Public Comment

Anonymous

CFSAC Members:

First, I wish to thank the FDA for last month's Drug Development Workshop. The meeting was an excellent example of how agencies can engage advocates in positive and productive dialogue.
Second, I would like to share with you the five recommendations that I believe you should designate as the highest priority for the Secretary. As the FDA meeting showed, these priorities are fundamental to getting new treatments approved and many of them have been recommended by this Committee more than once. 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.

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 into 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.
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.
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.
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.
5. **Classify ME/CFS at G93.3 in the ICD-10-CM.** This multi-part recommendation pertains to classification of CFS in ICD classification systems. The first two of four parts are: (a) CFSAC considers CFS to be a multi-system disease and rejects any proposal to classify CFS as a psychiatric condition in the U.S. disease classification systems.(b) CFSAC rejects the

current classification of CFS in Chapter 18 of ICD-9-CM under R53.82, chronic fatigue unspecified, chronic fatigue syndrome, not otherwise specified. recommends that these changes be made in ICD-10-CM prior to its rollout in *This was included in the High Priority List.*

Thank you for your efforts on behalf of people affected by ME/CFS. I hope your High Priority list will reflect what will do the most good to help us.