US Department of Health and Human Services

Chronic Fatigue Syndrome Advisory Committee (CFSAC)

Fourth Meeting

At

Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 505
Washington, DC 20201

June 21, 2004

9:00 AM to 5:00 PM

MEETING SUMMARY

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I. Members in Attendance

A. Voting Members

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

B. Ex Officio Members

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

C. Executive Secretary

- Dr. Larry E. Fields

II. Invited Speakers

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

III. Committee Members Absent

- Dr. William C. Reeves
- William C. Anderson

IV. Chairperson

A. Call to Order and Request for Roll Call

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

B. Introductions and Opening Remarks

Dr. Bell noted that today's meeting would focus on the committee's recommendations. He quoted Dr. Vance Spince, a researcher in England who wrote in the prefix to a book called *Shattered*:

> I can think of no illness where such a powerful schism exists between those who suffer from it and those whose responsibility is to care for them. How can it be that an illness and affects 100,000 to 200,000 persons of all ages in the U.K. and maybe as many as 1 million people in U.S.A. is no longer referred to in medical textbooks, is not cited in medical research indexing systems, and rarely features in the syllabus of undergraduate education and medical schools. Why have the experiences of these patients been largely ignored, their testimonies

> somewhat undervalued, even ridiculed, and their request for assistance met often with prejudice and disbelief.

The task of the committee is to come to terms with this schism in order to make recommendations to DHHS. Dr. Bell noted that Ms. McCleary and Ms. McLaughlin's presentations would be moved to the Development of Recommendations section of the meeting.

He noted that the committee has made one recommendation, which was sent to Dr. Beato. Her reply is as follows:

> Thank you for your recent letter outlining the activities of CFSAC and communicating an initial recommendation from the committee regarding additional positions in the CFS program at CDC. We recognize the importance of your challenging work and appreciate the time and expertise that you and your members are committing to this issue. As requested, I am forwarding this recommendation to Secretary Thompson.

Ms. McCleary added that Bill Jimson, Chief Operating Officer at CDC, indicated that they were following through with the recommendation and would expedite those positions to the CFS research program.

C. Approval of the Minutes of March 22, 2004

Dr. Fields noted that the minutes would be posted on the website.

The following corrections were noted for the March 2004 meeting minutes:

- Page 32: "Fitzgerald" should be "Fitzpatrick"
- Page 51: "Cummerford" should be "Commerford"
- Page 38: "organs" should be "origins"
- Page 38: "1984" should be "1988"

A motion was made to approve the minutes and the minutes were accepted. Dr. Bell noted that the complete minutes will be posted on the website once they are approved.

V. Executive Secretary

A. Operational Matters

Dr. Fields noted that they continue to have a well-utilized email and web site. They have received a number of comments ranging from personal challenges and requests to observations about events in Canada and the U.K. In terms of operational matters, there will be two public comment sections.

VI. Classification of CFS in ICD-9-CM and ICD-10-CM

Donna Pickett

Ms. Pickett noted that NCHS is responsible for the implementation, maintenance, and update of the international classification of diseases. NCHS houses the North American Collaborating Center for ICD for US and Canada. There are ten international collaborating centers for ICD. ICD has been used for classifying causes of mortality (death registration) for almost 100 years. It is also used for the collection of morbidity statistics, including records and surveys, health care claims, and utilization information, and is also used as a basis for prospective payment.

ICD-9-CM is a clinical modification of WHO's ICD-9 code. The WHO version is a four-digit code and the ICD clinical modification is a five-digit code, which is an expansion of the amount of information that can be captured using the clinical modification. The ICD-9-CM was implemented in 1979 and has been updated annually since 1985 through the ICD-9-CM Coordination and Maintenance Committee, which meets twice a year. The committee receives proposals from users of the classification to modify the classification to represent more clinical detail about a condition or to add new information to the classification. The proposals come from hospitals, physician groups, and researchers. The meetings are open to the public, who can provide comments on the proposals.

ICD-9-CM is used for the following purposes:

- Tracking national and state trends
- Tracking Medicare trends
- Quality Indicators
- Reimbursements
- Bench marking

- Research
- Public health reporting
- Strategic planning

Though NCHS has lead responsibility for the update and maintenance of ICD-9-CM, it does not have authority over how those codes are used by some entities, particularly those that deal with coverage and reimbursement.

In terms of CFS, NCHS received its first request to modify the classification in 1990. At that time, index entries were added for CFS. NCHS received a second request in 1997 to add a new code to the classification. This new code was implemented in October 1998. CFS and related conditions were already classified by WHO to code 780.7, malaise and fatigue. In updating ICD-9-CM, a unique five-digit code (780.71) was added specifically for CFS.

WHO has already implemented ICD-10. The U.S. moved to this new code for mortality statistics in 1999. For morbidity applications, the U.S. is still using ICD-9-CM. ICD-10 was published in 1995 and represents the broadest scope of any ICD revision to date. The changes include alphanumeric codes, restructuring of certain chapters and categories, and the addition of new features. As of October 2002, WHO has authorized the publication of ICD-10 versions in 37 languages. One hundred thirty-eight countries have implemented the code for mortality and 99 countries have implemented the code for morbidity. ICD-10 was implemented for mortality reporting in the U.S. in 1999.

ICD-10 and ICD-10-CM are intended to replace ICD-9-CM in the U.S. There has been a restructuring of where CFS appears in the classification. In ICD-9-CM, CFS has a unique code in Chapter 16, Signs and Symptoms of Ill-Defined Conditions. In ICD-10, WHO has reclassified the condition and moved it to Chapter 6, Diseases of the Nervous System. Within this chapter, there is a unique code, G93.3, Postviral Fatigue Syndrome, which captures all of the terminology used to describe CFS.

The implementation of ICD-10-CM is part of the standards adoption process specified in the Administrative Simplification provisions of HIPAA. This process requires public hearings. More than eight hearings by the National Committee on Vital and Health Statistics (NCVHS) have been held between 1997 and 2003. NCVHS has issued a letter of recommendations to the Secretary of DHHS, recommending that the rule-making process begin to replace ICD-9-CM with ICD-10-CM. DHHS is currently considering the recommendations and the Notice of Proposed Rulemaking (NPRM) has not been published. When the NPRM is published, there would be a public comment period and then a final rule. Information on this process and the codes can be found at http://www.cdc.gov/nchs/icd9.htm.

Ms. Pickett noted that she is unsure about the timeframe for approving ICD-10-CM, over which there is a lot of controversy. There are many supporters, but there are many organizations with concerns about the costs and the return on investment. NCHS believes that there is a benefit due to the expanded information that can be captured in ICD-10-CM.

Dr. Bell provided a summary of Ms. Pickett's presentation. ICD-9 placed CFS under 780.71, Chronic Fatigue. There has been confusion between the symptom, chronic fatigue, and the illness, CFS. From the committee's perspective, it would be important to adopt ICD-10, which identifies the illness as a disease of the nervous system.

Ms. Pickett added that ICD-9-CM created a unique code for CFS. It is still classified under Chapter 16 because a condition cannot be moved from one chapter to another under WHO guidelines. ICD-10 was placed in Chapter 6, based on WHO guidelines. She added that she believes enough support for the change to ICD-10-CM exists.

Ms. Fitzpatrick asked if there were separate meetings for changing ICD-9 and ICD-10. Ms. Pickett noted that ICD-9 is only used in the U.S. and the WHO version of ICD-10 has a separate updating cycle.

Dr. Robinson asked how long it would take before NPRM is published. Ms. Pickett responded that she is not sure. Based on the projection of an extensive public comment period, Dr. Robinson noted that it might be almost a year after NPRM is published before a final rule can be made. He asked if it was critical that a final rule be in place prior to the adoption of ICD-10-CM.

Ms. Pickett responded affirmatively. HIPAA rules require a final rule to be in place. Also, the final rule would have to designate a transition period, which can be 2 to 3 years.

Dr. Robinson added that the longer it takes to adopt the new code, the longer it would take to see results. The committee may want to recommend a fast track of this approval.

Dr. Patarca asked if there has been any feedback from neurologists and how the new code was placed under Chapter 6. Ms. Pickett noted that the ten international collaborating centers all have input into the updating process, but she does not know the specifics on how the classification was placed under Chapter 6.

Dr. Bell asked if it would be redundant if the committee made a recommendation to DHHS for the adoption ICD-10. Ms. Pickett responded that it would not be redundant and that DHHS welcomes comments from all groups.

Dr. Gantz asked about the timing of the committee's recommendation. Ms. Pickett responded that DHHS would welcome comments and recommendations at any time.

Ms. Fitzpatrick noted that under ICD-10, CFS has been placed in the hands of neurologists. Ms. Pickett responded that this is incorrect. When a disease is listed under a specific chapter, it does not mean that it is within the domain of the specialty group. This is not how the classification is structured. They are classified based on important features or how it should be looked at in terms of data.

