US Department of Health and Human Services

Chronic Fatigue Syndrome Advisory Committee (CFSAC)

Third Meeting

At

Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 800
Washington, DC 20201

March 22, 2004

9:00 AM to 5:00 PM

MEETING SUMMARY

Table of Contents

I. Members in Attendance

A. Voting Members

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

B. Ex Officio Members

- William C. Anderson, Office of Medical Policy, Social Security Administration (SSA)
- CDR and 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., SSA, Office of Medical Policy
- Dr. Eleanor Hanna, Office of Research on Women's Health, National Institutes of Health (NIH)
- Dr. William C. Reeves, Viral Exanthems & Herpesvirus Branch, NCID, CDC
- Dr. William A. Robinson, Center of Quality, Health Resources and Services Administration (HRSA)

C. Executive Secretary

- Dr. Larry E. Fields

D. Invited Speakers

- Patricia D. Fero, Wisconsin CFS Association, Inc.
- K. Kimberley McCleary (Kenney), The CFIDS Association of America (CFIDSAA) and Member, HHS CFS Coordinating Committee (CFSCC)
- Dr. J. Terrell Hoffeld, Scientific Review Administrator, NIH
- Jill McLaughlin, National CFIDS (Chronic Fatigue Immune Dysfunction Syndrome) Foundation (NCF)

II. Committee Members Absent

- Dr. Nahid Mohagheghpour (excused)
- Patarca anticipated

III. Chairperson

A. Call to Order and Roll Call

Dr. Bell welcomed and thanked Chronic Fatigue Syndrome Advisory Committee (CFSAC) members for their participation and requested the roll call. Dr. Fields completed the roll call.

B. Introductions

Dr. Bell asked Dr. Komaroff to introduce himself. Dr. Komaroff noted that he is at Harvard Medical School and has worked for many years on CFS research.

C. Minutes of the December 8, 2003 Meeting

Dr. Bell had two corrections to the minutes. First, in the vote regarding the name change, his recollection was that all voted in favor, except for Dr. Lapp, who abstained. Other members agreed. He also requested that “carbon dioxide” be corrected to “carbon monoxide” in Mr. Donnay’s remarks.

He then asked if other members had specific comments about the minutes. Ms. Stevens thanked HHS for providing the minutes earlier.

There was a motion to accept the minutes with these corrections. The motion was seconded and all voted in favor.

D. Opening Remarks

Dr. Bell reminded the voting members of the committee that the purpose of the meetings is to develop specific recommendations for Secretary Thompson to implement. He noted that Dr. Fields provided him with recommendations from other advisory committees as examples of what their recommendations may look like.

He noted that since this is the third meeting, he would like to put together some specific recommendations over the next 2 months. He asked that everyone keep in mind during the meeting that the materials discussed must be translated into specific recommendations.

He then brought up the issue of the name change. To clarify the process for the public, he noted that in the first meeting the recommendations from the Name Change Workgroup were presented to CFSAC. Since no one had seen those recommendations until that time, they were not discussed at the first meeting. Rather, the recommendations were reviewed after the meeting and discussed via email, which was appropriate for this committee to do. Through these discussions, the committee decided not to take on this issue as one of its major tasks. Therefore, they came up with a position paper, which was voted on at the second meeting. Ten people voted not to take up this issue, and one person abstained. The underlying assumption was that if there were new evidence presented or new issues brought up, the issue can be reopened at any time.

Dr. Bell asked if this issue should be reopened, noting that all the members of the committee have a free and open say on this issue, and that there has been no coercion as to their positions. He then asked if there were any comments on the reopening of the discussion on the name change. As a technical point, he noted that the previous committee was the CFS Coordinating Committee (CFSCC). The Name Change Workgroup was a subcommittee of that previous committee and CFSAC is completely independent of CFSCC. Subcommittees are only obligated to report to their parent committee. By looking at the recommendations of the Name Change Workgroup at the first CFSAC meeting, they went beyond norm—CFSAC is not the parent committee for that workgroup.

E. Discussion

Dr. Bell then asked if CFSAC should have its own name change subcommittee. He shared that at the present time he does not feel that the name change will be beneficial to the patient community. He believes CFS is a poor name and is inadequate in the

end. He hopes that when there is scientific basis for a new name, the change will come quickly, but believes that now is not the proper time for such a change.

Dr. Gantz agreed with Dr. Bell's comments. He explained that nothing has changed scientifically in terms of pathogenesis. While the name is inadequate, it would be a disservice to change the name now since it will change again in the future. Though the name is inadequate, it clearly defines a group of patients. Dr. Gantz voted for not visiting this issue again until more information is available.

Ms. Stevens noted that the committee decided not to take on the name change issue during the last meeting. Though she too does not believe the name is adequate, she concurs with that decision.

Dr. Friedman agreed and explained that it is not the province of this committee to change the name. His investigation on how diseases are named showed that diseases are not named by advisory committees, the Secretary of Health, HHS, or the federal government. Though he agrees that the current name is not ideal, he noted that, from the perspective of a researcher of CFS, it would be very injurious to change the name. A name change would generate confusion and invalidate all of the previous data and research since the definition of the disease would be different. A name change could put the advancement of knowledge, cures, and treatment of this disease back by 10 to 20 years. The setback would be more injurious to current patients than the discomfort they feel or rudeness they receive due to the name.

Ms. McLaughlin shared that in terms of patient advocacy that this is still the largest issue. She noted that she represents them, and it is difficult. She asked why HHS would form a WG if they cannot change the name.

Dr. Bell noted that it was CFSCC that appointed the workgroup, not HHS.

Mr. Anderson noted that HHS is in bit of a bind on the name change issue. He is an ex officio member of the President's Committee on Intellectual Disabilities. This committee did change the name of mental retardation to intellectual disabilities. Consequently, the idea that the President and the Secretary of HHS cannot change the name may be erroneous, since it has been done before. He is not advocating for one way or the other, but noted that the administration has changed names before.

Dr. Reeves explained that what the Secretary of HHS does for the United States does not translate internationally. Mental retardation is not an illness. The big issue is not the Secretary of HHS decreeing a name change, but providing recommendations and advice as to what will help the patients in the end. Additionally, a name change decree will not be accepted internationally, unless it is scientifically based, indicating the pathophysiology of the disease.

Dr. Fields clarified that the discussion should focus on the recommendations that come to the Secretary via the Assistant Secretary. In either case, the options are the same. They can have open discussion of different points of view, which is important for transparency. They want to maintain transparency. The other option is to discuss pros and cons and to have both sides of the issue represented and on the table.

IV. Executive Secretary

Dr. Fields welcomed CFSAC. He noted that this is the third meeting, which is well ahead of the anticipated once-a-year schedule.

A. Communications

1. Web Site

He noted that the CFSAC web site has launched. As of March 10, 2004, there have been numerous visits to the site. He asked that comments be sent through the site, as there are individuals who have been designated to receive and direct comments to the appropriate locations. He noted that not all comments would receive individual responses.

He shared some of the comments that they have received and complemented the support group that works with him to handle these messages. There was a question about whether the site was fully functional, which it has been since its launch. In terms of content, there have been messages regarding access to the address, the name change, case definition, education for the public and patients, research and global coordination, funding availability, contact information, and occasional advertisements. There have also been comments from people with disabilities who have shared their challenges as patients; they have been successfully referred to the SSA. They set up a system to acknowledge the receipt of messages and to provide support on these messages.

2. Listserv

Dr. Fields noted that the CFSAC listserv has been launched and is fully functional. The listserv provides an option for CFSAC announcements to be sent to all of the enrollees at the same time. As a result, they can move ahead on the phasing of announcements and information flow. The listserv and the web site provide opportunities to send and receive information.

He again complemented the support team and recognized the work of Mary Jo Deering and Mary Mullaney. He said they have been tremendous in helping to get the site designed and through clearance.

B. Policy and Procedure

Dr. Fields noted that they are open to suggestions in terms of policy and procedure. Based on input and suggestions, they have amended the current agenda to reflect this feedback. They divided the public comment period into two sections, since some individuals have less energy later in the day or have to leave early. This is in direct response to feedback.

C. Summary of Public Comments

Dr. Fields explained that they created a framework for the public comment period to ensure that everyone has an opportunity to provide either oral or written comments. Each individual is given 5 minutes to provide their comments. Written comments will be entered into the record, and if there is additional time, it will be dedicated to public comments.

He asked if there are any questions.

Ms. Kenney asked if a vote needed to be taken before making formal recommendations to the Secretary. Dr. Fields responded affirmatively.

Dr. Bell asked if the voting needed to be in a meeting setting. Dr. Fields said a meeting setting would be optimal because of the opportunity to discuss the basis for the recommendation and that the public would have a chance to hear viewpoints on the recommendations.

Dr. Bell noted that they should draft the recommendations before the next meeting to allow for discussions and voting at the next meeting.

Dr. Gantz asked if Dr. Fields has met with the Secretary to summarize the previous meeting.

Dr. Fields noted that the recommendations go to the Assistant Secretary, and he has provided an update on the proceedings to that individual. He noted that they have received feedback and encouragement for more frequent meetings. As a result, they have decided to hold quarterly meetings. He noted that it is clear that everyone is committed to moving forward in a way that leads to recommendations.

Ms. McLaughlin noted that the public testimony patients have asked about proxy speakers. Since some people are too sick to attend the meetings, she asked if there was a process for which their testimonies could be read by another individual.

Dr. Bell responded that as part of FACA, any written material is entered into the record, but it would be difficult to extend the 5 minutes allotted for each speaker.

Dr. Fields responded that each person has 5 minutes and can read testimonies provided by those who are too sick to attend the meetings. They want to make sure that everyone that attends has the opportunity to provide input. If all comments have been provided and there is extra time, there will be an opportunity for additional comments. At that time, individuals who have already taken their 5 minutes can provide additional input.

Ms. McLaughlin asked if the testimonies could be attached to the minutes.

Dr. Fields noted that testimonies are typically written into the minutes, but that they would consider attaching them. He then thanked everyone for their input and noted that he and his staff work diligently to make accommodations.

V. Invited Guest Speakers

A. Dr. J. Terrell Hoffeld: The Scientific Review Process, Scientific Review Administrator, NIH

Dr. Hoffeld welcomed the opportunity to speak to CFSAC. He noted that he recognized that the whole process of the awarding of research grants by NIH is a "huge black box." As a result, he is accustomed to giving presentations on the process, which range from 15 minutes to 2 hours. He hopes to keep today's presentation between these extremes because he does not want to overburden the committee with too many details. He encouraged the committee to ask questions during the presentation.

The Public Health Service was started in 1798 as a series of hospitals for sailors and seaman. Over the years, some of these hospitals developed their own laboratories. A hospital on Staten Island had an interest in doing research, thus it became an official function of that hospital. By 1937, when the first institute, the National Cancer Institute, was founded by an act of Congress, there were already five divisions of the National Institute of Health. When Franklin Roosevelt dedicated the Bethesda campus in 1941, it was still called the National Institute of Health.

The public began to recognize that this National Institute of Health did not provide enough coverage for various diseases. Therefore, in 1946, four institutes were created and the numbers have been growing ever since that time. Of the current institutes, almost all of them have the ability to fund extramural grant research. There are a few institutes, such as the Center for Scientific Review (CSR), that does not have funding authority and act only as service organizations.

Through the years, those independent divisions the first national institute, which were founded to conduct research, were charged with the responsibility of ensuring that research was being conducted on important areas of science. As a result, each institute developed an extramural program to fund scientists outside of the institute. The intramural programs are not assigned diseases and the scientists who are there are allowed to do research of their interests. Ever since Dr. Strauss left the bone marrow research program to become the National Center director, there has been no one to take his place in terms of doing research on CFS. As a result, these programs are no longer a major issue for CFS.

The extramural programs are responsible for awarding grants, contracts, and cooperative agreements. Grants are typically money given to an individual. These individuals are free to decide how to use the funds, but are becoming increasingly monitored. On the other end of the spectrum, contracts are awarded for a specific task and are very carefully monitored. In between these extremes are cooperative agreements, in which the government specifies the terms of the project. The recipient works under close supervision, but there is no expected outcome.

There are many differing ideas of the best way to fund research. As a result, there are numerous mechanisms in which research is funded. He presented a slide that showed the percentage of fiscal year 2004 NIH funding (totaling $27 billion) by mechanism. Research project grants (R01) represented the largest portion of the budget at 54%. Other mechanisms include research centers (9%), research training (3%), contracts (10%), and research management (4%). Intramural research is only 10% of the budget.

Dr. Bell asked if Centers of Excellence were included in the research center category. Dr. Hoffeld replied affirmatively.

There are three ways in which the government promotes research. The simplest approach is the program announcement (PA), in which institutes announce and encourage areas for research. Though the government is trying to encourage research in a specific area, there are no specific funds set aside for this approach. Applications are reviewed by the CSR along with unsolicited grant applications. The advantage of this approach is in the two-layer formal review process. After the scientific and technical review, there is a national advisory council review, which helps to advise the institute director in regards to the relevance to policy. If the institute declares that

they have some policy interest in this area of research, they can consider the application even if it does not score as well.

Another approach is the request for applications (RFA). An RFA is preferred by most researchers since it defines an area of research that one or more institutes are interested in conducting. It specifies the amount of funds that will be spent, and unlike the PA, the applications are reviewed by a Special Emphasis Panel (SEP) set up by the institute. The SEP is an ad hoc review panel that is given the specific criteria for the RFA. This one-time review may weigh heavily specific areas that may not even be considered during regular CSR reviews.

The third approach is the request for proposals (RFP). RFPs are similar to RFAs, except that the award that it given is for a specific contract. It typically involves very narrow, closely defined research, such as the application of new technology.

He explained that a few a years ago, NIH did issue a PA on CFS. Like most PAs, it was broad, but did express the interests of all institutes interested in CFS. The PA encouraged those institutes to consider with preference any applications that have passed the initial scientific and technical review. In the two-layer review process, the review results of the initial Scientific Review Group is passed onto the potential funding institute. The institute's National Advisory Council then reviews the application, advises the institute director, and makes recommendations on funding.

Dr. Hoffeld then discussed where applications are reviewed. RFAs are reviewed by an institute committee, rather than the CSR. CSR conducts reviews for all of the institutes, including R01, academic research enhancement grants, postdoctoral fellowships, small business innovation research, and shared instrumentation grants. Individual institutes are responsible to review projects that use mechanisms unique to that institute. This is advantageous to the individual institute because it allows them to apply review criteria. Applications that are reviewed by individual institutes include program projects, centers, institutional training grants, career awards, and small grants.

