Public Comment

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First, I wish to thank Dr. Terri Michele and all of her colleagues at the FDA for last month's Drug Development Workshop. This meeting was an excellent example of how agencies can engage advocates in positive and productive dialogue. There is a path forward for treatments and the other issues we face. That path forward requires ALL stakeholders to cooperate and participate. I hope that other agencies will follow FDA's example, particularly as NIH and CDC continue to develop new case definitions. I was struck by how many people, including Dr. Michele and Dr. Maier, commented at the Drug Development Workshop that they learned things about ME/CFS that they had not heard before. For that reason alone, you MUST engage the patient community at the outset of efforts like developing new case definitions. We have much to learn from each other, but we can only do so if we are listening to each other at every stage of the process.

Second, I wish to thank Dr. Nancy Lee for her swift response to Public Citizen and the inclusion of the High Priority Recommendations list on this meeting's agenda. Dr. Lee and Dr. Gailen Marshall have also taken steps to more fully engage with the advocacy community between CFSAC meetings. I appreciate their willingness to find ways to improve these meetings so that you may better serve the needs of ME/CFS patients and their families.

Third, I hope we can learn from the controversy over that High Priority Recommendations list. CFSAC members, you were asked to identify the priorities through your subcommittees, and some time in January 2012 your input was combined into a document and shared with the Assistant Secretary without public discussion, comment or vote. This High Priority List was not mentioned at either of your 2012 meetings, and was not even released to the public until January 2013. The Designated Federal Officer of this Committee is ultimately responsible for ensuring full compliance with the Federal Advisory Committee Act, and Dr. Lee took swift corrective action when this error was pointed out by Public Citizen. But any of you could have raised this concern sooner. You knew how this had been done and no one said a word, at least to the public. You have a responsibility to ensure this Committee fulfills its purpose and complies with federal law. If the list had been published in 2012, if someone has just asked a question about it at a meeting in 2012, we would have discovered – and corrected – this violation of FACA a year ago. I ask that you remain vigilant, and raise questions and concerns about this Committee's work and how it is being done.

Regarding your High Priority Recommendations List, I would like to share with you the five recommendations that I believe you should designate as the highest priority for the Secretary. These recommendations address the most urgent and fundamental needs of ME/CFS patients. Many of them have been recommended by this Committee multiple

times, and all of them tie into issues raised in the FDA Drug Development Workshop as barriers to finding effective treatments.

In selecting recommendations, I urge you to include the full wording of these recommendations as originally passed, not the edited versions that appear in the CFSAC Recommendations Chart. I have found multiple inconsistencies between the Chart and the text actually approved by this Committee. Furthermore, in the first iteration of this List, you combined and edited recommendations to create new versions. While I am the first person to say that there is room for improvement in order to make all of your recommendations specific and actionable, I assumed that for purposes of this List you are limiting yourself to recommendations you have already made.

1. **NIH should fund ME/CFS research commensurate with the magnitude of the problem, and issue an RFA specifically for ME/CFS.** You made this recommendation in May 2011, and included an edited version of it in your original High Priority List. This Committee has made recommendations to increase NIH funding for ME/CFS research many times, but this recommendation asks for "funding commensurate with the magnitude of the problem," and I believe that is critical language to be included in the high priority list. I acknowledge that NIH funding does not exist in a vacuum, and that in order to secure such funding we will need several orders of magnitude increases in the number of grant proposals. But we would take a giant step forward towards that goal if NIH could say, as FDA has done, that its doors are open to such proposals. Instead, NIH funding for ME/CFS research DECREASED by 29% in 2012 to the lowest level since 2008. What signal does that send to researchers?

   > *ME/CFS is an illness with enormous economic and human costs. The April 2011 NIH State of Knowledge Workshop identified a number of gaps in what is known about the illness. To address these gaps warrants an interagency effort comprising, but not limited to, NIH,CDC, and AHRQ. Further, the focus should be on interdisciplinary discovery and translational research involving interacting networks of clinical and basic science researchers. Areas to be examined would include the following: identification of patient subsets for detailed phenotyping and targeted therapeutic interventions, biomarker discovery, systems biology approaches and disability assessment. To facilitate the above goal, CFSAC recommends that ME/CFS research receive funding commensurate with the magnitude of the problem and that the NIH (and/or other appropriate agencies) issue an RFA specifically for ME/CFS. (5/11)*

2. **Pool resources to create Centers of Excellence, using physical or virtual locations.** You made this recommendation in November 2011, and included it in your original High Priority List. Creating regional centers for research and treatment has been recommended by this Committee many times, and I believe these centers are an essential part of any plan to make progress against ME/CFS.

This Committee has discussed NIH's MAPP initiative for Chronic Pelvic Pain Syndrome on several occasions. That initiative came with $40 million of dedicated funding to attract proposals. The same effort is needed here.

> *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. (11/11)*

3. **NIH should issue a $7-10 million RFA for outcomes measures, and biomarker discovery and validation.** You made this recommendation in October 2012. An RFA with set aside funding to attract a greater number of proposals is a critical and immediate need to jump start research. I am tired of the chicken and egg debate of which comes first, the money or the larger number of proposals. Here's a novel idea: do both at once. Advocates, organizations, and researchers should do everything in their power to encourage more proposals, and NIH should pony up dedicated funding. Let's see what happens.

> *CFSAC recommends that you instruct the NIH to issue an RFA (funded at the $7-10 million range) for projects to establish outcomes measures for ME/CFS diagnosis, prognosis and treatment which would include but not be limited to biomarker discovery and validation in patients with ME/CFS. (10/12)*

4. **Hold a stakeholders' workshop to reach a consensus on case definition.** You made this recommendation in October 2012. We cannot wait two or more years for the current CDC and NIH case definition processes to unfold. We need immediate action to achieve consensus on the appropriate case definition for this disease so that research, treatment development and patient care all reflect what we have learned since the 1994 Fukuda case definition was published. Furthermore, the FDA meeting demonstrated the value that patients and caregivers bring to policy discussions. All stakeholders must have the opportunity to participate in this process, as the consequences will affect our lives for years to come.

CFSAC recommends that you will promptly convene (by 12/31/12 or as soon as possible thereafter) at least one stakeholders' (ME/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. (10/12)

5. **Remove the CDC Toolkit for healthcare providers from the CDC website.** You made this recommendation in June 2012. Despite CDC's point-blank refusal to follow this recommendation, I ask that you include it in your High Priority list. The Toolkit does not reflect the current best clinical practices, and patients' experiences show that the information in the Toolkit is misused and can be harmful to patients. CDC seems to take the view that providing imperfect information is better than no information. But I have had doctors and physical therapists prescribe graded exercise that progressed on a schedule rather than according to my symptoms, and every single time it made me much sicker. Regardless of what CDC intends, the reality is that this is how the CDC information is being used in the real world. CDC cannot simply cover its eyes and pretend that this is not happening. It is. Many healthcare providers are misapplying CDC's advice and it is hurting patients. It is not unreasonable to ask CDC to stop making things worse for us while they work on improving their advice. On your agenda for this meeting is a discussion of how to get more clinicians involved in diagnosing and treating ME/CFS patients. Ceasing to use information that is inaccurate and incorrectly applied seems to be an obvious prerequisite to such an effort.

    CFSAC asks that the Centers for Disease Control and Prevention (CDC) remove the CFS Toolkit (both English and Spanish versions) from the CDC website. (6/12)

Committee members, thank you for your efforts on behalf of people affected by ME/CFS. I hope your High Priority list will reflect what is most needed to make significant progress.