Dr. Friedman asked when does an included disease rise to the occasion whereby morbidity and mortality data would be collected. CFS is a recognized disorder; however, there are few organized efforts to collect morbidity or mortality data. Ms. Pickett responded that the ICD-9 code for CFS has existed since 1998. As a result, some data have been collected. She added that she is not aware of anyone who has published or looked at the data.

Ms. McLaughlin asked if it was a problem that CFS, under ICD-10, has two different codes. Ms. Pickett noted that there is a code in the R code, which is Signs and Symptoms of Ill-Defined Conditions, but it is an unspecified code. If the specific language listed under G93.3 is not used to describe the condition, the case would be coded with the R code. The R code is the symptom and G93.3 is the illness.

VII. American Association for CFS

Dr. Dharam V. Ablashi

Dr. Ablashi noted that the American Association for CFS (AACFS) was chartered as a non-profit, professional organization in Oklahoma in December 1992. It is the only professional CFS organization in the world. Its membership is open to researchers, clinicians, healthcare workers, providers, and representatives from the CFS patient organizations. AACFS has international participation; three of its board members are from Belgium, Sweden, and Japan.

AACFS's mission is to promote, stimulate, and coordinate the exchange of ideas related to CFS and FM research, patient care, and treatment. AACFS also engages in education through conferences, meetings, and a newsletter. At their biannual international CFS/FM conference, clinicians, healthcare workers, and researchers present and discuss science for the benefit of patients.

Educating professionals on CFS is a great challenge since many practicing physicians do not believe that CFS is a real entity. Some of the AACFS board members feel that it would take a great deal of time, patience, and financial resources to stimulate other clinicians to diagnose and treat CFS. Many physicians are also confused since the

etiology is still unknown and there is no known, universally accepted treatment. To overcome these problems, participation from government agencies, medical associations, and teaching institutions is needed. Information on home remedies also causes confusion.

Recommendations for improving education include:

1. There is a need for a more comprehensive and effective CFS brochures for professionals. These brochures should be brief and to the point and circulated to family practitioners, internal medicine specialists, healthcare workers, neurologists, and psychiatrists.

2. Diagnosing CFS is still a problem. Some physicians use the CDC definition. Others use their own criteria, while others prefer the Canadian definition. A clear definition and criteria should be established and recommended by this committee and posted on the website.

3. Awareness of CFS in the medical community will be more acceptable if state medical associations and AMA endorse CFS and publish review articles from CFS experts.

4. The AACFS International conference is a good means of sharing knowledge about CFS. Some of its sessions are very popular. The proceedings and videotapes of the conference are also suitable educational materials.

5. An occasional refresher course on CFS would be helpful. Such courses should be CME accredited or approved by an authoritative body and would help spread awareness of the latest information about CFS.

6. Since the majority of physicians are busy, attempts should be made to bring the information to them through 1-day educational regional meetings held at medical centers.

7. AACFS is compiling a list of CFS experts who can educate clinicians and healthcare workers. In the past, AACFS speakers have been invited to participate in conferences organized by CFS patient groups.

8. AACFS is educating its members through a newsletter.

9. It is important that physicians take advantage of several online evidence-based, medicine-teaching resources. The American College of Physicians maintains a teaching model for physician information and education resources at www.acponlin.org. CDC maintains CFS information at www.cdc.gov/ncidod/diseases/cfs/inf.htm. The *Medical Journal of Australia* published guidelines are available at www.mja.com.au.

10. Centers of Excellence need federal and local support to supply training and information on state-of-the-art diagnosis and treatment. The centers should also have a hotline for CFS information.

11. Educational speakers should be funded and provided for Grand Rounds at academic institutions around the country.

12. Pharmaceutical companies should be allowed more flexibility in their educational support of CFS disorders on a symptom-by-symptom basis. They should be allowed to sponsor education without specific FDA approval.

13. Attempts should be made to educate medical providers about how to collect and supply information. A determination needs to be made in Social Security Disability to remove discrimination facing CFS patients.

14. Healthcare corporations should be educated about CFS. Their funds or non-profit status should be withheld until they educate their providers and offer better assessment of care for CFS patients.

15. NIH and CDC should work with Social Security Disability to establish better tools to assess function and disability in CFS.

16. This committee should consider formulating a brief booklet on CFS for doctors. It should also review existing materials on CFS and publish reviews in credible journals.

In summary, educating practicing physicians, healthcare workers, and providers is central to the CFS healing process, and this would require coordination, resources, and financial backing.

Dr. Ablashi added that they have received 126 abstracts for the 7th International Conference on CFS/FM. The conference has been divided into three sections: research, clinical, and patient. The proceedings and selected abstracts of the conference will be published in the *Journal of CFS*.

Dr. Bell asked Dr. Cavaillé-Coll to speak about the pharmaceutical companies' symptom-related classes. Dr. Cavaillé-Coll noted that pharmaceutical companies do sponsor classes under unrestricted grants, but that they do not have control over the curriculum. For investigational products that have not been approved, there are more FDA restrictions in terms of the language that can be used to promote these products. However, investigators can still present their findings in scientific meetings. Additionally, there are guidelines by different accrediting organizations for CME sessions.

Dr. Ablashi added that representatives from pharmaceutical companies are asking for more leniency in requirements for education.

VIII. Ex Officio Members

A. Dr. Barrett

Dr. Barrett noted that Dr. Reeves sends his regrets for not being able to attend. She added that there is a new article today in the *Journal of Cost Effectiveness and Resource Allocation*. The article is on the economic impact of CFS using data from the Wichita study. The data were used to look at current employment status and household income, which was applied to microsimulation methods in order to estimate the economic impact of CFS. The results include:

- Fatigued individuals were less likely to work and have lower incomes than non-fatigued individuals.
- There was a 27% reduction in employment attributed to CFS.
- Those that were able to work had reductions in productivity and the number of working hours.
- The estimated annual dollar lost per individual due to CFS is $20,000, which translated into $9.1 billion annual loss in the U.S..
- These losses are similar to other conditions, such as digestive system disorders and infectious diseases.
- These costs do not take into account medical and healthcare costs.

B. Dr. Hanna

Dr. Hanna noted that Bill Reeves and Suzanne Vernon would be coming on November 18 to present their centers concept to develop a collaborative effort between NIH and CDC. She added that they expect to have the RFA on the early notice system in early November.

C. Dr. Robinson

Dr. Robinson noted that HRSA has been supporting Dr. Patarca and the Education Subcommittee. He added that Staci Stevens had raised a question on the Department of Education's participation on the impact of CFS on children.

D. Dr. Desi

Ms. Fitzpatrick asked if there were any feedback on the effectiveness on the video training, and how many people it reached.

Dr. Desi remarked that they did receive high marks on the training, with a 98% satisfaction rate. He added that he does not know how many people were reached, but the video was broadcasted across the country.

IX. Research Subcommittee Update

Dr. Mohagheghpour

A. Subcommittee's Charge

The subcommittee on CFS Research Funding was charged by CFSAC to examine NIH and CDC funding levels for CFS research and recommend implementation of processes to encourage and promote research in all areas of CFS.

B. Goal

The goal of the subcommittee is to encourage and promote CFS research in all areas.

C. Background

Since 1998, NIH and CDC have conducted a broad range of research to determine the prevalence, cause, risk factors, pathogenesis, and diagnosis of CFS. Research indicates that the prevalence of the illness among adults ranges from 100 to 800 out of 10,000 people, and that the majority of these individuals have seriously impaired functional capability. Biological markers, treatment, and preventions are still unknown.

According to the report issued by the NIH Office of Budget, from FY1999 to FY2003, NIH allocated approximately $31.6 million to the study of CFS through intramural and extramural grants. The budget spent by CDC has yet to be provided.

D. Issues

The issues that have been identified are:

- The pathogenesis of CFS remains unexplained.
- Investigators in the fields of clinical neurology and immunology and infectious diseases have not turned their attention to CFS.
- A perception among some investigators is that NIH and CDC do not place a high priority on supporting CFS research.
- There is no organized mechanism for CFS investigators to share ideas, collaborate, and pool their energies and patients to study CFS.
- There is a misperception that CFS is only an illness of women and of more affluent people.

E. Recommendations

The subcommittee's recommendations are:

1. DHHS should attract investigators in the fields of clinical neurology and immunology and infectious diseases to conduct CFS research by funding a group of well-known CFS investigators to write review articles and by endorsing their final documents for publication in high-impact journals.
2. DHHS should provide funds for investigator-initiated CFS research, and, in concert with NIH and CDC, DHHS should fund special emphasis, extramural grants through RO1, RO3, R21, and the NIH Director's Pioneer Award. The Director's Pioneer Award is a good fund mechanism because it provides funding for 5 years.
3. DHHS should provide support and funding for intramural-staffed laboratories committed to CFS research, rather than having separate, isolated labs.
4. DHHS should provide funds to develop an international Network of Collaborators that would allow for more centralized, multidisciplinary CFS-related research. Future research efforts must apply an integrative approach because CFS is characterized by dysregulation of a number of highly integrated modularly systems. Forming multidisciplinary research teams would provide a platform to conduct well-controlled, methodologically sound longitudinal studies to clarify the pathophysiology and would develop effective treatment modalities. In addition, the proposed network would serve as a venue for serum and tissue banks for future investigations.