The CSR is essentially an economy of "manpower" for NIH. When the original NIH was given the responsibility for extramural awards, every division formed its own Study Sections. Many of these Study Sections used the same people, who were becoming overworked. In 1946, the CSR was formed around breadth of science, rather than a specific disease or institute. The CSR includes about 100 chartered FACA committees and a large number of Special Emphasis Panels, which are ad hoc committees that review applications that fit outside of the regular Study Section's purview.

The CFS Study Section of the CSR is a Special Emphasis Panel, which meets three times a year. It is not a chartered Study Section because it does not meet the criteria requiring a certain number of applications. Most chartered Study Sections review 60

to 100 applications per round, while the CFS Study Section receives 15 or fewer applications per round. Though it does not qualify to be FACA (Federal Advisory Committee Act) chartered, it can be much more responsive to applications since membership to the group is not required. Rather, participation in the group can be at ad hoc to include varying experts as needed. As a result, rosters may and do change from meeting to meeting.

The CSR serves as the central receipt point for most PHS grant applications. It also receives some CDC, FDA, and SAMSA applications. When applications are received, they are distributed to the appropriate agency within CRS. Referral officers then review the scientific content of the applications to determine which institutes may have an interest in the application. They assign a primary institute and determine the appropriate Study Section within CSR for review.

There are more than 60,000 grant applications submitted to NIH each year, resulting in an enormous amount of paper use. NIH is looking to transition to electronic submissions of applications in this decade. Of the total number of applications, an average of 25% to 30% are funded. Over the last 5 years, the budget has been increasing, but has flattened out this year as planned by Congress 6 years ago. Additionally, the number of applications has been growing. In 1976, there were 27,213 PHS applications and 64,187 in 2003.

Dr. Hoffeld reiterated that the referral officers have the responsibility of looking at the science and determining which institutes have interest in the application. There is a book, updated every 2 years by all of the institutes, that states their interest in science. The book also clearly defines where there are conflicts, in which each institute provides its particular interest in the overlapping areas. The Review Groups and Study Sections also update their list of criteria and overlapping areas on a regular basis. This redundancy with the institutes is helpful to eliminate conflicts of interest when applications are submitted by NIH scientists that would be most appropriately reviewed in the Study Section in which that applicant is a member.

He then discussed peer reviewers. The criteria for selection of peer reviewers include demonstrated scientific expertise, doctoral degree or equivalent, mature judgment, work effectively in a group context, breadth of perspective, impartiality, interest in serving, and adequate representation of women and minority scientists. Each reviewer should meet all of the criteria, but Scientific Review Administrators (SRA) will have their own hierarchy of criteria importance. As an example, Dr. Hoffeld, after scientific expertise is demonstrated, requires that the reviewer be able to put together a committee.

Each reviewer must sign the following Certification of No Conflict of Interest statement:

> This will certify that in the review of applications and proposals by (study section) on (date), I did not participate in the evaluation of any grant or fellowship applications from (1) any organization, institution or university system in which a financial interest exists to myself, spouse, parent, child, or collaborating investigators; (2) any organization in which I serve as officer, director, trustee, employee or collaborating investigator; or (3) any organization which I am negotiating or have any arrangements concerning prospective employment or other such associations.

He noted that competitors are not generally regarded as having a conflict of interest, because they have the most appropriate expertise. As long as they agree not to use the information for their own benefit, they may serve on the Study Section that is reviewing a competitor's application.

Confidentiality is very important to the entire process. Any information pertaining to an application should never be disclosed to the public. The actual meetings are reported in abbreviated minutes in terms of their overall process, and each application has a summary statement. Both documents are confidential, except when the application is funded as a grant.

The review criteria for research grants include: significance, approach, innovation, investigator, environment, and overall evaluation. The definition of each criterion is as follows:

- Significance: Does the study address an important problem? How will scientific knowledge be advanced?
- Approach: Are design and methods well developed and appropriate? Are problem areas addressed?
- Innovation: Are there novel concepts or approaches? Are the aims original and innovative?
- Investigator: Is the investigator appropriately trained?
- Environment: Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?

There is no standard direction on weighting these criteria, and each review group is responsible for determining how to weigh each criteria.

There are additional considerations for clinical studies because there are human subjects involved. There include:

- Is the proposed study exempt from human subject review?
- Are there any apparent risks to the human subjects?

- Are the protections adequate?
- What are the potential benefits to the subjects and to mankind?
- Are the inclusions of minorities and both genders adequately addressed?

Common problems in failing applications include:

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions

The reviewers may recommend one of three options. They can score the application, from a 1.0 (perfect) to 3.0 (average). They can leave the application unscored, ranging from below average to unacceptable. This option was started about 5 years ago to decrease the time spent on applications that could not benefit specifically from the comments of the reviewers. The third option is deferral, which is used for applications that contained a single item that was not well defined, but critical for its success. This option is rarely used.

Based on the priority score, the percentile is the rank of an application relative to others reviewed over three cycles. It indicates the percentage of applications with better priority scores. Percentiles are calculated using the following mathematical formula: percentile equals (relative rank - 0.5) x 100 / # of applications.

Dr. Lapp noted that when they went to CRISP for the various studies funded in 2004, there was a score on the left-hand side. He asked what that score was. Dr. Hoffeld explained that they were the percentiles.

Dr. Hoffeld then discussed the mission of the extramural program. Its mission is to manage a portfolio of investments to improve health through science. It does this by:

- Identifying scientific opportunities
- Fostering the best science

- Ensuring proper stewardship
- Promoting effective communication

Lastly, he discussed what determines which awards are made. These are scientific and technical merit in Study Sections, program considerations from the advisory council and the program institute staff, and the availability of funds. Ideally, for Congress, awards would be distributed in priority order until funds run out.

He reiterated that the determinants of which awards are made include scientific merit, program considerations, and availability of funds (internal decision), and that awards are given out in priority order until funds run out. It does not typically work this way because sometimes applications are awarded out of order and given special consideration. In addition, many institutes provide partial funding to reserve funds for applications at the lower half of the priority list.

B. Discussion

Dr. Bell thanked Dr. Hoffeld and noted that he wanted to learn more about where things have broken down in regards to CFS.

Dr. Bell explained that a big problem in science is that the definition of science tends to break things down into their smaller denominations (e.g., right-handed proteins). The same has happened in clinical medicine; the neurologist talks about the cognitive problems, the rheumatologist the joint problems, etc. No one seems to be looking at the overall picture of CFS, and the current system has not been successful in managing that. He asked Dr. Hoffeld if he had any suggestions on how to approach this problem.

Dr. Hoffeld noted that there are reviewers who have the technical expertise but not an appreciation for CFS. Though he tries to select reviewers that have both the expertise and the appreciation, it is often difficult because at times the expertise is too new to the field and thus requires reviewers with that expertise from a different field.

Dr. Lapp asked if the names and resumes of the reviewers are available to the public, and asked how their interest in CFS could be known.

Dr. Hoffeld noted that CSR posts the roster approximately 4 weeks prior to the meeting at www.csr.nih.gov. Resumes are not provided with this roster. Information on reviewers can be found in CRISP, a database of all funded applications; PubMed; community of science databases; and other resources.

Dr. Lapp clarified that there is no central place to find the background of these people.

Dr. Hoffeld noted that this was correct and that a central location for resumes are not required by FACA.

Dr. Komaroff thanked Dr. Hoffeld for a clear presentation. He noted that they still have a Special Emphasis Panel that reviews CFS research, but an institute no longer owns it. He asked what the implications are.

Dr. Hoffeld noted this is more of an institute issue than a review issue. He noted that the Study Section is charged with looking at the scientific and technical qualifications, independent of which institute it might go.

Dr. Komaroff noted that he understands that the panel only looks at the scientific merit of the application, but that funding decisions also include programmatic interests. He asked if there is no institute that declares a programmatic interest, does this diminish the likelihood of funding.

Dr. Hoffeld noted that there are institutes that have expressed an interest in CFS. He noted the one institute that has expressed a diminished interest in the last 2 years has not diminished the interests of the other institutes. In one review 2 months ago, there were program staff from seven different institutes. Dr. Komaroff said that this was reassuring.

Dr. Gantz asked if there were recruitment efforts to place someone in the intramural position to cover CFS. Dr. Hoffeld said he is not sure if there have been any recruitment efforts, but he suspects that they are continually looking for someone. He noted that there are only a few individuals who could fill this position and that it would require a major career move.

Dr. Hanna noted that there is a small intramural program in the National Institute of Neurological Disorders and Stroke, led by Dr. David Goldstein.

Ms. Stevens asked if there are any reasons why there seems to be general resistance to CFS research. Dr. Hoffeld noted that in his personal view there is stagnation in the field based on the quality of the applications that have been received. There are no new areas (“hot leads”) clearly defined for people to pursue.

Dr. Bell asked if NIH would be open to a new director of intramural studies. Dr. Hoffeld explained how the intramural program works at NIH. Investigators are brought on usually at junior levels. As they develop their own research programs, they become independent investigators. It is rare that senior investigators are brought in to lead entire programs because they tend to go to universities.

Dr. Bell agreed that there is a perceived stagnation in the field, but noted that there are also some areas that seem exciting, such as autonomic instability. He asked if

there are applications for research in this area for CFS. Dr. Hoffeld said that they have gotten applications in this area that are being funded.

Dr. Lapp explained that there is a concern that none of the 2003 and 2004 applications that have been approved. The current grants in CRISP are those that were approved 3 years ago. He asked why the number of approved applications has been dwindling over that last 2 years.

Dr. Hoffeld noted that the recent applications are weak in the innovation criteria.

Dr. Lapp noted that Dr. Steve Strauss's group, the National Center for Complimentary and Alternative Medicine (NCCAM), have papers that do not rise to the same level of scientific scrutiny to which Dr. Hoffeld is referring. He asked how this institute is being funded to do their therapeutic studies, which CSR is not typically approving.

Dr. Hoffeld explained that they have a number of applications that are assigned to the Alternative Medicine Center. At this center, many of the reviewers that serve are reviewers in these very specialized areas, such as tai chi or acupuncture; do not have PhDs; but have shown to be credible in advising the committee. He finds most of the committee members are very receptive to and want to learn more about these alternative medicines.

Dr. Lapp asked if the NCCAM is being judged on a lower level than CFS. He said for CFS, CSR was not interested in treatment as opposed to mechanisms and methodologies. He asked why there are different criteria levels for CSR, compared to alternative medicine group.

Dr. Hoffeld explained that the only applications he sees for alternative medicine are for CFS, and those they are judged on the same standard.

Dr. Lapp asked if copies of Dr. Hoffeld's presentation could be made available, to which he replied affirmatively.

Ms. Stevens asked what needs to happen to stimulate research in CFS. Dr. Hoffeld replied that Dr. Hanna, who is the Chair of the Trans-NIH Coordinating Committee, is probably the person to answer. He noted that the committee put together a PA 2 years ago. There has been some success with the PA, but not to the extent that they were hoping. He noted that to encourage more success, they need to identify a single entity to justify and fund a RFA.

Ms. Stevens asked if they have a CFS program officer. Dr. Hoffeld replied affirmatively and explained that each institute has a person on the Trans-NIH Coordinating Committee.

Ms. Stevens asked if that person needed to have expertise in CFS. Dr. Hoffeld explained that that is up to the institute, but that most of the people he has met from that committee have either a research background or a strong interest in that field.

Ms. McCleary asked about the track record of the applicants who have come through the SEP in terms of CFS; how many applications have come through and how many have been funded.

Dr. Hoffeld noted that a few years ago, about 20% to 24% of applications were funded. Typically, they receive less than 35 applications per year.

Mr. Jon Sterling noted that CFS Association of America (CFSAA) has a research grants program that has received 36 applications. He asked Dr. Hoffeld how he could reconcile this difference with the small number of application received by NIH, since NIH has a lot more money.

Dr. Hoffeld said that people get intimidated with the "black box" of NIH. Many people see NIH grants as too complicated or an unreachable goal. They do not recognize that NIH has small start-up grants of $15,000. If people apply for more start-up grants, they may be able to accumulate enough data to move to a full, long-term research project.

VI. Organizational Updates

Dr. Bell noted that they are 30 minutes behind schedule and that he is reluctant to cut into the public comment period. As a result, some time will be taken from the CFS Education section.

A. Patricia D. Fero, Executive Director, Wisconsin CFS Association, Inc.

Ms. Fero thanked CFSAC for the opportunity to speak and noted that there are numerous organizations that should also be afforded the opportunity to speak before this committee. Dr. Bell asked her to submit a list of suggested organizations. Ms. Fero agreed.

Ms. Fero said that her full report is divided into two parts: projects and grants. She noted that she did not have enough copies of the full report for the committee, but provided a copy to Dr. Bell.

1. Projects

She began by discussing the Wisconsin CFS Association (WCFSA). She noted that the organization started in 1987. In 1994, after they set up the support groups, they

formed a medical advocacy committee. They started with the University of Wisconsin hospitals and clinics and sent out a petition with 2,000 signatures asking to set up a CFS program. By 1995, they had a program coordinator nurse, who attended the 1996 AACFS conference in San Francisco. After 6 years of meetings, little progress was made with the university.

To continue to proactively support the growing number of CFS patients, the WCFSA formed PANDA (Patient Alliance for Neurological Disorders). The ultimate goal is the same: to create, implement, and support a clinic for patients with like disorders.

For marketing purposes, they kept the "PANDA" acronym, but the focus has changed into a fatigue consultation clinic. This was not done because they believe in "Chronic Fatigue Syndrome." Other illnesses (both rare and common) were included since that their patients are not satisfied with the care they receive.

She noted that the document entitled "PANDA" includes information on the Robert Wood Johnson Foundation's Improving Chronic Illness Care (ICIC). The program looks not only at CFS, but also at the broader public healthcare system.

They have designed a PANDA proposal, which has an emphasis on intake (medical and quality of life assessment), diagnosis, medical treatment, intervention to improve quality of life and health (self management with help), primary care collaboration and medical education, and prevention of further illness to new patients and secondary illness to patients with chronic conditions.

She presented the last *Lifeline* newsletter, which shows a picture of a house where their organization will be located. The organization will end up with a sizeable amount of money from various individual donors. She also shared a brochure on CFS that is not based on scientific research but written from the patients' point of view.

