US Department of Health and Human Services

Chronic Fatigue Syndrome Advisory Committee (CFSAC)

Second Meeting

At

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

December 8, 2003

9:00 AM to 5:00 PM

MEETING SUMMARY

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Members in Attendance

Voting Members

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

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. 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)

Executive Secretary

- Dr. Larry E. Fields

Invited Speakers

- Jill McLaughlin, National CFIDS (Chronic Fatigue Immune Dysfunction Syndrome) Foundation (NCF)

- Mr. Jon B. Sterling, Chairman, The CFIDS Association of America (CFIDSAA) and Member, HHS CFS Coordinating Committee (CFSCC)

Committee Members Absent

- Dr. Anthony L. Komaroff (excused, see below)

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. Larry Fields completed the roll call and thanked the committee.

Advisory Committee Meeting

Dr. Bell then asked CFSAC members who were not at the inaugural meeting to briefly introduce themselves. He explained that the East Coast snowstorm may prevent Dr. Komaroff from attending the meeting.

Introductions

- **Dr. Drue Barrett** works in the Office of Science, NCEH, which merged with ATSDR. Her background with chronic fatigue mostly involves veterans health concerns and Gulf War Syndrome symptoms.

- **Dr. Charles W. Lapp** is a physician specializing in internal medicine and pediatrics. He has a private practice based in Charlotte, North Carolina, which is almost exclusively focused on CFS and fibromyalgia (FM) patients.

- **Lyle D. Lieberman** is an attorney based in Miami, Florida, and he was first involved with CFS when he was serving as a U.S. administrative law judge with SSA from 1978–1980. At that time, they saw patients and claimants

with symptoms that were later described as CFS. Since he returned to private practice in 1980, he has worked in the area of social security disability law and has represented approximately 150 to 200 CFS patients.

Dr. Bell thanked the members for their introductions.

Minutes of the September 29, 2003 Meeting

Dr. Bell noted that he found it helpful to review the detailed September meeting minutes and encouraged the other members to read over them very carefully. He stated a preference to receive the future minutes earlier, if possible. He asked CFSAC for their comments on the minutes.

Dr. Hanna submitted a correction to her remarks and an addition to her introduction in the minutes. Prior to the meeting, Dr. Mohagheghpour also submitted a correction to her introduction.

The changes were noted, and Dr. Bell motioned to accept the September minutes into the record. The motion was seconded and all voted in favor.

Presentations

Executive Secretary

Dr. Bell then asked Dr. Fields to discuss organizational matters.

Organizational Matters

Dr. Fields followed up on logistical issues that were previously raised by CFSAC.

Communications

Website

Dr. Fields explained that they have begun to develop the website requested by CFSAC. He noted that it will purely provide CFSAC-related information and that its format will be consistent with the HHS website. They pulled an internal team together and are almost done with the process.

Listserv

Dr. Fields noted that a CFSAC listserv will be available with subscription via the NIH listserv website. The listserv will allow CFSAC-related information to be forwarded to interested individuals. Dr. Fields then asked Dr. Mary Jo Deering from ODPHP, who is familiar with HHS electronic information requirements and has been assisting with these issues, to discuss the listserv.

Dr. Deering said she would make copies of the instructions on how to sign up for the listserv and that members can subscribe to the listserv online to by going to http://list.nih.gov.

Dr. Fields said they will use the listserv to announce when the website goes live. He added that website will also have a central email address to receive information.

Other Issues

Dr. Fields then discussed the public comment period, noting that CFSAC is a FACA (Federal Advisory Committee Act) committee and must follow FACA policy accordingly. He explained that since they want to ensure maximum opportunity for input from multiple individuals, each individual will be allowed a 5-minute period to speak. He added that individuals may share remarks on behalf of others within the same 5-minute period. He said they invited anyone from the public to comment.

Dr. Fields asked if there were any other operational issues. Dr. Bell asked if the committee were to decide to invite someone to discuss a policy or a position, would there be funding available for this purpose? Dr. Fields explained that if there is a desire to have other expert input, they would work with CFSAC and the Chair.

Dr. Friedman asked if the CFSAC website address is known. Dr. Fields responded that they will share that information when the website goes live. Ms. McLaughlin then asked about the central CFSAC email address, and Dr. Fields responded that the information on the address will be posted on the website.