5. DHHS should disseminate CFS research data from new initiatives at workshops and scientific meetings.
6. DHHS should help correct the gender perception of CFS by using the title, "Chair, Trans NIH Working Group for Research on CFS," when the Associate Director of the Office of Research on Woman Health administers CFS research. In the U.S., approximately 1/3 of adult patients are male; therefore, the suggested title would portray a truer picture of CFS incidence.

F. Discussion of Recommendations

Dr. Bell noted that the subcommittee's recommendations are to the Secretary, and not specifically to CDC or NIH. He added that research recommendations are not just for research, but will also impact patient care.

Dr. Bell began by reviewing recommendation 1. He recommended that recommendation 5 be added into recommendation 1 to condense the recommendations into general topics.

Dr. Gantz added that recommendation 1 should not be first recommendation because DHHS will not fund investigators to write review articles on CFS. Dr. Komaroff added that he is not aware of any precedent for a department endorsing a publication.

Dr. Patarca noted that the education subcommittee discussed the same topic. One way of getting CFS articles published in high-impact journals is to solicit the cooperation of various professional societies.

Dr. Bell asked how DHHS should be involved in this approach. Dr. Patarca added that these should be a funding mechanism for this type of collaboration with these professional societies.

In addition to the national societies, Dr. Patarca added that the most successful events have been those that have involved grassroots organizations and local and regional groups.

Dr. Mohagheghpour added that one of the reasons the research subcommittee supported the idea of article funding and endorsement is that it takes a long time to get an article published. Dr. Gantz noted that DHHS is not able to change this.

Dr. Friedman noted that an idea of how DHHS could help promote articles is to have DHHS sponsor the production of monographs. Dr. Bell added that CDC has done this to a certain degree. Dr. Friedman noted that this would be an extension of the activity. The monograph might go to every physician in the U.S.

Dr. Gantz noted that this approach might not attract more researchers into the field, which is more in line with the committee's primary goal to enhance CFS research. Dr. Friedman added that, as a professor who has a CFS center at his university, the turn off that was caused by the withdrawal of funds from the center has done much damage. To attract researchers to the areas of CFS, you must convince them that there is a steady base of money that will fund them for a significant number of years. If DHHS wants a serious commitment to CFS, they must provide significant funding for CFS.

Dr. Patarca added that there are other issues in addition to funding. The decision to exclusively focus on CFS might affect a professor's chances at tenure and promotion as well.

Dr. Bell noted that one potential way to make the liaison to professional societies is to update the CDC monographs. He asked if this was worth pursuing. Dr. Patarca added that it is not a question of worth, but of logistics and which agency will take on the responsibility. One of the problems with this approach is that agencies would like to make these types of decisions based on historical data. However, there are very little data on the impact of previous monographs.

Dr. Friedman noted that the mechanism that will be most effective is through the professional organizations. He added that the need to use the power of CFSAC to lobby these organizations for their participation. Dr. Bell asked if that was the role of the committee. Dr. Friedman noted that they are an advisory committee to DHHS. However, the most direct route may be the most effective group. He added that the recommendation could be restated to give this committee funds to go to these professional organizations.

Dr. Bell asked the full committee if they should act as independent advocates for CFS or if they should focus on advising DHHS. All of the members stated that the committee should focus on its role as an advisor, but that they should continue to seek input from professional organizations. Dr. Bell concluded that the committee would hold on contacting the professional organizations.

Jonathan Sterling added that the recommendations are vague and not particularly directed to the federal government agencies that can carry forth the recommendations.

X. Public Comment

A. Dianne Saba

Ms. Saba began by stating that the majority of the CFS community opposes the name "CFS" and are boycotting any organization that has taken money to brand or promote "CFS." As a result, CAA's membership has dropped from 20,000 to less than 7,000, and now relies more on CDC funds than membership dues. On the other hand, the National CFIDS Foundation (NCF) membership list continues to grow.

NCF funds groundbreaking research, is wholly supported by its membership, and is staffed by dedicated volunteers. Since NCF is now the largest national CFS patient organization, it should be fully recognized by CDC and included as a patient representative in CDC sponsored activities. Additionally, all of the national organizations should be listed on the CDC website.

NCF requests that national patient organizations have representation on CFSAC and its subcommittees. Patients pay dues for this representation because they are too ill to attend. Since the CFSAC charter is up for reauthorization in September, this request should be specified in the new charter.

The CFS community is severely disabled and requires webcam/videoconferencing for future CFSAC meetings. The meeting can then be broadcast via the Internet and archived for subsequent viewing.

The CFS community demands that more funds be allocated to "blood" studies and that all funding cease on fatigue research projects. This cessation of funding also includes the CAA fatigue ads that are harmfully promoting fatigue as the central issue of CFS. No explanation was ever given to the majority of the CFS community on how this award was made, who determines how the money will be used, and who has oversight.

The CFS community asks for the resignation of Dr. William Reeves, and that another representative from CDC be appointed.

On October 13, 1999, a meeting of CFS patient advocates and CDC took place. One of the recommendations was to "assess the risk of CFS being spread by blood and blood products, and if such a risk is found, develop a prevention strategy for protecting the nation's blood supply." It appears that CDC, along with other respected researchers in the U.S. and Europe, has completed some studies on the blood of CFS patients. These studies have revealed numerous biological diagnostic markers.

While blood testing has documented for years that a high percentage of CFS patients have EBV, Herpes 6, and mycoplasma in their blood, transmissibility of CFS in blood

transfusions was finally documented in the DeMeirleir study. Using the percentage of 4.5% obtained in that study, it is reasonable to assume that 45,000 of the 1 million U.S. CFS patients may have acquired their disease from the blood supply. She asked where the attempt is to guard the U.S. blood supply and to inform the medical community, the media, and the general public.

CFS patients and their advocates demand:

- That the information contained in the current CFS studies, detailing the biomarkers in CFS patients' blood, be immediately disseminated to the media, the general public, and the medical community.
- The name change issue be reconsidered and that the Name Change Workgroup be allowed to give a thorough presentation to the CFSAC.
- ME be recognized, which is recognized by WHO as a neurological disease that has its own diagnostic criteria.

Shirley A. Bentley, President of the U.S. Chapter of Common Cause Medical Research Foundation, stated:

> Special attention should be paid to the fact that blood testing has revealed that U.S. patent #5,242,820 states, "mycoplasma frementas is implicated in…CFS…," patent held by U.S. government, human herpes virus 6 (U.S. patent #5,604,093, formerly called HBLV, found in CFS, patent held by DHHS), ciguatera toxin, low blood volume, coagulation problems, hemorrheologic irregularities, apoptosis, cardiomyopathy inverted t-waves. Our blood does not lie.

Nowhere in the U.S. Constitution or the Bill of Rights does it state that people are to be persecuted for being sick. Why is the CDC website for CFS information listed at NCI/DoD? We are patriotic, law-abiding American citizens, whose tax dollars have been used against us. This is criminal and has to stop. It is time for CDC, NIH, and AMA to work with us, for us, and not against us.

B. Lori Tylutki

Ms. Tylutki noted that she is an ICU critical care nurse. She was recently diagnosed with CFS after an intestinal bacteria infection. She is here to turn the tragedy that has happened in her life into a positive, by using her experiences to better the life of others. She does not want to be the problem, but contribute to the solution.

The most important thing this committee and the federal government could do for people with CFS is to educate the medical community. The committee members are here because God has chosen them to be a voice. However, the average physician

does not have a comprehensive understanding, and therefore, they do not know how to keep the illness and its symptoms manageable, or even think of CFS as an authentic illness to make a diagnosis.

Never before has she run up against so much opposition and poor attitudes towards symptoms of this illness. She became disenchanted with the medical community and was ashamed to say that she was part of that profession. As a nurse, part of her job is to be a patient advocate. As a patient, she was too sick to advocate for herself, and no one in the health profession was advocating for her.

She sought treatment from alternative medicine because she did not get relief from conventional medicine. With the supplements and mineral replacements, her symptoms became manageable. Once she felt better, she researched options in CFS literature. She wrote to authors of articles to ask for help. This is how she met Dr. Friedman and learned of CFSAC. She was elated because she knew that there was a voice, and that meant hope for those with CFS.

What do people with CFS do who are not assertive or too sick to advocate for themselves? They fall through the cracks and suffer because physicians are at a loss of how to keep symptoms under control. Patients lose hope and do not know where to turn.

