

# ***Speak-Out! The Life You Save May Be Your Own!***

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## Background:

The Chronic Fatigue Syndrome Advisory Committee (CFSAC) was formed by the Department of Health and Human Services (DHHS) in 2003 to serve as a Federal Advisory Committee (FAC) to the Secretary of the DHHS. As a Federal Advisory Committee, the CFSAC was and is subject to the rules and regulations that govern FAC's. The Committee consisted of eleven members each selected for experience and/or outstanding leadership in some aspect of Chronic Fatigue Syndrome (CFS). In addition to the eleven voting members, non-voting, ex-officio members from other federal departments/agencies were appointed to advise the Committee. The liaison between the Committee and the DHHS is the Executive Secretary (now known as the Designated Federal Officer or DFO). The DFO and the Chair of the CFSAC (the latter chosen by the DHHS from the 11 members of the Committee) jointly preside at the meeting. The primary responsibility of the DFO is to advise the Chair on procedural issues.

In its first year of operation, the CFSAC divided itself into 3 subcommittees: Research, Education, and Social Security/Disability. Within one year's time, each subcommittee came forward with recommendations. The parent committee (the CFSAC) discussed, modified, and transmitted these recommendations to the Secretary of the DHHS through an Assistant Secretary. Despite repeated requests for an acknowledgement of receipt of the recommendations from the Secretary, it took more than two years to obtain any response. During that time, the Committee was unsure of what actions it should take despite being advised to keep making recommendations to the Secretary. Failure to make recommendations would jeopardize the existence of the Committee. However, were the Committee to continue making recommendations, would further recommendations be confusing? Would the Secretary act on recommendations in the order they were received? Would the Secretary believe that the newer recommendations should take precedence over previous recommendations?

In the end, the Secretary did respond to the initial set of recommendations. The Secretary responded not by stating whether he accepted or rejected the submitted recommendations, but by stating how ongoing activities within the DHHS attempt to satisfy or meet the recommendations. Many members of the CFSAC find the performance of the DHHS in supporting the CFSAC and the response of the Secretary disappointing. The Secretary never met with the Committee, and took two years to respond to the recommendations. The Secretary never accepted or rejected the Committee's recommendation nor entered into a dialog with the Committee.

The CFSAC was chartered as a FAC for three years. As the conclusion of the third year drew near, there was concern as to whether or not the charter would be renewed. Eventually, the charter was renewed. However, the charter was changed. Under the

original charter, the Committee decided upon the frequency of Committee meetings in Washington, D.C. The Committee decided upon quarterly meetings. I believe there is unanimity among Committee members that quarterly meetings worked well. Under the new charter, meetings are limited to two meetings per year: one Spring and one Fall. These meetings are 2 days in length. Several members have been told that DHHS reached this decision for financial reasons. Two-day meetings create a hardship for the CFS patients who serve on the Committee. One member reported that she had suffered a serious CFS relapse following the first two-day meeting. There has been no response to this concern from the DHHS.

Where are we now?

### **The Effectiveness of the 2003-2006 Subcommittees:**

**Social Security/Disability** - In large part, the success of this subcommittee is attributable to the cooperation of the ex-officio advisor for Social Security/Disability. The request for data concerning the success/rejection ratios of CFS patients receiving or being denied benefits was honored. Differences in this ratio between states were detected. Training/retraining of adjudicators was put in place in an effort to bring the adjudicators to the same level of understanding and same knowledge base regarding CFS.

**Education** - Despite letters to national organizations in the health professions requesting information about CFS education for their members, no such information was obtained. Despite the need for a national diagnosis and treatment manual to educate healthcare providers about CFS, the suggestion to create that manual was deemed inappropriate. The recommendation to create a minimum of 5 Centers of Excellence that would include an educational component for physicians was ignored. The proposal to place CFS in the curriculum of medical schools was ruled untenable.

**Research** - The Research Subcommittee recommended, to the CFSAC, increased funding of investigator- initiated research by the National Institutes of Health. The Subcommittee also recommended increased funding for intramural CFS research at the Centers for Disease Control and Prevention (CDC). I took exception to these recommendations and, as a member of the Research Subcommittee, I wrote a minority report entitled, "Fish or War." I likened the traditional method of funding CFS research to fishing: entice people to apply for funds, choose the ones you like, and discard the others. I suggested a different approach to CFS research: declare war on CFS and mount a wartime effort to conquer it. (Convene a body of researchers and experts on CFS and related diseases. Determine what needs to be known about CFS. Devise a multi-faceted research plan to obtain the needed answers. Divide the needed research work among the people willing to do the work.) The minority report was brought forward to the parent committee. Many of the research recommendations adopted by the CFSAC came from, Fish or War. The final, Advisory Committee recommendations were somewhat softened versions of the Fish or War proposals, and were incorporated into the missions of the proposed CFS Centers for Excellence.