Dr. Fields then transitioned to the follow-up presentations to the last meeting, including further discussions on CDC's case definition activities. Dr. Fields thanked all of the previous presenters and Dr. Reeves for his willingness to present again.

Ex Officio and Member Presentations

Dr. Williams Reeves

Dr. Reeves explained that his presentation focuses on CDC activities as regards case definition. He began by explaining that CFS has been studied for more than a decade and that there are at least 3,000 peer-reviewed articles in MEDLINE investigating CFS.

Though there have been some good studies, he said that a consistent association of specific markers with CFS has not been found in on multiple studies over time. He then explained the major reasons why this is the case. First, there are at least four different case definitions that have been published in peer review literature. He noted that the 1994 CFS research case definition is the most recent one and that various people have applied it differently. Second, existing case definitions are based on expert consensus, rather than data. In addition, case definitions are based on self-reported symptoms that are common and not uniformly assessed in most studies.

Dr. Reeves then reviewed the 1994 CFS research case definition, which describes fatigue as persistent and relapsing for at least 6 months, not alleviated by rest, resulting in a substantial reduction in activities, and having no explanatory medical or psychiatric causes. There also must be at least four of eight accompanying symptoms: post-exertional fatigue, unrefreshing sleep, impaired memory/concentration, headaches, muscle pain, multi-joint pain, sore throat, and tender lymph nodes. In summary, the CFS research case definition is defined by symptoms and disabilities and is not empirically derived. There are no specific confirmatory physical signs or laboratory abnormalities.

Dr. Reeves noted that CDC has been involved in CFS case definition from the beginning. CDC convened the International CFS Study Group in 2000, which includes all of the major authors of previous CFS case definitions. The study group met annually since 2000 to discuss CFS research issues. Dr. Reeves explained that they determined at their first meeting that the largest research issue is CFS case definition. They also decided to focus on resolving what they defined as the largest outstanding problems. Dr. Reeves shared that the study group has addressed:

- Ambiguities associated with exclusionary and comorbid conditions
- Instruments to measure fatigue intensity and disability associated with fatigue
- Instruments to document CFS case-defining symptoms
- Recommendations for future research

Dr. Reeves shared that a study group article, "Identification of Ambiguities in the 1994 Chronic Fatigue Syndrome Research Case Definition and Recommendations for Resolution," would be published in approximately 2 weeks in *BMC Health Services Research* (http://www.biomedcentral.com/bmchealthservres/). He noted that they specifically sought out this journal because it is free, listed on MEDLINE, and will be available online for anyone to access. Dr. Reeves explained that his presentation would review the recommendations made in this manuscript.

Exclusionary and comorbid conditions

Dr. Reeves said the first area the study group considered was exclusionary and comorbid conditions, which are very problematic. He explained that the initial case definition stated that patients with severe chronic fatigue must undergo a clinical examination to identify underlying, contributing, and comorbid conditions that require treatment. He said that this is pivotal for CFS and can be written into the new case definition.

The presence of a medical or psychiatric condition that may explain the presence of chronic fatigue and accompanying symptoms excludes classification as CFS in research studies. Such individuals confound study results and must be excluded or stratified. He noted that the study group also spent a substantial amount of time discussing clinical settings. In clinical settings, patients with exclusionary conditions may be diagnosed and managed as having CFS on the basis of the physician's medical opinion.

Dr. Reeves noted that permanent medical exclusions for research purposes were not included in the previous case definition. The article specifies them as follows:

- Organ failure (emphysema, cirrhosis, cardiac failure, chronic renal failure). Dr. Reeves noted there is little controversy in this area.

- Chronic infections (AIDS, hepatitis B or C). Dr. Reeves noted that these individuals would be excluded from research settings, but just because an individual has one of these infections does not mean, by the definition, that the symptoms are being caused by AIDS or hepatitis. This determination would require a clinical evaluation.

- Chronic inflammatory disease (lupus, Sjogrens, rheumatoid arthritis, inflammatory bowel disease, chronic pancreatitis)

- Major neurologic diseases (MS, epilepsy, stroke, head injury)

- Diseases with systemic treatment (organ transplant, systemic chemotherapy, and radiation of brain, thorax, abdomen, or pelvis)

- Major endocrine diseases such as hypopituitarism or adrenal insufficiency

- Primary sleep disorders such as sleep apnea or narcolepsy

Dr. Reeves then described bases for temporary medical exclusions from research studies. These conditions include:

- Medication use, sleep deprivation, hyperthyroidism, diabetes, or infection discovered at onset. Dr. Reeves said that these conditions need to be treated and the individuals reevaluated to see if their fatigue is improving.