After obtaining a copy of the *Consensus Manual for the Primary Care and Management of CFS*, she thought every physician needed a manual like this. If the federal government distributed similar manuals, it would benefit everyone. Also, every patient needs to know that one exists. Standard guidelines recommended by the federal government would do three things:

- Validate the illness.
- End physician frustration.
- Restore the hope among CFS patients.

If they had standard guidelines, physicians would have a better understanding of the symptoms from a pathophysiological point, and would be able to restore patients to a functional level with proper treatment. The guidelines need to contain a blend of allopathic and alternative medicines.

She has been told by an infectious disease doctor that he personally did not believe in CFS. When asked if he had read any literature or research on CFS, he responded that he did about 10 years ago. She has also heard that there is nothing that can be done to help her, that there is no cure or treatment, and that she should learn to live with it. These are statements by physicians who do not have a complete understanding of

CFS. This is why there is great need for standard guidelines to be distributed to every healthcare professional.

The most important thing CFSAC can do is act. She asked CFSAC to not just sit and talk, and plan and reorganize. Put your plan into action.

C. Victoria Bell

Ms. Bell began by thanking Dr. Lapp for hearing the medico/socio/economic harm the word "fatigue" creates. After long years of injustice, as a federal committee sitting member, Dr. Lapp's use in mission and in practice of "Myalgic Encephalopathy" and intent to drop "CFS" demonstrates leadership, courage, and a forward-minded shift.

The primary advocacy issue of two decades, the name of this illness remains officially unaddressed. A new name in the U.S. must be implemented at the WHO and North American Collaborating Center (NACC) ICD classification levels. Synchronization with NACC is a clear imperative for an official declaration issued from DHHS via CFSAC. Effecting the name change is not within the domain of housebound, disabled patients with difficulty simply accomplishing portions of activities of daily living.

The objective of WHO and its global collaborating centers is to "promote the development and use of the classifications to contribute to their implementation by multiple parties as a common language." A new U.S. name modification needs to be in reasonable accord as common language with the terms currently used by WHO world neighbors, "Myalgic Encephalomyelitis" and "Myalgic Encephalomyelopathy," and under ICD-10 G93.3 classification, with WHO-approved common language congruent with the terms above.

"Fatigue," in any form, must go, for all reasons previously presented by researchers, patients, and clinicians. The name issue does not require branding, but a new brand of thinking and neo-postallopathic respect and reciprocity. Increasingly, we inhabit a participatory universe. Across the continuum of daily life—accessing knowledge, information, and each other—we interact in the international convergence of the Cyber Age and the Neo-Postallopathic Era at an ever-increasing exponential rate. In a shift of epic proportions, medicine has been altered forever, with increasingly informed patients and decreasingly informed clinicians. This is due not to the fault of the clinician, but to the sheer magnitude of new developments.

This new era requires interdependent respect and reciprocity, not dependence. No longer does the 20th century allopathic dependence work—the clinician/researcher as all-knowing expert and the patient attendant upon the clinician's/researcher's every breath. No person on the planet remains unaffected as the titanic ship of our worldwide medical architecture struggles to accommodate this inexorable tidal wave.

The impact of this unfolding drama requires a correspondent shift from the helm (CFSAC)—a shift into 21st century thinking. This shift bears directly on the multiple issues at stake and the multi-system nature inherent in this disease.

Together, CFSAC and DHHS are the hope of every ME/CFS patient worldwide. The light you are capable of shining out of the long years of darkness in this disease is your greatest charge. She noted that their work product would produce a mighty leap forward resounding with decency, fairness, and rightful action around the globe.

The distinctions in use and impact of medical versus vernacular terminologies are central when devising a reciprocally beneficial name for this interdependence. Participating with you in this new era, patients actively seek knowledge and information, access to hot-off-the-press research, medical databases, and search engines, and to engage in daily interactive communication with the researchers themselves. Many physicians foster interdependent patient-clinician teams exchanging information. This requires using common language. Patients have honored the researcher and clinicians by learning their complex terminology.

In the face of the respect they have given by learning this language, they request the grace of reciprocal respect by honoring them with a new name using language that conveys the gravity of their disease—a name not utilizing vernacular terms such as "chronic" or "fatigue," which are too easily converted into elementary vernacular interpretation. In vernacular English, "fatigue" means after a catnap or a night's sleep, one will be restored to healthful vigor. With "ME," this simply does not happen. Nor have vernacular understanding of the ubiquitous medical meaning of "fatigue" occurred in our disease in 16 years, despite two efforts to market and brand it.

Ms. Bell asked the committee to adopt the 2003 ME/CFS Canadian Clinical Working Case Definition and Diagnostic Protocol, most critically in physician and emergency response education. In making CFSAC's recommendations, she asked that they hold in mind:

- The Hippocratic Oath: First do no harm.
- CFSAC faces many choices and your actions will affect not only the current generation of U.S. ME/CFS patients, but those who will follow.
- Medicine is about science. It is equally about humanity. She asked CFSAC to make their choices with careful intention, not only from the science, but coupled with their hearts.

D. Lauren Bean

Ms. Bean is 21 years old and the daughter of Diane Bean. She has had CFS since the spring of 1998 and it began with mono. Some of her early symptoms included

difficulty concentrating, skin sensitivity, stomach distress, body temperature problems, and blood pressure problems. When she sought help from specialists, she encountered many difficulties. She was told by a dermatologist that CFS does not cause skin sensitivity, and a GI specialist concluded that it was either an allergic or parasitic reaction. As a result, specialists should be educated about symptoms that are not directly related to fatigue or pain and asked to look at the problems more holistically. Alternative medicine seems to have more respect and understanding for the whole person. For example, the skin is directly related to the liver, a principle of Chinese medicine. Though this may not lead to a cure, it may improve the quality of life for patients.

E. Diane Bean

Ms. Bean noted that her family has been dealing with Lauren's illness for over 6 years. Both she and her husband are Foreign Service Officers for the State Department, and they have very demanding jobs. As a result, caring for Lauren has been a struggle, and she has not been able to attend CFSAC meetings prior to the last meeting. At the last meeting, she heard about the stagnation in research, and the conversation in general appeared circular. She knows she is speaking to the choir, but she is here to urge that they begin to speak to the choir directors. Raising the profile of this illness is the only way to get a sustained response. Top health officials (e.g., the Secretary, the Surgeon General, and the CDC Director) must talk to the public about the physical suffering of the patients, the economic drain of 800,000 sick individuals, and the psychological cost to family. They need to challenge the medical community to solve this problem. This was done with AIDS—once the top policy makers spoke publicly to the medical profession, researchers responded. This can happen with CFS. She urged the committee to advocate for an aggressive public information campaign.

Even after the publicity surrounding Laura Hillenbrand, there are still physicians who dismiss the illness. Secretary Thompson and Director Gerberding need to make it medically and politically unacceptable to blame the patients and dismiss the symptoms. This is not happening. At the State Department, there are those who know about their situation. Once a month, someone will tell her how their doctor tells them CFS is a psychological disease. Additionally, there is a coworker that came down with mono. Ms. Bean is convinced that she has CFS, but her supervisors dismissed this idea and gave her a hard time about the leave she was taking, so she resigned. The message is not getting through, and it must come from the top.

XI. Development of Recommendations

Dr. Bell noted that the next 2 hours would be spent on formulating the committee's recommendations.

Dr. Bell stated that the general topic has to do with the tone of the letter to Secretary Thompson. He asked if the tone of the recommendations should be gentle and soft spoken, or more aggressive and demanding.

Dr. Friedman added that the recommendations should take into account the past history of funding and the lack of success in terms of finding a cause, treatment, and cure for this disease. Therefore, they need to take a new approach to funding CFS research. The existing structure needs to be modified so that they can have a more effective mechanism for funding and assessing CFS research.

He noted that there needs to be more CFS investigators, and that there are a number of mechanisms to do this. First, investigators need to be assured that there is steady funding of more than 2 years. One of the possibilities is to establish research centers. This is being used by NIH and the federal government in ever-increasing numbers. There is a proposal for research centers for Muscular Dystrophy. This committee should adopt the language of this proposal for a CFS research center proposal. This committee should be very specific in its recommendation of funding at least four centers at cost of $1.5 million per center per year, for a minimum of 5 years.

Dr. Desi asked how successful Europe has been in producing tangible results. Dr. Friedman responded that their success rate is about the same as the U.S. They have more in the pipeline, but they are working with much less money. They consider us to be the premiere site for biomedical research and rely on the U.S. Additionally, they get university and industry cooperation continent-wide. As a result, they have more control and interplay. On the other hand, it seems to be more competitive, rather than cooperative, in the U.S. Having a stable funding mechanism, established centers, and an oversight committee, will allow for a more cooperative approach. In U.S. CFS research, all of the work is done in isolation with different protocols. As a result, that data are anecdotal. There needs to be a standardized approach. He added that he would like to see cooperative research centers established, as well as a number of other mechanisms, including the RO1s and a number of smaller grants.

