

**AUG -3 2012**

Gailen Marshall Jr., MD, PhD  
Chair, Chronic Fatigue Syndrome Advisory Committee  
Professor and Chair Professor of Medicine and Pediatrics  
The University of Mississippi Medical Center 2300 North  
State Street, N416 Jackson, MS 39216-4505

Dear Dr. Marshall:

I have received the recommendations developed by the Chronic Fatigue Syndrome Advisory Committee (CFSAC) during its November 8-9, 2011, meeting. The advice and counsel provided by CFSAC serves as a valuable resource in the Department of Health and Human Services' (HHS) efforts to properly address the issues and concerns pertaining to chronic fatigue syndrome.

Since the meeting the Department has carefully considered your recommendations. Dr. Nancy Lee, the Designated Federal Officer for CFSAC, has worked collaboratively with the *ex officio* representatives to the committee to provide responses to the recommendations developed at the meeting. The enclosed document contains information about activities currently undertaken by HHS to work with public health experts and members of the chronic fatigue syndrome community to increase knowledge and provide a better understanding of this debilitating health condition. I have shared the committee's recommendations with Secretary Kathleen Sebelius.

The Department is committed to addressing this condition. I commend you and your committee members for the important work you do.

Sincerely yours,

/s/Howard K. Koh

Howard K. Koh, M.D., M.P.H.  
Assistant Secretary for Health

Enclosure

cc: Dr. Christopher R. Snell

RESPONSES TO RECOMMENDATIONS FROM THE CHRONIC FATIGUE  
SYNDROME ADVISORY COMMITTEE (CFSAC)

REF: November 8-9, 2011 CFSAC Meeting

*Recommendation 1: This recommendation addresses the process by which CFSAC transmits recommendations to the Secretary and the Secretary communicates back to CFSAC whether or not a recommendation was acted upon. CFSAC recommends that this process be transparent and clearly articulated to include regular feedback on the status of the Committee's recommendations. This communication could originate directly from the Office of the Secretary or be transmitted via the relevant agency or agencies.*

Procedures are in place to ensure that recommendations made by federal advisory committees are properly handled. The CFSAC charter stipulates that the Committee provides advice and recommendations to the Secretary, through the Assistant Secretary for Health (ASH). Initially, the CFSAC recommendations are sent to the ASH for review. After reviewing the recommendations, the ASH forwards them to appropriate officials within the Office of the Secretary and the Operating and/or Staff Divisions that may be impacted by the Committee's recommendations. A letter is sent to acknowledge receipt of the recommendations. A response may be prepared to accompany the letter which describes any actions that the Department may take in response to the recommendations made by the Committee. All pertinent information about the recommendations is provided to the designated Federal officer (DFO). The DFO then provides the information to the Chair and the Committee.

*Recommendation 2: CFSAC recommends to the Secretary that the NIH or other appropriate agency issue a Request for Application (RFA) for clinical trials research on chronic fatigue syndrome/myalgic encephalomyelitis (ME/CFS).*

The National Institutes of Health (NIH) funds research on myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS); investigators are encouraged to submit proposals for ME/CFS research, including clinical trials, through two funding announcements that are currently open for submission of applications. The next deadline for receipt of applications is October 24, 2012. In fiscal year 2011, NIH funded two applications for clinical trials on ME/CFS. NIH has received few applications proposing ME/CFS research, and even fewer applications proposing ME/CFS clinical trials. It is unclear whether the paucity of ME/CFS clinical trial applications reflects the current status of the field or an acknowledgement that clinical trials are difficult to design for a complex and multi-faceted illness. Clinical trials are challenging to design and conduct for all diseases, with basic requirements of a well-defined patient population, valid measurement instruments, appropriate safeguards for subjects, and generalizability of the clinical trial outcomes to the larger affected patient population. NIH is taking action to stimulate ME/CFS research across NIH through the regular monthly meetings of the Trans-NIH ME/CFS Working Group (WG). The WG discusses the current status of ongoing research on ME/CFS and proposes methods to increase the number and quality of research applications submitted to NIH

ranging from preclinical research to clinical trials. In addition, the WG is focusing on the recommendations from the April 2011 State of the Knowledge Workshop on ME/CFS to develop priorities. The outcome from these planning sessions will suggest a range of activities and research.

**Recommendation 3:** *CFSAC would like to encourage and support the creation of the DHHS Interagency Working Group on Chronic Fatigue Syndrome and ask this group to work together to pool resources that would put into place the "Centers of Excellence" concept that has been recommended repeatedly by this advisory committee. Specifically, CFSAC encourages utilizing HHS agency programs and demonstration projects, available through the various agencies, to develop and coordinate an effort supporting innovative platforms that facilitate evaluation and treatment, research, and public and provider education. These could take the form of appropriately staffed physical locations, or be virtual networks comprising groups of qualified individuals who interact through a variety of electronic media. Outreach and availability to underserved populations, including people who do not have access to expert care, should be a priority in this effort.*

HHS leadership has identified the need for a Department-wide plan to address ME/CFS. The Department established the HHS Ad Hoc Workgroup on ME/CFS to develop a plan and to identify opportunities for interagency collaboration. The HHS ME/CFS plan will highlight recently initiated programs and future agency-specific and cross-agency activities. In developing the report, the Ad Hoc Workgroup will consider recommendations made by CFSAC. After completion, the ME/CFS plan will be posted on the CFSAC website. The DFO, Nancy C. Lee, M.D. is responsible for providing leadership and coordination for development of the HHS ME/CFS report.

**Recommendation 4:** *This multi-part recommendation pertains to classification of CFS in ICD classification systems:*

- a) *CFSAC considers CFS to be a multi-system disease and rejects any proposal to classify MEICFS as a psychiatric condition in the U.S. disease classification systems.*
- b) *CFSAC rejects the current classification of MEICFS in Chapter 18 of CD-9-CM under R53.82, chronic fatigue unspecified, chronic fatigue syndrome, not otherwise specified.*
- c) *CFSAC continues to recommend that MEICFS should be classified in ICD-10-CM in Chapter 6 under Diseases of the Nervous System at G93.3 in line with ICD-10, the World Health Organization, and ICD-1-CA, the Canadian Clinical Modification and in accordance with CFSAC's recommendations of August 2005 and May 2011. CFSAC rejects CDC's National Center for Health Statistics (NCHS) Option 2 and recommends that MEICFS remain in the same code and the same subcode as myalgic encephalomyelitis because CFS includes both viral and non-viral triggers.*
- d) *CFSAC recommends that an "excludes one" be added to G93.3 for chronic fatigue,*

*R53.82, and neurasthenia, F48.8. CFSAC recommends that these changes be made in ICD-10-CM prior to its rollout in 2013.*

Development and implementation of the guidelines for the ICD-10 fall within HHS under the purview of the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services. Use of the revised codes will provide robust and specific data that will improve patient care and enable the international comparability of health care data. On February 16, 2012, the Department issued a press release announcing that HHS would initiate a process to postpone the date that certain health care entities must comply with the ICD-10.

A proposal to change the classification of *ME/CFS* in ICD-10-CM was presented at the September 2011 Coordination and Maintenance (C&M) *Committee/CDC/NCHS*; a subsequent proposal was received on January 12, 2012 and will be presented at the September 19, 2012 C&M meeting for additional discussion.