U.S. Department of Health and Human Services

Chronic Fatigue Syndrome Advisory Committee (CFSAC)

Fifth Meeting

At

Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 705A
Washington, DC 20201

September 27, 2004

9:00 AM to 5:00 PM

MEETING SUMMARY

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I. Members in Attendance

A. Voting Members

- Dr. David S. Bell—*Chair*
- Nancy C. Butler
- Dr. Kenneth J. Friedman
- Dr. Nelson Gantz
- Dr. Anthony L. Komaroff
- Dr. Charles W. Lapp
- Dr. Nahid Mohagheghpour
- Dr. Roberto Patarca
- Staci R. Stevens

B. Ex Officio Members

- CDR Dr. Drue H. Barrett, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC)
- Dr. Marc Cavaillé-Coll, Division of Special Pathogen and Immunologic Drug Products (DSPIDP), Food and Drug Administration (FDA)
- Dr. Laurence Desi, Sr., Social Security Administration (SSA), Office of Medical Policy
- Dr. Eleanor Hanna, Office of Research on Women's Health, National Institutes of Health (NIH)
- Dr. William A. Robinson, Center of Quality, Health Resources and Services Administration (HRSA)

C. Executive Secretary

- Dr. Larry E. Fields

II. Invited Speakers

- Dharam V. Ablashi, American Association for Chronic Disease Syndrome (AACFS)
- K. Kimberley McCleary, The CFIDS Association of America (CFIDSAA) and Member, HHS CFS Coordinating Committee (CFSCC)
- Jill McLaughlin, National CFIDS (Chronic Fatigue Immune Dysfunction Syndrome) Foundation (NCF)
- Donna Pickett, National Center for Health Statistics (NCHS), CDC, HHS

III. Committee and Ex Officio Members Absent

- Dr. William C. Reeves
- William C. Anderson
- Lyle D. Lieberman

I. Chairperson

A. Call to Order and Request for Roll Call

Dr. Bell called the meeting to order and requested roll call. Mr. Fields noted that Dr. Reeves, whose father recently passed, would not be attending the meeting. He then conducted roll call. He noted that Dr. Barrett is an alternate for Dr. Reeves.

B. Introductions and Opening Remarks

Dr. Bell commented that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) charter has been extended for two more years. CFSAC has submitted recommendations to Dr. Beato, who will then forward them to the Secretary of DHHS. The recommendations will be available to the public as a three-page letter.

Due to the impending hurricane, a number of flights have been rerouted. As a result, the meeting will adjourn at 4:00 PM and the second public comment section will be held at 2:45 PM.

Dr. Bell noted that the committee received a request from Ms. Jean Harrison, president of Mothers Against ME (MAME). Ms. Harrison asked for the CFSAC meetings to be video taped and provided on DVDs or videotapes. Other aids are problematic; audiotapes do not provide a full impression of the meeting and webcasts are not accessible to those without Internet access. Additionally, cognitive difficulties prevent some from being able to read the transcripts, which also do not capture subtle nuances. These requests are made under Section 504 of the Rehabilitation Act.

C. Approval of the Minutes of June 21, 2004

Dr. Bell asked for comments on the June 21, 2004 minutes. Ms. Barrett noted that on page 10, Suzanne Vernon's name is misspelled as "Susan Burnen." A motion was made to approve the minutes with changes and all members voted to accept the minutes.

D. Discussion

Dr. Bell asked for comments on Ms. Harrison's request.

Dr. Komaroff commented that the request is a laudable goal if an organization wished to videotape the meetings. However, it is not clear if DHHS should conduct the videotaping.

Dr. Gantz concurred.

Dr. Bell noted that an attorney has looked into this matter and asked her to provide her comments.

Patricia Mantone, Office of the General Counsel, DHHS introduced herself. In the opinion of the Counsel, DHHS is not legally required to provide the videotaping. DHHS, at its discretion, can choose to videotape. However, there is no legal requirement. DHHS holds the meetings in a reasonable location for persons with disabilities and provides minutes for those unable to attend. These mechanisms do provide reasonable access to these meetings.

Dr. Bell commented that this request identifies one of the central issues in the disability of CFS patients. People tend to think of disability as lost of sight, lost of limbs, an inability to push and pull, etc. However, the disability of CFS works differently. It is an inability to sustain an upright posture for a long period of time. This is one of the reasons for the request and a central misunderstanding of the illness. Dr. Bell hopes that over the coming years, the committee will be able to address this specific disability as well as those in the past, such as making the building accessible.

Dr. Friedman asked if the financial impact on DHHS has been investigated.

Ms. Mantone responded that they have not looked into the costs.

Dr. Friedman suggested that if the costs of videotaping and producing minutes were comparable, videotaping may be an viable alternative.

Dr. Bell responded that if the committee videotaped its meetings, it would set a precedent for governmental functions. However, there would be nothing to prevent a support organization or a member of the public from videotaping.

Dr. Komaroff added that it would be better to permit an outside entity to videotape the meetings—the costs can become prohibitive for the government.

Dr. Bell proposed that, at the present time, the CFSAC meetings will not be videotaped by DHHS. He recommended that private organizations consider this as service to those with CFS. He then asked if it was legal for a member of the public to videotape these meetings.

Ms. Mantone recommended that such a person should first ask for permission of the committee. It should also be made clear at the meeting that it will be videotaped to allow members of the public to object.

Dr. Friedman asked what will happen to the videotape after it is produced. Will the organization sell it or distribute it for free or at cost? He added that the meetings are a product of the committee and that he would not want an organization to make a profit from it.

Dr. Bell noted that the distribution or sale of the videotape would not be the committee's affair. It would be the same as a member of the public writing about the meeting.

Dr. Fields asked about still cameras.

Ms. Mantone replied that photographs are different from videotapes. In general, it has not been recommended that still cameras be announced before a meeting.

Jonathan Sterling added that travel is difficult for CFS patients. He suggested holding a CFSAC meeting in conjunction with a AACFS conference to allow other parts of the public to participate.

Dr. Komaroff supported Mr. Sterling's idea, but noted that this would not happen until 2006.

Dr. Bell noted that the CFIDS Association of America and the National CFIDS Foundation have been invited guests at all four meetings. It has been asked if there

should be a rotating schedule to include other groups over the next four meetings. This would entail the ability to comment on the proceedings and to provide a 15-minute organizational update. He asked for comments.

Dr. Gantz added that no organizations should be excluded. Rather than having a rotating schedule, he would like to allow any organization to participate.

Dr. Friedman noted that, for the committee's efficiency, organizations that are interested in participating should submit a proposal or summary of their activities before meeting dates. The committee would then select those that it would like to hear from.

Dr. Komaroff supported Dr. Friedman's suggestion.

Dr. Bell added that it was a good idea and asked Ms. McCleary to comment.

Ms. McCleary responded that there are a number of groups around the country of varying size, scope, and focus. She added that the committee would be well served to have several voices represented at these meetings.

Dr. Friedman moved to invite the patient advocacy community to submit summaries of its activities before the announced meeting dates. The committee will review the activities and invite those that it chooses to make an oral presentation.

Dr. Bell added that the summaries could be submitted via the website. The motion was seconded and all were in favor. He added that the summaries would only be a paragraph or two on what the organization plans to present. The committee would then select the organizations and determine the length of their presentations.

Dr. Patarca asked if the summaries would be made publicly available.

Dr. Fields responded affirmatively.

Dr. Bell added that any submission via the website would be open and public. He asked Dr. Fields to determine this new process.

II. Invited Organizational Updates—CFIDS Association of America

K. Kimberly McCleary

Ms. McCleary presented on a report entitled, "Analysis of NIH-Funded Research on Chronic Fatigue Syndrome Shows a Trend of Decreased Support: Fiscal Years 1999–2003." The report represents four months of research on NIH funding on CFS projects.