She then discussed the 2004 AACFS 7th International Conference on Chronic Fatigue Syndrome, Fibromyalgia, and Related Illnesses, scheduled for October 8 to 10, 2004. When they started PANDA, they had a verbal agreement with Dr. Natelson, who was then the president of AACFS, to hold patient seminars. When Dr. Ablashi became president and set the goal of making this an international conference, they noted that they could host the conference but could not pay for or organize it.

She added that WCFSA also collaborates on research studies to get participants for researchers.

2. Grants

Ms. Fero asked if it is reasonable to assume that patients' experience in the trenches reflects decisions made by CFSAC. She asked if what happens here today will have

an impact on what happens in Madison. She shared the following observations, noting that they are not conclusions.

First, fibromyalgia (FM) is diagnosed in ever increasing numbers with a difference, as in Milwaukee, where there is a clear medical bias against the CFS diagnosis. An FM seminar in Milwaukee can easily draw 500 people. As she speaks with patients, they express dissatisfaction with their medical care and upon questioning, she often finds that these people could easily have CFS. There is a widening gap between how people think about FM and CFS. She asked if existing policies and procedures encourage that divide and whether this is a positive direction for both/all populations. FM patients can see very good rheumatology clinics in Madison, who are turning away CFS patients because they consider it a neurological illness. CFS patients do not have a specialty.

Second, internal medicine people tend to reject the CFS diagnosis. In general, they believe that CFS is some sort of 'crud," but they have no clear way to define it and believe that nothing can be done. Ten to 15 years ago, CFS patients were considered an interesting anomaly and fibrositis was the term for FM. CFS research predates FM research and she asked if there was a logjam somewhere in CFS research that accounts for this apparent lag.

Third, CFS patients provide a financial burden on the medical institution. They are messy and time consuming, and may be noncompliant. This has gone on year after year. As a 20-year patient who reads research, she sees ME/CFS clinical biological studies from the French team, the Italian and Israeli teams, a good deal from the UK, as well as from other international researchers. She is not seeing similar studies come out of NIH and asked why NIH funds so few CFS studies.

Fourth, clinicians and researchers tell her that grants for CFS biological and treatment studies are almost nonexistent and almost impossible to obtain. She asked whether CFSAC could make some recommendations. She investigated for herself the number of grants awarded for CFS and FM between 2001 and 2003. She did a search on CRISP by review panel on ZRG1 and ZRG5 grants. She is interested in this time period because on May 30, 2002, it was announced that the research centers were being shut down.

She presented the number of CFS and FM grants, including new grants. Taking into consideration those that overlap between CFS and FM, there were five new research grants in 2001. In 2002, there were three new research grants, and four for 2003. In total, there were 12 grants funded by CFS/FM SEP in 3 years. She asked if there is a way to see if these are actually CFS research or just "such as" studies. A "such as" study is a study that includes a list of different diseases that are presented as examples of the types of diseases that the study is interested in. It is not a study that is specific to CFS.

Of the five new grants in 2002, one is a "such as" study. In 2002, the Craig and Hassett grants are "such as" studies, leaving only one new grant specifically for CFS. In 2003, two of the four grants are "such as" studies, leaving a new total of seven new grants specifically for CFS between 2001 and 2003. She asked if someone else could duplicate her efforts to see if these numbers are accurate. She noted that she has no confidence that CFS research grants will be awarded and that her organization needs the support of the agencies. She asked what assurances she has that NIH is interested in funding CFS research. With the three CFS research centers gone, what plans are in progress to fund studies in the areas of research cited in the 1999 GAO report?

The attachments to her findings include:

- CRISP 2001 to 2004 search, CFS and FM
- CSR selection for grant reviewers
- CSR area description of musculoskeletal, oral and skin sciences (MOSS), and its study sections that include CFS/FM
- SEP information
- SEP rosters (8/11/03, 12/05/03 to 3/31/04)

She noted that this is important because it is reflected in the disinterest shown at University of Wisconsin at Madison.

Dr. Bell thanked Ms. Fero for her presentation and the information she provided. He noted that she should be cloned and run a city organization in every state. He said she is a testament to what a private citizen can do without federal funding.

Ms. Fero asked if the presentation could be copied for the rest of the committee members. Dr. Bell replied affirmatively and moved the meeting to the public comment section.

VII. Public Comment (Part 1)

Dr. Fields explained that he would give people notice when 1 minute remains in their time limit.

A. Carol Rowland

Ms. Rowland explained that she would discuss CFIDS, which is both a personal and political issue for her. She is here to enlist the federal government's participation in fighting this devastating disease.

She suffered with CF symptoms for 6 years before she was correctly diagnosed by an immunologist at Georgetown University Medical Center. Various doctors prescribed anti-inflammatory drugs, muscle relaxers, antibiotics, and antidepressants. She was sent to psychologists, neurologists, behavior modification therapists, myofacial massage therapists, and pharmacologists, to no avail. She noted that what she really needed was a physician who would "hear" her and take her symptoms seriously; not someone who, after thousands of dollars of tests, would dismiss her and tell her that she should consult a psychiatrist.

It has been her experience with the medical community that unless a patient has "classical" symptoms, which can be confirmed by tests, or symptoms which are "typical" for a particular disease, doctors are at a complete loss as to how to proceed. Many mainstream physicians are not aware of CFIDS, and do not know the disease or its symptoms, the tests that should be performed, or the protocols to be followed. She explained that this is unfortunate because there are many good physicians who would like to help their patients, but instead become frustrated and angry when they confront a disease like CFIDS, which does not fit into a conventional medical category.

She explained that physicians' awareness and education should be the cornerstone in any strategy to conquer CFIDS. It took many years for CFIDS to be recognized as a real and physical process. Hopefully, as time goes on and more physicians become aware of this disease, patients will no longer have to accept being labeled as "crazy." The federal government has a role in making CFIDS a mainstream medical concern, and increased funding for the education of physicians is imperative. CFIDS is a serious public health problem, which can affect all races, sexes, and ages, though it is approximately three times more common among women.

Many women suffer from CFIDS at a time when they are most productive in their professional careers, or when they are completely engaged in their family lives. The disease takes both a personal and professional toll. In addition, it has a multidimensional effect on an individual's quality of life. CFIDS's negative repercussions influence individuals, families, and our society as a whole.

According to CDC, CFIDS is three times more common than HIV infection among women, and 25 times more common than AIDS among women. CFIDS is more prevalent than lung cancer (33/100,000) or breast cancer (26/100,000). This illness has a direct impact on the nation's economy. A recent CDC report stated that the economic cost of CFIDS is $9.1 billion per year in lost productivity and tax revenues. Given the current fiscal climate in this country, it behooves the federal government to give CFIDS and its wide-ranging consequences the attention that it deserves.

Ms. Rowland is a proud volunteer of the CFIDSAA, based in Charlotte, NC. This association is the nation's leading nonprofit organization dedicated to conquering CFIDS. Since its inception in 1987, the association has invested more than $12

million in programs devoted to education of the healthcare community, public policy initiatives, and the rigorous promotion of scientific research.

One of its main objectives is to make CFIDS a priority for the administration's healthcare agenda. This would involve increased federal funding devoted to CFIDS research and education, as well as services, support, and compassion for CFIDS patients. Although the administration and Congress is preoccupied with homeland security, the war in Iraq, and the upcoming presidential elections, now is the time for the government to become more responsive to the needs of the CFIDS community. Public health service officials at NIH and CDC should make CFIDS a priority, given its magnitude and its impact on the public.

Increased, rigorous scientific research will provide the tools required for effectively diagnosing, treating, managing, and curing CFIDS. For example, the federal monies appropriated to NIH for research on CFIDS have barely increased between FY 2002 and 2004. Therefore, she proposes that the HHS increase its financial support to both NIH and CDC. She would like to see allocations of at least $10 million per year to NIH for CFIDS studies to explore the cause and progression of CFIDS, identify diagnostic markers and treatment, focus on pediatric CFIDS, and increase its outreach efforts. CDC should continue providing funding for CFIDS research and education in the amount of $10 million per year as well. The funding it has provided for educating physicians is very important and should continue to be increased.

She feels fortunate that she is among the individuals with CFIDS who has been correctly diagnosed. More than 80% of people with CFIDS remain ill, with little or no medical treatment, and struggle everyday. This statistic clearly demonstrates the profound lack of knowledge about this very real medical condition.

The US government has a role in combating this staggering health crisis, which affects the nation's economy and productivity, as well as the individual lives of many of its citizens. Ultimately, the entire nation will profit from a proactive federal CFIDS initiative.

B. Carey Czarniawski

Ms. Czarniawski noted that there are an estimated 800,000 people in this country with CFS. Approximately 10% have been diagnosed and are presumably receiving some form of treatment, in which she is included. She is 36 years old and has been sick for 13 years. She is also in the even smaller percentage of CFS patients that receive Social Security Disability and Medicare.

She noted that she has been diligent in seeking medical treatment. She has been part of the CAA lobbying effort in Washington, DC. She has participated in the clinical trial of Ampligen. She is a board member of the New Jersey Chronic Fatigue

Syndrome Association (NJCFSA) Additionally, in the coming months, she will be leading one of the NJCFSA support groups.

She is active in the pursuit of a solution and understanding of this illness and feels lucky to have a diagnosis. She feels lucky to receive disability benefits, Medicare, and the invaluable support of family and friends. She shared that she should be "cresting to the top of the hill," but that she is not even close.

Progress has been made towards an understanding of CFS, yet she is still running into some very basic roadblocks. CFS remains an invisible illness, not understood by the greater public and still met with a suspicious eye by many medical professionals. Seeking a diagnosis 12 years ago, she saw nine doctors, none of which could help her, and some of which simply refused. Eventually, she found an excellent ID specialist, Dr. Joseph John. Unfortunately, he has relocated and she has been unable to go to a new ID specialist because she cannot afford the initial appointment and testing.

Finding a new GP that is responsive to her concerns has been difficult. Even now, she finds herself in the role of educator and CFS "salesman," instead of being the patient. Her new GP and OB/GYN are more accepting of CFS, but they just do not know enough about the illness. Since the majority of patients with CFS are women, their GPs and OB/GYNs are most often the first places that they seek treatment, help, and answers. She noted that she gladly accepts the responsibility to partner with her physicians. Essential to that partnership is the physician's basic acceptance of CFS and more than a cursory knowledge of the illness.

In New Jersey, the medical and CFS communities have combined efforts to create a Consensus Manual for CFS. This is a monumental stride towards the better understanding and treatment of CFS. This manual needs to be in the hands of every primary care doctor, OB/GYN, ID specialist, neurologist, and rheumatologist in the country.

She has also faced difficulties with insurance. She reiterated that she has Medicare and noted that she cannot afford secondary insurance. Medicare does not afford her the access to many of the types of treatments or testing that could benefit her. Proper and frequent testing is not adequately covered and, in some instances, not even allowed by Medicare. Currently, treating CFS means only addressing the symptoms. She has tried sleep aids, tri-cyclics, painkillers, anti-inflammatories, Ampligen, and steroids with no real sustainable success. She has found some relief with alternative therapies, such as chiropractics and acupuncture. The accepted treatment protocol for CFS does not seem to sufficiently extend to alternative therapies or allow for the length of time these treatments are needed. She noted that pursuing symptomatic relief for CFS with disability and Medicare as her main resources is impossible.

Any chronic illness has a ripple effect, emotionally and financially. She cannot imagine where she would be without her mother's help. She uprooted her life to care

for her sick adult child. Her husband is patient and encouraging. They are both more patient with her CFS than she is. They allow her to focus on her small victories and support her through her difficulties. They have both chosen to alter their lives dramatically to accommodate her illness.

She has spent every day for the past 13 years in pain, with a fever, fatigued beyond description, and frustrated by her depleted intellect. During what should have been the most productive years of her life, she has focused on managing these constantly surprising limitations. She has had to accept financial and emotional support that she never dreamed she would need. She cannot remember what it feels like to be healthy and accepts the fact that she may always be sick, but she does not feel sorry for herself.

CFS is her challenge, not her curse, a choice she makes every day. She is more than her CFS. She has struggled to build a foundation of skills and spirit to cope with this illness, but she is missing some bricks. She appreciates this committee's accomplishments and efforts to expand awareness and understanding of CFS and treatment options, but more needs to be done. She needs to be able to access appropriate and adequate treatment. She needs to be believed.

C. Sharyn Williams

Ms. Williams noted that she is Carey Czarniawski's mother. She decided not to use her prepared remarks. Her intent was to make sure that CFSAC would understand what this disease has meant to her family, but she feels Ms. Czarniawski has been more eloquent on this topic than she can be. She does not know what CFSAC's job is exactly, but she comes to this committee expecting it to provide a voice in HHS and have impact. She expects it to be that "point of power" between the resources that could be applied and the needs of the CFS patients.

She believes CFSAC's job is to seek out the best practice models. Her first choice is that they find a cure for CFS and get her daughter the hospitalization coverage that Congress receives. In the meantime, she would like them to support, demand, and promote best practice models. If CFSAC wants a "Fero cloning" program, that is what they should support, because she is clearly best practice.

These best practices must have a study component, an economic component, a best business application component, and a lab that the rest of the country needs to know about. The guidance from CFSAC about what the model should be would be most valuable. There is a lot of noise, but little impact.

D. Dr. Beverly Bugos

Dr. Bugos began by expressing her envy for the previous speakers for working on this problem together. She noted that she felt like an orphan because she does not have anybody with whom she can work. She was one of the lucky ones because she did not have doctors that did not believe in her. Her doctors immediately began testing her and discovered that she had orthostatic intolerance and reasons for why she could not lift her head off the bed in the morning. One of her doctors, a cardiologist in the Washington, DC area, has conducted research on orthostatic intolerance. As a result, she did not have the same problems of identification, as did the other patients.

In policy matters, things are not black and white, though people try to make them that way. Historically, science and medicine has called diseases by other names, such as "consumption," because they did not know what it really was. Today, when you go to the hospital for chest pains, you are not turned away and told you have heartburn, until they test you for other things. Unfortunately, CFS patients are turned away, because of the word "fatigue." She noted that that word should be removed as quickly as possible.

There have been studies that show that using the word "fatigue" with medical students does change the way medical students treat patients. There seems to be an agreement among the majority of patients that there is a problem with the term "chronic fatigue syndrome." They would like to have something like "neuro endocrineimmune dysfunction syndrome," as noted by the general disability policies studies on the stigma of CFS, conducted by DePaul University and the University of Illinois, published in the Journal of Disability Studies (no. 14, in 2004).