The Secretary of the DHHS would not fund the CFS Centers for Excellence.

For the May 2007 CFSAC meeting, the second meeting of the renewed CFSAC, all membership slots have been filled. The subcommittee structure of the renewed CFSAC is similar to the structure of the original. There are three subcommittees:

- o Research
- o Education
- o Patient Care

The items that will be considered by these subcommittees are unknown at the time of this writing. Similarly, the Agenda for the May 17/May 18 meeting of the CFSAC has not been disclosed at the time of this writing.

### Areas of Concern (As I See Them)

- o Research The National Institutes of Health is test-piloting a new way of funding research called the Roadmap Initiative. If my understanding of this initiative is correct, grants would no longer be given for the study of specific diseases. Rather, grants would be given to explore “themes.” I disapprove for several reasons: (1) The Roadmap Initiative would make it more difficult to track the dollars spent on CFS because CFS research per se would no longer be funded, and (2) Individuals wishing to perform CFS research would either not be funded or would have to broaden their research interests to satisfy the broad initiatives of the Roadmap. A telephone conversation with an NIH administrator voicing these concerns drew the following responses: (1) For now, the Roadmap Initiative will not be used to fund all of NIH’s extramural grants. Some funding of extramural grants will be available through the traditional channels. (2) We should wait and see to what extent the Roadmap Initiative will be used. My response is: CFS needs dedicated research. NIH has been funding CFS research under the current clinical case definition since 1994. What is the result of thirteen years of NIH-funded research? We do not know the cause CFS. There is not one drug manufactured specifically for the treatment of CFS. CFS patients need research dedicated to the treatment of CFS and to finding its cause. We need direct research. We need that research now! There should be no obfuscation of the accounting of funds spent on CFS research. The CFS Community has the right to know how much money is being spent on CFS research.

- o Education The CDC is spending \$4 million on a “Spark Awareness” campaign aimed at educating both the lay public and healthcare practitioners about the symptoms, diagnosis and treatment of CFS: How is that money being spent?

- o A May 12th, 2007 CFS Awareness Program in Burlington, VT, was attended by 30 patients. Of the 30 patients, one patient saw a CFS public service announcement (PSA) on television twice, and another patient saw a CFS PSA on television once. Not one patient heard a CFS PSA on the radio. How many radio PSA’s, and how many television PSA’s are being aired in which states?

- o At that same CFS program, the CDC’s “CFS Toolkit for Healthcare Professions” was displayed. Patients were asked if they had seen the Toolkit in any office of their

healthcare professionals. They were also asked if they had received the CFS Patient Information booklet contained therein. Not one patient had seen the Toolkit in their healthcare provider's office nor had any of them been given the CFS Patient Information booklet. How effective is the Spark Awareness campaign?

Many questions regarding CFS education need answers:

- o What is the status of the CDC's healthcare provider educational programs?
- o What methods are being employed to promote these programs?
- o What assessments are being employed to monitor the effectiveness of the promotional programs?
- o How are these programs being modified subsequent to the evaluation of their effectiveness?
- o What assessments are being used to measure the success of the various educational programs?
- o What new educational materials have been developed for physicians and patients?
- o What is the plan for developing new materials and/or updating existing ones?
- o Why is it that New Jersey's, "A Consensus Manual for the Primary Care and Management of Chronic Fatigue Syndrome," has been adopted by Vermont, is being considered for adoption by other states, and has been translated into Japanese, while there is no equivalent manual being written by the CDC or the DHHS?
- o Why is the International Association for CFS/ME writing an Emergency Room treatment guide as a resource for emergency room physicians who treat CFS patients? Why is the CDC or the DHHS not writing this manual?
- o What are the positions of the American Medical Association and the American Association of Medical Colleges on CFS education in medical schools?
- o The New Jersey Chronic Fatigue Syndrome Association has mounted a medical school scholarship program to encourage medical students to learn about CFS while they are in medical school. This scholarship program was announced at a CFSAC meeting. A request was made at a CFSAC meeting for a national medical student scholarship program modeled after the program in New Jersey. That request has been ignored. What prevents the federal government from sponsoring such a scholarship program?
- o **Patient Care** - The CDC's Spark Awareness campaign employs the slogan, "Get diagnosed, get treated." Who will do the diagnosis and who will do the treating? Aside from printing a few pages summarizing information concerning CFS in the CFS Toolkit for Healthcare Professionals, what real assistance is there for diagnosing or treating CFS patients?
- o How is the DHHS increasing the number of qualified physicians capable of treating CFS?
- o How is the DHHS increasing the number of qualified healthcare providers capable of treating CFS?
- o How is the DHHS increasing the experience of physicians in treating CFS?
- o How is the DHHS increasing the experience of other healthcare providers in

treating CFS?