She presented a graph showing CDC and NIH funding for CFS from 1990 to 2003, as reported by the agencies. The total funding over this period was $131 million. In 1999, CDC funding surpassed NIH funding for the first time.

Appendix B of the report presents information provided by the NIH budget office. The information includes an aggregate sum for each fiscal year and the individual award amounts. Project abstracts were also provided, but were not included in the report.

The general findings of the report include:

1. The total five-year funding was $31.6 million.
2. There were 76 studies with 200 individual awards.
3. Of that total, 7.5 percent were intramural and 91.7 percent were extramural.
4. There were 53 investigators at 43 institutions (only one was outside of the United States).
5. Eight NIH institutes participated in supporting this research, though 47.8 percent came from NIAID.
6. The RO1 mechanism was used by 52.6 percent of the grants.
7. $8.3 million (26.3 percent) was for the Cooperative Research Centers program, which was discontinued by NIAID in 2002.
8. The largest single year award was $475,828, which is the average amount for RO1 grants across the board.
9. There were nine treatment studies (less than 15 percent).
10. There were three adolescent studies (3 percent).

Additional research sources for the report included:

1. CRISP database for project descriptions and review sections
2. Principal investigators
3. Published literature (Medline)
4. NIH program officers

In conducting the research, there were a number of studies that did not directly support CFS research. Twelve studies were found to have no support for CFS. These projects involved psychobiology of ethnicity, stress and disease, pathophysiology of neuroimmune communication, vascular disease, atherosclerosis, and chronic muscle diseases. The total value of these 12 projects was $5.24 million.

There were nine studies for "related" conditions. They involved muscle disorders, lime disease, orthostatic intolerance, delayed sleep phase syndrome, syncope, chronic multi-symptom illnesses, rheumatic diseases, fibromyalgia, and gulf war syndrome. This research totaled $1 million, which, when adjusted for direct CFS support, came out to be $502,866.

Ms. McCleary then presented a graph showing NIH-reported CFS funding compared to the adjusted funding, as described above. She noted that since the total funding in any given year is less than $8 million dollars, any reduction to that amount is severe. In 2003, the adjusted amount was below $4 million, the lowest amount since 1992.

The report makes two recommendations. First, extramural research efforts should be stimulated. This could include:

- A well-funded and well-publicized Request for Applications (RFA). The RFA symbolizes NIH's interest in a specified area and is preferred over a program announcement.
- An active outreach to investigators in related fields, which has been effective in other fields, including aging.
- Establishing a Centers for Excellence program for CFS, where there is a multidisciplinary approach to research and clinical and treatment studies. These centers include a care component and therefore are different from the Cooperative Research Centers.

The second recommendation is that intramural efforts should be expanded through a new working group of investigators.

Ms. McCleary asked if there were any questions.

Dr. Gantz asked if there was any data on 2004.

Ms. McCleary replied that they do not have 2004 data. She added that it took a year and a half to get data up to 2003 and asked the committee to help facilitate the ongoing stream of information from NIH in a timelier basis. In addition to NIH information, they also looked publications from the grants to see how many publications there were that related to the care of patients with CFS. Dr. Gantz commented that many of the funded projects do not seem be producing output.

Ms. McCleary concurred but did not know why they were not being published.

Dr. Lapp noted that many of the current projects will be running out in 2004 and that there have not been many new projects that have been recently accepted. As a result, the projections for CFS funding appear to continue on its downward trend.

Ms. McCleary responded that reported data showed new research for each year is stable. However, this does not account for irrelevant studies.

Dr. Lapp mentioned the pioneer grants, which involves a two-step process that starts with a letter of intent.

Dr. Mohagheghpour added that if the letter is accepted, the investigator is invited to submit a full grant application.

Dr. Komaroff commented that the committee should be concerned about two aspects of the report. The most important is the total funding for CFS. The second is the apparent misclassification of studies. He asked what the evidence was for the 12 misclassified projects.

Ms. McCleary responded that either the investigator said there was no connection to CFS, the abstract did not mention CFS, or the resulting publication did not mention CFS. If two of these conditions were met, the study was deemed misclassified.

Dr. Komaroff then asked how the classifications were applied.

Ms. McCleary responded that the classifications came from the NIH Office of the Budget, and some program offices were not aware of or involved in the classifications. Therefore, there appears to be a central mechanism that is determining these classifications. Some institutes, such as NCI, use relevancy scores. However, there was no information that this type of mechanism was used.

Dr. Lapp asked if there were grants counted towards CFS, as well as another category.

Ms. McCleary replied that she did not have enough information to answer the question. She added that this is an issue that many advocacy groups are beginning to challenge. There has also been Congressional interest in terms of how the funds are allocated and counted.

Dr. Patarca asked if there was data on private organization funding and whether the existing data included other mechanisms, such as credos submitted by the private sector.

Ms. McCleary responded that the data included every mechanism used by NIH. In terms of private funding, CFIDSAA has supported over $4 million in research and has made four awards to pilot studies.

Dr. Patarca asked about CFIDSAA's funding trend.

Ms. McCleary noted that the funding was consistent through the 1990s.

Dr. Gantz asked why 2004 data is not available.

Ms. McCleary noted that FY2004 ends at the end of September and the budget office will not have 2004 data until March or April 2005.

Dr. Desi asked where the non-intramural and non-extramural money went.

Ms. McCleary responded that there was a small amount dedicated to a project for which she could find no information. However, she believes the money was for a conference.

Dr. Desi then asked how CFS funding compares to other NIH funding, in terms of trends.

Ms. McCleary noted that in aggregate amounts, CFS funding is at the bottom of any list. However, she is not clear how CFS compares with other funding, in terms of trends.

Dr. Hanna added that there is a list of spending for all diseases on the NIH website.

Dr. Patarca asked if this list also included educational activities.

Dr. Hanna replied that it does not include educational activities.

Dr. Bell thanked Ms. McCleary for her presentation.

III. Ex Officio Members

A. Food and Drug Administration

Dr. Marc W. Cavaillé-Coll

Dr. Cavaillé-Coll commented that he has nothing prepared for the meeting, but asked for questions or comments.

Dr. Patarca asked if there has been a change in the level of drug submissions from the private sector.

Dr. Cavaillé-Coll responded that it has been steady. In total, there are less than 20 different projects currently active.

Dr. Gantz asked about Pregavalin and Ampligen.

Dr. Cavaillé-Coll noted that he cannot comment on the status of these drugs under IND. He cannot confirm or deny the existence of an IND or the existence of a new drug application under review. He recommended that these questions be asked of the manufacturers.

Dr. Fields asked if there were any conflicts of interest arising from Dr. Gantz's question. There were none.

Dr. Patarca asked if applications to the FDA were similar to NIH funding trends.

Dr. Cavaillé-Coll responded that it fluctuates. He added that when a product is approved, the reviews are posted on the FDA's website and, in the event of an FDA Advisory Committee meeting, the briefing package is made available 24 hours before the meeting.

B. Centers for Disease Control and Prevention

Dr. CDR Drue H. Barrett

Dr. Bell expressed the committee's condolences for Dr. Reeves' father.

Dr. Gantz proposed that the committee send an acknowledgement to Dr. Reeves. The motion was seconded and all voted in favor.

Dr. Fields then read the obituary statement.

Dr. Barrett noted that Dr. Reeves sends his regrets for not being able to attend. He is driving back from California. However, Dr. Barrett will be presenting on behalf of Dr. Reeves.

The Wichita study analyses are continuing. There are four manuscripts ready for submission for publication. They deal with the clinical characteristics of CFS, the symptom inventory for evaluation of CFS, cognitive functioning, and orthostatic intolerance.

Dr. Barrett then asked Dr. Komaroff to speak about the recent meeting in Cold Spring Harbor.