She also called attention to a conference held on October 3rd by MERGE that shows how people with orthostatic intolerance have not been able to hold down jobs. They are also finding that orthostatic intolerance may also be associated with acute and chronic infections, which many believe to be at the root of ME/CFS. For example, she has had lyme disease for a long time that may have resulted in ME. She believes that they are going be seeing many discoveries from viruses and their impact, which will benefit people 10 years from now.

There is an ICD code, so there is no need for the education plan in this area. That plan will be needed when a new term is developed. In the meantime, there is a code and a name for a neurological disease. When there is a patient that exhibits prolonged fatigue, they should be tested immediately. It should not be assumed that that person has "heartburn." It should be assumed that these patients have some neurological endocrine disease. Both cognitive behavioral therapy and neuroendocrine immune deficiency treatment need to be tested for.

E. Peter S. White

Mr. White noted that he is a Board member of the Central Virginia Chronic Fatigue and Fibromyalgia Association. He is also the father of two daughters afflicted with CFS, one resolved and the other presenting for the past 3 years.

He noted that this is his second presentation to CFSAC and that he would like to expand on one of his themes previously presented. Before doing so, he restated two fundamental actions that are needed to make progress with CFS. First, a fundamental change with our approach to CFS is needed, in that a solution focus is mandatory. Second, unified and integrated methods must be implemented, with government research and implementation organizations, academia, the healthcare industry, private physicians, and nonprofit organizations.

With regard to CFS research, numerous organizations contribute in a variety of manners. They include NIH and CDC. They also include nonprofit organizations, which in some cases have a unique patient focus and also support direct research. The government organizations conduct research in all of the appropriate medical disciplines for a major illness, such as CFS, yet there are a number of issues with these research activities. First, there is an apparent lack of coordination and integration of the current research. Second, funding appears to be severely lacking. Third, there are a number of barriers to successful research activities.

A cursory review of the published research shows that the organizations conducting this research are doing so independent of each other. CDC and NIH have funded basic research, but so have nonprofit and private organizations, which have established their own individual way forward. This has the unintentional side effect of letting the larger independent medical community decide what to pursue, with no coordination towards a solution.

To resolve this problem, a "research roadmap" can provide the needed vision, planning, and assessment of the necessary activities. He presented an outline of a "high-level" roadmap. First, the various disciplines must be integrated and have a solution focus toward the desired outcome of potentially multiple solutions. Their activities should have the intermediate assessments and reviews to ensure their mutual and collective needs are being met. The government's research and disease organizations should take the lead to provide the financial resources and implement the roadmap, with oversight by the various independent and nonprofit organizations.

Assessment is one key to success of any endeavor, and CFS research is no different. Periodic reviews are required to determine progress and allow for medical and patient community input. Additionally, these forums would enable valuable cross-disciplinary interaction. In addition to measurement, progress should be gained through management actions, such as identification of the "next step," all with the focus to the solution. Implementation should include an outreach program to major

research institutions that heretofore have not been actively involved with current CFS research. Without question, funding must be increased to reflect the importance of its resolution.

Another barrier to research activities is the co-mingling of CFS with other illnesses in the procurement process. This gives the appearance of a lack of solution focus and leaves the research up to the medical research community marketplace. This has the unintended effect of reducing the success rate of research grant proposals. He recommends that research grant procurement actions be solicited and evaluated specifically for CFS and integrated with the roadmap.

Another barrier to the needed research actions is the name change issue. Many others, both in this forum and via working groups, have addressed this. The unfortunate side effect of not appropriately changing the name is the trivialization of the condition. More importantly, it places CFS research outside the realm of widely accepted medical research at major institutions. While NIH and CDC are held in high esteem, the majority of their research is outsourced and if the major institutions do not embrace the condition as a career path, then CFS is destined to remain on the fringes.

He restated that a solution focus is desperately needed. Additionally, all research activities must be integrated, between the basic research and clinical, along with the education and patient support and care.

VIII. Organizational Updates (Continued)

A. K. Kimberly McCleary, CFIDSAA

Ms. McCleary noted that she was formerly known as K. Kimberley Kenney. Last month marked her 14th year of service with the association. She sees her primary role at the association as a recruiter, recruiting resources, people, and partners to study CFIDS.

Upon reading the minutes from the December meeting, which she did not attend, she noted that there was a comment that she did not fully appreciate. It was Dr. Bell's statement during the discussion of the name change that the disrespect patients experience is not just caused by the name. She noted it is a statement that has started some of the activities that the association has undertaken. For example, they have already changed the name, to which the stigma that exists now is not transferred. She noted that she would be reviewing some of the activities that the association is doing now—before an official decision on the name change is made—to reduce the stigma and increase acceptance among members of the public, research and medical communities, etc.

The association has funded about $4 millions in research since 1987. From 2002 to 2003, they funded about $450,000 of research. For this year, they have received 25 applications from around the world. Based on their letters of intent, ten applicants were selected and invited to come back with full proposals. Unlike SEP, they are seeing an increase in applications to about 25 to 30 per year.

The association is educating providers about diagnosing and managing CFIDS. She noted that questions have been raised about the association's contract under the CDC's' CFS provider education services. It has been a tenet of the association to shift the burden of funding research and education efforts from patient groups to the federal government and corporate entities, and the contract with CDC is a step in the right direction. People affected by the illness are the least capable of paying for the research and educational needs.

The association is also trying to understand the factors that underlie the doubt that patients experience. They have conducted social science research using focus groups and public polling to understand what some of the issues are. The data from the research confirmed what they knew about the complex interaction between societal values, personal experiences, and the lack of familiarity and understanding of the illness.

They are now looking at ways to motivate people to care. People who read Laura Hillenbrand's article in the *New Yorker* said that they never knew or understood the disease until they read her article. The association is trying to understand what it was about that article that got people's hearts and minds to engage. They hope to adapt this more broadly to improve the ways people are treated when they tell others that they have CFIDS.

They are also looking at new ways to use technology to help people engage in public policy and the empowering activity of advocacy (i.e., advocating for themselves). They are launching an action center on their web site that will enable people from their homes to engage with lawmakers and public health officials. This election cycle is a timely opportunity to get people engaged in the process of the federal government and to give them a better sense of control.

She then echoed what Ms. Fero and others have said about building a critical mass of researchers and educated healthcare professionals, to generate greater concern in the public so that there will be more people thinking about this in a way that will lead to better care and treatment of those with CFIDS.

B. Jill McLaughlin, NCF

Ms. McLaughlin thanked CFSAC for the invitation to provide an update, information, and input on behalf of the patient community. She reported that since the last meeting

in December, another child with CFS has committed suicide after being removed from the home to foster care. Though this makes people uncomfortable, it does convey the urgency of the situation and the need for greater all around efforts. Patients cannot wait until all of the issues have been conclusively resolved to get basic medical care and services. The UK recently allocated 8.5 million pounds for services and programs, but the comparable has not happened in the US. She suggested that some of the remaining payback funds be allocated to services that directly impact patients.

Based on the feedback from the patient community, she explained that the name change still remains the single most important and universally agreed upon issue. Regardless of the committee's position, she suggested that there is an obligation to give the Name Change Workgroup a fair and thorough hearing. This group of federally appointed experts recommended that a name change is necessary. She noted that they went beyond the name change and addressed the problems with the definition by recommending the recognition of subgroups with names and definitions already established in the medical literature.

She noted that education and funding are important and referred to a statement by Dr. Fields: "I am incredibly humbled by the enormous importance of very simple things." Beyond campaigns and advertising, in this particular instance, the name change could be the perfect example of a simple solution. A name change, in and of itself, could stimulate interest in the illness, which has been steadily dwindling, and provide a better understanding of the illness. She then quoted Marc Iverson, former president and founder of the CFIDSAA, and his belief that efforts to change public attitudes are virtually hopeless and wasted with the present name.

She noted that those who are able to change the name are reluctant due to the extensive requirement for education and funding efforts, yet there now is an education campaign in place with the means and resources to overcome such a problem. She suggested that there is a double standard.

She explained that not effectively resolving the name change and definition affect funding and patient support. The historical precedent demonstrates the impact of a name on an illness. She described the history of naming Hodgkin's disease, which was formerly called lethal midline disease, as an example. The legacy name inhibited funding and intimidated researchers who inferred that the assumption statement was bad and needed to be challenged. The name change that was accepted decades ago is recognized as a major milestone in understanding and treating the disease. She then referred to a statement, which she believes was from Secretary Thompson: "There are no incurable diseases, only diseases whose cures have not been found." They will not find it if they do not look, and she expressed concerns about sending the wrong message about CFS.

Ms. McLaughlin suggested that CFS must undergo a name change. Though some argue that there is not enough conclusive research, there is sufficient information to establish an appropriate name and definition. She alleged that without a name change, CFS would continue to suffer from a lack of progress. How CFSAC handles the name and definition issue will directly impact patients' medical care. The case definition and diagnostic criteria should be explicit in the name. Low-grade exercise and cognitive therapy are still considered treatments for CFS, but exercise, in fact, worsens a patient's condition. She asked how exercise could be considered both a cure and a cause of ME.

She noted that the most important reason to recognize ME is provided by Dr. Ramsey. He notes that those who continue to work until they collapse have the worst chance, and those who have early diagnosis and the most bed rest have the best prognosis. She noted that patients have been and continue to be harmed by the failure to recognize this critical aspect of ME. The tragedy is that if patients were properly diagnosed early by their doctors, they could have had a chance to recover. She expressed the need to adequately deal with the fundamental problems, despite their contentiousness, and not get distracted by secondary issues. Progress can be made with the change to a sufficient, although imperfect, name and definition in medical culture.

In closing, she thanked NIH for providing $1 million in funding to study ciguatoxin and chronic illnesses, including CFS.

IX. *Ex Officio* Members

A. Dr. Hanna

Dr. Bell noted that a majority of the NIH part was covered by the morning presentation. He noted that a letter requesting specific information on funding CFS projects was sent to Mr. Turman, NIH's budget director. He has yet to receive a response.

Dr. Hanna noted that they had just completed a report on this issue. She does not have clearance to share the report but will share information from it later that will answer all of Dr. Bell's questions. Dr. Bell asked if this could be done via email in 2 to 3 weeks. Dr. Hanna replied affirmatively.

Dr. Komaroff asked if there were any privileged, sensitive, or confidential information in the report.

Dr. Hanna explained that this report was specifically prepared on a request from Congress. The whole report is directed towards their request, but it does include a 5-year listing of all the funding, from which she can excerpt parts for CSFAC. The report is not privileged, sensitive, or confidential.

Dr. Hanna explained that NIH tries to address CFS as an interdisciplinary issue that covers all of the institutes. It does not have a home institute but is funded by many institutes. Just because Dr. Steve Strauss is not doing research at NIAIDS, it does not mean no one is interested. She explained that Dr. Goldstein, a neuro-cardiologist intramural researcher, has a small part of his program focused on CFS. They are going to have the first meeting of the new Scientific Interest Group for the intramural community. It will be on scientific integrated medicine and focus on CFS and other illnesses. They are trying to spread interest across the intramural community, but it is difficult.

Dr. Gantz asked if it would help to have a funded position to champion the cause of CFS research. Dr. Hanna said that is what she is supposed to be doing by coordinating all of the institute representatives. Dr. Gantz said if it would be helpful if she had some assistance, since this is a major undertaking. Dr. Hanna said she is not sure.

Mr. Sterling said he has been coming to CFSAC meetings for many years. Dr. Dean's and now Dr. Hanna's roles have been coordination. He does not underrate or underestimate the difficulties that coordination has, but there also has to be more direction and drive. There has not been an increase in funding anywhere near what the prevalence of information has shown. This is not Dr. Hanna's fault, and he noted that he appreciates her work and her being here under such trying circumstances. He noted that this committee has every right to recommend to the Secretary that if he wants to give this the drive that it deserves, he should create a position in the director's office to lead the charge for CFS advancements, as well as a bench lab.

Dr. Hanna clarified that her office is in the office of the Director. The Associate Director of Women's Health is responsible for CFS. Mr. Sterling asked if that was her only responsibility, to which Dr. Hanna replied negatively. Mr. Sterling then asked whether being housed in the Office of Research on Women's Health makes it less of a responsibility to the other institutes. Dr. Hanna said she does not think so since there are so many institutes cooperating.

Mr. Sterling noted that it has been 10 years since these committees first started, and that they are now spending less money on research than in 1994. Something has to change to push this forward.

Dr. Fields, for clarification, restated that Mr. Sterling is suggesting to this committee to consider up-leveling that position.

Ms. Fitzgerald noted that it would be in the best interest of the CFS community to have intramural research at NIH. If there were someone doing research at NIH, this might generate some articles and encourage more proposal requests. She asked if they could recommend the funding for an intramural researcher who has at least some interest in this area.

Dr. Gantz added that he thinks the person should have full interest in CFS. It is an important enough problem that warrants the full dedication of the researcher for a number of years.

Ms. Fitzgerald noted that without a major university fully committed to CFS, without an intramural research program, and with unfilled CDC positions, somebody has to spearhead the research.

Dr. Gantz agreed that they should recommend an intramural researcher at NIH.

Ms. Fero asked if the 2001 PA application went through the SEP. Dr. Hanna responded affirmatively.

Dr. Bell suggested moving on to education and returning later to the *ex officio* members.

X. Dr. Roberto Patarca: CFS Education

Dr. Patarca joined the committee by phone. Dr. Bell asked if they should formally make education a subcommittee of this committee. Dr. Gantz motioned to make education a subcommittee, and Dr. Komaroff seconded. All voted in favor. Dr. Bell asked Dr. Patarca to be the leader of this subcommittee, and he agreed.

Dr. Patarca apologized for not being able to attend in person. He explained that when the idea of the subcommittee was being discussed, several people came forward, and the subcommittee is now almost as large as the main committee is. They initially thought about including Ms. Butler for the school nurse education, Ms. Stevens and Ms. Fitzpatrick for the occupational and physical therapists, and Dr. Freidman, Dr. Gantz, and Dr. Patarca to cover the other healthcare professionals. He has also exchanged emails with Dr. Komaroff, who is also interested.

He noted that Dr. Robinson offered to mediate the subcommittee's conference calls, but because of limitations in resources, they never had a conference call. He asked if the discussions are opened to the public, how would they handle that, and what guests could be invited. There were several suggestions of including healthcare professionals who already had experience in education, as well as patient group liaisons such as Kim McCleary and Jill McLaughlin. He explained that there have been discussions

about how proactive the subcommittee could be because they were an advisory committee. This led to the question of conflict of interest because several members are already involved in educational activities.