Dr. Friedman noted that there is a lot of discouragement when grants are rejected. Therefore, it is important to have a mechanism in which there is an abbreviated initial process for approving research subjects. He recommended that there be a program that would have a two-tiered process of grant applications. The first tier would involve a letter of intent or an abbreviated application process and would request information on the goals, the process of obtaining data, and what the significance of the proposal would be. If the review committee likes the proposal, then a full

application would be requested. This will let the researcher know that the proposal is acceptable and has a high probability of being funded. Without this two-tiered process, the best research ideas may be rejected because the study section deems the investigator lacking in experience.

Dr. Bell asked how this could be translated into a recommendation and read the fourth recommendation of the Research Subcommittee. He noted that the subcommittee is recommending an international Network of Collaborators (INC).

Dr. Friedman commented that this recommendation is another issue. International centers are groups of individuals who have their own protocols. What he is looking for is something within the U.S. that has a structure with oversight and would award money for protocols that are run in the U.S.

Dr. Mohagheghpour added that Dr. Friedman's definition of the INC is different from the definition used by the subcommittee. Additionally, the NIH Director's Pioneer Award does exactly what Dr. Friedman is suggesting.

Dr. Lapp noted that Dr. Reeves has introduced the idea of coordinated research network (CRM), which would cover this type of international arrangement. He recommended that Dr. Reeves be invited to the next CFSAC meeting to discuss this concept. He added that they need a resource where patients can go to get diagnosed and treated, as well as research centers.

Dr. Bell asked if the recommendations for Centers of Excellence and the INC are mutually exclusive. Dr. Gantz responded that both recommendations are desirable, but this depends on available resources. Dr. Komaroff added that it would be helpful if the recommendations were prioritized, and that the Centers of Excellence would ensure cooperation and common protocols in data collection. Ms. Fitzpatrick added that the priority is to do something in the U.S.

Dr. Bell asked if the first sentence of the fourth Research Subcommittee recommendation could be agreed upon as a bullet point. All voted in favor of accepting the recommendation. The next bullet point will deal with the Centers of Excellence.

Dr. Friedman added that the Muscular Dystrophy centers are described as centers whose purposes are to increase basic and clinical research in all forms, promote side-by-side basic translational and clinical research, provide resources that can be used by the research communities, and provide training and advice for researchers and physicians who provide initial diagnosis and treatment, including rehabilitation, care for cognitive and behavioral concerns, and therapy for other complications.

Dr. Bell asked what they would call this center.

Dr. Cavaillé-Coll asked what kind of network model are they looking for.

Dr. Barrett added that Dr. Reeves' plan for a coordinated research network focuses on having a consortium of investigators in which support would be given to standardize instruments and methods, establish prospective cohorts, and conduct novel experimentation and research. The structure would involve clinical research centers, a specimen repository, a data management center, and a central administrative center.

Dr. Bell asked if this was a fixed group or would they use, for example, private medical offices or university centers. Dr. Barrett responded that it is not a fixed group.

Dr. Hanna noted that anything that they fund must be put out for competitive bids.

Dr. Patarca asked how these centers will integrate community doctors and not become elitist cliques. To access patient samples, integration with local doctors is necessary.

Dr. Bell noted that there are three bullet points, as follows:

- DHHS should provide funds to develop an international Network of Collaborators that would allow for more centralized, multidisciplinary CFS-related research.
- DHHS should encourage clinical research and treatment centers within the U.S. that utilize state-of-the-art information and techniques.
- A specimen repository, a data management center, and a central administrative center should be included within these centers.

Dr. Bell read the third recommendation of the Research Subcommittee: DHHS should provide support and funding for intramural-staffed laboratories committed to CFS research.

Dr. Gantz noted that his goal of this recommendation was to have a funded individual with a laboratory and staff to focus on CFS research—a CFS czar with a single laboratory within NIH.

Dr. Friedman added that a laboratory within NIH has a lab chief, with several investigators under him. He recommended that this is what they should propose—a laboratory within an institute at NIH, with a lab chief and several senior investigators, that is dedicated to CFS research. Dr. Gantz added that this was in line with what he had in mind.

Dr. Bell asked the committee if they were in favor of this as a bullet point. The committee replied affirmatively. Dr. Bell then moved to the second Research Subcommittee recommendation and proposed the following language:

> To expedite the issue of RFAs with broad institutional support and sufficient set-aside funds to attract senior-level researchers to engage in the study of CFS, DHHS should fund special emphasis, extramural grants through RO1, RO3, R21, and Director's Pioneer Award mechanisms.

Dr. Ablashi noted that he was informed that CFS grants were not being funded because they did not meet quality requirements. The problem is that CFS grants are reviewed with other non-CFS grants, not in a special CFS study section. As a result, CFS grants always received the lowest scores.

Dr. Bell asked for other comments on this bullet point.

Ms. McCleary noted that there is a decline in CFS funding and the number of new investigators. This recommendation would have multiple positive implications in the field, reinvigorate current researchers, and attract new researchers. This recommendation should also establish a CFS-specific application process, outside of a more general review of all applications.

Dr. Bell asked the committee to vote on using the term, "special emphasis panel (SEP)." Several members noted that this was an imperative.

Dr. Hanna added that there is an SEP. Dr. Lapp responded that the SEP does not have any CFS specialists. As in alternative medicine, CFS needs a different level of reviewers, so that more clinical and general topics are accepted. Dr. Hanna added that they try to select panel members who are experts in the specific grant. They do not need to look for non-degreed, non-scientific individuals, because many of the mechanisms that need to be studied are grounded in the medical field.

Dr. Bell asked about adding, "reviewed by a special emphasis panel knowledgeable in CFS."

Ms. McLaughlin asked if a standing panel would be more appropriate. Dr. Hanna noted that a standing panel versus a special emphasis panel has to do with the number of applications and the topics that are being covered. The SEP focuses on CFS, FM, and TMJ.

Ms. Fitzpatrick added that there is a pool of people to pull from to review applications, and that the whole panel would not be knowledgeable in CFS. The committee is, however, recommending that the panel consist of only people who are knowledgeable in CFS.

Mr. Lieberman asked if the committee could get the credentials and backgrounds of the reviewers. Dr. Bell noted that it is not the role of this committee to review

panelists. Dr. Lapp added that they could not get this information, but they could only get the names of the reviewers.

Dr. Friedman added that the people who review an application are very critical to its success. When a grant application is sent to a committee for review, that committee assigns a grant to a primary and secondary reviewer. The rest of the committee does not read that grant, but relies on the recommendations and summaries of the primary and secondary reviewer. That grant is dependent on just these one or two reviewers. Dr. Gantz added that the chair of the committee also reviews all grants. Dr. Friedman responded that, in his experience, not all chairs review all grants.

Dr. Mohagheghpour added that she shares Dr. Gantz's experience. Dr. Hanna noted that there are often three reviewers, and that the chair does review the grants. Only the lowest grants are not reviewed.

Dr. Bell asked if it should be a standing panel or an SEP. Dr. Komaroff added that standing panels require enough applications. If there are not enough applications, having a standing panel is a bad idea.

Dr. Bell added that he has no problem with an SEP, as long as CFS-expertise is stated.

Dr. Lapp noted that the panel is looking for people who have previous experience, work in major institutions, and have a long track record. For CFS, this is not the case, which is trying to bring in new blood, and they are not going to satisfy the above conditions. Whether it is a standing or special emphasis panel, there needs to be more latitude, similar to alternative medicine.

Dr. Bell asked that they leave the specific wording of this recommendation for the subsequent email correspondence.

Dr. Gantz noted that another recommendation should be to emphasize, promote, and fund research in children with CFS.

Dr. Bell suggested for a bullet point, "DHHS consider participation of the DoD, VA, ED, NIDIR in future meetings of the advisory committee."

Mr. Sterling added that in the past, DVA and DoD were involved as ex officio members.

Dr. Robinson suggested that the Agency for Healthcare Research and Quality (AHRQ), which is responsible for looking at a variety of measures, be included in future meetings. They can address quality of care issues that patients complain about. He added that, in terms of the tone of the recommendations, a point of urgency needs

to be addressed. In this regard, the committee may want to invite these other organizations to get their input now.

Dr. Bell moved the discussion to recommendation 6 of the subcommittee: "DHHS should help correct the gender perception of CFS by using the title, 'Chair, Trans NIH Working Group for Research on CFS,' when the Associate Director of the Office of Research on Women's Health administers CFS research."

Dr. Mohagheghpour explained that Dr. Hanna's current title makes CFS appear to be a women's disease. To resolve this misperception, a new title should be used.