Dr. Komaroff noted that it was a small meeting of 30 people. Two-thirds of the attendees were leading immunologists and one-third were investigators interested in the clinical syndrome of CFS. Scientifically, it was an exciting meeting in demonstrating the potential of current technology to investigate lymphocyte function. The impact it may have on CFS remains to be seen.

Dr. Barrett announced that Dr. Reeves will be starting a new activity with Lockheed, Caltech, and MIT, to use their supercomputers to analyze the Wichita study data. They will be working on developing an empirical definition of CFS.

The AACFS meeting, which CDC is cosponsoring, will be held October 8–10. Dr. Reeves' group will be conducting a workshop on the chronic fatigue research network.

Starting in November, there will be a new study looking at CFS in Georgia. This will include 60,000 individuals in the metropolitan Atlanta area. It will also include Macon and its surrounding rural area. It will be a longitudinal study, which will look at the prevalence of CFS. It will also look at access to healthcare, healthcare utilization, and healthcare delivery and will include economic analyses. This study will feed into clinical studies conducted by Emory investigators. They are also starting a CFS registry in Georgia, which will be expanded regionally and nationally. This registry will also feed into clinical studies.

The support for the physician education effort is continuing and there is a contract, which will begin at the end of September, that would focus on public awareness activities to compliment the physician awareness activities.

Dr. Desi asked if the case definition study was before or after the epidemiologic study.

Dr. Barrett responded that the case definition study will be using data from Wichita, rather than Georgia.

Dr. Desi then asked what case definition will be used in the Georgia study.

Dr. Barrett responded that she is not sure.

Dr. Patarca asked about the multi-center study.

Dr. Barrett asked Dr. Hanna if she could provide more information on this study.

Dr. Hanna added that there is a meeting set for November 18, at which Dr. Reeves will discuss the project with the CFS working group.

Dr. Patarca asked if the genomic signature for CFS is now part of the Wichita study.

Dr. Barrett noted that Dr. Reeves had not mentioned this issue.

Dr. Bell asked if there were any follow-up on the committee's recommendation to add three new positions at CDC.

Dr. Barrett noted that Dr. Reeves mentioned that there was some progress made in that area.

C. Social Security Administration

Dr. Laurence Desi Sr.

Dr. Desi noted that he does not have anything to report and asked if there were any questions.

Ms. Stevens asked if the CFS training videotape was available to the committee.

Dr. Desi responded that he does not know, but would look into it.

D. Health Resources and Services Administration

Dr. William A. Robinson

Dr. Robinson noted that he has not been doing any specific work related to CFIDS, except for working with Dr. Patarca and the Education Subcommittee. In addition to that, there is one tool that HRSA has been developing, which could be tied into the work of this committee. The tool is called the HRSA Geospatial Data Warehouse, which has the capability of mapping and sharing HRSA's various resources, including names of grantees, health and training centers, and the Ryan White HIV/AIDS program sites, among others. This information will be made available online to the public. Dr. Robinson noted his willingness to make a presentation to this group on this tool.

Ms. McCleary added that the CDC Georgia study is trying to increase public and provider awareness about CFS to maximize enrollment. She commented that HRSA could help them with outreach.

Dr. Robinson presented an example concerning tuberculosis. HRSA asked the CDC to identify particular hotspots for which HRSA to might provide resources to assist the work of the Tuberculosis Advisory Committee. Though they were unable to point to specific counties or cities for a variety of reasons, HRSA was able to show them what data it could provide at the state, county, and city levels. These data included information on every grantee, including the abstract of work, award amounts, and

street addresses. The same thing can be provided for Macon county or any other county in Georgia.

Dr. Patarca asked how the data on CFS patients were collected.

Dr. Robinson responded that those data are not in the system at this time.

E. National Institutes of Health

Dr. Eleanor Hanna

Dr. Hanna noted that the program announcement (PA) is being reissued and is up on the early notification system (ENS). Comments should be coming in by the end of the week and all issues need to be resolved by the end of October. The announcement will be published in November and will include RO3s and R21s. They are working on revising the second draft of the RFA, which will be up on ENS by late November or early December. On November 18, Dr. Reeves will be coming to discuss the CDC/NIH collaboration. Other agencies can sign on to these PAs and RFAs.

The website is almost ready for them to do a mock up, thanks to Sandy Solomon. They have commitments from all the members for their contributions, which is due in early November. At that time, the website will be ready for testing. Dr. Hanna asked if CFSAC members would like to be testers.

Dr. Bell agreed to test the website and asked for testing information via email.

Dr. Hanna mentioned that there are a number of upcoming meetings that may be of interest. The first one is in the planning phase and does not have a date yet. It will deal with the issue of stigma of difficult to treat conditions. The meeting will be NIH-wide. The second conference deals with fibromyalgia, which is being coordinated by the Oregon Health and Science University. NIAMS is funding this workshop, which will be held at the Marriot Warden Park in Washington, D.C. on November 11–12. In June, there will be a State of the Science meeting for chronic insomnia, sponsored by NIH.

There will be two conferences held by the Office of Research in Women's Health. One is an interdisciplinary research symposium, which will be held at the Nature Center on October 4–5. The second is the Family Hormonal Health Symposium, which deals with child health, human development, and the perplexity of problems caused by undiagnosed pituitary tumors.

Dr. Patarca asked if there was a way for someone to search for CFS activities.

Dr. Hanna responded that the new website will allow for such a search.

Ms. Stevens asked how often the NIH CFS workgroup meets and who is involved.

Dr. Hanna answered that they were meeting every month while they were working on the website. However, they traditionally meet four times a year. The members include representatives from the Center for Scientific Review (CSR); National Heart, Lung, and Blood; National Institute of Childs; Health and Human Development; National Institute of Mental Health; NIAMS; NIADS; AMCAM; and nursing. The next meetings are scheduled for October 21 and November 18.

IV. Public Comments—Part 1

A. Dr. Lucinda Bateman

Dr. Bateman is a general internist from Salt Lake City and she is here at the request of and on behalf of her CFS patients. In her practice, she has 20 patients taking Ampligen. She did her medical training at the Johns Hopkins School of Medicine and has been practicing for nine years.

In 2000, she redefined her clinic as a fatigue consultation clinic and has since seen 700 patients, of which most have CFS or FM. From this group, 20 patients were selected for the Ampligen 516 study, and all 20 patients completed every aspect of the study. There was no compensation for this study except for the ability to receive the drug. The drug was administered twice per week, and there were significant side effects, such as discomfort and flu symptoms. The study consisted of 12 weeks of a baseline study, 40 weeks of double-blind, placebo-controlled administration, and 24 weeks of open label—50 percent of the patients received placebo in the 40-week administration.

Dr. Bateman added that her patients have said that they have improved on this drug and that this is the best intervention she has seen in terms of function improvement. Dr. Bateman did not have access to the data; however, it was clear who was receiving the drug. She saw a clear plateau of those receiving the placebo and a clear improvement in a majority of those receiving the drug.

When the study was completed, eighteen of the 20 patients agreed to continue receiving the drug. Among these patients, there is a CPA, two nurses, two social workers, a financial consultant, a veteran pharmaceutical representative, two students, and two housewives. Nine patients showed definite improvement and six patients were on the drug for too short of a time to show significant improvement. Response to this drug is slow. Those patients who were on placebo during the study and participated in the open label may not have been on the drug long enough to show signs of improvement.

Dr. Bateman noted that Ampligen is an effective intervention for CFS patients. Her patients would like to see this drug approved by FDA as soon as possible. Additionally, this drug should be made available to those patients who responded to it; once the drug was removed, their progress was lost. Two of her patients were planning to attend this meeting, but could not attend due to financial reasons and illness from relapse off the drug.

Lastly, Dr. Bateman added that she would like to see a larger effort made to understand why this drug works. This drug provides powerful evidence for the nature of CFS. She then asked if there were any questions.