Dr. Fields commented that FACA subcommittees are not required to be open to the public since they involve preparing a body of knowledge for the full committee. The charge of the subcommittee is to facilitate the development of recommendations by this advisory committee to be presented to the Secretary via the Assistant Secretary. In terms of conflict of interest, they are all under the same regulations, and the details can be worked out.

Dr. Patarca added that there is the issue of funding their meetings and the data gathering phase for the development of recommendations. Several members have discussed ideas about looking into state health departments and other venues for data that will require resources to secure information. He has also received letters from various individuals with very specific requests for the subcommittee.

Dr. Bell noted that these are matters that are to be discussed in the subcommittee's first meeting. The full committee is designated to support the subcommittee and would assist in making that first meeting happen. He noted that this is the third meeting of the full committee. This committee needs to draw up its recommendations that are to be voted on at the next meeting. As a result, there is some urgency for the subcommittees to sort through the information in order to come up with suggestions for recommendations. He asked if there were any discussions now that would help with that process.

Dr. Patarca noted that they already have a list of recommendations. Even in the first meeting, they had recommendations, which were deemed too general. This brought up the issue of productivity because recommendations that are more specific would require deeper investigations into the matter. The recommendations are very straightforward because members already knew what they wanted and how to go about it, having the experience of having dealt with it. So, the subcommittee is ready with its recommendations.

Dr. Bell said that was excellent and asked if there were any questions.

Ms. Fitzpatrick noted that they have an educational packet in New Jersey that has been disseminated to instate physicians, which seems to have had a positive impact. She asked if it would be a good idea to consider a wider dissemination of that packet as a recommendation. The other request is for more information on the contract between CDC and CFIDSAA, as to what is planned in the future and what has already been worked out from an educational standpoint.

Ms. McCleary noted that she provided the committee a handout with the strategic plan outline for the current fiscal year. The outline is a laundry list of things they are

under contract to perform by September 2004. The contract is for 1 year, with 4 option years, and they are in the first option year.

Dr. Patarca asked if the next full meeting was scheduled. Dr. Bell said the fourth meeting has not been established, but the communications within the subcommittee can move forward.

Dr. Robinson asked Dr. Patarca to give him a call about coordinating the educational subcommittee's next meeting. He noted that he may be able to work with Dr. Fields' staff to put together the meeting. Dr. Patarca thanked Dr. Robinson for his help.

Ms. McCleary distributed to the committee members a tool that CFIDSAA has developed as part of the CDC contract. It is based on feedback from primary care providers, physicians, nurse practitioners, and PAs. It is intended to be a quick reference guide for primary care providers, who are not CFS experts, when considering a CFS diagnosis.

Dr. Patarca noted that some patient organizations have expressed unease about being excluded from the subcommittee. They asked if they then tell people that the topics will be discussed in the full meeting and that the subcommittees are just preliminary meetings where they will discuss the topics for the full meeting.

Dr. Bell responded affirmatively. The real discussion in terms of the committee will take place at the next full committee meeting. Dr. Fields explained that the reason for this is that a subcommittee cannot assume the responsibilities of the committee. As a result, this work should be conducted at the full committee meetings.

Ms. Stevens suggested that they direct some of the public comments at the next meeting to education. Dr. Bell said that would be an excellent suggestion, but not something they can require. They could encourage it though.

Mr. Sterling answered Ms. Fitzpatrick's question about the New Jersey educational packet. He noted that Dr. Friedman had already asked about copyright issues and indicated that he could give her more information.

XI. *Ex Officio* Members (Continued)

A. Dr. Reeves

Dr. Reeves explained that he did not have a lot to report from the last meeting. They are continuing the education efforts that have been discussed. They are also in the process of doing a lot of research and trying to publish a lot of data. They are trying

to get several studies underway, and a major part of these efforts is the epidemiological study that he presented on previously.

One of the unique things that he has not stressed in the past is the spin offs that occur and the collaborations. They have collaborations with NIH through an interagency agreement and can develop MADB (micro array database) systems. This data processing system is used to combine the epidemiologic with the gene readouts. They got a custom PNI chip that contains all of the genes involved in all neuroendocrine pathways that involve the central nervous system.

They are in the midst of testing specimens from 4 years of follow up in their Wichita study. He noted that he discussed this study in a previous meeting, which focuses on determining the prevalence of and risk factors for CFS in five metropolitan, urban, and rural populations. It is in IRB review and should commence in a month. The study will involve 30,000 people in defined populations. They are in the process of negotiating a contract to continue this work and to sponsor inpatient studies of people with CFS in the general population. The research program is ongoing, and the things he has discussed are on track.

Dr. Bell asked Dr. Reeves some questions based on the minutes from the last meeting. Dr. Bell referred to the diagnostic criteria instruments. He shared that he made a serious attempt to obtain these tools and apply them in his clinical practice and was not able to. He noted that there were financial, proprietary, and technical constraints. He would need, for example, to buy a new computer. He is concerned that there are a number of clinicians who have an interest in CFS and may want to present data at the CSFAA or other meeting whose data does not count because they do not have the appropriate sub-categorization. There could be an increasing gap between the researchers, such as those in the centers, and researchers who are trying to continue their clinical practice at the same time. If this gap increases, there will be even less communication. He asked if there is a way to bridge this gap, perhaps by going to the clinical criteria as the Canadians have done.

Dr. Reeves responded that he does not have an easy answer. When they first presented these criteria at the AACFS meeting, they were asked to make everything accessible on the web. They thought the case definition was clear and easy but it turned out not to be when it was put into practice. He noted that Dr. Bell, Dr. Lapp, and half a dozen investigators have contacted him to get copies of these materials. Many of the instruments are patented and proprietary, and he does not have a solution around this. Some of the ones that are not patented and proprietary, such as CIDI for psychiatric disorders, require training. Others, such as CDC's symptom inventory, are still in the process of being revised. He suggested that this is a useful topic and would like to work with CFSAC to do this. He noted that this is an education effort to get information out to practicing physicians. If there is a way to make standardized

instruments that can be made available, he noted that Dr. Komaroff and Dr. Gantz have experience administering them.

In terms of a clinical case definition, Dr. Reeves noted that he does not have good answers because they are primarily interested in research. Dr. Jim Jones in their office is working very closely with a CDC collaborative group called Brighton Collaboration, which attempts to draft more simple standardized case definitions that can be used in clinical and public health sectors. They have been working on a case definition for CFS.

Dr. Bell asked if there is any way that CDC could find a group of instruments that are public domain and could be administered by clinicians in an hour for preliminary studies. He acknowledged that they could not use the full CIDI or many other instruments for this purpose.

Dr. Reeves explained that they are in the process of putting together a publication validating the CDC symptom inventory. They have done additional work in this area to come up with a standard instrument with scores to identify symptoms. This is what they do it for their studies. The important instruments that the case definition revision addressed are how to document fatigue. The Multidimensional Fatigue Inventory and the Checklist of Individual Strength are the two instruments recommended by the international group. These instruments are proprietary. SF36 is the instrument the international body recommended for evaluating, summarizing, and quantifying disability. This is also a proprietary instrument that must be bought. Also important to CFS is measuring psychiatric comorbidity, which requires CIDI. CIDI is available to WHO but copies not just given out.

Dr. Reeves noted that clinicians can go through psychiatric comorbidity and physical causes in the way they normally do. These issues are more critical in research. A symptom checklist is free. How a physician evaluates disability for someone applying for social security disability benefits is another issue. If someone is in clinical practice, then they are going to do things somewhat differently than someone doing research.

Dr. Bell explained that this is an important issue for patients because many are denied benefits by private carriers. The excuse that is frequently given is that they do not fulfill the CDC research criteria. In Dr. Reeves's recent paper, it is clearly stated that these are research criteria. From a practical perspective, it is still being used against the patients.

Dr. Reeves thinks that part of the solution may be physician education. CDC's published case definition states that patients with fatigue that cannot be explained by a physical or psychiatric cause and is accompanied by four to eight symptoms can be CFS. Any physician can do this, but disability is a separate issue. He noted that they heard some good presentations from SSA and others, and eligibility for social

security is not through diagnosis but through the disability. One can diagnose this without doing everything that is in the case definition. With diagnosis, it is very clear-cut, and a simple instrument like the symptom checklist can do this. What physicians tend to ignore is the necessity within their medical ability to determine if there is a medical or psychiatric disease that can be treated.

Dr. Lapp asked Dr. Reeves about the questionnaires he suggested. He explained that before they had computers, they used to send the SF36 and other instruments to a house with a computer, which would then send the results back. Would the CDC consider taking in the forms that are filled out by researchers or clinicians, processing them, and returning them, or could they consider subsidizing these tests for physicians with a number of CFS patients?

Dr Reeves responded that he is not sure. He noted this would involve two issues. First, there are copyright issues and the question of whether the federal government can get a license. Second, there is the question of whether CDC, which is supposed to be doing research to find ways to prevent and control this disease, should be subsidizing SF36 analysis by investigators. He explained that anything they give out takes away from CDC's research. He noted that these are the types of costs that could be absorbed by portions of a research grant.

Ms. Fero made an observational comment. She noted that there has been a lot of discussion of measuring psychiatric comorbidity. When she hears these discussions, she is reminded that there are people falling over because they cannot sit up for more than a few minutes, and this is a much larger issue.

Dr. Reeves explained that if a physician taking care of a very ill patient, he/she will look for what can be done immediately to treat the patient. Any physician must take these things into consideration.

Ms. Fero acknowledged that this is probably not within Dr. Reeves's purview, noting that her comment relates to physician education and where CFS patients are referred. She understands that there are some psychiatric issues and the need to treat what is possible. However, they often hear physicians not wanting to treat the physical illnesses.

Dr. Bell asked that this issue be added to the education discussion.

Dr. Reeves clarified that they are talking about two different things. First, there are research criteria for studies trying to look at the CFS pathophysiology and risk factors. In these studies, it is critical to identify accompanying conditions, so they do not confound the results. This is the primary intent of the research case definition and the recommended instruments, so that the comorbid conditions that are either exclusionary or stratified variables are removed. Physician education and recognition, diagnosis, and management are different things. If faced by an ill patient, a physician

is not going to stratify the individual and put them in the research program. They are trying to design good, well-rounded instruments for patients with unexplained illnesses, so that physicians can put the patient in the right category to provide the right kind of care.

Dr. Komaroff said that one of the tasks is to look for synergy between the different agencies. When he looked at the Georgia study, he asked if theoretically there could be NIH-funded studies that could be tacked onto CDC's studies to achieve economies of scale. He noted that the CDC studies contain extremely well characterized, epidemiologically defined cohort. He asked if there are questions that CDC would like to and could address using supplementary NIH funds.

Dr. Reeves responded that this is always true. One of the things they are trying to do in the Georgia study—he noted that they talk about extramural and intramural and collaborations with universities—is to have senior faculty from Emory University in the CDC CFS research group meetings. They have senior faculty in departments of neurology, endocrinology, and psychology who are very active in research. Emory University is examining the possibility of applying for an NIH grant for a Center of Excellence. One of the goals of the Georgia study is to funnel people into a GCRC study. They also hope to initiate a patient registry in Georgia, which will begin when the first phase of the study is completed. The registry would funnel patients into every university center for fatiguing illnesses. Under NIH or other funding, they would be enrolled in studies on various interventions.

Dr. Robinson noted that with physician education they sometimes forget that psychiatrists are also physicians. They have the capacity to spot and feed back those patients who were referred to them inappropriately. As a result, it is important that those psychiatrists are included in the physician education process.

Ms. McLaughlin added that all illnesses have fatigue, and that that may not be the way to look at it. Earlier they heard that HHS cannot rename the illness, but CDC named CFS and came up with the definition. She referred to recent studies that provide outcome measures and the Canadian definition developed by an international panel of experts. She questioned why they need a bureaucratic research definition when this panel did not. Something may be good for a research group, but if it is not applicable to the patient population, then it does not do much good. She did not see what was wrong with the Canadian definition, which does recognize people who cannot exercise. Many patients are worse off because they exercised and were not properly diagnosed.

As a point of clarification, Dr. Fields noted that HHS has not made any statements regarding this issue. The Secretary cannot do anything in the absence of a CFSAC recommendation on this and other issues.

Dr. Reeves clarified that CDC does not have a CFS case definition. CFS was first defined in 1988 by a committee that CDC helped put together. This committee wrote a peer-reviewed article. In 1994, CDC convened another group of experts, which included everyone who had worked on any CFS case definition ever published, to reexamine that case definition. This international group, by consensus, wrote the current, only peer-reviewed, internationally acceptable research case definition for CFS. There are no others. A third international group was reconvened, again with every leading researcher on CFS (except one who was too busy to come), and published a peer-reviewed article on their recommendations for how this case definition should be used. The government has never mandated these international consensus, peer-reviewed articles that have been accepted internationally.

Mr. Sterling noted that the minutes of the last meeting reflect that they were three FTE positions short.

Dr. Reeves explained that the position that was withdrawn has now been restored. They hired a GS-14 NIH senior epidemiologist, who has worked on chronic diseases of viral origins. They are still in discussion with CDC about the other FTEs.

Ms. Stevens asked if it would be appropriate to recommend that the CDC research program be fully staffed by filling the FTE positions. Dr. Bell said they could communicate via email to formulate the exact recommendation, then recommend and vote on it at the next meeting. He noted that he would not be against making a recommendation at this meeting, but that he was not sure they were ready to work out the wording.

Dr. Komaroff asked if time is of the essence. He agrees that the language should be carefully thought through, but is concerned that deferring this to the next meeting may compromise CDC's ability to be fully staffed.

Dr. Reeves said time is of the essence in all of these things. FTEs take a longer time to fill.

Dr Gantz suggested a vote on this proposal and Ms. Stevens asked to make a motion.

Dr. Bell asked to make it a preliminary request to the Assistant Secretary of HHS that the current FTE positions at CDC regarding the study of CFS be filled. This will be done as an urgent priority. This will be a preliminary request and their whole discussion and other aspects of the CDC request may follow.

The motion was seconded and all voted in favor. Dr. Bell explained that he will put that submission in writing and submit it to the committee within a week's time.

B. Dr. Cavaillé-Coll

Dr. Cavaillé-Coll said he did not have prepared remarks and asked if there were any questions from the committee.

Ms. McLaughlin asked about blood transmissibility with CFS and ciguatoxin. She asked if there was any way to follow this issue. Dr. Cavaillé-Coll responded that this would have to be addressed by CDC.