Dr. Hanna noted that the Trans NIH Working Group for Research on CFS, which she chairs, is a working group comprised of representatives from every NIH institute. They work jointly on projects, such as RFAs and the program announcement. She added that the title change, if adopted, would not move CFS out of Women's Health.

Dr. Robinson added many individuals have a number of titles, depending on the specific role that they are in at any given time. If the purpose of this title change is to give clarity in terms of the "hat" that the person is wearing, this does not need to be done by the DHHS Secretary.

Dr. Mohagheghpour inquired as to whom this recommendation could be made. Dr. Bell asked Dr. Hanna if she could speak to her supervisor on this matter. Dr. Hanna added that even if her title is changed, there is still the issue of Dr. Ken's title, which is Director of the Office of Research on Women's Health.

Dr. Bell requested that they not include this recommendation. Dr. Komaroff agreed with Dr. Bell.

Dr. Hanna added the CFS will eventually be moved from the Women's Health website. There is a draft action plan, and specific timelines will be available in a week or two.

Dr. Bell proposed another bullet: "DHHS, through NIH and CDC, continue to sponsor focused workshops in specific areas of CFS, and to invite investigators not currently working on CFS who have been identified as having an interest in this illness."

Dr. Gantz added that this was a good recommendation.

Ms. Stevens asked how successful past workshops have been on generating new investigators and new ideas. If they were not successful, how could they be improved?

Dr. Hanna noted that there was a State of Science symposium. After the symposium, the working group has had a specific symposium on neuroimmune mechanisms in CFS. That was a very productive workshop. There were more than 100 attendees from all over the world. The main goal was to involve NIH intramural researchers, and half of the participants were from the NIH intramural program. The RFA will be based on that workshop.

Dr. Patarca noted that his subcommittee recommended a biannual frequency for these workshops. Another recommendation is to create partnerships with professional societies, professionals themselves, and patient organizations to facilitate the creation of these workshops. The workshops with the greatest impact were those that had the broadest partnership. The recommendation could read: Grants or funding for patient organizations, healthcare professionals, professional societies, etc.

Dr. Fields noted that this is recommending a formal sponsorship. Dr. Patarca added that these partnerships could draw upon nongovernmental funding sources.

Dr. Mohagheghpour recommended added a specific time interval (i.e., biannual) for these workshops.

Dr. Hanna responded that NIH could not do this biannually because it could take 6 months to 1 year to plan these conferences. She noted that annually would be more realistic.

Dr. Bell asked if there were other issues related to provider education that could be used for bullet points.

Dr. Patarca added a recommendation for specifying funds for education directed at healthcare professionals through live and web-based, regional and national workshops.

Ms. Fitzpatrick added that one of the best education tools is to get knowledgeable speakers funded to get to the national and regional meetings. Dr. Patarca added that they included the encouragement of the collection of qualitative and quantitative data on the impact of funded activities. These data are needed for decision makers, who are concerned with ROI.

Mr. Lieberman noted that the disabilities recommendation could fall within education. Initially, they were working on language to the effect that they would encourage continuing education for reviewers and adjudicators to improve the adjudication process in Social Security disability claims for individuals with CFS.

Dr. Bell asked if they would want to encourage education or improve upon the current system.

Mr. Lieberman noted that the regulations and rulings are in place. All they have to do is apply them. Since new adjudicators and new judges may not be aware of the new regulations, revisiting, retraining, and reminding them are the types of methods that could help.

Dr. Bell asked if there was a mechanism whereby the central disabling part of CFS could be communicated in a letter to adjudicators. Mr. Lieberman explained that the SSR 99-2p ruling does this.

Dr. Patarca noted that the Education Subcommittee wrote recommendations to address four target areas: content, format, impact, and funding of educational activities. Under content, the recommendation is to raise contextual awareness and use lessons learned in CFS and other diseases. It is proposing to educate on fatigue as a symptom, on its diagnosis and treatment in chronic fatigue illnesses; educate on CFS and its peculiarities; use lessons from pain, nausea, and other symptoms that were previously under-diagnosed and under-treated in the context of both recognized and poorly understood syndromes in different specialties; and address and raise awareness about the different populations affected by CFS.

Dr. Bell asked if the committee should recommend that DHHS encourage the ICD-10 classification of CFS.

The recommendation for format is to diversify means and emphasize practicality. It proposes to expand on the use of the worldwide web and other communication means; place CFS within appropriate disease categories; and generate practical up-to-date publications and reference guides.

The recommendation for impact is to increase outreach, recruitment, and follow-up. This proposes to take educational programs to diverse settings nationwide; recruit interest and help from professional organizations and high-impact journals; and encourage collection of qualitative and quantitative data on impact of funded activities.

The recommendation for funding is to raise need awareness and encourage involvement of others. It proposed to promote joint ventures with the private sector, as well as healthcare specialty groups.

Examples of how these recommendations could be achieved include:

- Grants to patient organizations, healthcare professionals, professional societies, or preferentially, partnerships among them to update, develop, and run nationwide and community-based CFS-related educational programs targeted at healthcare professionals, specialized societies, patients, and professional training programs.

- Grants for distribution of new and existing educational materials at local and nationwide levels.
- Grants for biannual live and/or web-based regional and national workshops or ground rounds on diagnosis, management, and treatment of CFS and other chronic fatiguing illnesses.
- Grants for education programs aimed at raising awareness for detection and intervention of disability among pediatric and adult CFS patients.

Dr. Bell suggested asking DHHS to encourage CDC to work on simplified CFS diagnostic tools for the practicing clinician. Dr. Lapp noted that Dr. Reeves does not like checklists. A checklist would cause all to be diagnosed with CFS.

Dr. Robinson noted that the pocket resource guide for practitioners is not overly detailed, yet contains enough information about how to make a diagnosis.

Dr. Bell added that this was exactly what he was referring to and that Dr. Reeves would recommend that guide as well.

Dr. Patarca asked if there was funding to broadly distribute the guide. Ms. McCleary noted that they are using the national, state, and regional provider group conferences as their main point of distribution. They began with primary care providers and are now expanding to more audiences. The guides are very popular.

Ms. McLaughlin noted that some of the content in the guide is inaccurate. Dr. Patarca added that there needs to be a general oversight group that would ensure the accuracy of content.

Dr. Friedman noted that the solution to this problem is to have a CFS education coordinating committee that would oversee all educational materials that are put out under the auspices of NIH and CDC.

Dr. Bell added that this would require an unrealistic amount of work.

Dr. Barrett noted that at CDC, all web content goes through an extensive review process before it is posted on the website.

Dr. Lapp asked if the Education Subcommittee has specifically recommended PSAs, posters, and advertisements. The recommendation could read, “Public education might include PSAs and advertisements that direct patients to credible sources.”

Mr. Sterling added that the campaigns might be used to raise public awareness for the general public, rather than just the patient group. This could help to alleviate some the misperceptions and stigma around CFS.

Dr. Robinson noted that PSAs should come from the Secretary or the Surgeon General. The Office of Public Affairs would develop and promulgate the campaign.

Dr. Fields added that most PSAs come from the agencies themselves, and most of the content is agency-based.

Dr. Bell asked if the recommendation could read, "DHHS generate, through a public awareness campaign, public service announcements including top officials to challenge the medical community to rise to the challenge of CFS."

Mr. Lieberman added that there could be a recommendation to have the Secretary remind all adjudicators to following the 99-2p ruling.

Dr. Bell suggested that he would take the lead on developing a position paper on these bullets. The first draft will be distributed to the committee for comments. It would go through six or seven drafts over the next several weeks, with 1 week between drafts. He asked if they should vote on the paper at the next meeting.

Dr. Patarca added that there should be a period for public comment.

Dr. Bell noted that once a consensus is reached, they will plan to post the paper on the website and ask for public comments.

Dr. Fields asked if there was a discussion on randomized control trials within the centers or networks.

Dr. Komaroff noted that he assumed from Dr. Reeves' presentation that one of the goals of the network is to conduct clinical trials.

Dr. Patarca added on behalf of the Education Subcommittee that all of the subcommittees have done a lot of homework to arrive at these apparently simple statements. He encouraged the public to look at all those who have been contacted to draft the reports behind these recommendations.

Dr. Bell emphasized that the subcommittees have done an enormous amount of work. He asked if the next CFSAC meeting could be in September.

Dr. Fields noted that the current charter would expire by September and would have to be renewed. The renewal process is underway and there is no indication that there are any problems.

Dr. Bell asked if the meeting had to take place in Washington, DC. Dr. Fields responded that it is not required that the meeting be held in Washington, DC, but that the issue is budgetary.

Dr. Bell noted that the next meeting would be held on September 27. He explained that if the charter is not renewed, the recommendations would be submitted after they have approved them, with public input, via email.

Dr. Bell noted that the committee members would be receiving via email a copy of an IOM paper entitled, *NIH Extramural Center Programs: Criteria for Initiation and Evaluation*, that would be relevant to the committee's recommendation for an extramural center program.