Dr. Fields asked if there were any conflicts of interest regarding this drug.

Dr. Bateman noted that she was the principle investigator on the study, so that would be the only conflict.

Dr. Fields noted that drug approval processes are not discussed publicly. For the public, there are links on the website for this type of information. However, specific details will be difficult to discuss here.

Dr. Cavaillé-Coll thanked Dr. Bateman for her comments and noted that he has received numerous emails and letters from the Salt Lake region. Someone from the FDA Office of Special Health Issues has contact with one of Dr. Bateman's patients to provide some information on the review process. FDA cannot confirm or deny the existence of a new drug application or an IND. However, if and when FDA receives a new drug application for CFS, it will give it all of the consideration that it deserves.

Dr. Bell asked if the decision to provide the drug after the study was up to FDA or the manufacturer.

Dr. Cavaillé-Coll clarified that investigational drugs can only be used under an IND. There are many different ways in which a company might make products available after a clinical study, which is up to the company. However, companies are not obligated to do this. Study AMP511, which was allowed to proceed in May 1997, allowed patients, who were not eligible for the controlled study, to have access to Ampligen. The company has also stated that patients who have completed study 516 would have the opportunity to enroll in protocol 511.

Dr. Bateman noted that her group was approved for the 511, but many of her patients are unable to afford the drugs. She would like to see other mechanisms for patients who cannot afford the drug.

Dr. Cavaillé-Coll added that the FDA authorized the company to charge for the drug on a cost recovery basis. The company is not allowed to promote, advertise, or make a profit.

Dr. Gantz asked about the toxicity of the drug.

Dr. Bateman responded that they had no significant toxicity.

Dr. Gantz asked if the patients were able to recognize whether they were receiving the drug or the placebo through side effects.

Dr. Bateman answered that some of the patients were able to recognize the drug.

Dr. Patarca acknowledged and congratulated Dr. Bateman for her contributions to the Education Subcommittee. He commented that Ampligen was stagnant for many years, yet appears to be coming back through these studies. He asked why this is happening and if this was initiated by investigators or the company.

Dr. Bateman noted that she does not have those answers.

B. Steven Du Pre

Mr. Du Pre was unable to attend and his testimony was read by Elsie Owings. Ms. Owings noted that she will be reading two additional presentations, Victoria Bell's and her own. She then read Mr. Du Pre's testimony.

It is time to make primary changes in the way this disease, Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS) is treated, named, and categorized in clinical and research arenas. I say this first because definitive physiological abnormalities are detected in ME/CFS patients, and second because there is realization by researchers that problems with the case definition of CFS confuse research and make it unsafe clinically.

In clinical and research context, the following has become clear:

1. A definition that relies on "fatigue" does not represent the experience of those whose major symptoms are neurological and immunological.

2. A neurological disease, ME was hijacked by CDC perfunctory epidemiology in 1988 and by the semantics about fatigue, resulting in nonsensical categorization of "fatigue" terms—that is, CFS is treated as a subset of chronic fatigue and chronic fatigue is treated as a subset of prolonged fatigue. Now we see plans to subsume ME/CFS in the broad category of "fatiguing illnesses." The consequence of this is that therapies that may help others will significantly harm those with the distinct disease ME/CFS, where metabolic abnormalities in brain and muscle composition and enterovirus sequences in muscle cause the disease to become more grave in both scope and in loss of functionality.

3. The clinical and research use of "CFS" and the broad Fukuda definition have blocked efforts to properly treat large patient cohorts and reproduce research findings, both the core of scientific investigation. In addition, the name "CFS" and the Fukuda definition have worldwide negative impact. Seymour Grufferman, MD, formerly of NIH, noted that you are not going to get a fair shake if you call this 'chronic fatigue syndrome' because that carries with it a judgment.

Two focus groups conducted a focus group designed to detect perceptions about CFS in September 2003 with 20 primary care physicians. A typical quote from one physician:

> CFS is a lay diagnosis. I will not legitimize an illness that is not backed up by fact. CFS is not a fact; cancer is a fact.

Few physicians are aware of the objective, multi-systemic dysfunctions in ME/CFS available in peer-reviewed medical journals. Most physicians will not let go of this bias, and no amount of education programs about "CFS" and "fatigue" sponsored by the government will aid those with ME/CFS.

We know that CFS is not viewed as a legitimate disease by most physicians and medical institutions, resulting in the universal experience of ME/CFS patients receiving inattentive and poor medical care, once the name "CFS" is spoken or appears in a medical record. Thus, most are harmed more than helped by the name. Even aware general practitioners do not recognize the gravity and truly disabling nature of this disease—not just the myelopathy and weakness, but also the post-exertion illness and worsening of pain and other symptoms that are the punishment for that exertion.

Recommended actions include:

1. Dissemination of information in ME/CFS studies detailing biomarkers in ME/CFS patients' blood and evidence of clearly reproduced abnormalities to the media, the general public, and the medical community.

2. Recognition of ME, as classified by WHO, as a neurological disease with its own diagnostic criteria. Use of Myalgic Encephalomyelopathy, approved by WHO with the proper neurological ICD classification, as common language, would also be acceptable in clinical and research settings.

3. Adoption of the clinical working case definition in the Canadian consensus criteria for ME/CFS, assembled by a team of experts, with primary emphasis on ME, acting as a simultaneous replacement for CFS.

C. Dr. Beverly Bugos

Dr. Bugos provided the following testimony.

So much important information has been written recently, such as the petition created by the ME/CFS patient community, written by Elsie Anne Owings and signed by over 850 people and counting, and the "Information of ME/CFS," posted by Jill McLaughlin on the 21st of September, which was not sponsored by NCF, but is accurate and important.

I would like you to take a moment to look at the big picture. If this committee thinks its charter is to look at any disease that has fatigue as one of its symptoms, then you will not finish in any reasonable timeline. I understand that you are called upon to look at CFS. CFS was called ME until 1988, when some people in the United States changed it to CFS.

Currently, the United States is behind other technologically developed countries in terminology, official criteria, and research efforts for ME/CFS. Why is this? It is because you continue to focus on the word "fatigue." It has been said many thousand times that "fatigue" is a problem name. It is not a medical term and it is not a disease, but one of the symptoms of a disease.

It is as if you are trying to study chronic pain syndrome. Many diseases have pain. To study chronic pain is one thing; to study a disease that has chronic pain as one of its symptoms is very different. Cancer is an excellent example. You have chronic pain with cancer, but you need to look at the disease to help relieve those symptoms.

Are you looking at ME/CFS with the 12-year-old ICD10 codes and under G93.3, a neurological disease? Alternatively, are you studying all of the diseases with symptoms that have chronic fatigue? Is your mandate to study a symptom of many diseases or a disease? Are you trying to study chronic pain/chronic fatigue management? On the other hand, are you trying to find a cure and more understanding for this disease that has devastated us so much?

It has been my understanding that you are to study the disease. Until you direct your attention to this issue, you will be going in a thousand different directions at once. Money will be wasted and patients will not be helped.

D. Victoria Bell

Elsie Owings read the following testimony of Ms. Bell.

In this country, there exists a grand epidemiological divide, partitioning the United States into not just the two Americas currently in political-speak vogue. There is a

third divide—victims of the disease ME, many homebound, are literally "home alone" in the third America. This third America is characterized by the co-infection of structural violence—abusive silence from federal health agencies and professional advocates; extreme and relative poverty and inequality; lack of access to disability benefits; and the concomitant lack of access to medical care, insurance, competent testing, treatments, food, housing, and the basic civilized human soul needs of social integration, loving kindness, dignity, and respect.