Ms. McLaughlin then asked about amyloids and if they had gone any farther. Dr. Reeves responded that they are still working on this area, and it is too premature to discuss it at this time.

C. Dr. Robinson

Dr. Robinson had no report except that as the subcommittee on education continues to meet, he will continue to encourage specificity in terms of what exactly the committee wants.

Dr. Bell added that the education of children affected by CFS is an important issue, and that it should not be solely focused on medical education.

Dr. Robinson noted that education remains the purview of the Department of Education (DOE). As a result, there are some areas where DOE, HRSA's Maternal and Child Health Bureau, and CDC's Division of Adolescent and School Health have collaborative responsibilities. He suggested involving someone from DOE to gain their perspective. The specificity of whose area and what you would like to see would come out of the question: "What would you like to see?" Depending on what you would like to see at the various education levels would determine who would need to be most active.

Dr. Gantz noted that that is an important point for school children, where parents are called delinquent because their children are ill. The nurses and school systems need to be educated to understand the illness.

Dr. Bell said he would email Dr. Patarca to include education for children.

Ms. Fitzpatrick asked from a practical diagnostic standpoint, what is the youngest age that people can be diagnosed with CFS.

Dr. Bell said it is extremely difficult to diagnose CFS in young children. It is easier when kids are in adolescence and the symptoms become full blown. He acknowledged that he does not know how to approach this in an organized way.

Dr. Lapp said that the two things they look at in children are the level of fatigue and the cognitive difficulties. Both of these are difficult to determine until they are with peers. Age five is the youngest he is comfortable with a diagnosis because at that age, they are in school.

D. Mr. William Anderson

Mr. Anderson explained that SSA has an interactive video training (IVT) for their 80,000-member staff. The IVT will be shown on April 1st and is primarily directed at their litigators, such as general counsel and those that have involvement with the courts. He asked people to let him know if they want to see the video. Seeing it live will be more challenging, but he noted that he would try to arrange it if anyone is interested. They have gathering sites all across the country, and it can be viewed from any one of their offices. The script is completed and the rehearsal is scheduled for next week.

Secondly, he noted that everyone asks how many people are allowed or denied. They have been tracking this in his office very closely. The numbers this year are running true to form to previous years. Years ago, they use to follow ICD-9 coding, then moved to impairment codes. When they published the ruling on CFS, they implemented an impairment code for CFS. Their ability to use data relies on the accuracy of those who make determinations. As a result, they are very hesitant about presenting numbers because they are not sure people are correctly applying the impairment codes.

In 2000 (starting in August), there were 2,000 total case filings, with 4,326 in 2003. In 2000 (starting in August) there were 255 allowances, and 833 in 2003. They are also tracking allowance rate trends. They are concerned about the variations they have state by state in almost every category where they do disability determinations, especially in those that are more subjective, such as CFS. As a result, they are going to bring some cases into the central office before they are adjudicated, which is not normally done.

Dr. Bell asked Mr. Lieberman if this would be an area that would benefit from a subcommittee. Mr. Lieberman responded affirmatively and expressed his willingness to lead that group. Dr. Gantz moved to create a subcommittee on SSA disabilities, and Dr. Lapp and several others seconded the motion.

Mr. Sterling asked what kinds of disabilities (e.g., private or long-term) would be included. Dr. Bell noted that it would be difficult to approach private disabilities, but that it would be up to the subcommittee members to decide.

All voted in favor.

E. Discussion

Mr. Lieberman said that on February 27th, he spoke on CFS at a seminar in Atlanta. The seminar was well attended and received by practitioners, as well as members from OHA, staff attorneys, and members of the General Council's office. The reason for the attendance was the keynote speaker, Commissioner JoAnne Barnhart. Commissioner Barnhart is a dynamic and terrific leader, and will be the focal point in bring the SSA disability system into the modern age. During the seminar, she stated that it is important for those who are disabled to be allowed benefits as soon as possible. When a person files a claim, the initial two decisions are made by the state. These are called the initial level and the reconsideration level. Therefore, if a person is allowed at those levels, they are not required to go through the federal process.

After the last meeting, he was given the charge to examine how to assist those at the initial and reconsideration levels. To do this, he spoke to present and past DDS physicians, longtime adjudicators, individuals from QA, and colleagues who are well known practitioners in New York, Los Angeles, Dallas, and Chicago. He could not get a number for the proportion of claimants with CFS who were accepted for disability. He tried the Freedom of Information Act, and was told that that information was not collected. He was hoping to get a consensus on how they were helping clients at the initial and reconsideration levels, but each group had their own unique perspective. The adjudicators said they need more training. The QA people said they know about SSR 99-2p on how adjudicators are supposed to deal with these cases, but they do not see the records because so many are declined. The state agency physicians said that unless they see it in an MRI or x-ray, they cannot rate it. Some even asked what SSR 99-2p was.

He shared an example that he gave in his seminar. When the SSR came out and there was training across the country with DDS personnel and administrative law judges, it was hoped that they would decide cases from the same book and get the same results. Through the years, the attitude of DDS was that that was for the judges, but not for them. They have a 25% turnover rate in adjudicators at the DDS level, mainly because they are underpaid. As a result, there are people who have never heard of or trained on SSR 99-2p. SSR 96-7p states:

> Because symptoms, such as pain, sometimes suggest a greater severity of impairment than can be shown by objective medical evidence alone, the adjudicator must carefully consider the individual's statements about symptoms with the rest of the relevant evidence in the case record in reaching a conclusion about the credibility of the individual's statements if a disability determination or decision that is fully favorable to the individual cannot be made solely on the basis of objective medical evidence.

> An individual's statements about the intensity and persistence of pain or other symptoms or about the effect the symptoms have on his or her ability to work may not be disregarded solely because they are not substantiated by objective medical evidence.

As part of his talk at the seminar, he attached the page where the DDS physician has to determine whether or not the complaints that the patient has are credible. The page reads:

> The claimant is a 30-year-old female with multiple allegations. The allegations are not well supported by objective data.

This statement is totally opposite of what the ruling states. He could have picked up 50 of these. The training for the General Council's office and those involved in litigation is important, but he asked about training for the people at the front end.

Mr. Anderson had several comments. First, he noted that one should be careful about asking state institute adjudicators if they are aware of SSRs because they will say "no." When SSRs are published, they are printed verbatim in the Program Operations Manual System (POMS). As such, these SSRs are given a POMS number, which is familiar to most adjudicators.

Second, he noted they have some good policies regarding pain and subjective symptoms. With the help of CFIDSAA, they have a good SSR that discusses how to evaluate CRS. He noted that this is like: you can lead a horse to water, but you can't make him drink. There is a tremendous amount of misconception and disagreement about CFS and FM in the medical community. This is why they are told that when they walk through SSA's door, you have use SSA rules, which does recognize subjective symptoms.

The challenge of the SSA is that it is a federal program that is operated in conjunction with 54 state agencies. Those agencies are staffed by state employees and though they must follow SSA rules, it is a challenge to get their full attention. SSA looks at 50% of the state allowances and 2% of their denials. Through this QA process, the SSA gets a good sense of where more information and training is needed.

Keeping all necessary parties on the same page on rulings and procedures is a tremendous challenge. In addition to Mr. Lieberman's DDS-level example, this problem also exists at other levels. Attorneys are also being trained because they have to defend decisions that have the faulty reasoning as in Mr. Leiberman's example. There were two training sessions on CFS. One occurred when the ruling was issued and another about a year ago.

Mr. Lieberman agreed that some judges fall into the same categories. However, if allowances are going to be granted early in the process that is where the training has to be. Mr. Anderson agreed.

Mr. Sterling asked if SSA had sufficient staff to move forward with training. Mr. Anderson said that it is a difficult question. About 6 years ago, they were tremendously understaffed. Since then, they were able to staff up but lost a few more. They are under budget pressure and would like more staff, but he has enough to do what he has described. He currently has one ongoing study of live cases (those that are being adjudicated before the client is notified of a decision) to fix problems before adding to the claimant's problem. The problem with that is that the initial case processing time is 85 to 90 days, so when it gets to them, they have to send it back quickly. Once this study is completed, he will be able to move forward on the CFS study, which is about a month away.

Ms. Fero observed that in Madison, CFS claims are usually processed in the first or second round.

Mr. Lieberman said that 37% of cases were awarded at the initial level in FY 2003. In the Stone Mountain, Georgia office, they had 87 CFS cases, of which five were allowed (less than 6%). Mr. Anderson said that of all cases that are allowed, almost 75% are allowed at the DDS level.

Dr. Bell suggested that the subcommittee pursue theses issues and have specific issues clarified by the next meeting.

XII. CFS Miscellaneous Matters

Dr. Bell suggested that they begin the discussion of miscellaneous matters with CFSAC's charge as a committee. His understanding is that they are an advisory committee and that their term is for 2 years. He then asked Dr. Fields for clarification.

Dr. Fields explained that the function of the committee is to provide recommendations to the Secretary, through the Assistant Secretary, on CFS.

Dr. Bell asked about timeframe. Dr. Fields explained that they can make recommendations as soon as they want and that CFSAC exists under a 2-year charter. This charter is scheduled to expire in September 2004, and they are in the process of renewing it for another 2-year cycle.

Dr. Bell asked if the current charter expires on September 1, 2004. Dr. Fields responded that he believes the date is September 5, 2004. Dr. Bell noted that the next meeting should be before this date and that they had agreed to aim to hold four

meetings. He added that summer is always a difficult time and asked for suggestions for meeting dates.

Dr. Fields noted that they are on a quarterly schedule and have been scheduling the meetings close to the end of the month, with the exception of December because of the holidays. Consequently, they could begin to talk about specific months.

Dr. Bell asked CFSAC about June and suggested they tentatively aim for mid-June. He asked Dr. Fields to move forward with this timeframe. Dr. Bell expressed his hope that they will have recommendations to discuss and possibly vote on for the next meeting.

Dr. Fields noted that September marks a year out and suggested they query about the end of September. This would make the timeline far in advance in the interest of communication and transparency. Dr. Bell asked if it would have to be before September 5. Dr. Fields explained that they already have the June meeting before then and that the reauthorization process is underway and standard for the most part.

Dr. Bell asked about personnel and if they change on a regular basis. Dr. Fields explained that support is provided and laid out in the budget on a year-to-year basis. He noted that the charter framework is in place and outlines how the support is set up. They do not anticipate any dramatic changes. He thanked and recognized Mary Mullaney for pulling this meeting together, as well as Mary Jo Deering. They have been fortunate to get two FTEs to support CFSAC, and they also made sure they had funding for quarterly meetings.

Dr. Bell then reviewed additional corrections to the December meeting minutes. The revisions included a spelling correction in Dr. Beverly Bugos's name and providing the full name of the Bascom Palmer Eye Institute. He asked for discussion, and no one responded. Dr. Komaroff motioned to accept the revisions. The motion was seconded, and all voted in favor.

Dr. Bell then opened the floor to discuss other matters.

Dr. Friedman noted that there was some discussion about reprinting the New Jersey CFS manual but copyright issues exist. He hoped they could make a preliminary determination about whether CFSAC wants to recommend making it an educational component. If so, he can begin working on these issues.

Ms. Fitzpatrick explained that the manual contains quality material and has benefited the state in which it was disseminated. As a member of the Education Subcommittee, she would be inclined to recommend trying to disseminate it more widely. She asked for clarity about funding issues and if they should be just concerned with making the recommendation.

Dr. Fields explained that this recommendation could come to CFSAC from the subcommittee for discussion. If the recommendation were then forwarded, it would be in the context of recommending that quality materials that are considered best practices be examined for further dissemination. This would be enhancing what is working by identifying the gaps and taking full advantage of existing efforts.

Dr. Bell asked Dr. Fields about the CFSCC recommendations, which they had discussed obtaining at the last CFSAC meeting. Dr. Fields responded that the process is still in progress and that they are creating a table with the recommendations as inputs with some commentary on the context and any outcomes that resulted. He hopes to provide a report to CFSAC at the next meeting.

Dr. Bell then referred to their discussion at the December CFSAC meeting about possibly approaching the Robert Wood Johnson Foundation about funding educational efforts. He noted that this ties into the Education subcommittee and that Dr. Fields was going to explore whether this would be possible for CFSAC to recommend, since the foundation is not under the aegis of this committee.

Dr. Fields responded that this discussion should be integrated into the Education subcommittee's discussions because there are other funding sources as well. This would allow them to look at all of the rational options, including the Robert Wood Johnson Foundation. He explained that their role is supportive, and they do not want to take the lead on what the subcommittee is working on. A recommendation would have to be in place before action is taken.

Dr. Bell asked if there were other issues.

Ms. McCleary noted that at the first meeting Ms. Fitzpatrick or Ms. Butler had suggested commending Laura Hillenbrand for her efforts in raising awareness about CFS. She brought a 6-minute segment on DVD for CFSAC could review at the end of the meeting, if time permits. She explained that Ms. Hillenbrand discusses what it was like being a high visibility person.

XIII. Public Comment (Part 2)

Dr. Bell then turned the meeting over to Dr. Fields for the public comment period.

A. Marly McKibben

Ms. McKibben introduced herself as a patient advocate from South Florida and proceeded to read her statement with Ms. McLaughlin's assistance.

Ms. McKibben expressed her gratitude for being able to travel to Washington DC and speak to CFSAC on behalf of PANDORA, Inc. (Patient Alliance for Neuroendocrineimmune Disorders Organization for Research and Advocacy). She noted that she is also speaking on behalf of the following groups:

- The Chronic Fatigue Syndrome and Fibromyalgia Empowerment Group at Memorial Hospital West, Pembroke Pines, Florida
- The Chronic Fatigue Syndrome and Fibromyalgia Empowerment Group at Temple Sholom, Pompano Beach, Florida
- The Chronic Fatigue Syndrome and Fibromyalgia Empowerment Group, Clay County, Florida
- The Miami Coral Gables CFS/CFIDS Fibromyalgia Support Group, Miami, Florida
- "The Non Group" in Broward County

She thanked and wished CFSAC well on behalf of the South Florida neuroendocrineimmune disorders community and hoped to convey the concerns of people with neuroendocrineimmune disorders as they battle such an insidious illness.

She shared that she is optimistic about CFSAC's commitment to accomplish their assigned tasks and believes the committee has the well being of all CFS patients in mind. CFSAC will be facing many difficult issues, and the road to a final consensus and the creation of national policies for neuroendocrineimmune disorders will be bumpy.

As a patient advocate, she noted that her attendance at the meeting raised the concern of her physicians and could be a serious cost to her health. She explained that she was there because of the importance of CFSAC's work to the neuroendocrineimmune disorders community and, consequently, to herself.