Dr. Bell asked if two or three recommendations should be prioritized and emphasized. Dr. Komaroff asked if there should be major and minor recommendations (two tiers). Dr. Bell asked the committee members to prioritize the recommendations during the email response process by indicating three or four major recommendations. Additionally, other recommendations can be added during this process.

XII. Public Comment

A. Cheri Borsky

Ms. Borsky discussed two topics. First, a few years ago, Ms. Borsky went to a hematology specialist for an option on her 30% below normal blood volume test. When she mentioned her CFS diagnosis, the doctor said that he looked into CFS in the 1970s and 1980s and found that the patients were nuts. She thought to herself that she knew what he was talking about, and that some of her decisions while ill were quite strange. She suggested that the CFS community start to incorporate these types of symptoms and the consequences of these symptoms into the CFS picture, so that they are used as a diagnostic tool, instead of used to degrade CFS patients.

There is a tendency to move as far from this problem as possible, in part to avoid any association with psychiatric illness—since that does not fit the CFS patient's experience. Also, it is precisely to avoid having the illness delegitimized. However, with CFS, there are often emotional liability changes, poor decision-making skills, questionable alternative treatments tried in desperation, and other behaviors that appear abnormal to the layperson.

Sometimes, CFS patients report dreams that are more vivid, and there seems to be a break with reality and reasonable expectation of others. This goes hand-in-hand with the denial or dismissal of being sick, which is so much a part of the illness. Additionally, many patients report a period of 5 to 6 years where they had no symptoms to report, but were not okay. Often, these off-base changes happen to them during that time period, so the person is dismissed because they were not part of the obvious CFS onset.

Like Alzheimer's, these could be part of the effective CFS symptoms. If doctors started to incorporate these problems into the diagnostic picture, and they were fully explained to physicians, then the ways in which these symptoms are used to delegitimize CFS could instead be used to better understand how severely impacting the illness is.

The other topic deals with the 6-month waiting period for diagnosis. Specifically, she would like to see an encouragement of people trying and being allowed to rest as part of the treatment at very early onset. It might make the difference in how many CFS patients there are in the long term. Studies have shown that patients with more severe illness, where initial hospitalization was needed, have a better prognosis in the long run. It is presumed it is because they have had more rest at the beginning. Early IVs may also make a difference.

In her family, she caught the initial head cold from her mother. They were both very ill. Her mother rested for 3 months, but she had started a new job and did not rest. Her mother is essentially well, and she has not been working for 7 years. The doctor waited the 6 months to tell her that this was CFS. He never explained how serious or long term it could be, even though he was very familiar with the illness. If she had known early on, she would have opted to take short-term disability leave. At that point, she was still seeing some improvement when she rested. By the time she left work 5 months later for long-term disability, rest was not helping.

Ever since the discovery of penicillin and vaccinations, our culture as a whole assumes we are immune to viruses. She would like to see incorporated into the efforts to teach physicians about CFS an emphasis on early detection, early treatment that includes rest, and taking the severity seriously at onset. It is time for CFS to be considered a potential serious consequence at the onset of viral infection.

Dr. Bell commented that looking at viral infections as a pre-CFS-like illness is very interesting. He noted that some of his patients have mono for weeks, which can lead to something else. However, there is no mechanism to look at this at this point.

B. Steve Du Pre

Mr. Du Pre's comments were read by Victoria Bell.

Mr. Du Pre expressed his confidence that CFSAC is capable of bringing a new day for the ME/CFIDS patient community, which has experienced 15 years of unrelenting disdain from the majority of the medical community and general public. He alleged that this disdain is a result of the CDC's failure to recognize a serious disease that already had a name and criteria, plus inclusion in the ICD since 1969. Dr. Leonard Jason's two attribution studies in 2002 and 2004 provide clear and substantive evidence that in the practical clinical arena, patients who were said to have myalgic

encephalopathy (in the 2002 study) were treated by the medical staff with the seriousness that the disease deserves. In contrast, the name "CFS" brought about a trivializing attitude on the part of the staff.

He noted that it is dangerous to continue this situation with the CFS name and the lack of definitive criteria (which could be remedied by adopting the ME/CFS Canadian Consensus Criteria—at least the Clinical Case Working Definition with the possible addition of cardiac abnormalities proven by Dr. Lerner and mitochondrial encephalopathy proven by Dr. Cheney) because patients can receive wrongheaded treatment protocols such as CBT, GET, or some psychiatric emphasis which militate against a solid treatment protocol for a multi-systemic physiological disease. The seriousness of this situation has been brought home to him recently with the knowledge that two of his friends with the disease (both have had it for about 17 years) are now in the end stage organ failure phase, dealing with liver and pancreatic failure. He asked how much longer this tragic train of events must continue to take place with no basic changes in regard to the name change and solid diagnostic criteria. Such changes could in turn can lead to research that is substantive and helpful in bringing the disease under control.

The long black train includes other tremendous losses: jobs, financial security, the ability to go out socially and maintain friendships, the ability to take road trips, the strength to maintain recreational pursuits, and in the majority of cases, spouses. The additional weight of a trivializing name and lack of definitive criteria and the resultant loss of hope of significant research are too heavy to bear for the patient community. They will never give up the struggle for changes in each of these three areas, no matter how weak they are or how many die before the changes are made. He noted that the CDC and the CFIDS Association of America plan to "brand the name CFS" in the public consciousness would not work.

He acknowledged that Dr. Charles Lapp has pragmatically moved forward by using myalgic encephalopathy to replace the name "CFS." Dr. Charles Shepherd in the U.K. also uses this term in his disability reports, while at the same time keeping the ICD code 93.3 category of ME as a neurological illness. Dr. Enlander has come out in favor of Ramsey's Disease as a way to honor the doctor who did the initial work on this disease. The engine to turn the corner is in place, and he noted that they are asking CFSAC to start the process of bringing justice to this moribund clinical situation.

He noted that he has had ME/CFIDS since 1991.

C. Marla McKibben

Ms. McKibben's comments were read by Kim McCleary.

Ms. McKibben shared that she is sincerely encouraged at the CFSAC steps to address crucial issues affecting the neuroendocrineimmune disorders community in the U.S. There is much to be done. PANDORA appreciates the opportunity to once again express their concerns.

She noted the importance of the June 21, 2004 CFSAC meeting with the committee's review of the medical codes assigned for CFS and the implications they carry. This should give a very good idea about how confusing it is for the patient community and for the physicians who are trying to heal them.

She predicted that it would probably demonstrate the facts to CFSAC, which show how vulnerable the situation leaves CFS patients. It will probably demonstrate the need to come up with a more viable name for this neuroendocrineimmune disorder instead of using the current one. If not, then it might give CFSAC the capability and knowledge that might require the committee to think outside the box and in establishing a new, much more beneficial paradigm in terms of new proposals to resolve this issue.

She could not express any stronger the importance of CFSAC being their leader in these efforts.

PANDORA has tirelessly contacted their Florida Congressmen in Washington to address research funding, ERISA laws, and medical, employer, and community educational programs about neuroendocrineimmune disorders such as CFS. The advocacy volunteer work is ongoing.

They received several responses from senators and representatives in their area and would like some guidance from CFSAC as far as maximizing the committee's influence, dedication, and support they need to have to keep CFSAC in place. She asked what would happen to the committee if September 2004 is going to be CFSAC's last meeting for its term. She asked what would be of the future, noting that these are primarily PANDORA's questions that they would like to present at this meeting.

D. Lynn Roister

Ms. Roister is a professor at DePaul University, where they started a program to help people with chronic illness get a college education. She has a son who has had CFS for 18 years. When they began they were treated cruelly. She stressed the urgency of doing something. Even though things have improved, most of the medical care has been poor and has done nothing for him. People continue to be demeaning and have blamed him or his mother. As a result, public awareness is absolutely crucial. This type of discrimination and treatment needs to be made politically unacceptable.

Her son in 6th grade, when he got sick, was called a genius by his peers, but cannot finish school or work, has no social life, and has no realistic hope of marrying and having a family. Her own family was torn apart by this illness. She and her husband divorced.

The costs are enormous, and many families are not able to manage them. The psychological costs are also enormous. For children, without self-esteem, they have no chance of establishing who they are. There is enormous urgency to do something about this. She also asked for real clarity in the committee's recommendations so that they are not too generic and easily dismissed. She likes many of the recommendations and wants to make sure they get acted upon.

E. Dr. Mary Schweitzer

Dr. Schweitzer noted that this is the best of the committees and that the members have worked harder than anybody else on this issue. She believed in the committee from the beginning and continues to believe in it. However, there are two things missing in the recommendations. She is concerned that they have lost the sense of urgency, which was the one thing that they all feel CFSAC must get out there.