In the words of Dr. Paul E. Farmer, Chief of Harvard Medical School's Social Medicine and Health Inequalities Division at the Brigham:

> From the point of view of a physician, it seems obvious that tackling poverty and inequality is central to any good-faith effort to protect the rights of the poor. The terrorism of money thus far evades and is abetted by existing legislation. It may well prove to be the biggest threat to recent gains in both health and human rights.
>
> …unpromising are approaches that rely solely on appeals to governments. Careful study reveals that state power has been responsible for most human rights violations and that violations are usually embedded in contexts rife with structural violence…[that is] social and economic inequities that determine who will be at risk for assaults and who will be shielded from them.
>
> I argue that equity is the central challenge for the future of medicine and public health…Drawing on the work of many, I underline the pathogenic role of inequity.

Structural violence inequities abound against victims of ME. They include:

1. CDC is the protagonist of structural violence and abuse of state power globally. The compounding CDC actions of outright dismissal, circa 1985, of misnaming in 1988, and of current continual broadening and deliberately obfuscating definitions based on a non-defining fatigue model inclusive of myriad chronic illnesses, have created an absolute void into which have fallen those with the discrete pandemic disease ME.

2. DHHS Secretary Tommy Thompson announced on primetime television, several months ago, a crisis of obesity—for many, though not all, brought on by the excesses of an affluent, narcissistic, couch-cuddled, and inappropriately industry-licensed culture—meanwhile continuing the long-standing human rights abusive silence towards victims of the disease ME.

3. The dearth of funding at NIH.

4. Despite reported corrective efforts, it is a fact that the Social Security Administration (SSA) continues, by denial of benefits, to commit ME victims to poverty. This makes SSA one of the leading perpetrators, guaranteeing and setting in motion the ensuing forms of structural violence.

   A PWME, who testified at the December 2003 CFSAC meeting, gravely ill since 1991 with a two-inch case file, was denied SSDI on August 2004, without a full review of her complete file. For lack of money, continuing any medical care and treatment is impossible, and, as documented in literature and expert clinical practice, she is making herself more ill by appealing this denial and struggling to work, simply to put food on the table, while sliding deeper into the abyss of poverty—a travesty for which there is no excuse. This is one in thousands of similar SSDI cases.

   Deeply disappointing were the focus and findings of the CFSAC Disability Subcommittee's June 21 report. It was acutely lacking in investigating the uneven granting of SSDI awards, not only state-by-state, but jurisdiction-by-jurisdiction. As evidenced in the above-mentioned case denial, advice to perilously ill and cognitively-challenged ME patients regrettably relying on SSA representatives for help in making their applications—on a woefully inadequate form for this multi-systemic disease—is, at best, inconsistent and, in this case, as well as others, completely lacking in efficacy.

Dr. Paul E. Farmer wrote, "When it is a matter of telling the truth and serving the victims, let unwelcome truths be told. Those of us privileged to witness and survive such events and conditions are under an imperative to unveil—and keep unveiling—these pathologies of power."

Dr. Desi noted that SSA, by statute, has certain criteria by which it has to evaluate applications for disability. Part of that statute and subsequent regulations include symptoms and laboratory findings, not symptoms alone. There is a specific SSA ruling that provides guidance for the evaluation of claimants who state they are disabled because of CFS. Things sometimes go awry, but the process provides specific guidance on how these individuals are to be evaluated. When someone is denied, there is a specific process for appeals.

Ms. Owings responded that the SSA form is not well adapted for CFS. The forms include questions about arm and leg mobility. CFS patients can move their arms and legs. However, they can only do this for a short period of time. As a result, they are not employable. Their functional hours are so limited that they are disabled. Yet, this is difficult to convey on SSA forms. Additionally, the SSA forms requires laboratory finds for benefits approval. However, CDC states that there are no laboratory findings that are acceptable for CFS.

Dr. Desi noted that there are a number of diagnostic studies that are being looked at. The absence of positive diagnostic studies would tend to indicate CFS as an explanation. The other problem is that CFS is a syndrome, a constellation of symptoms, for which they do not know the pathophysiology. As a result, they do not know if it is a single disease.

E. Edmund (Ed) Jalinske

Mr. Jalinske noted that this is his first CFSAC meeting and provided the following testimony.

I have known many of you only on paper and on websites. It is a pleasure to see your faces here in person. I am a law student at George Washington University and I represent a small percentage of people who have significantly recovered from CFIDS. Four years ago, I came down with a mono-like illness, which is a typical trigger for many people with this disorder. Subsequently, I was faced with having to see numerous doctors.

I figured out what was wrong with me by Googling it. Unfortunately, that speaks to the fact that there is not a lot out there. People have to be very proactive in this process, which is unfortunate. Over two years, I saw 15 doctors. All of them told me that it was all in my head. I have been an athlete all of my life. I was a Division 1 tennis player. I was recruited by a baseball team. When you are an athlete, you get to know your body in a certain way, such as muscle memory. As an athlete, I knew something was wrong. The fact that I had to go out there and seek things out on my own, with no help or guidance from anyone, was terrifying.

I do not know what to talk about in terms policy because I am not as well read and learned as the previous speakers. However, I would like to make it known that I am in this for the long haul. I would like to be an advocate for young people suffering from CFIDS. I am here to learn more and to share my own tale. I am sure that you know that this is a wide-ranging disease. It affects people from all walks of life, to varying degrees.

My illness was probably one of the more benign forms, though not initially. For whatever reason, my body responded positively to the disorder and I am at 95 percent now. I am well enough to go to school fulltime and teach tennis.

Many young people struggle with this disease and there needs to be more support. I am looking for anything anyone on this committee can suggest about increasing awareness among young people. I know that there is some information out there, but there is not enough, given the number of people with CFIDS and the epidemic proportions of this condition. Young people would benefit greatly from having the support of doctors.

Dr. Gantz asked Mr. Jalinske where he was living when he became ill.

Mr. Jalinske responded that he was in Madrid.

Dr. Patarca asked which results from Googling were most helpful.

Mr. Jalinske commented that finding a specialist in New York City was most helpful. His current physician is Dr. Richard Firshine. He is able to function on a relatively normal level with the aid of medication, such as stimulants and sleep aids. However, he still stuffers from neuro-cognitive impairment.

Dr. Patarca asked if he joined a patient support group.

Mr. Jalinske joined CFIDSAA, which has been helpful for information. Internet resources are helpful, but only to a certain extent. He added that the information is not targeted to younger people.

Dr. Bell noted that there are two relevant areas that will be discussed. First is the Centers of Excellence, which will allow people to get help easier. The second is the recommendation related to helping children.

Dr. Gantz asked Dr. Desi to bring the SSA criteria for CFS to the next meeting.

Dr. Desi replied that he would and that the criteria was also on SSA's website.

V. Recommendations Status

Dr. Bell reviewed the process of how the recommendations were formed. The recommendations were developed in a public process and at the last meeting, CFSAC came to an agreement on the recommendations. Afterwards, the wording of the recommendations were fine-tuned. However, the essential intent and meaning were not changed. The recommendations were made in a three-page letter to Dr. Beato, sent on August 23.

Dr. Fields added that Dr. Beato would forward the recommendations to the Secretary. The Secretary then reviews the recommendations and follows on from there.

Dr. Bell noted that the recommendations were essentially unanimous. Everyone voting member of CFSAC provided input into drafting the recommendations and there were no major disagreements on specific issues. Dr. Bell then read the introduction of the letter, followed by each of the recommendations.

A. Recommendation 1

We would urge the DHHS to direct the NIH to establish five Centers of Excellence within the United States that would effectively utilize state-of-the-art knowledge concerning the diagnosis, clinical management, treatment, and clinical research of persons with CFS. These Centers should be modeled after the existing Centers of Excellence program, with funding in the range of $1.5 million per center per year for five years.

