CFS.