Dr. Leonard Jason, 5 years ago, estimated 800,000 Americans have CFS, of which 90% are not diagnosed. Dr. Reeves says it is 70%. This 70 to 90% range is unacceptable and demands a level of urgency that is not getting across.

She added that she is concerned about some of the tautology going on here. There is no research because there is no money. There is no money because applications go to non-CFS grants. Applications go to non-CFS grants because there is no research. She asked where they could get dispensation for this problem.

This is also the case for the categorization of CFS. ICD-10 fits better, yet CFS cannot be put in with postviral disease syndrome and ME because it cannot cross chapters. Again, she asked where they could get dispensation for this problem. She added that it would be 5 years before ICD-10 is approved.

There are tests. If there were no tests, she would not know that she has CFS. There are tests that work for many with CFS. More importantly, there are tests that work only for those with CFS. This information should be out there. She added that she knows of people who got better after they were diagnosed and treated for mycoplasma.

She is concerned about the idea of replacing the old CFS clinics with Dr. Reeves' plan to institute fatigue clinics. She warned against using "CFS-like," because it will mean fatigue.

Finally, Dr. Schweitzer offered the following bullet point: We request that a working group be convened to consider adopting the Canadian ME/CFS consensus criteria.

She asked the committee members to raise their hand if they believe CFS is a "somatization" illness. She asked those who do not believe it is a "somatization" illness to raise their hands. She asked why some were unable to raise their hands for the latter question.

F. Victoria Bell

Ms. Bell wanted to give Mr. Lieberman input on disability. Education is needed for SSA, but also for patients. If she had not received information from another patient, she would probably still not have attempted to fill out the green form. Without her help, she would not have been able to figure it out. She would not have included attachments or collected her own records.

Ms. Bell added that California is a fast track state within SSA for CFS. However, she has discovered that there still are disparities in the timeliness of application processing, which ranges from being awarded within 1 month of submitting the application to the 2-year appeal process to being involved in a very long review process.

Dr. Desi noted that these experiences with SSA are not unique to CFS applications. There are many variables that can affect the timeliness of the application process.

Mr. Lieberman added that there is no state that is on a fast track on anything. Due to the backlog in all states, along with different levels of support, there are these disparities. He added that district offices would help you fill out forms. If the adjudicators at the lower levels followed the rules, this may resolve the case sooner.

G. Jonathan Gilbert

Mr. Gilbert introduced himself as a Senior Consultant with the Department of Family Medicine at the University of Maryland in Baltimore. He holds national certifications as a Diplomate in Chinese Herbology and a Diplomate in Acupuncture with the National Certification Commission for Acupuncture and Oriental Medicine.

He noted that what he has learned about chronic fatigue over the past 10 years might surprise CFSAC. Having specialized in chronic neurological conditions using Chinese herbology methodology, his protocol has restored functioning to clients with symptoms associated with chronic fatigue, fibromyalgia, irritable bowel, and associated pain.

His clients have reported to him that within 4 to 6 months, or 9 to 12 months in complex cases, that they no longer suffer from the effects of chronic fatigue and/or fibromyalgia and the associated pain and irritable bowel symptoms. At this point, the client no longer takes an herbal formulation.

He requested an opportunity to speak at the next CFSAC meeting to discuss his findings and provide additional information about the strategy he uses for working with these conditions. His goal is to provide a viable care option to those who are debilitated and suffering with chronic fatigue. He noted that he has provided CFSAC with printed materials, including his public comments and his biography.

Mr. Gilbert thanked CFSAC for their support and national leadership they provide to the chronic fatigue medical, healthcare, and patient communities and for the opportunity to address them. He also offered to make himself available after the meeting or by phone for further questions.

Dr. Bell asked Mr. Gilbert for his perceptions on the Division of Alternative Medicine headed by Dr. Strauss. As a practitioner, Dr. Bell added that he does not know how to evaluate the information on alternative medicine.

Mr. Gilbert noted that Dr. Bell should be skeptical about believing any of the marketing materials promoting over-the-counter herbal drugs. In his work, Mr. Gilbert does not write a single patent or formulation for a particular disease. Instead, each formulation is based on his examination of each individual patient. It is extremely difficult to create a Western paradigm for Chinese herbology. It takes even pharmaceutical companies 20 years to determine the ingredients of a single herb and turn it into a product, let alone a formula that would fit everything. As a result, the quality of care is based on the practitioner.

Dr. Mohagheghpour noted that there are many variables to herb quality, including the season and time of day of harvest, and the part of the plant from which it originated. She asked how he could ensure the effectiveness of his herbs.

Mr. Gilbert noted that it is ensured through the Chinese methodology in which the herbs are made. Chinese herbal medicine remains the longest standing form of medicine still continually practiced. Over the past 3,000 years, at a conservative estimate, the Chinese have managed to create methodologies whereby they can maintain, within a certain range, qualities of the herbs used by the practitioner. The trick is to find a good pharmacist. He uses powders, which tend to be of a standard quality. That question is almost a red herring because it is easily overcome.

H. Barbara Commerford

Ms. Commerford noted that she is a disabilities attorney in New Jersey. In the disability field, there is nothing more critical to persuade a fact finder than medical research and demonstration that a person suffers from certain signs and symptoms. She not only deals with SSA, she also had the burden on convincing large insurance companies who write disability plans that her CFS/FM clients are real victims of a physical disorder.

The most important recommendation heard today is the Centers for Excellence, because they are conducting medical research, which is extremely persuasive to people, and the signs and symptoms are being documented by people who understand the illness. There is nothing worse than having a report from a physician dismissing signs and symptoms that a patient reports. She asked the committee to prioritize their recommendation for the Centers for Excellence.

XIII. Open Discussion

Dr. Bell asked Dr. Ablashi if he feels there is any way DHHS, through CDC or NIH, could interact in a better way with clinicians.

Dr. Ablashi noted that AACFS does not have much communication with NIH or CDC. AACFS provided a list of 50 CFS experts to NIH for a grants review. They have not received any feedback on this list and do not know if those experts are being used to review grants. In their upcoming meeting, NIH and CDC will be given an opportunity to give a presentation on the grants process.

In the last AACFS newsletter, Dr. Ablashi reviewed three papers. The results of the CDC study on mycoplasma were negative, while the studies coming from Belgium are finding mycoplasma species. Which is true? They would like to see better communication, both with CDC and NIH.

Dr. Mohagheghpour asked if they have considered sending the same sample to three different laboratories, since this is a standard method of quality control.

Dr. Ablashi noted that this is what they are proposing. This is the same problem they are facing with HHV6. While CDC studies were negative, studies published by other groups in the U.S., Germany, Italy, and France have found a subset of patients that have an active infection of EBV or HHV6. If the patients are treated for these infections, they get better. Yet, HHV6 is not included in CDC studies, because CDC and NIH are biased against these viral infection theories.

Dr. Bell asked if an intramural-staffed laboratory committed to CFS could manage this type of problem. Dr. Hanna responded that she was not sure, because in the intramural program each laboratory has its own purview.

Ms. McLaughlin asked if the committee could recommend Dr. Mohagheghpour's suggestion about sending controlled blind samples. Dr. Bell added that this has been done over the years.

Dr. Komaroff added that this is a good example of what a collaborative network could test. They could start a study with multiple centers, and standard criteria for data and specimen collection.

Dr. Mohagheghpour noted that every lab should have a negative and positive control. Centers are doing this. For example, a lab in Los Angeles would send samples to labs all over the world. These controls are needed.

Dr. Friedman noted that what is being discussed is essentially a matter of calibration. This is not the purview of an intra-NIH laboratory. If the research centers are funded, calibration and the service of samples could be incorporated into their mission.

Ms. McCleary noted that one of the most important things that this committee can do is it establish CFS/CFIDS as a public health priority. The magnitude of this illness warrants that designation because of its prevalence, severity, chronicity, the lack of long-term data, and economic impact. She urged the committee to be specific and targeted, to prioritize the recommendations, and to utilize existing mechanisms and organizations.

Dr. Robinson asked Mr. Gilbert if he is collecting data on his patients. If so, he asked if he is sharing that information through NIH.

Mr. Gilbert has approximately 300 cases of people who have been diagnosed with CFS, fibromyalgia, or ME. They are all presently well, and remain well for up to 7 years without the need for a follow-up. That work is currently being collated for the purposes of commencing an NIH research program in the use of Chinese herbal medicine as a lynchpin of a protocol that involves other areas, including mind/body/spirit and nutrition. This is the only way to address this condition.

Dr. Bell turned the discussion to the idea of establishing CFS as a public health priority. He asked if the committee wanted to make a statement to this effect, independent of a formal recommendation, which will take several months.

Dr. Fields suggested that they do have a mechanism, which is similar to the one employed for the three positions at CDC. Dr. Bell noted that they could try to expedite a recommendation to DHHS that CDC establish CFS as a public health priority.

XIV. Adjournment

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