- Conditions that resolve such as pregnancy, breast feeding, major surgeries, and some sleep disorders.

- Major conditions whose resolution maybe unclear for at least 5 years such as myocardial infarction or COPD.

- Morbid obesity (mass body index (BMI) > 40). Dr. Reeves noted that the previous case definition specified a BMI in excess of 45. In 1994, they did not implement the NIH consensus on morbid obesity.

Dr. Reeves then reviewed exclusionary psychiatric disorders, which are psychiatric conditions that prevent a subject from accurately reporting symptoms and have fatigue as a reasonably anticipated symptom:

- Lifetime diagnosis of bipolar affective disorder, schizophrenia, delusional disorders, dementias, and organic brain disorder

- Alcohol or substance abuse within 2 years

Dr. Reeves said that a major change to the 1994 case definition is that resolved major depressive disorder/psychotic features, bulimia, and anorexia are no longer exclusionary. The 1994 definition stated that a lifetime history of any of these conditions were exclusionary.

Dr. Reeves then share the study group's findings on proper psychiatric evaluations. They determined that a reliable detection of psychiatric illness requires a structured interview. He noted that the 1994 case definition recommended the use of the Diagnostic Interview Schedule (DIS) but that many advances in psychiatry have been made since then.

He noted that the group currently recommends use of the Composite International Diagnostic Instrument (CIDI) for research studies and clinicians. CIDI is a psychiatric diagnostic instrument developed and supported by the World Health Organization. It is in the public domain and available in several languages. Dr. Reeves added that the Structured Clinical Interview for DSM-IV Axis I (SCID), the mainstream instrument used in psychiatric research in the US, could also be used.

He also noted that the study group recommends that stratification must be considered for research studies. He explained that psychiatric comorbidity with CFS or any chronic illness can impact research studies.

Evaluation of the symptom complex

Dr. Reeves explained that the case definition specifies fatigue as central to this illness and defines it as:

- Of new or definite onset (i.e., not lifelong) clinically evaluated, unexplained, and persistent or relapsing fatigue for at least 6 months duration.

- Not the result of ongoing exertion. Dr. Reeves noted that CFS patients experience worst symptoms with physical, emotional, or mental exertion, but the symptoms should not be caused by ongoing exertion such as running marathons or working several jobs while raising a family.

- Not substantially alleviated by rest. He noted that many CFS patients use rest as a coping mechanism, which can help, but the symptoms are not substantially alleviated.

- Resulting in substantial reduction in previous levels of occupational, educational, social, or personal activities.

Dr. Reeves explained that a major problem with the case definition is that it does not discuss assessment of fatigue. Typically, patients were simply asked if they experienced fatigue. The study group recommends use of a standard measure of fatigue. The Checklist Individual Strength (CIS) and Multidimensional Fatigue Inventory (MFI) are validated, standardized instruments that are available internationally. He noted that the

study group recommends CIS, while CDC uses MFI because they believe it has some advantages.

Dr. Reeves explained that the Krupp Fatigue Severity Scale and the Chalder Fatigue Scale are sometimes used but that the study group felt that they were not as all encompassing as CIS or MFI.

Dr. Reeves then discussed functional disability, which was not measured in the previous case definition. The group recommends that all patients being evaluated for CFS in research and clinical trials be evaluated for the intensity and disability associated with the fatigue. He noted that the Medical Outcomes Survey Short Form 36 (MOS SF-36) is a standardized instrument that measures five dimensions of function with scores that have been normed in a variety of populations and different diseases. He added that the study group also recommends the Sickness Impact Profile (SIP) as an acceptable substitute.

Dr. Reeves summarized his discussion of the documentation of CFS case-defining symptoms by noting that:

- Debilitating fatigue must be accompanied by at least four to eight symptoms.
- Symptoms must have persisted or recurred during at least 6 consecutive months
- Symptoms cannot have predated the onset of fatigue.

He added that the study group recommends that the functional impact of the cumulative symptom complex — not just disability due to fatigue — should be the primary determinant for classification of CFS.

