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February 14, 2013

By postal and electronic mail

William B. Schultz
Acting General Counsel
Department of Health & Human Services
200 Independence Avenue SW
Room 713-F
Washington, DC 20201
William.Schultz@hhs.gov

Dear Mr. Schultz,

On behalf of Jennifer Spotila and Public Citizen's Health Research Group, we are writing to call to your attention to and ask you to halt violations of the Federal Advisory Committee Act (FACA) by a Department of Health and Human Services (HHS) advisory committee, the Chronic Fatigue Syndrome Advisory Committee (CFSAC), which is housed within the Office on Women's Health. Ms. Spotila is a chronic fatigue syndrome (CFS) patient and activist who has a keen and personal interest in federal policy regarding CFS. Public Citizen's concern for the proper functioning of advisory committees stems from its long history of advocacy, in both legislative and judicial fora, for openness in government proceedings and the regular participation of Public Citizen's Health Research Group in the meetings of HHS advisory committees.

We have become aware of the following problem: CFSAC subcommittees have been transmitting recommendations directly to HHS officials without public debate and approval of the full committee, as required by both CFSAC's charter and FACA. Specifically, at its November 2011 public meeting, the CFSAC decided to create a distilled list of its most important recommendations for the Secretary.¹ But the process of creating the list of key recommendations for the Secretary did not occur in the full committee or in public. Instead, various subcommittees met in private to identify the recommendations to prioritize, which Dr. Nancy Lee, the Designated Federal Officer for CFSAC, then compiled into a single list that was discussed with Assistant Secretary for Health Dr. Howard Koh. The final document, dated January 2012 and titled "High Priority Recommendations from CFSAC," was never discussed or approved by the full committee or in a public session.² Additionally, the document was not

¹ The minutes of that two-day meeting are available in two parts at the following locations:

(1) http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac_min-11082011.pdf

(2) http://www.hhs.gov/advcomcfs/meetings/minutes/cfsac_min-11092011.pdf

² The recommendations are available at:

http://www.hhs.gov/advcomcfs/recommendations/high_priority_recommendations_01142013.pdf.

posted on the committee's public website for an entire year (the document is dated January 2012, but it was posted just last month).

CFSAC's statutorily-mandated charter provides the following regarding subcommittees: "The established subcommittees shall provide advice and/or make recommendations to the parent Committee. The *subcommittees may not report its [sic] findings directly to any Federal official* unless there is specific statutory authority for such reporting."³ The transmission to Assistant Secretary Koh of recommendations developed by subcommittees and never approved by the full committee constitutes "subcommittees . . . report[ing] [their] findings directly to any Federal official" in violation of this provision. Additionally, FACA § 10(b) requires that the minutes of advisory committee meetings be made public.⁴ By acting through subcommittees closed to the public to develop the January 2012 "High Priority Recommendations from CFSAC," CFSAC circumvented the public openness requirement of FACA.

The FACA violations deprived Ms. Spotila and the public generally of important rights to observe and participate in the advisory committee process, which can have significant influence over federal policy. Making advisory committee recommendations through a public process allows interested members of the public such as Ms. Spotila to comment, enables all members of the full committee to contribute to the decision, and allows the public at large to review the work of advisory committees. Public oversight of the work of advisory committees is one of the central goals of FACA. *See Cummock v. Gore*, 180 F.3d 282, 285 (D.C. Cir. 1999).

We ask that you act to ensure that CFSAC complies with FACA and with its own charter going forward. We also ask that you return the January 2012 "High Priority Recommendations" document to the full committee for review, so that whatever action CFSAC chooses to take regarding those recommendations or any other transmission to HHS be debated and approved by the full committee, in public, as required by FACA.

Thank you for your attention to this matter.

Sincerely,

Michael A. Carome, M.D.
Public Citizen's Health Research Group

cc: Howard K. Koh, Assistant Secretary for Health
Nancy C. Lee, Director, Office on Women's Health

³ The charter is available at: <http://www.hhs.gov/advcomcfs/charter/index.html> (emphasis added). The charter requirement is at 5 U.S.C. App. 2, § 9(c).

⁴ *See* 5 U.S.C. App. 2, § 10(b).