- o What mentoring programs exist for physicians?
- o What mentoring programs exist for other healthcare providers?
- o What centers exist for physician training?
- o What centers exist for other healthcare provider training?
- o What centers exist to which patients can be referred?
- o What centers exist to which patients can self-refer?
- o The State of Nevada, and a philanthropic family in Nevada, are investing \$12 million in a CFS Institute at the University of Nevada. If one state and one family can establish an institute for CFS, why does the Government of the United States of America claim that the federal government has insufficient resources to make such an allocation?

What Needs To Be Done (As I See It)

At the National Level

The federal response to CFS needs to be increased. This will not happen unless the federal government perceives a great need to do so. There are two opportunities for the public to demonstrate the need for an increased response at the federal level.

Opportunity #1: The CFSAC meetings provide the best opportunity for members of the CFS community to be effectively heard by the federal government and to have their testimony placed into public record. Once in public record, that testimony cannot be denied.

Members of the CFS community should attend CFSAC meetings and testify. Members of the CFS community include patients, their families, their relatives, their friends, their caregivers and their healthcare providers. CFS community members willing to come and testify before the CFSAC should notify the DFO of the CFSAC preferably via e-mail at: [anand.parekh@hhs.gov](mailto:anand.parekh@hhs.gov). Do not send letters via the U.S. Postal Service. Mail going to the DHHS via the U.S. Postal Service is subject to inspection for biological and chemical warfare agents, and will be delayed in delivery by weeks. Mail sent via FedEx is delivered within a reasonable timeframe.

Individuals who testify at a CFSAC meeting are limited to a 5-minute presentation. Your comments should be written down either verbatim or in outline format. You should practice your presentation prior to delivery to ensure that it will fit within the 5-minute window. You may speak about anything that is relevant to your experience with CFS or some other individual's experience with CFS. Some possible topics you might wish to address in your presentation include: healthcare treatment, access to healthcare, financial concerns, CFS education for patients, physicians and/or other healthcare professionals, and the funding and status of CFS research.

If you cannot attend an advisory committee meeting, you may encourage someone else to attend in your place. You may also submit a written statement with a request that it be read into the record. The Vermont CFIDS Association has made videos of some Vermonters with CFS telling their stories. The Vermont CFIDS Association intends to send an edited copy of this tape to the next CFSAC meeting with the request that it be played during public testimony. The patient advocate group in

Florida is bringing photographs of its members to the Advisory Committee meeting and will place these pictures on empty attendee chairs at the meeting. The purpose will be to demonstrate that, were these patients well enough, they would have attended the meeting.

It is vital that the CFS Community show a strong presence at Advisory Committee meetings. Failure of the CFS Community to show a strong interest in the work of the CFSAC may be construed as a lack of interest and/or lack of need for the CFSAC. If there is little interest or little construed need for the CFSAC, the DHHS may decide to discontinue the CFSAC. If the CFSAC is discontinued, we will have lost our voice in Washington, D.C. We will have also lost our opportunity to educate the ex-officio members of the Advisory Committee about CFS. This would be unfortunate because the ex-officio members of the Advisory Committee are high-ranking supervisors in other, related departments and agencies of the DHHS.

Opportunity #2: Establish a relationship with the U.S. Representatives and Senators in your state. The CFIDS Association of America sponsors a lobby day. This is a day when individuals of the CFS Community are encouraged to come to Washington, D.C. and speak with their elected officials about their CFS-related concerns. The CFIDS Association of America will provide you with training on how to lobby your elected federal representatives. This training usually occurs a few days before the designated lobby day. More information about such training may be obtained from the CFIDS Association of America. Their website is: [www.cfids.org](http://www.cfids.org).

I believe a more effective approach is to develop a relationship with your federal Representative to Congress, and your federal Senators in their hometown offices. I would recommend telephoning their offices and ascertaining which of their assistants deal with healthcare issues. I would speak with those individuals, having short and to-the-point conversations, concerning the difficulties you are experiencing and how you believe the federal government can and should help. The object should be to develop a sympathetic friend in the legislator's office, one who would be willing to articulate your concerns and ideas to the Representative or Senator for whom they work, and act as an advocate on your behalf. This approach may be more effective than a once-a-year visit to a Representative's or Senator's office in Washington, D.C.

At the State Level

The CFS Community should form a statewide patient advocacy group in every state. There are several models for the establishment of such groups. In New Jersey, for example, the New Jersey Chronic Fatigue Syndrome Association (NJCFSA) charges a membership fee. CFS patients who cannot afford the membership fee pay a reduced fee or have their membership fee waived. No CFS patient is denied membership because of financial situation. In Florida, the statewide patient advocacy group is privately and philanthropically funded.