Dr. Reeves then reviewed the accompanying symptoms list, which is the same list from the 1994 case definition: post-exertional malaise for more than 24 hours; unrefreshing sleep; impaired short-term memory or concentration; headaches of a new type, pattern, or severity; muscle pain; multi-joint pain without the swelling or redness; sore throat; and tender cervical/axillary lymph nodes. The study group recommended standardized instruments for each of the symptoms.

Dr. Reeves noted that the study group is not aware of any standardized instruments that measure the entire symptom complex but that they recommend using either CDC's Symptom Checklist or the Somatic and Psychological Health Report (SPHERE). He explained that CDC uses the Symptom Checklist in all of its research studies and provides it to many other investigators. The checklist, however, is not a validated instrument that provides composite summary scores. He added that SPHERE measures some of the symptoms and is used widely in the UK as a screening instrument.

Dr. Reeves explained that there are no good all-encompassing, standardized instruments that measure unrefreshing sleep. He named the Pittsburgh Sleep Questionnaire as the most generally available standardized, validated instrument; it was developed to measure

sleep quality in psychiatric studies, and it is not as applicable to CFS. He noted that Dr. Harvey Moldofsky's group at the University of Toronto has published papers on the Sleep Assessment Questionnaire (SAQ©), which diagnoses most primary sleep disorders. This is a proprietary instrument that requires payment for use. He added that more recently the CDC Sleep Questionnaire was developed in collaboration with Emory University. Although it is not validated or standardized, it collects necessary information and is recommended for use.

Dr. Reeves explained that most CFS patients also complain of severely impaired short-term memory or concentration, which is even harder to measure than unrefreshing sleep. He said that that the study group recommends that research studies use the Cambridge Neuropsychological Test Automated Battery (CANTAB), which measures all dimensions of cognition and is applied in approximately 1 hour. CANTAB, however, is suitable for research but not clinical settings and is relatively expensive to use. Rozelle Test Battery (RTB) was developed by an Australian investigator and is very similar; it is entirely in the public domain and is completed on a laptop computer. More recently, Dr. Benjamin Natelson's group has published the Cognitive Function Index (CFI), which is not standardized and validated to give summary scores.

Dr. Reeves then noted that five of the eight CFS defining symptoms involve pain. The study group recommends that all studies, including clinical studies, use the McGill Pain Questionnaire (MPQ).

In conclusion, Dr. Reeves noted that the study group manuscript will be on posted on CDC's website. He then summarized the study group's recommendations:

- CFS studies must use a standard case definition.
- CFS must assess subjects using standardized methodologies, which has not been done in all past studies.
- Publications must describe how the definition was used; it is not enough to say that the 1994 case definition was used.
- Publications must adequately describe study subjects.
- Development of an empiric case definition is an imperative; the study group suggests not modifying the case definition until an empiric case definition is developed, except to clarify it in the ways that they recommend.

Dr. Reeves noted that several individuals have worked on the empiric definition. CDC developed one for Gulf War Syndrome. They developed one for a CFS-like illness based on their San Francisco study. The analysis from the Wichita study is expected to be published in December. A large CFS meta-analysis is also being completed internationally, which will examine approximately 30 sites to determine the instruments

that have been used and to derive an empiric case definition. He added that they hope to have final analysis of a larger national data set submitted for publication by mid-year.

Dr. Bell thanked Dr. Reeves and asked the committee if they had any questions.

Q & A and Discussion

Dr. Lapp thanked Dr. Reeves for his presentation, noting that no one agency or individual has done more than CDC in objectifying CFS as an illness. Dr. Lapp noted that sleep apnea has always been a major issue for his patients and that it is listed as an exclusionary condition in the case definition. He acknowledged that there are several people suffering from sleep apnea without any significant fatigue symptoms. Unfortunately, however, he said that attorneys use the case definition in court to exclude patients with treated sleep apnea from receiving benefits. He asked Dr. Reeves why sleep apnea was included on the list and what is the degree of sleep apnea that they refer to. Dr. Bell clarified the question by asking if the study group made any clear distinctions between clinical and research settings.

Dr. Reeves responded that there is an entire paragraph included on this issue. If a provider is caring for a patient with an exclusionary condition and the provider believes the patient has CFS, then it is an acceptable clinical diagnosis. He added that sleep conditions are very confusing, since almost any primary sleep disorder can result in CFS-like symptoms and almost any illness that can result in CFS-like symptoms can result in sleep disorders. Individuals who have influenza, rheumatoid arthritis, or poorly managed diabetes have problems with their sleep. Just because someone has sleep apnea does not necessarily mean that they have, by definition, symptoms of CFS.