She noted that CFSAC may have heard the issues she will be discussing before but explained the importance of repeating them to ensure the messages are loud and clear. She also asked CFSAC for future feedback on these issues.

First, Ms. McKibben asked that CFSAC proceed in changing the CFS name. CFS is not a good brand name. There are many health conditions with which "chronic fatigue" is described as one of the major symptoms. She used the term "brand" because she believes that branding this condition with the CFS name is misleading and confusing. Branding is a well-known practice in the business and marketing world. It is the way to send a message and to be recognized by the masses or by the targeted audience when one mentions a product, concept, or service.

Her remarks noted that the term "CFS" does a poor job in describing the illness and inspiring respect and credibility towards the patients, and it does not truly reflect the overall symptomology. It does not promote finding a cure because the main symptom described by the condition is one that everyone in this country will experience at one time or another. She explained that we are a "tired and fatigued nation." For someone with CFS, hearing someone say, "Well I am tired and fatigued too, I must have CFS," does not ring true and trivializes the condition.

She explained how the overall lack of knowledge about CFS and the lack of a good brand name in the US are causing collateral side effects for CFS patients. The majority of CFSAC members are familiar with and therefore aware of the implications of using this term. She urged the committee to address the situation.

Current research is showing that CFS is a condition that affects the neurological, endocrinological, and the immune systems, and there is enough current research to support a name change. PANDORA requests CFSAC not abandon the Name Change Work Group. Though there are several important issues that must be addressed, she explained that the name change issue is the top issue patients want CFSAC to address. She explained that she has heard many discussions over the years in CFS support group meetings, chat rooms, patient conferences, and national and local CFS/CFIDS organizations. She asked the committee to address this issue immediately.

Ms. McKibben noted that CFSAC is composed of individuals who are highly qualified to come up with a viable national solution. She advised them not fall into the trap of thinking that tackling the name change issue requires additional time and research. PANDORA believes that branding CFS with a more suitable name will increase research and ultimately allow a cure to be found. PANDORA believes that not acting on the name change now will disenfranchise the neuroendocrineimmune disorder/CFS community from CFSAC's efforts.

She suggested that although it is not listed in CFSAC's mission statement, it is one of their "collateral duties" to energize and unify the CFS community, which could be done by working on a name change. Accomplishing this task will make establishing national guidelines and policy successful. On behalf of PANDORA, she requested CFSAC give top priority to the name change issue. She encouraged the committee not to discard the efforts of the Name Change Work Group.

Ms. McKibben then referred to the second and third items in CFSAC's charter, which are to examine "current and proposed diagnosis and treatment methods for chronic fatigue syndrome" and the "development and implementation of programs to inform the public, health care professionals, and the biomedical, academic, and research communities about CFS advances." She explained that it is an imperative to assign a specific medical code under an umbrella that does not allow any misunderstanding about CFS. There is current relevant research showing that CFS is not a psychiatric

condition or a psychological one**.** This concept is outdated, only hypothetical, and unscientific. She encouraged CFSAC to use current scientific, medical, and clinical research to move forward, strongly, loudly, and courageously.

She shared that Ms. Rebecca Artman, chairperson of PANDORA's Legislative and Advocacy Committee, told her that presently there is no specific medical code or medical billing code to use when someone is diagnosed with CFS. She explained that it is difficult, if not impossible, to acquire medical treatment. Insurance companies (health, disability, and long term), for example, do not provide access to treatment or pay for disability benefits because they believe that the condition does not exist.

Even worse, she explained that this leads to the automatic lumping of CFS with mental and psychiatric disorders and its exclusion in most of the disability policies. Currently, ERISA employer long-term disability and private disability insurance policies are either completely excluding CFS and fibromyalgia syndrome (FMS) by only providing the typical 2-year window of benefits. If a claimant has this type of policy, the insurance companies deny the benefits anyway, making it financially counterproductive and less attractive to hire an attorney to fight for your rights. She added that if a CFS patient is able to rejoin the workforce, the individual would not be covered if he/she suffers a serious disabling relapse because of preexisting condition clauses.

Persons with neuroendocrineimmune disorders are blatantly discriminated against, regardless if they paid their premiums on time or if these benefits are made available through an employer. The reality is that when the benefits are needed the most, they are often painfully denied. Currently, the disability insurance companies are listing CFS in their policies as a self reporting illness, which implies the patient is in charge of the diagnosis. If the CFSAC truly accomplishes its mandates, these hurdles will no longer be encountered.

The third issue raised in Ms. McKibben's remarks was NIH funding for CFS. She asked for a clear public accounting of the monies NIH has spent on CFS research over the last 10 years, as well as an explanation for the sharp decline in funds for the last 3 years.

The fourth issue raised by PANDORA suggests that CFSAC form a subcommittee to develop policies to increase CFIDS research efforts. She asked CFSAC to prioritize the methods they advise for increasing this funding.

The fifth request Ms. McKibben made was for alternative ways for the CFS community to communicate with CFSAC. She suggested CFSAC explore bringing some of the committee meetings to major cities in the US. A sure way to stay in touch with the neuroendocrineimmune disorders community is to attend and share their message actively at the many patient/medical conferences, which occur from time to time in many areas of the country.

She explained that CFSAC needs to do a better job in reaching out to the national and local organizations, which have a stake in their accomplishments. Though these organizations may not be equal in their agenda and representation, most have a strong impact in their geographic areas.

As the governmental body created specifically for CFS matters, she challenged CFSAC to strongly influence the Office of the Secretary by addressing these matters. If CFSAC accepts these challenges, she offered PANDORA's unequivocal support and appreciation.

She thanked CFSAC again for the opportunity to speak on behalf of PANDORA and invited the committee members, particularly those who live in South Florida, to join them in promoting Awareness Day for CFS, FMS, Gulf War syndrome and multiple chemical sensitivities by attending their 4th Annual conference "Inspiring Hope Through Awareness" on May 14, 2004 at the Pompano Beach Civic Center, Pompano Beach in Broward County, Florida.

B. Eileen Holderman

Mr. Jon Sterling read Ms. Holderman's statement aloud since she was too ill to attend the meeting. He shared that she is a good friend who he met during one of the lobby days in Washington, DC.

Ms. Holderman wished CFSAC and the meeting attendees a good day and introduced herself as a woman living with CFIDS and FMS. She was diagnosed approximately 10 years ago and took a medical leave of absence from her job at the Metropolitan Museum of Art in New York City. She has been on social security disability ever since. As her health permits, she advocates on behalf of the nearly 1 million American men, women, and children contending with and/or disabled by CFIDS.

On Oscar night February 29, 2004, Ms. Holderman slipped into a black evening gown, beaded jewelry, high heels, lipstick, and curled locks to attend a fundraiser honoring Laura Hillenbrand for the Academy Award best picture nomination for the film based on her best-selling book, *Seabiscuit: An American Legend*, and for shining the spotlight on her personal struggle with CFIDS.

When she arrived at the gala, she encountered people representing the patient, academic, medical, scientific, government, and non-profit communities, as well as members of the press. She noted that she received numerous compliments on her appearance, which were worthy of the stars they watched on the screen. While she appreciated the compliments, she wished she felt as good as she looked.

That night she looked glamorous, but her appearance betrayed how terrible her body felt. The climb to the top of the stairs upon entering the snazzy restaurant took

monumental effort and left her already feeling exhausted for the night. She experienced sensory overload as she greeted and met guests and competed with the loud music and flickering lights from the big screen televisions. Though she enjoyed watching the Oscars and rooting for Ms. Hillenbrand, the music and images induced a headache that stayed with her for the rest of the evening.

While the conversation was stimulating and focused on the worthy cause of CFIDS, her cognitive impairment overpowered her with an inability to consistently articulate her thoughts and recall what was last said in a conversation. When she stood in her high heels, her excruciating chronic muscle and joint pain reminded her that she was not a Hollywood star but a patient with CFIDS who is primarily homebound. Problems with her bladder dictated that she only drink bottled water and refrain from eating spicy hors d'oeuvres every day of her life. Fortunately, the ladies restroom was just steps away because it is a place she must frequently visit. While she applied her lipstick that night, she did not need blush since her low-grade fever gave her rosy cheeks.

That night reflects her 10-year journey of losses and gains battling these chronic and incurable illnesses. She lost her good health but acquired an education about her illnesses. She lost her job at the museum but became a patient advocate for CFIDS. She lost her active family life but created ways to stay connected with loved ones. She lost her athletic endeavors but found yoga. She lost her husband when he abandoned her because of her illnesses but rediscovered a friend she had known for 35 years. She lost her life savings defending a divorce action against a spouse who refuses to acknowledge her disabilities and his obligation to financially support her but received help from her family. She lost her voice in the matrimonial court system because of corruption and lack of disability awareness but overcame adverse judicial rulings through her faith in God, support from the CFIDS community, and an attorney who she is teaching to advocate on her behalf.

Ms. Holderman shared that after leaving the gala that night, she stopped outside her hotel with her friend to admire a sidewalk artist's work. He admiringly invited her to sit for her portrait. Because she was depleted from her efforts that night, that chair looked especially inviting. As she sat there, it was as if the artist peered into her soul and used his talent and a piece of chalk to portray her story. As she gazed up at her portrait, she saw herself looking back at her. She saw a woman living with CFIDS—a woman weary yet resilient, disabled yet beautiful, challenged yet wistful.

After Mr. Sterling finished reading Ms. Holderman's statement, Dr. Fields held up the portrait for CFSAC to see.

Dr. Fields asked if Barbara Commerford was present to give her remarks, and Mr. Sterling responded that she was also too ill to attend the meeting.

C. Christine Kraus

Ms. Kraus thanked CFSAC for the opportunity to speak today. She introduced herself as part of WCFSA, along with Ms. Fero. She shared that they call Ms. Fero a powerhouse even though she has CFS and is often ill.

Ms. Kraus shared that this August will be her 20-year anniversary of having CFS. This is a milestone in her life and a chance to reflect. She then asked how they have done since 1984. In Wisconsin, their Board of Directors is made up of volunteers who are all CFS patients. Many of them have problems staying on course, thinking clearly, verbalizing ideas, following through, and staying healthy enough to contribute the way they would like. They struggle.

Because every single thing that the board does takes a toll, they have to prioritize. They publish *Lifeline*, a quarterly newsletter in which they take great pride. They keep the organization's infrastructure sound and solvent, and they have now accepted the challenge of hosting the 2004 International AACFS Conference. She does not know where they get the nerve. The biggest change she has seen in the 15 years she has been on the board is that the goals are becoming more ambitious.

She explained that much of their effort went into organizing CFS Awareness Day on May 12th. They would set up information tables in hospitals and distribute their brochures in hope of informing some health professionals about CFS; they were attacking a forest fire with squirt guns. They also spent years trying to work within the system by meeting with administrators and doctors in various medical centers. This, however, brought them no closer to being able to offer their members the medical help that they so desperately need. Most patients do not expect a cure but just some relief from symptoms and maybe some understanding of the complexities of CFS.

Her greatest disappointment is that they have not gotten very far in 20 years. She explained that so many horribly ill patients are still being mistreated and are slipping through the cracks. Their board members have heard some heartbreaking stories. She shared that they are desperate, and probably naïve enough to believe their best chance for good patient care is to open a clinic. The PANDA clinic will treat illnesses such as chronic lyme, post polio, lupus, Gulf War syndrome, and CFS. She noted that they have yet to obtain the collaboration they need with a medical group but are confident that they will. They are fundraising, brainstorming, recruiting, and struggling. She added that PANDA will be offering more than medical care and have good ideas on intake procedures, social services, and care giving. They are very determined to make the clinic a reality, and she referred to Margaret Mead's belief: "Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed it is the only thing that ever has."

She noted that a pertinent question is why CFS patients are so underserved by our advanced medical community. She asked why their chance at good medical care is coming through the efforts of these compromised patients. She shared that she can get so sick that it will not occur to her to take medication, push to liquids, or call her doctor. She is often too sick to be in charge of her own care, but she must be responsible for helping to change how medicine is being practiced for CFS patients.

Ms. Kraus noted that 20 years is a long time to wait and that the science will eventually catch up and provide the last few pieces of the puzzle. She explained that the science must be encouraged and generously funded. In the meantime, there has to be a widespread, proactive protocol that will treat symptoms and relieve some of the suffering. She noted that most often CFS is not fatal but is robbing them of their lives. In the past, the WCFSA tried to bring hope to their members, but now they are working on real help. The patient need for treatment cannot be overstated, and they are determined not to let another life slip by unnoticed.

In closing, Ms. Kraus thanked CFSAC for their help and consideration.

Dr. Fields called the remaining names on the public comment list. Since none were present, he opened the floor to new speakers.

D. Dr. Mary Schweitzer

Dr. Schweitzer thanked the committee for another opportunity to share her remarks. She noted that she brought the written remarks of two other CFS patients in Wisconsin and Georgia, since she was unsure if they made it into the record.

Dr. Schweitzer also brought some information that was published in the UK Parliament's equivalent of the US's *Congressional Record*. In the UK, they have decided to use the term CFS/ME until a scientific name is developed and to follow title ICD10 G93.3. Dr. Schweitzer explained that she has been suggesting introducing CFS/ME as a new name for some time. They are a part of the international community and research is being done internationally.

In addition, she shared more information from the UK on Action for ME's a 1% Campaign Petition. Several years ago, she published her analysis showing that $8.3 billion is lost to CFIDS. The UK found that 335 million pounds are lost in revenue, benefits, and healthcare annually for the 240,000 people with ME.

Dr. Schweitzer noted that there is opportunity cost. People are struck at the age when they should be and want to be most productive. As an economics historian, she explained that this portion of GDP is important. The 1% idea is to take 1% of the $9 billion in losses, which is $90 million, and invest it in research. She suggested making

this a goal in the US and not compromising for $16 million or less. This figure does not account for money lost in lost taxes.

Dr. Schweitzer also brought the petition from the Name Change Workgroup but noted that it was attached to Ms. McLaughlin's statement. She asked CFSAC to examine the petition again, noting the amount of work done. She and many others have been impressed by the work of the Canadian group, which includes some Americans. They need a new name for CFS, and CFSAC has to address this issue since the "f" word is what denies most of them treatment. Most of the doctors she talks to in Delaware simply tell her they do not believe in CFS.

