

International Association for
IACFS/ME
Chronic Fatigue Syndrome

Dedicated to Promotion of Scientific Research and Improved Patient Care

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MEMORANDUM

To: Michael Miller, Associate Director for Science Sarah Wiley,
Associate Director for Policy Steve Monroe, Director of Division of
Viral & Rickettsial Diseases
U.S. Centers for Disease Control & Prevention

From: Fred Friedberg, PhD
President
International Association for CFS/ME

Date: May 23, 2009

Re: International Association for CFS/ME's Recommendations for the
CDC's Five Year Strategic Plan for CFS Research

As president of IACFS/ME, I would like to thank the CDC for this opportunity to comment on their 5 year strategic plan for CFS research. The IACFS/ME is an international organization of 500 biomedical and behavioral scientists, clinicians, and educators that promotes, stimulates and coordinates the exchange of ideas about CFS and related illnesses. Our organization has sponsored a biennial research and clinical conference since 1992. The most recent IACFS/ME international conference (March 2009) attracted professionals and patients worldwide, and included representation from CFS program directors at NIH and DHHS. Noticeably absent from our 2009 meeting was the senior leadership from the CDC CFS research program.

The new director at CDC has the opportunity to reinvigorate CFS research at CDC, as well as reinstate CFS as a public health priority, as emphasized by Drs. Julie Gerberding and John Agwunobi at the November 2006 launch of the CDC's CFS public awareness campaign at the National Press Club.

The CDC's draft five year strategic research plan (released April, 2009) lacks sufficient substance and detail. As such, the IACFS/ME is unable to directly respond to or endorse this plan. Rather, we suggest the following course of action.

CFS as a Public Health Priority

The IACFS/ME requests that the CDC declare CFS a public health priority and restructure its efforts in a new direction that is capable of handling this unacknowledged crisis. Of greatest importance, the CFS community needs

strong and visionary new leadership from the CDC, the recognized world public health authority, to remove the enduring stigma associated with being a patient or patient's family member. This stigma and skepticism about the illness is also a deterrent to those professionals who would consider entering the field of CFS as researchers or clinicians.

CDC's own epidemiologic studies have identified more than a million (and up to four million) CFS sufferers in the U.S. with as many as 85% of the patients still undiagnosed (www.cdc.gov/cfs/mission.htm). Further, the CDC has indicated that CFS is as debilitating as multiple sclerosis, lupus, rheumatoid arthritis and similar chronic conditions with an annual economic impact of at least \$9.1 billion due to the disability of CFS patients (www.cdc.gov/cfs/mission.htm).

Yet, CDC sponsors no prevention or clinical treatment research. This is a major concern given (a) the large number of severely ill and undiagnosed patients, (b) the inadequacy of CFS diagnostic criteria which are based on subjective clinical symptoms, instead of well established biomarkers, and (c) the absence of effective, evidence-based treatment options. Any strategic research plan that falls short of declaring CPS a public health priority with funding appropriate to this designation will fail to address the urgent needs of these 1-4 million medically underserved patients.

Promotion of Extramural Research

After twenty-five years of research on this disabling illness, it is now possible to model and develop effective therapies and prevention efforts. If the CDC is sincere in its desire to move the field forward, it will support extramural research in addition to refocusing intramural resources into these understudied areas.

.Developing collaborative relationships with extramural CFS researchers should be one of the highest priorities of the CDC's 5 year strategic plan. Use of non-competitive contract procedures should be limited to the extent possible.

To develop an extramural research effort, we request a public-private partnership program that involves the collaboration of the CDC with the IACPSIME and other key CPS stakeholder groups. This program would (a) prioritize the most important areas of research in an effort to move the science forward in the most efficient manner possible, and (b) administer a competitive research grants program that will facilitate the collaboration between intramural and extramural teams of researchers.

Recommendations of the IACFSIME

We realize that making CFS a public health priority and developing research partnerships will not happen overnight. However, there are a number of recommendations that CDC can readily enact to begin to change the face of CFS, as follows:

1. In order to implement a robust strategic 5-year program, the CDC needs to identify a CFS program leader who is a progressive, open-minded, and dynamic manager with a sense of urgency commensurate with the pressing needs of the CPS community.
2. The CDC should undertake comprehensive public and professional awareness campaigns and launch educational initiatives to fully legitimize the illness of CFS and reduce its stigma. Evidence-based information should be used to promote the understanding of CFS among medical providers and the public as a serious and often devastating illness.
3. The CDC should support extramural research into the pathophysiology of CPS in order to achieve the critical goals of objective diagnosis and effective treatment. Such efforts should eventuate in the identification of biomarkers that will justify:
 - a. a new case definition that accurately defines clinical subgroups of patients; and
 - b. the relabeling of CFS with a more appropriate and credible name.
4. In the spirit of public resource sharing, the CDC should make available research study protocols and the epidemiologic, clinical and laboratory data from all studies conducted by the CDC's CFS research program since 1984 to all researchers, clinicians and other interested parties.
5. The CDC should establish a bio-repository of all samples collected and determine how this could be made available to the research and biomedical community.

6. The CDC should abandon its use of the empirical case definition for CFS (<http://www.pophealthmetrics.com/content/5/1/5>) and make a public statement in this regard. The CDC's empirical case definition has been highly criticized by expert CFS epidemiologists because the empirical case definition is overly broad and based on subjectively determined criteria (<http://www.iacfsme.org/IssueswithCDCEmpiricalCaseDefinitionandPrev/tabid11051Default.aspx>).
7. The CDC should take a pro-active leadership position by exploring its potential role in developing an international clinical trials network in collaboration with CFS clinicians, private industry and university-based researchers to test therapeutic interventions that are directed at biologically appropriate subgroups.
8. The CDC should partner with the IACFSIME, the only national and international professional organization representing investigators and clinicians working in this field, to develop evidence-based diagnostic and treatment guidelines for the management of CFS.
9. The CDC should work towards the implementation of the DHHS CFSAC recommendations (<http://www.hhs.gov/advcomcfs/recommendations/index.html>).

The IACFSIME appreciates this opportunity to comment on the CDC's five year strategic plan for its CFS program. We look forward to working with the CDC to achieve our mutual goals of establishing new evidence-based research programs, improving clinical care, and offering comprehensive healthcare provider education with the ultimate objectives of (a) eliminating the suffering caused by CPS and (b) working toward the eradication of this serious illness.