Dr. Reeves explained that they classify sleep apnea and narcolepsy as only exclusionary primary sleep disorders because there are interventions that allow them to determine if these sleep disorders caused the CFS-like symptoms. He added that Dr. Dedra Buchwald's work has shown that effectively treating a primary sleep disorder does not make any difference for CFS. The study group believes that appropriate treatment for primary sleep disorders should be conducted before diagnosing CFS.

Dr. Lapp agreed with Dr. Reeves. He added that he recently reviewed the literature on sleep disorders, and most publications say that 60% of CFS patients have sleep disorders, which would exclude more than half of the patients.

Dr. Lapp asked if Dr. Reeves was suggesting that for every case that gets submitted for research, that each patient be evaluated using the instruments for psychiatric evaluation, functional disability, fatigue, pain, and other symptoms discussed in the presentation.

Dr. Reeves responded that they recommend that all CFS patients in both research and clinical settings undergo a complete evaluation, which should be done with any patient. This evaluation would include taking a full medical history, a head-to-toe examination, and basic laboratory work. The study group recommends that those evaluated for CFS have a structured psychiatric evaluation. In private practice, they recommend a

psychiatric consult be obtained when deemed necessary, though they do not necessarily recommend using the full CIDI or DIS instrument. In research studies, they recommend measuring functional disability and pain. They do not recommend, however, cognitive assessments or sleep studies in all research studies.

Dr. Patarca inquired about the impact that medications have on research outcomes, which is a major problem in getting people outside of clinics involved with CFS. Patients have often tried 20 to 30 medications that are affecting the results.

Dr. Reeves responded that they recommend a careful medication history that considers and records potential secondary effects of the medications. They did not recommend which specific medications should be excluded. He noted an article on medication use by CFS patients in the general population, which has just been published by Biomed Central in *Health and Quality of Life Outcomes*, a MEDLINE-indexed, peer-reviewed journal in the public domain. He said they have articles coming out on this issue, but they do not go into detail for the same reasons that Dr. Patarca mentioned.

Dr. Friedman thanked Dr. Reeves for all of his efforts, noting that he would like to see these efforts continue. He then asked what the prognosis was for continuing this type of work. For example, does CDC have the adequate infrastructure and support to continue or even accelerate this work?

Dr. Reeves responded that they are in the last year of payback funding and are actively working with the agency to develop out-year funding. The agency is very interested and supportive of their work in the research program, and the restored funds were specifically focused on accelerating the research. He added that the indications he has received show the agency's willingness to support the program. Dr. Bell asked if it would be valuable for CFSAC to make a statement in support of the research program, and Dr. Reeves responded affirmatively.

Dr. Friedman asked if there are any lingering barriers to attracting top scientific researchers to CFS. Dr. Reeves responded that the biggest barrier to recruiting researchers is the nature of CFS. He said they have been fortunate with the CDC research program to have a talented group of researchers who are interested in CFS and the challenges it provides, but he noted that this is not true everywhere. He said there are many extremely talented researchers working on CFS in academia and the government, but there are probably many more working on AIDS, SARS, influenza, and other more popular research areas. He explained that they are trying to recruit for several senior-level positions within the CDC program but that there is no agency bias; CDC has been very proactive and interested in CFS.

Mr. Lieberman commended Dr. Reeves and CDC for their efforts and expressed a particular interest in defining functional limitations. With social security disability benefits, he explained that he is assuming that they can get the adjudicators to understand that CFS is a medical determinable impairment and can result in extreme fatigue. The adjudicator then must determine the severity of the functional limitations. If these could

be quantified, it would have a profound effect on people's ability to obtain social security benefits. He noted Dr. Reeves's interest in quantifying impairment in a research setting but asked about clinical settings.

Dr. Reeves responded that they have discussed this issue and do recommend quantifying functional limitations in clinical settings; however, he is not currently involved in clinical practice. When they wrote the 1994 case definition, they said this illness must substantially reduce a person's ability to do specific activities, but this became increasingly difficult to define. When they would ask patients in their research studies if they were impaired from doing various types of work, they would respond negatively, and when these individuals were given the MOS SF-36, they scored in the bottom 20%. As patients come to grips with the disease, they do not realize how badly it affects them.