In addition, Dr. Schweitzer proposed that no federally funded clinic or doctor that receives federal funding should be allowed to deny the existence of CFS. She asked how this denial could be allowed when CDC recognizes it as a debilitating, life-altering illness. She is unsure of how to move forward with this recommendation, but it is like the discrimination against any other group.

Dr. Schweitzer sees a sense of urgency in CFSAC. She is hearing more suggestions and ideas. It took 2 years, but she believes they have done a good job of coming together and can accomplish things. Like the speakers from Madison, Wisconsin, she does not want to lose anyone else and feels like she is in a battle zone. She does not know where the 80% to 90% of undiagnosed individuals are. She has met people who were living in the streets because they have CFS. She suggested CFSAC worry about where these people are.

In closing, Dr. Schweitzer noted how the estimated number of people with CFS has risen through the years. With the bad flu season, she predicted another rise. The last data they have are from 1996 or 1997. When they do a study in 2005 to 2006, she believes the estimate will increase to over 1 million people. This is cause for alarm, and those with CFS will tell CFSAC how scary this illness is.

She thanked CFSAC for the opportunity to speak and bring written materials on behalf of those who could not attend the meeting. She expressed great hopes for CFSAC and wished that they be renewed.

E. Other Public Comments

Dr. Fields asked if there were other public comments.

Ms. McKibben commented on Mr. Anderson's remarks about SSA, the approval of claims for CFS, and how CFS is sometimes not listed as the primary illness. The way the system works is that people with CFS and FMS often get diagnosed with depression. She suggested they examine this issue since they create an environment for the approval of claims and it is happening across the country.

Mr. Lieberman explained that SSA tries their best to use any possible impairment to support a claim. When a claimant completes the form that describes their impairments, if the person shows any signs of a psychiatric impairment, that individual is required to see a psychologist or undergo a mental health examination.

F. Other Discussion

Dr. Bell opened the floor for other discussion by building on Mr. Lieberman's comments. As a clinician who sees several CFS patients, he routinely tells his patient who are applying for social security to consider getting the benefit for 2 years as practical advice; it is rare to get it in the first or second years. Secondly, with disability, the issue is whether the person has the ability to perform full-time work. For social security disability, it is well known by most of the patients and attorneys in upstate New York that if you apply under depression, it is a much easier case. Patients do this as a routine. He noted that if a person has a simultaneous disability, this would sabotage that disability.

Dr. Bell then asked Dr. Reeves about the case definition. A part of this definition emphasizes symptom severity and clarity strongly. As a clinician, he would see the disability of this illness in three discrete areas: cognitive, orthostatic intolerance, and pain. When patients come in with symptoms, he gets a sense of how disabled they are based on their presentation and an assessment of these three types of symptoms. He asked if there is a way to coordinate this between CDC and SSA to make it easier for SSA to assess claims.

Dr. Reeves responded that he does not know. Though the communication is easy, he suspects that the codification is more difficult. He explained that he has not had to address how to obtain or document disability. The SF36 is one standard way to document. When they were working through the case definition, instruments that easily document chronic pain were not available. Simple ways to document impaired cognition are also not readily available. One of the ways they become available is when they are published and become a part of the literature, which will hopefully be the case with their symptom checklist in the next 6 months.

Dr. Reeves explained that in their Wichita clinical study, they devised a scoring algorithm for their symptom inventory. This will document the accumulated symptom severity. They will have measures, but it will take some time to complete. They will benchmark this against a half-day's testing of cognitive function, the SF36, and all the measures they did in the clinic. They will have a simple symptom inventory that can be administered and scored in a simple standardized way and that has been normed against standard measures of disability. It will take time for it to get out and become acceptable. Conversations with SSA would be simple, but the problems come in trying to get things accepted.

Mr. Lieberman explained that the doctors are really the key at SSA at the lower levels, and it is hard, as Mr. Anderson mentioned, for them to get out of "doctor mode" and into the "social security law mode." The 99-2p ruling came out after a year of working through parts of it. It was supposed to be the vehicle that allows SSA to deal with the difficult challenges. They are still having a challenge. Most CFS patients are under age 50. At this age for disability purposes, these individuals have to show that they cannot do any sort of sit down, full-time job. With a 48-year-old nuclear scientist, for example, the question is not whether they can do their profession. The issue is whether they can do a job like taking tickets at a movie theater. CFS patients who are the most severely impaired, cannot do a 40 hour per week sit-down job. When he was a judge deciding these cases, it was called Epstein-Barr virus. When people would come in and the judge believed that something was wrong but could not determine the illness, they would turn to things like bringing in a psychiatric medical advisor, since that is how cases were decided. In some cases, this is harmful to the patient. In time, he hopes that there will be more response from SSA physicians. Once that happens, he believes the rest will fall into place.

Dr. Bell asked for additional comments.

Ms. Fero explained that when she first started, there were 267 groups, but today there are far fewer. She no longer knows how many organizations there are now, but they are doing the lion's share of the public service work. She asked if there is a funding source to support projects as there is in the UK. She named Dr. Betty Dowsett's center for neurological disorders as an example. She asked if there is a source in CDC or NIH for projects or if they always have to have the university collaborator. For their group and their PANDA project, she is not sure if they can get an academic to work with them and asked if any mechanisms are set up for this purpose.

Dr. Bell responded that he is not sure where the mechanism is set up, but that there are many ways to apply for funding. The important issue is that over the past 5 years a sense of despair seems to have settled over the CFS community, which disturbs him. His perception is that the support groups he remembers being so active seem to have given up. During the first meeting, it was suggested that perhaps the public service announcement (PSA) could be made available to support groups who could then try to get it broadcast by local stations. HHS could do its part by making the PSA available, but the burden of responsibility would be with the support group, which is a difficult burden to bear.

Ms. Fero responded that there is hopelessness, but on a practical level, the support groups are scattered and the state groups have disappeared. If they connect with someone who wants to find a clinical population to work with, it can be a problem. These things are all interrelated. She noted that there are projects, such Ms. McKibben's PANDORA project, happening around the country, and there should be a way to support these efforts.

Building on Ms. Fero's comments, Mr. Sterling explained that good researchers who were conducting studies would turn to support groups as a valuable resource to find a patient base. They would go to support group meetings but would not guarantee that an individual would be included in the study. He noted that there is a good reason for why these groups are disappearing. It is a natural outcome of volunteer-run support groups whose volunteers are mostly sick and burn out over time. In his state of New Jersey, for example, local support groups have dwindled from 15 to about 7 or 8 active ones. They still do a great work on a state level, such as the manual that was discussed earlier and conferences and CME credits that are recognized by the major state medical institutions. They will have a booth at the Medical Society of New Jersey and will expose 500 physicians to accurate information about CFS. He noted that it is getting harder and harder to do these activities.

Mr. Sterling noted that the BBC news is reporting on how 8.5 million pounds are being invested in 12 new centers that are treating CFS/ME patients around the UK. There are also 28 support teams that are providing rehabilitation programs and home care services. They have a statement of support from their health minister, itself a PSA, which recognizes CFS/ME as a debilitating and distressing condition that affects people of all ages and poses a challenge to the national health service. He noted that people are always talking about getting accurate measures, and this is an idea to build on. He would like to think that they are on their way to this through the Centers of Excellence and CFIDS clinical trial groups. He said they have their own model with AIDS, which is also a syndrome. This is one of the reasons why patients are getting disillusioned and dispirited, and this type of action is required to address this sense of hopelessness. There was the hiatus between CFSCC and CFSAC and level research funding despite the severity of the disease.

Ms. Stevens asked that the differences and implications of these differences between Centers for Excellence and clinical trial groups be put on the agenda. Dr. Bell suggested they add this to the NIH ex officio portion of the meeting but asked if they would like to discuss it now. Dr. Hanna explained that the Centers for Excellence are under Secretary's office, not under NIH.

Dr. Lapp suggested they should form a subcommittee to look at current research and funding for the future. The Centers of Excellence could be included in the issues.

Dr. Hanna explained that funding these types of projects would require a whole new funding allocation especially for that project. Currently, the appropriate vehicle for projects like this would be the Roadmap Initiative, which she has mentioned before. If they were to start something new such as new centers or clinical trial groups, funding would have to be allocated specifically for that project.

Dr. Bell asked if they would like to form a subcommittee to examine the research funding issues. He noted that they have spent the majority of the time discussing this issue at the last three meetings, and they are close to developing a preliminary

recommendation. He suggested they formulate some basic recommendations and spend some time at the next meeting discussing them. Then they can decide whether they should look at the long-term issues separately. He asked for other ideas.

Ms. Fitzpatrick asked if Dr. Bell's suggestion would include a Research subcommittee. She shared that she was under the impression that they had one but never voted on it.

Dr. Bell clarified that they do not have a specific subcommittee for this area since they spent most of their time, including much of their communications, looking at this issue. He noted they could form a Research subcommittee to examine long-term planning, which would go beyond the initial recommendations they are trying to put forward. Ms. Fitzpatrick responded that it would be a good idea because it would give them a group that could work on issues between meetings.

Dr. Lapp restated his motion to form a third subcommittee to examine current research and funding possibilities for the future. The motion was seconded and all voted in favor. Dr. Bell noted that they need a leader for the subcommittee but was reluctant to nominate Dr. Mohagheghpour without her present. He asked for other volunteers, and no one responded. Dr. Lapp noted that although he made the motion, he does not do research.

Ms. Fero asked, as a point of order, whether a researcher should act as chair if he/she is writing grants. Dr. Bell explained that if researchers are writing a recommendation that directly affects their financial position, then there is a conflict of interest, but he is assuming that this will not be the case.

Dr. Komaroff added that it is not uncommon for scientists to recommend more investment in the field of research. This is not a conflict of interest. A conflict of interest arises when a specific issue that you are directly financially associated with passes before a committee that you can influence. Dr. Fields added that HHS would be able to ensure adjudication of these issues.

Dr. Bell agreed to use email to come up with a chair for the Research subcommittee over the next several weeks.

Dr. Bell then asked Ms. McLaughlin for a report on her work with patient organizations to identify other specific issues.

Ms. McLaughlin explained that she had been in touch with some organizations. The name change is still the biggest issue, and she referred to Dr. Jason's study on how the name directly affects patient care. Other issues include the need for services. She explained that there are two prongs, research and what needs to be done in the meantime. She is trying to convey what they are hearing, and as Dr. Schweitzer and

Mr. Sterling shared earlier, it is pretty dismal among patient groups. They gave up their support groups because people are too sick.

Ms. McLaughlin explained that they are still a volunteer organization and have a niche, but they cannot offer anywhere near what is needed. There is no way they could compete with the government. The UK has stepped up and done a lot. They have had parliamentary proceedings and new centers. They also have a group called the 25% Group. She explained that there are talking about people who are bedridden and some are on feeding tubes. Some people cannot even talk on the phone and can barely whisper. These individuals are not getting treatment or medication, and she does not know if this is CFS-specific or true for all individuals who are homebound.

Ms. McLaughlin explained that feels she is in a difficult position and shared that she knew the woman who committed suicide. This woman was not depressed, was very intelligent, had an intelligent family, and had resources, but she knew she was getting worst and put a gun to her head. NCF got a call from the family but is not prepared to deal with situations like this.

Ms. McLaughlin noted that CFSAC seems to be very dedicated, involved, and committed to doing things, and this is not about blame. Whatever has happened, whether they cannot get care or people sneer at them, patients feel like people hate them. She appreciates CFSAC's efforts and knows that they cannot direct all HHS efforts no matter how dedicated they are. She suggested that they have another subcommittee to put together an evidence-based report. She asked if it would be possible to do a very thorough review of the literature and include all of the treatments. A report was done previously when there were not many treatments, and CFIDSAA put out a good press release that got picked up by the Associated Press. There are people with lung and other problems that are still being told to exercise.

Dr. Bell responded that CFSAC does not have the ability or the charge to do a comprehensive review.

Dr. Bell then referred to their first meeting when they gave the charge to Ms. Fitzpatrick to come up with draft roles for CFSAC. Dr. Bell asked that her read them aloud for the committee to vote.

Ms. Fitzpatrick explained that at the last meeting, they had several drafted items and realized that they could not attend to all of them. They discussed limiting them to three items. She is not sure if the wording is excellent. The three items focused on:

- To be attentive to the concerns of the community impacted by CFS

- To increase community awareness of the nature, scope, and quality of life impact of CFS for public education, primary provider education with an emphasis on diagnosis and management, ancillary health care professional education with an emphasis on continuing care and treatment of patients, and CFS patient education. Ms. Fitzpatrick noted that she did not include third party payer education, though it is an area of concern to her personally.
- To increase the research being conducted on CFS through increasing the amount and sources of revenue funding the research and by promoting the application of hypothesis-driven research. She noted that she added "hypothesis-driven research" in parenthesis because of the emphasis place on it in the last meeting's minutes, though it may not be the appropriate wording.

Dr. Lapp made a motion to email the draft for committee review and if they agree, they can pass it.

Dr. Bell asked Ms. Fitzpatrick if she agreed, and she did. Dr. Bell then requested that Ms. Fitzpatrick email the document to CFSAC so they can work out the wording issues. Ms. Fitzpatrick agreed to clean up some of the language and email it to members.

Ms. Fitzpatrick then asked if there was anyone they want to invite to address CFSAC at the next meeting. In the past, they discussed inviting someone from AMA to present what they are doing to educate physicians. She asked if this was appropriate or if there is anyone in the Washington, DC area available to do this.

Dr. Bell responded that it is an excellent idea and that it should be given to the Education subcommittee. They can come up with a list of invited speakers related to education. He suggested she speak directly with Dr. Patarca.

Ms. Fitzpatrick added that she thinks they could get statements from AOJ and ETA as examples of what they are doing in this area. She asked if they have the ability to send letters on CFSAC stationery. Dr. Bell explained that all CFSAC communications have to be voted on by the entire committee and that it would not be appropriate to send out letters that imply that they came from HHS.

Ms. Fitzpatrick asked if she could write the letter and have it sent through Dr. Fields' office. Dr. Fields suggested that the Education subcommittee would be the appropriate way to engage with his office. Dr. Bell also offered to send it out under his own name as he did with the letter to Mr. Turman.

XIV. Wrap Up

A. Action Steps

Dr. Fields noted that there was a request to make Dr. Hoffeld's presentation available, so they will engage with him to get it posted and provide copies.

B. Timelines (Including Dates of Remaining FY2004 Meetings)

Dr. Fields noted that the dates for future meetings will be in June and September, so planning, coordination, and communications can begin.

XV. Adjournment

Dr. Bell adjourned the meeting and thanked everyone for attending.