Dr. Bell commented that this is the heart of the recommendations. When a primary care physician (PCP) has a patient for whom he is unable to treat a particular malignancy, he can send that patient to a Center of Excellence (COE). If a COE is not available, the patient could feel neglected or disrespected because the PCP is unable to help. When a COE is available, the patient receives the needed treatment, and the PCP is kept up-to-date on the progress of the patient by the COE. It is essential for PCPs to have a mechanism in place whereby patients can go to receive state-of-the-art treatment. He added that the main limitation of the previous centers program was that it did not have a clinical component, which is essential. Though the recommendation does not specify a clinical component, it states that the COEs should be modeled after existing COEs, which have a clinical component.

Dr. Patarca added that the COEs should also include an educational component, which should be a requirement for funding.

Dr. Robinson asked if the existing COEs have an education component.

Dr. Patarca responded that it was not part of the model. He added that these centers should not operate as isolationist centers, which was one of the problems with the previous centers. Competition is a good driving force, but we need center integration; we need them to share samples and methods. Another important issue is the accountability of these centers.

Dr. Gantz commented that education is not specifically mentioned in this recommendation and asked if the letter and recommendation should be modified.

Dr. Bell responded that his understanding is that CFSAC was not going to micromanage each of the recommendations and intentionally left out the details. However, CFSAC can refine the recommendations. If they receive notification that a recommendation will be acted on, CFSAC can provide further comments.

Dr. Barrett noted that DHHS might also want to look at centers established by the Department of Veterans Affairs. These centers have an education, a clinical, and a research component. They also have collaboration among the different centers.

Dr. Patarca added that this model also integrates social workers, addresses disabilities, and many other patient issues. He noted that from the beginning, CFSAC discussed having a vision for the whole field. However, he does not believe the recommendations clearly reflect their vision.

Dr. Bell commented that CFSAC addressed the issue of whether it should be aggressive and detailed, or whether it should be broad and general; the latter was chosen. If the recommendations are acted on, CFSAC will be able to provide opinions that are more detailed.

Dr. Mohagheghpour noted that if all of the details were added to the recommendations, they would be too long to be reviewed. Once the recommendations are approved, CFSAC can define the activities of COEs.

Dr. Patarca asked if the recommendations convey all that CFSAC has discussed.

Dr. Bell responded that the recommendations, though not inclusive of the full breadth of their discussions, convey the request for a substantial increase in support.

Dr. Patarca added that the recommendation reminds him of the previous centers. The recommendation does not differentiate the new centers from the previous ones.

Dr. Fields commented that his understanding of the discussions was for CFSAC to provide recommendations for where DHHS should place its emphasis. (CFSAC members received sample recommendations, some of which were detailed and some which were general.) Additionally, he noted that the current recommendations, rather than more detailed ones, are more appropriate for the Secretary.

Dr. Bell asked Dr. Komaroff for his comments on this recommendation, based on his experience with the previous centers.

Dr. Komaroff noted that the existing COE models are different from the previous centers and that the recommendation is fine as it stands.

Dr. Robinson asked if the previous centers were under a specific appropriation.

Dr. Hanna noted that those centers were funded by NAIDS.

Dr. Bell noted that it is not up to CFSAC to decide where the money comes from or how the internal politics are conducted.

B. Recommendation 2

We would urge the DHHS, through the NIH, to expedite the issue of an RFA with sufficient set aside funds to attract senior level researchers to engage in the study of

CFS. DHHS should fund extramural grants, reviewed by a special emphasis panel knowledgeable in CFS, through RO1, RO3, R21, and Directors Pioneer Award mechanisms.

Dr. Bell noted that this recommendation is not as specific as recommendation 1, but it is also asking for a substantial increase in attention to CFS.

Dr. Lapp asked about the specific funds for the upcoming RFA.

Dr. Hanna responded that the funds are reaching $4 million.

C. Recommendation 3

The DHHS should provide funds to develop an international Network of Collaborators that would allow for multidisciplinary CFS-related research using standardized criteria accepted by the international CFS research community. Such a network would pool a large number of patients from around the world and would require investigators to develop and employ common protocols.

Dr. Bell noted that this recommendation is already underway, which is headed by Dr. Reeves.

D. Recommendation 4

DHHS should provide support and funding for an intramural staffed laboratory committed to CFS research.

E. Recommendation 5

The DHHS should promote, encourage, and fund research directed toward the diagnosis, epidemiology, and treatment of CFS in children and adolescents.

Dr. Barrett noted that the Georgia study would be collecting data on the prevalence of CFS among children.

Dr. Hanna added that NIH has a five-year study of post-mononucleosis cases in adolescents.

Dr. Desi asked if the NIH study was retrospective or prospective.

Dr. Hanna replied that it is prospective.

F. Recommendation 6

The DHHS, through the CDC and NIH, should continue to sponsor, even accelerate, focused workshops in specific areas of CFS and to invite investigators not currently working on CFS who have been identified as having an interest in the illness.

Dr. Bell noted that it would become clear over the next two years whether these broad recommendations are being implemented.

Dr. Patarca asked if the recommendations were broad enough. He asked if they should be working on placing CFS in a broader category, such as chronic disease, rather than just funneling down to CFS in particular.

Dr. Hanna responded that that happens anyways. For example, the Rare Diseases Committee will deal with CFS in an upcoming conference.

Dr. Patarca commented that the recommendations seem to support efforts that are already underway, rather than creating something new.

Dr. Bell noted that the task for CFSAC for the next year is to work out the details.

Dr. Patarca asked if and how these recommendations, if acted on, are going to change the negative perceptions in the field of CFS. How will the results be measured? Will working on CFS hurt an academic's career? Will CFS patients receive treatments that are more respectful?

Dr. Fields commented that the details of design, implementation, measurements, and metrics could be determined after the general recommendation is accepted.

Mr. Sterling added that the COE program would generate more respect for CFS and its patients.

Dr. Friedman noted that he has concerns similar to Dr. Patarca—how does one get national attention to this problem? In the era of Sputnik, the United States believed it was lacking in science. In response, the federal government announced a new program, the National Defense Education Act, to entice young people into careers in science. An effort of this magnitude is what is needed to resolve the gap in CFS funding.

Dr. Patarca added that there needs to be a lot of work done in thinking of the driving force and vision of these recommendations. Additionally, there are many questions and issues that need to be addressed. For example, what effect will COEs have on existing CFS clinics? Will it alienate them? Will there be turf wars? How will the centers be selected? These questions need to be addressed because they will affect the direction and efficacy of the centers.

Dr. Bell noted that the committee should wait until a decision is made before discussing Dr. Patarca's questions.

Dr. Patarca noted that he disagrees because the recommendations are not as strong as they could be if there was a better vision. Anyone could have come up with the wording of the recommendations without having five meetings. The recommendations are sound and useful, but they need to be supported by a vision and details that support the vision.

Dr. Fields suggested that the committee first deal with whether the recommendations should be forwarded to the Secretary. If the answer is yes, the committee can then deal with the details and hypotheticals. He added that hypotheticals could be useful in guiding constructs for a set of questions for which there are no direct answers, as long as it is constructive. Additionally, visioning is difficult and time consuming. He proposed that if someone wishes to discussion visioning, that person should suggest it as an agenda item.

Ms. McCleary added that the Coordinating Committees had a subcommittee to develop long-term, mid-term, and near-term goals, which she offered to share with the committee.

Mr. Sterling commented that the previous committee had an agenda subcommittee, which helped the chair coordinate agenda items.

Dr. Bell responded that this is an excellent idea. He will ask for ideas for the next agenda and set it in advance.

G. Recommendation 7

The DHHS should pursue making CFS a topic of training for healthcare providers, wherever appropriate, at regional and national conferences sponsored by the Department.

H. Recommendation 8

The DHHS should encourage continuing education for Social Security reviewers and adjudicators. The secretary of DHHS should recommend that adjudicators follow the Social Security Policy Ruling 99-2P, which specifically clarifies policies regarding CFS.