Dr. Reeves added that for social security purposes, instruments that are validated and standardized should be considered acceptable. They also allow patients to be followed as they are treated or as interventions are implemented in both research and clinical settings. MOS SF-36 measures a variety of domains. The different domains that these instruments measure can suggest specific areas for intervention. They recommend that both clinicians and researchers use these instruments to document impairment. Mr. Lieberman added that this could provide another level of objectivity to the results.

Dr. Bell referred to the AIDS experience and asked if CDC could take the lead in putting together a package of public domain instruments that would be very useful for clinicians who are just getting exposed to CFS, particularly if patients come to their offices with disability issues. Dr. Reeves responded that he would like the committee to consider and make recommendations on this issue.

Dr. Reeves explained that he gave a very similar presentation at the last American Association of CFS (AACFS) meeting, and he was asked if CDC could put some of these instruments on the website. He shared that CDC would not be opposed to this idea but that it may be difficult to do since many of the instruments, like the MOS SF-36, are proprietary. He said that there might be a way for CDC to do this for clinicians, but people can also learn these instruments "too well" and know what the responses are supposed to be. He noted that the article will be on the website and suggested that CFSAC explore this issue.

Dr. Cavaillé-Coll thanked Dr. Reeves for sharing the information on these tools and said he would like to see more work in this area. He asked if the instruments require training. Dr. Reeves responded that some instruments do; DIS requires some medical training, and SKID requires psychiatric social work or nursing training. He noted that others, such as MOS SF-36 and the CDC Symptom Checklist, do not.

Ms. Butler asked about the cost of diagnostic testing, especially for patients who do not have medical insurance. Dr. Reeves responded that they have not recommended anything that a competent health care provider should not already be doing; if a patient with CFS symptoms sees a health care provider, then MS, cancer, and other illnesses should be

ruled out. He noted that other aspects, such as documenting disabilities with MOS SF-36, are mixed issues. This may be one way that patients can obtain third party coverage.

Dr. Reeves explained that many of the other instruments are more for research purposes. If someone is being tracked in detail after entering the treatment protocol, they should probably be used. He emphasized that they primarily focused on research purposes and that a major objective for use of the case definition is to determine markers, risk factors, and etiologic agency. In their discussions, however, they acknowledged clinicians have critical needs for assessments in CFS patients.

Ms. McLaughlin expressed a concern with CDC payback funds. She explained that they have seen several reports that show that the payback funds were not being spent but carried over. She asked what this meant in terms of CDC's commitment to CFS, noting that this money should have been used in 1995.

Dr. Reeves responded that the program was given $12.5 million in payback funds to strengthen and revitalize the research program over a 3-year period. He explained that they could have given all of the funding away, but they decided that developing the best multifaceted, integrated research program possible would be the best use of the funds. Their model was to fund program-oriented research.

Dr. Reeves said they are still spending payback program funds. In FY 2003, CDC allocated $5.2 million to the program, which was supplemented by $1.5 million in payback funding from NCID and $1.6 in payback funding from the Office of the Director, CDC. Of this $8.3 million, 80% of this funding is spent extramurally on grants, contracts, and organizations other than CDC. They do not have an unrestricted grants program. He explained that approximately $4 million remains, which may be extended through this year and possibly through next year; this provides greater flexibility and better stewardship of the money. He explained, for example, that they are operating under a continuing resolution with the federal budget. The payback funds allow this money to be available at the beginning of the year irrespective of the continuing resolution.

Mr. Sterling asked Dr. Reeves if they have enough full-time employees to move forward this year and next year with the CFS program.

Dr. Reeves responded they do not; they have three vacant FTEs that they are trying to fill. He added that one FTE was taken away, for which they had a candidate; they are currently appealing the decision at the division level. Mr. Sterling then asked if the program has what it needs to move forward and if there is anything that CFSAC could do to help.

Dr. Reeves responded that it always hurts to lose an FTE when a program has momentum. He added that about three-fourths of their staff are in non-FTE positions. CDC provides a lot of training to these individuals, but with no job security or benefits, they lose many of these people. Dr. Reeves explained that the health of any program

requires an appropriately funded staff with the commitment of various organizations to support them.

