

Public Comment
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Thank you to the FDA for the report “The Voice of the Patient”(1) which has a very good characterization of ME produced as a result of docket and meeting input and active listening by FDA (2). I believe the section “Overview of ME and CFS” would have been strengthened by using information from the Canadian Consensus Definition for ME (3,4). It is also noteworthy that the FDA report, produced (within 50 days) of the close of the docket (August 2, 2013), was promptly disseminated by FDA to meeting participants and is easily accessible on the FDA website (5).

And now on to the not-so good ---- HHS (6) has a Strategic Plan (7) that gets updated every four years. Goal number 4 of the current plan (8) promotes transparency, as well as a culture of public participation and collaboration. The draft strategic plan for HHS FY2014-2018 builds on that, saying in part: “Every operating and staff division within the Department is committed to ensuring the efficiency, transparency, accountability, and effectiveness of HHS programs.” (9)

And yet, with total disregard for transparency, public participation and collaboration, and unbeknownst even to the CFSAC committee members (10), HHS arranged for the IOM project (11).

I have very serious reservations about the IOM project.

Among other things I do not think that it is an accurate interpretation of the CFSAC recommendation from Oct 2012 (12).

I have reservations about the Statement of Work for the IOM project. It seems vague. Vagueness does not bode well for any project let alone for one costing one million (U.S.) dollars. It states:

“For the purposes of this document, ME/CFS shall be used to refer to Myalgic Encephalomyelitis (ME), Chronic Fatigue Syndrome (CFS), Chronic Fatigue and Immune Dysfunction Syndrome (CFIDS), Neuroendocrine Immune Disorder, and other terminologies in use for this illness.” (13)

Yet when Mary Dimmock asked for clarification of the scope of disease the contract deals with, Dr. Nancy Lee (CFSAC DFO) and Ms. Kate Meck (of the IOM) each indicated that the scope would be determined as the project goes forward (14).

Spending a million dollars on the IOM project without carefully defining the scope of disease seems as though the project was not thoroughly planned out in advance. An issue as vital as the scope of the disease should not be undecided at this point in time.

But if it IS undecided, when will it be decided, by whom and how?

There is also the question of how the committee members are selected. We currently have no information about selection criteria.

And how will delineating the scope of the disease affect the selection criteria for the committee?

Let's return now to the concepts in HHS' strategic plans of public participation and collaboration, efficiency, transparency, accountability and effectiveness.

Are these in any way evident in:

the stunning lack of transparency with which the IOM project was developed?

the vague scope of disease of this project?
the lack of clarity on when the scope will be decided, by whom and how?
the lack of transparency on selection criteria for committee membership?

As part of HHS, NIH is subject to the same HHS strategic plan. But are the concepts of public participation and collaboration, efficiency, transparency, accountability and effectiveness evident in the NIH Evidence-based Methodology Workshop (EbMW) on ME/CFS that is being coordinated by the NIH Office of Disease Prevention?

HHS needs to require greater accountability for the accurate implementation of its strategic plan because the Strategic Plan attributes of:
public participation and collaboration,
efficiency,
transparency,
accountability,
and effectiveness,
are not in evidence in either project.

Notes and links

- (1) ["The Voice of the Patient Report: Chronic Fatigue Syndrome and Myalgic Encephalomyelitis"](http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM368806.pdf)
<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM368806.pdf>
- (2) April 25th 2013 PFDD meeting <http://www.fda.gov/Drugs/NewsEvents/ucm369563.htm>
- (3) ["The Voice of the Patient Report: Chronic Fatigue Syndrome and Myalgic Encephalomyelitis"](http://www.fda.gov/Drugs/NewsEvents/ucm369563.htm)
<http://www.fda.gov/Drugs/NewsEvents/ucm369563.htm>
- (4) "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols" overview:
<http://www.hhs.gov/advcomcfs/meetings/presentations/canadiandoc.pdf>
- (5) "Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Clinical Working Case Definition, Diagnostic and Treatment Protocols" full document:
<http://www.mefmaction.com/images/stories/Medical/ME-CFS-Consensus-Document.pdf> (pp.7-115)
- (6) Department of Health and Human Services <http://www.hhs.gov/>
- (7) Strategic Plan and Priorities Strategic Plan 2010 – 2015 <http://www.hhs.gov/strategic-plan/priorities.html>
- (8) "Goal 4: Increase Efficiency, Transparency, and Accountability of HHS Programs" 2010-2014
<http://www.hhs.gov/strategic-plan/goal4.html>
- (9) "Goal 4: Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs" 2014-2018 <http://www.hhs.gov/open/recordsandreports/strategic-plan.pdf>
- (10) CFSAC members are appointed by HHS "to provide advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health (ASH), on issues related to chronic fatigue syndrome (CFS)" (6) <http://www.hhs.gov/advcomcfs/charter/>
- (11) "Diagnostic Criteria for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome"
<http://www.iom.edu/Activities/Disease/DiagnosisMyalgicEncephalomyelitisChronicFatigueSyndrome.aspx>
- (12) The full text of the recommendation states:

“CFSAC recommends that you will promptly convene (by 12/31/12 or as soon as possible thereafter) at least one stakeholders’ (Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS)experts, patients, advocates) workshop in consultation with CFSAC members to reach a consensus for a case definition useful for research, diagnosis and treatment of ME/CFS *beginning with the 2003 Canadian Consensus Definition for discussion purposes.*” [emphasis added]
<http://www.hhs.gov/advcomcfs/recommendations/10032012.html>

(13) <https://dl.dropboxusercontent.com/u/57025850/MECFS%20IOM%20SOW.pdf>

(14) <http://www.occupycfs.com/2013/11/27/which-disease-is-hhs-studying/>

As of 29 November 2013, no links (and little information) are readily available for the NIH Evidence-based Methodology Workshop (EbMW) on ME/CFS.

All other links accessed 29 Nov. 2013