Public Comment

Anonymous

Dear CFS Advisory Committee,

First, a thank you to the FDA for last month's Drug Development Workshop.
As someone who's paying out of pocket for an experimental (Rituxan) treatment, who is seeing great benefit from the treatment, I can assure you that there is some help already available in the pharmaceutical community.

As of today, the insurance companies are taking advantage of the inability or lack of desire within the FDA to approve medications as an excuse not to provide coverage for ME/CFS medications, and they classify my current off-label-treatment as experimental. Thus they are off the hook paying for any of it; in their short-sited view, they'd rather pay for another decade or more of my ME/CFS induced high medical costs. The FDA is enabling the insurance companies to behave in this manner. The FDA and especially the CDC, with the antiquated thinking promoted in their CDC Toolkit, are working against the very patients they were established and are chartered to help.

The recent FDA meeting was an excellent example of how agencies can engage advocates in positive and productive dialogue. I hope that other agencies will follow now FDA's example, particularly the NIH and most especially the CDC as they both continue to develop new case definitions.

I would like to share with you the top seven recommendations that I, as a patient for more than a decade, believe you should designate as the highest priority for the Secretary.
The priorities are fundamental to getting new treatments approved and many of them have been recommended by the 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. **Fund CDC research into biomarkers and viral etiology**. Provide adequate funding to CDC to effectively carry out a detailed 5-year plan. This should include, but not be limited to, immediate progress in these priority areas (Resubmitted from May 2009 with minor modification to [a]): *a.* Identification of biomarkers, with increasing efforts in viral etiology of CFS: (10/09) *This was included in the High Priority List in heavily modified form.*

2. **Adopt the term "ME" across HHS programs instead of CFIDS or CFS. If this is too large of a jump, adopt "ME/CFS" across HHS programs.** (10/10)
   This was included in the High Priority List.
   *The **CFS** should be dropped because of how much it does to belittle and demean this illness*

and stagnate any progress on the illness.

3. **Classify ME/CFS at G93.3 in the ICD-10-CM.** This multi-part recommendation pertains to classification of CFS in ICD classification systems: (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. (c) CFSAC continues to recommend that CFS should be classified in ICD-10-CM in Chapter 6 under Diseases of the Nervous System at G93.3 in line with ICD-10, the World Health Organization, and ICD-10-CA, the Canadian Clinical Modification and in accordance with CFSAC's recommendations of August 2005 and May 2011. CFSAC rejects CDC's National Center for Health Statistics Option 2 and recommends that CFS remain in the same code and the same subcode as myalgic encephalomyelitis becauseCFS includes both viral and non-viral triggers. (d) CFSAC recommends that an "excludes one" be added to G93.3 for chronic fatigue, R53.82, and neurasthenia, F48.8. CFSAC recommends that these changes be made in ICD-10-CM prior to its rollout in 2013. (11/11)

   This was included in the High Priority List. This is apparently necessary to help the illness be acknowledged as real; thirty years of medical practitioners telling patients it is their own psychological problem has proven that this change is necessary.

4. **NIH should issue a $7-10 million RFA for outcomes measures, and biomarker discovery and validation.** 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)
   Yes, more work on biomarkers. Let's find out what the cause of the illness is so we can make an accurate attempt at curing it instead of the existing focus of spreading incomplete (because there is no real cause identified) information to patients and caretakers.

5. **Remove the CDC Toolkit**. 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)

   The CDC toolkit is insulting, belittling, and demeaning to patients. If we had a similar toolkit treating HIV/Aids patients the same way, the medical community would be in an uproar and the toolkit would have ceased to be spread as CDC sanctioned many many years ago.

   Sadly, we ME/CFS patients are essentially invisible since we must spend the majority of our energy on day –to-day existence activities.

   The CDC Toolkit is a big roadblock in addressing this issue in a scientific way since it encourages a blame-the-victim approach.

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 and do all that you can to bring the CDC into the 20th (yes not even 21st) century.
The Toolkit does not reflect best clinical practices, and patient experiences, including my own, show that the information in the Toolkit is misused and is often harmful to patients.

6. **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 particular recommendation asks for "funding commensurate with the magnitude of the problem," and that is critical language to be included in the high priority list.

7. **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.

A high percentage of those of us who are sick with this illness are Type A personalities, and we were highly effective people, contributing greatly to society and its technological and other advances.

We'd like to get back to contributing, earning our own living again, and enjoying a life. A real life. Not one reduced to basic existence by this illness.

I sincerely thank you for your efforts on behalf of people like me who are affected by ME/CFS. I hope your High Priority list will reflect what will do the most to help us.

And, I hope you will do all that you can, and more, to ensure the High Priority list successfully implemented this time so we can move on with solving the problem of this illness.

Thank you very much,

Signed: A patient relying on your effectiveness