Public Comment
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My name is Edward Burmeister. My wife has suffered from myalgic encephalomyelitis (ME) for almost 8 years. I am providing these comments in the hope that the Department of Health and Human Services ("HHS") will step outside of its bureaucratic shield of secrecy and self-protection and provide real and useful answers to questions regarding the contract with the Institute of Medicine ("IOM") and demonstrate an understanding and furtherance of the interests of those who suffer from this debilitating disease.

Recently, on November 15, 2013, HHS apparently authored (I say "apparently" because the document was distributed through the CFSAC listserv without attribution of authorship) a document entitled "FAQs on the HHS contract with the IOM to recommend chemical diagnostic criteria for ME/CFS."

The FAQs were remarkably evasive and unhelpful. As a result I am setting forth my FAQs, or at least my "Qs" regarding this contract ("IOM Contract").

Q: Why did HHS enter into this contract in such a rushed and non-transparent manner?

To my knowledge, the first public notice of this potential contract was published (without any press release or distribution through CFSAC's listserv) as a sole source solicitation on FedBizOpps on August 27, 2013, less than one month before the contact was entered into on September 23, 2013. On September 4, 2013, the sole source solicitation notice was cancelled in response to "all the concern from the public." 19 days later, the IOM contact is entered into, the same day that 35 ME/CFS clinicians and researchers strongly urged Secretary Sebelius (in an open letter) to abandon the idea of the IOM contract and endorse the 2003 Canadian Consensus Criteria for ME/CFS ("CCC") (which letter was subsequently signed by 16 additional ME/CFS experts, only one of the original signers having withdrawn her signature).

Given the concerns expressed by the 50 experts and the obvious red flags raised by giving this contact to the same organization that had renamed Gulf War Illness as "Chronic Multisymptom Illness," HHS needs to explain the urgency and lack of transparency in entering into this contract, as well as how it managed (if it in fact did) to avoid federal contracting requirements regarding conflicts of interest and full and open competition.

Q: To further transparency, why not make the IOM Contract public, along with associated documents such as the justification for other then full and open competition?

Because of HHS' refusal to publish these materials, at last three patients have been forced to submit FOIA requests for this information, with no documents yet provided to my knowledge (my wife is one of the three). If HHS has nothing to hide, why put sick patients through the time and effort required to put together such an FOIA request?

This stonewalling and lack of transparency by HHS, along with the rushed noticed of this contract, raise serious questions about the contracting process itself.

Q: Given the IOM report on Gulf War and Health issued earlier this year, and its findings and reliance on the treatment of "Chronic Fatigue Syndrome" (recommended therapies: cognitive behavioral therapy, antidepressants and graded exercise therapy), why should the ME/CFS patient and expert community have any confidence that this IOM Contract will produce a different conclusion regarding ME/CFS or a label that is much different than "Chronic Multisymptom Illness?" In fact, doesn't the IOM report on Gulf War and Health create an institutional conflict of interest, which should disqualify IOM for this contract? Even though an at least somewhat different committee will presumably be involved in the ME/CFS study, the Gulf War IOM report specifically states that the IOM as an institution, along with the committee, is "solely responsible" for the content of the report.

This seems to be a clear institutional conflict of interest. Consider the embarrassment for the IOM if it were forced to abandon or highly unlikely to happen, so the outcome of the IOM ME/CFS study is already pre-determined.

How can we as patients, clinicians and researchers have any confidence in how the committee for the ME/CFS study will be selected, what will transpire in the non-public meetings and how the final conclusions will be reached?

Q: How can HHS justify spending $1 million on developing diagnostic criteria for ME/CFS when a consensus among ME/CFS experts has already been reached on adopting the CCC and a stakeholders'-meeting alternative, as specifically recommended by CFSAC, would much better serve to finalize the criteria/case definition based on the CCC?

This approach would be much less expensive, much more transparent and free of institutional conflicts of interest and supported by the ME/CFS community of patients, clinicians and researchers.

A final comment regarding CFSAC: One has to wonder whose interests CFSAC is trying to serve. If CFSAC wants to be viewed as supportive of the ME/CFS community of patients and experts, as opposed to a lap dog of the federal government, then it needs to stand up and make a clear statement in support of its own recommendation and against the IOM contract.