Dr. Desi noted that SSA is currently providing training on a regular basis. Additionally, since SSA is not part of DHHS, he is not sure how this recommendation would be accomplished politically.

Dr. Fields commented that it would be possible for the leadership at DHHS to talk to the leadership at SSA to encourage the continuing education. There are examples of this type of exchange.

Dr. Friedman asked if CFSAC should review the training materials for the SSA reviewers and adjudicators.

Dr. Bell asked if it was their job to put forth recommendations or to be more active.

Dr. Patarca added that it would be important to receive feedback from other agencies about the viability of the recommendations.

Dr. Bell noted that CFSAC has been actively seeking input from ex-officio members.

I. Recommendation 9

The DHHS should increase public education on CFS through a public awareness campaign. Discrimination in healthcare, education, and the workplace should be actively confronted.

Dr. Barrett noted that the CDC funding for the CFIDSAA public awareness activities is new money from the Office of the Director, in response to some of the CFSAC deliberations.

Dr. Desi asked if the recommendation dealt with education and legal activity.

Dr. Bell noted that the recommendation primarily focuses on education.

J. Recommendation 10

We would encourage the classification of CFS as a "Nervous System Disease," as worded in the ICD-10 G93.3.

K. Recommendation 11

The DHHS should consider participation of the Department of Defense, Department of Veterans Affairs, Agency for Healthcare Research and Quality, and the National Institute of Disability and Rehabilitation Research as ex-officio members of the CFSAC for future deliberations of recommendations.

L. Discussion on Recommendations

Dr. Komaroff noted that CFSAC has not received a formal response for its March recommendation on the CDC slots. He hopes that such a response is forthcoming.

Dr. Desi commented that Dr. Reeves has indicated that those positions are ready to be filled.

Dr. Fields added that there was a letter from the chair acknowledging the recommendation.

Dr. Bell noted that there has not been a letter regarding action.

Mr. Sterling commented that the chair of CFSAC could request a meeting with the Secretary to discuss the intent, scope, and purpose of the recommendations.

Dr. Gantz moved to approve the recommendations. The motion was seconded and all voting members approved the recommendations.

Dr. Bell noted that he would meet with anyone from Dr. Beato's or the Secretary's office to discuss the letter in detail. He asked the committee if a meeting should be requested and who from CFSAC should attend the meeting. There was a general consensus that this was a good idea and that all CFSAC members should attend.

Dr. Bell noted that he would draft a letter requesting a meeting with the full committee once he receives notice that the recommendations were received.

VI. Public Comments—Part 2

A. Elsie Owings

The following testimony was provided by Ms. Owings.

My name is Elsie Owings and I am from Western Michigan. I have had CFS for 16 years and I am not normally involved in advocacy. Recently, I wrote a petition and was asked to come here to present the petition. However, I will not discuss the petition. Instead, I will discuss why I was motivated to write the petition.

CFSAC is an advisory committee and does not set final policies. Those policies are set by higher agencies, and patients have experienced a harsh reality with this process. We hear about case definitions that are based on empirical evidence, and patients face the reality that CFS is intentionally being drowned in a sea of fatiguing illnesses.

This is the result of those who would abuse the system to get money for projects that have nothing to do with CFS. We are all aware of a psychiatric group in England that has broadened the definition of CFS to obtain a large amount of money to promote CDT and exercise therapy. In the last few months, it is increasingly clear that this psychiatric approach has successfully crossed the Atlantic Ocean and become the pervasive approach of the mainstream medical profession.

For example, you can go to the Medscape website and get CME credit for a course on pediatric CFS, which assumes that the children are perpetuating their illness with de-conditioning and a fear of exercise. The Dr. Donahue advice column also purports that exercise is the cure for CFS. Additionally, the University of Michigan is staring a clinic for fatigue studies, including CFS. They have also stated that exercise is vital. This exercise approach has overtaken mainstream medicine. This is why patients harp on the name and criteria.

CFS patients fear what may happen if the specifics of the CFSAC recommendations are not fully discussed. Dr. Bell has recommended a broad-stroke approach, however, patients have had bad experiences when a broad-stroke approach is applied. I hope the standardized criteria are developed before the recommendations are implemented. Otherwise, CFS ends up getting lost in a sea of fatiguing illnesses.

The integrative approaches, which is assumed to be neurological, endocrine immunological, ends up being psychiatric. CFS may be the topic of training for healthcare providers, but on what will they be trained? Is it going to be the same garbage training as in the CME classes? The reason patients harp on the name and criteria is not respect, but research. They do not want the COEs to diminish their disease.

Dr. Bell noted that CFSAC needs feedback on materials currently being discussed. While it respects written statements, it encourages the public to provide comments of currently discussed issues, as Ms. Owings did.

Ms. Owings commented that this is best encouraged by providing the public with the information during the discussion period, before votes are taken. It would also help to allow the public to communicate with CFSAC outside of these meetings, since the majority of CFS patients cannot attend these meetings.

Dr. Patarca noted that this is a dynamic process. Nothing is set in stone and the committee incorporates feedback.

Ms. Owings added that when CFS is lumped into a larger category, funding for CFS is in effect reduced.

B. Dr. Mary Schweitzer

Dr. Schweitzer noted that she is happy to hear that the charter has been renewed. She added that the committee has good group dynamics and that the members are working well together. She hopes that many of the members continue to serve on the committee.

Dr. Schweitzer commented that when she was sick, back in 1998, she did a study and found that lost productivity due to CFS was $8.3 billion. One of the reasons there is a jobless recovery is because people with chronic illnesses, such as CFS, cannot work in the prime of their lives. Therefore, we are having trouble recovering from the recession. In other words, one third of that amount is lost revenue to the federal government. This argument will go further than arguing for the care of these patients.

Dr. Schweitzer commented on the international collaboration on CFS. The British use CFS to mean something that involves ten times the number of people compared to U.S. definition. Michael Sharp has commented that his definition of CFS includes ten times the people compared to CDC's definition. This is a problem that must be addressed in any international collaboration. For two years, a group in Canada worked on a new definition and concluded that they had to use ME, as well as CFS. CFSAC should talk to this group.

She noted that she has been on Ampligen since 1999. Before this drug, she would attend meetings in a wheelchair. After she spoke, she would have to lie down and rest. She remembers having certain markers; she had all the symptoms of encephalitis, except the fever. In Europe, she would have been diagnosed with encephalitis, but here in the United States, the absence of a fever would rule out this illness. Within six months of taking Ampligen, the markers have disappeared.

She added that there are many things about CFS that is not discussed in this setting. For example, no one talks about an exercise study that showed that within three minutes, a person with CFS would go from aerobic to anaerobic metabolism. In addition, there is a trick that has to do with putting one foot in front of the other, putting your arms out, and closing your eyes; a person with CFS would fall over.

Dr. Bell noted that these are complex issues.

Dr. Schweitzer responded that these are all things we know, but do not get used. She asked CFSAC to direct CDC to put on its website and include in its research, research done by other professionals published in peer-reviewed professional journals. CDC is insular; if they did not do it, they do not believe it exists. This is what happened with anthrax in Miami. There is good research out there that has been published. CDC's job is to disseminate information. Information that is in good peer-reviewed journals is usable information.

C. Edmund (Ed) Jalinske

Mr. Jalinske asked Dr. Bell why he would rather focus on the educational aspect in recommendation 9, as opposed to the legal perspective.

Dr. Bell commented that he did not realize that it was an either/or condition and that the recommendation was meant to emphasize education on CFS.

Dr. Patarca noted that the idea was that discrimination is mainly based on ignorance. If the ignorance were addressed, then the discrimination would possibly go down. There could be legal action, but that was not within the realm and expertise of CFSAC.