Dr. Patarca asked Dr. Reeves what percentage of their budget goes to education. Dr. Reeves responded that this question is difficult to answer. He explained that they have a contract to educate primary care providers but that they also consider the website, publications, presentations at meetings, and supporting meetings and groups as part of the education mission.

Dr. Bell noted that several people from the public appeared to have questions and asked that they please save these questions for the public comment period.

Dr. Bell apologized for not introducing Dr. Wanda Jones earlier and then asked that ex officio members continue their presentations.

Dr. Eleanor Hanna

Dr. Hanna noted that Dr. Mohagheghpour would be presenting on CFS research but clarified how NIH provides funding for CFS research. She explained that NIH funding depends on the number of CFS grants that are submitted, pass the scientific review process, receive good scores, and are funded. Each year, money allocated to the NIH Director's budget for CFS is based on the amount spent in the prior year. She said they spent $7.2 million on research in FY 2002. For FY 2003, they anticipated that the budget would be $7.5 million. She added that money spent on salaries, conferences, and other activities come from the institutes' and the Office of the Director budgets.

Dr. Hanna provided copies of summaries for NIH-funded programs that may be appropriate for CFS. In addition, she shared that they just completed scientific review for the first FY 2004 grants and would know outcomes at the end of the week. She added that they should have a summary of the meeting on the website by the end of the month and are working on a publication. They also hope to get the first draft of the RFA written by the end of January. Finally, she said she has begun to discuss internally the possibility of having an intramural program and promoting work on CFS within the agency.

Dr. Bell asked Dr. Mohagheghpour to provide her comments on research.

Dr. Nahid Mohagheghpour

Dr. Mohagheghpour presented on science funding for CFS, covering CDC studies, NIH-funded projects, future research considerations, and next steps. She explained that her goal was to share key challenges and opportunities for CFSAC to consider as they move forward with their mission.

She referred back to Dr. Reeves's presentation during the last CFSAC meeting and provided a broad overview of CDC epidemiological studies. She mentioned the population-based study in Wichita, which was published in the *Archives of Internal Medicine* (163:1530, 2003). She also explained that CDC is using two different

molecular approaches to map the epidemiology of CFS. The first approach, transcriptomics involves the search for bacterial DNA in plasma and is documented in *BMC Microbiology* (2:39, 2002). The second approach, proteomics, involves the search for dysregulated serum proteins. Composite data were previously discussed by Dr. Reeves.

Dr. Mohagheghpour noted that CDC has taken important steps to identify CFS biomarkers. She discussed a 2002 article in *Disease Markers* (2:39 18:193, 2002) focused on gene expression profiling of peripheral blood mononuclear cells. For this article, proteins that are significantly higher in CFS patients were examined. She mentioned another article, published approximately 2 years ago, that identified another protein as a possible biomarker. Dr. Kamaroff wrote an introductory article on this protein.

She also referred to CDC's work in developing microarrays to unravel abnormalities in the neuroendocrine, immune, and autonomic nervous system. Dr. Mohagheghpour noted that this work would be a positive step in the right direction.

Dr. Mohagheghpour then discussed NIH-supported CFS research and their support for Cooperative Research Centers (CRCs). She noted that the CRCs are important because they allow studies to be centralized and patient results compared. She described the CRC in Newark, New Jersey, which is headed by Dr. Natelson and funded from 1990 to 2004. This CRC's goals are to:

- Identify subgroups of patients with CFS based on differences of neuropsychological and cardiovascular functions.

- Perform longitudinal studies to determine both the pattern of illness and the interaction of the illness and psychosocial factors.

Dr. Mohagheghpour noted that it is important to stratify patients before they are included in research projects.

She then described the CRC in Seattle, Washington, headed by Dr. Buchwald at the University of Washington and funded from 1995 to 2004. Their goal is to determine the influence of genetics and environment on biological and neuropsychological characteristics using monozygotic twins discordant for CFS. The third center Dr. Mohagheghpour discussed is headed by Dr. Nancy Klimas at the University of Miami and funded from 1999 to 2004. Its goals are to study biology of orthostatic hypotension and to determine effects of stress hormones and inflammatory cytokines on NK cell function at the molecular level.

In addition to financial support for these three centers, NIH has funded 32 individual studies in FY 2003 at $7.5 million, based on a list generated from CRISP. The goals of these studies are to explore the involvement of infectious agents; altered autonomic

nervous, cardiovascular, and neuroendocrine systems; and dysregulated immune systems on the onset or progression of CFS.