However funded, statewide patient advocate groups should establish their individual goals. Representing as many CFS patients as exist within their state should be one goal. Establishing projects and working on them should be another. Most patient advocacy groups have patient education as one of their goals. Holding patient conferences and offering continuing education programs for healthcare professionals

are two ways of providing service to members, and creating public awareness and recognition of the organization. Efforts should be devoted to establishing recognition by, and a relationship with, state legislators. Statewide patient advocate groups need to address the statewide concerns of CFS patients:

- o Are there sufficient physicians and other healthcare providers within the state who are knowledgeable about CFS, and who can treat the state's CFS population?
- o Are there educational opportunities for healthcare providers to learn about CFS? Are social security/disability adjudicators within the state capable of recognizing CFS and do they recognize CFS as a legitimate illness?
- o What is the success rate of CFS patients being placed on disability within your state compared to the national average?
- o Is CFS research being performed in your state?
- o Do you have an institution within your state capable of housing a CFS research project?
- o Do you have researchers within your state who might be interested in performing CFS research?
- o Can you entice researchers in your state to perform CFS research?
- o Can your patient advocate group generate some "seed" money for pilot CFS research projects?
- o Can you identify a researcher capable of conducting a clinical trial for CFS?
- o Can you identify a sufficient number of patients within your state to support the performance of a clinical trial?
- o Are school systems within the state trained to recognize the symptoms of CFS in children and adolescents?
- o Are school systems within the state willing and able to accommodate students with CFS?
- o Does your state have a Department/Division of Youth and Family Services (DYFS)?
- o Is your state's DYFS aware of CFS?
- o Children with CFS often appear to have behavioral issues in the classroom. These children are then reported to DYFS. DYFS will investigate. Are the DYFS caseworkers in your state capable of differentiating CFS from other illnesses such as depression and behavioral issues?
- o Can you educate DYFS caseworkers about CFS so that they can identify CFS in school-age children?

## Summary/What Is At Stake

The CFSAC was born because of the political pressure brought by the CFS community on the federal government. The initial CFSAC submitted recommendations to the Secretary of the DHHS. A response was received. The charter for the CFSAC has been renewed for another three years. Its budget has been reduced. The last few advisory committee meetings have been poorly attended by the CFS Community. If this poor attendance is perceived as a lack of interest and/or support of the activities of the CFSAC by the CFS community, this advisory committee may cease to exist. If the CFSAC is not

supported by the CFS community either by attendance at the meetings or submissions of testimony to it, the CFSAC will lose its effectiveness and may be disbanded.

The federal government supports a modest research effort for CFS. The research effort is supported by funds given to the CDC and the NIH. Both of these federal agencies are going to receive less money with which to conduct CFS research this year and in upcoming years than they have in the past. The CFS community should be concerned by this decrease in funding.

There is documentation that, in the past, both the NIH and CDC took funds allocated for CFS research and used these funds for other research. Watchdog activity is necessary to ensure that funds allocated for CFS research are spent on CFS research. The NIH is changing the mechanism by which it awards extramural research funds. Its Roadmap Initiative will make it more difficult to track the funds being spent on CFS research. The Roadmap Initiative will, in my opinion, decrease the amount of research being conducted on CFS.

It has been approximately 15 years since the federal government started funding CFS research using the current, most accepted, clinical case definition of CFS. After all this time, we do not know the cause of CFS. After all this time, there is not one drug developed to treat CFS. We need more research dedicated to CFS, not less.

We need healthcare providers capable of treating CFS. The CDC launched a multi-million dollar CFS Awareness campaign in the fall of 2006. As evidenced by a recent poll at the May 12, 2007 CFS Awareness Meeting held in Burlington, VT, the Awareness campaign has had a minimal impact - if any - at least in some geographical areas.

We need healthcare provider education. We need healthcare provider education for providers in practice. We need healthcare provider education for those who are in school or training to become healthcare providers. If the CDC's Healthcare Provider Toolkit is not in the hands of the healthcare providers, then the CDC's campaign to educate healthcare providers has failed. It is time to move on.

We need CFS patient care. The CDC's Healthcare Provider Toolkit advocates getting diagnosed and getting treated. Where do patients go to get diagnosed? Where do patients go to get treated? Clearly, facilities are needed to train healthcare providers how to diagnose CFS and to train them how to treat CFS. Clearly, facilities are needed for CFS patient treatment. Thus far, there is one, private facility being built in Nevada. Is it reasonable to expect that this one, private facility will be able to accommodate the estimated one million CFS patients in the United States? Is it reasonable to expect that the private, philanthropic sector, or individual states, will provide the facilities needed to manage this healthcare crisis?

Your voice counts. Make your opinion(s) known! Contact the CFSAC and your state and federal representatives.



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