VII. Planning and Action Steps

Dr. Bell asked how many meetings were needed between now and next September, and the committee agreed to hold quarterly meetings. The next meeting will be held on January 10, and Dr. Bell asked the members to email suggestions for the agenda. He will then distribute the agenda within the next month. The following meetings will be held in March or April and in September.

Dr. Bell asked if there were any subjects members would like to discuss.

Dr. Komaroff proposed an action step for the NIH funding. There is some concern as to how well NIH activities are accurately associated with CFS, in both directions. This committee should look at some of the 12 CFS projects that may not have been relevant to CFS. CFSAC could form an independent judgment and work on a proposal that would guide NIH in determining CFS grants, through a subcommittee.

Dr. Bell noted that CFSAC is not an oversight committee and asked if this suggestion would run into the definition of an oversight committee.

Dr. Komaroff responded that this could be viewed as advice.

Dr. Fields recommended that CFSAC could look at this issue during the NIH ex-officio portion of the meeting.

Dr. Bell asked for volunteers for a subcommittee to look at this issue for the next meeting.

Dr. Fields clarified that this would be beyond the Research Subcommittee and would be either a new subcommittee or an ad hoc committee. A new subcommittee would have to be justified.

Dr. Bell commented that this would be an ad hoc committee, looking at an issue for one meeting. He then motioned to form an ad hoc committee to look at the criteria for classifying NIH-funded projects. He asked Dr. Gantz, Dr. Hanna, Ms. McCleary, and Dr. Komaroff to be members of this committee. All voted in favor of the motion.

Dr. Mohagheghpour asked for the names of the 12 grantees that are in question.

Ms. McCleary noted that they are listing on page 40 of her full report.

Dr. Field commented that CFSAC should consider a mix of topics and presenters for the next meeting.

Dr. Bell suggested having an invited speaker to discuss the topic of CFS and children. They could invite a professional and also a representative from a support group.

Dr. Patarca added that he would like to see clinical research and education as part of this discussion.

Dr. Lapp suggested having Dr. Reeves present on the NIH/CDC collaborative affair, as well as the Coordinated Research Network (CRN).

Dr. Bell added that this is different from having an invited speaker. He noted that there is a gap between pediatric researchers and pediatric patients. He would like to have presentations from both sides.

Dr. Patarca asked Dr. Bateman to make a formal presentation on her experiences.

Dr. Bell motioned to add these presentations to the agenda. All voted in favor of the motion. Regarding the speakers, the professional side could be a published researchers or a general practitioner. He added that the main discussion would involve how the definition of CFS in children by the CDC and academic standards is different from the patient's view.

Dr. Lapp recommended Peter Roe as a speaker.

Dr. Bell added Mark Smith as another potential speaker. He noted that he would ask Peter Roe to present an overview of the academic perspective. He then asked for suggestions for the patient representative.

Ms. McCleary recommended Rebecca Moore.

Mr. Sterling recommended Beth Warren, who is a youth trustee on a New Jersey CFS association. He also recommended encouraging the public testimony portion to focus on pediatrics.

Dr. Bell added Mary Robinson as another possible presenter. He will asked Rebecca More to represent the patient perspective.

Dr. Friedman noted that there were a couple of unfinished items on the education agenda report. Regarding the involvement of other healthcare practitioners in the initial screening of CFS, ADA has offered to publish criteria for diagnosing CFS so that dentists can act as screeners. The other item is the need for educational material, to be produced by DHHS, for physicians on diagnosing CFS.

Dr. Bell asked about the role of this committee in terms of educating ADA and dentists. Is it our job to educate or to identify and guide others within DHHS to do the educating?

Dr. Patarca added that the Education Subcommittee sent 25 letters to professional societies to get feedback for the recommendations. Only those that were personally approached by Dr. Friedman responded (ADA and AMA). Since so few associations responded, it is important to involve those that did respond. This may lead to more associations getting involved.

Dr. Bell commented that he is concerned about deviating too far from the stated objectives. He asked if there was a mechanism to carry out this suggestion.

Dr. Patarca suggested writing a recommendation to DHHS and bringing these associations to the meeting.

Dr. Bell asked about adding them as an agenda item.

Dr. Friedman noted that this would be an appropriate thing to do, but is concerned about what they will ask in terms of what CFSAC expects from them. Answering this may be beyond the CFSAC's mission. However, CFSAC should set up a framework for other healthcare providers.

Dr. Mohagheghpour asked if individuals from medical schools should also be invited.

Dr. Patarca noted that they did not respond.

Dr. Friedman added that the AAMC would not respond. Medical schools are in control of their curriculum, and the AAMC will not intervene. Additionally, medical schools do not want to single out any one disease.

Dr. Fields reviewed the charter and noted that CFSAC is to advise and recommend, as oppose to taking action.

Dr. Bell asked if there was a consensus to invite representatives from these associations.

Dr. Gantz opposed the suggestion. He does not see the dental community as primary screeners; gynecologists would be better screeners. The ADA should not be chosen simply because they responded.

Dr. Robinson added that it would not be productive to invite the ADA for that type of discussion.

Dr. Patarca noted that dentists are good primary screeners for other illnesses.

Dr. Bell asked if the Education Subcommittee could look at the possibility of inviting three separate associations for the spring meeting.

Dr. Komaroff added that actually inviting gynecologists and neurologists would be more effective than just sending a letter.

Dr. Bell noted that each of the presenters would speak for 20 minutes on how they see the illness and how the federal government could help them.

Dr. Friedman introduced the topic of the role of other government agencies and the coordination of the federal government's response to CFS. He would like to see DHHS take the lead, but not exclusive, role in leading a campaign to eliminate CFS.

Dr. Bell commented that this would be like declaring war on cancer.

Dr. Robinson reintroduced the story of Sputnik. He added that the decision to focus on science was not announced by an agency secretary, but the president of the United States, with the backing of the Senate and House. However, this is a smaller scale, with just one major department. Additionally, this is also a time when the budget is not tuned towards putting lots of money into CFS. One thing the committee can do better is to bring partners with resources to the table, including Medicare and Medicaid.

Dr. Bell noted that the committee would need feedback on the recommendations from the Secretary before it can begin to define its role in the coming year.

Dr. Friedman recommended that the committee charge ahead until it is pulled back. The problem demands immediate attention, and the more work it does, the more convincing it will be to the Secretary.

Dr. Mohagheghpour suggested that the committee could be proactive and consider how it is going to evaluate and monitor the progress of the recommendations.

Dr. Bell added that the COEs have a built-in review process.

Dr. Mohagheghpour responded that she is considering an external review.

Dr. Bell commented that the subcommittees could look more closely at the progress of the recommendations.

Dr. Hanna added that all existing centers are monitored. The RFAs have specific guidelines for what they are expected to produced. Each year, an outside committee evaluates their products. The overall plan for NIH is to have a model for evaluation for all centers.

Dr. Bell asked if this topic could be looked at by the Research Subcommittee on an ongoing basis, after they hear from the Secretary.

Mr. Sterling asked about the step-by-step process of the recommendations.

Dr. Fields responded that there is no defined timeline. However, the pathway is that the recommendations go from CFSAC to Dr. Beato, and from Dr. Beato to the Secretary. What the Secretary will do is not known.

Dr. Robinson noted that the Office of the Secretary might contact other agencies to get feedback on the recommendations.

Dr. Fields reiterated the fact that there is no defined procedure.

Dr. Bell added that if there is no response in two months, he would send a letter to request a meeting.

Dr. Fields commented that he would give a status report in that timeframe.

Ms. McCleary asked what would happen to the recommendations if a new Secretary is selected.

Dr. Fields answered that this is unknown. The expectation is that this will be handled in the same way the charter was renewed.

VIII. Adjournment

A motion was made to adjourn the meeting and all were in favor. Dr. Bell thanked the attendees for their participation and adjourned the meeting.