Dr. Mohagheghpour proposed the following considerations:

- Identify the primary pathologic locus/loci of CFS to facilitate intervention.

- Develop animal models to study the pathophysiology of CFS. She acknowledged the challenges posed by the differences in physiology and circulatory systems between laboratory animals and humans, adding that Dr. Bell could elaborate on this issue since she quoted one of his articles.

- Increase the supply of blood, serum, and tissue banks for future studies, particularly brain tissue if there are donations. Dr. Mohagheghpour said she strongly supports this recommendation, noting that it would greatly help investigators internationally.

- Use the standardized methodologies with quality assurance to better compare data between laboratories, since it is often difficult to see discrepancies in results due to the different methodologies used.

In closing, Dr. Mohagheghpour suggested that the long-term goal be to promote multi-center and international research and to recruit the necessary funds. For the short term, she suggested promoting CFS research by inviting experts to publish more review articles and coordinating more symposia.

Q & A and Discussion

Dr. Bell thanked Dr. Mohagheghpour and asked if she reviewed the 32 NIH studies funded at $7.5 million to analyze how closely they correlate to the concepts CFSAC has discussed. Dr. Mohagheghpour responded that she read all of the research summaries and those publications that she could access. She shared that the studies provide leads but none are close to finding an answer regarding biomarkers.

Dr. Bell asked if she thought these 32 studies were good, and Dr. Mohagheghpour responded affirmatively. Dr. Gantz then asked if they could get a list of the authors and studies, and Dr. Mohagheghpour responded affirmatively, explaining that Dr. Hanna provided her with a list from CRISP.

Dr. Mohagheghpour added that some of these studies were not hypothesis driven but verified or confirmed past publications, particularly those on immune dysregulation. She said that most publications point out that there is dysregulation of immune response, but they are not really biomarkers or the primary locus for CFS. Dr. Mohagheghpour referred to Dr. Hanna's presentation at the last meeting and said that future studies should be hypothesis driven.

Dr. Bell asked Dr. Mohagheghpour to share the list of studies with the rest of the committee, and Dr. Gantz added that the list would make it be easier to provide comments.

Dr. Lapp asked if the studies Dr. Mohagheghpour discussed are a stretch in this sense or are they addressing the issues that are central for CFS: diagnosis, treatment, markers, and methods.

Dr. Mohagheghpour responded that some of the studies could be considered peripheral, such as those on FM. She explained that the CRCs are examining CFS-related questions and that the Seattle CRC is doing particularly impressive work; this center had a unique opportunity to examine monozygotic twins, eliminating the question of genetic predisposition and allowing a definition of the environment.

Dr. Lapp asked if it would be helpful to establish a medical research council that would identify areas of need or if there is enough direction with CDC, NIH, and other existing resources. Dr. Mohagheghpour responded that it would be helpful to have council to incorporate the ideas that evolve with CFSAC. She noted that based on an AIDS research experience, it would be helpful to have more than one contract to conduct a study with patients, given the protocol of asking the question and asking the centers to come up with the results.

Dr. Lapp noted that NIH has an ongoing program announcement saying funds are available, but a medical research council would identify a specific need and specific researchers with expertise in this field. He explained that if they wanted to study proteomics, for example, they could possibly send packages out and entice them to study proteomics for CFS. He said that generating the interest in and more research on CFS is one of the major challenges for CFSAC.

Dr. Mohagheghpour agreed that this was a good idea and added that instead of selecting the institute to perform the study, they could solicit proposals to answer the questions they want to ask. Then they could fund the institute with the best program.

Dr. Patarca noted that the issue that Dr. Hanna "hit on the head" is getting people to do the research; funding is not the issue. He noted that one thing they could do, which was mentioned in the presentation, is to provide researchers with the resources they need to do the research with the sample banks. He added that this is a major issues faced by institutions because they need not only the specimen but also the clinical data to go with it.

Dr. Patarca explained that this is where Dr. Reeves's presentation about the different instruments and scores come into play. Information, such as the time of collection and how it was collected, is needed to understand the samples. He said that if they require funded institutions to help build these banks, whether it is through government agencies or a private institutions, then the material can be generated, creating a resource for researchers working on different markers and approaches.

Dr. Hanna suggested that CFSAC review the Roadmap Initiative on the NIH Director's home page, since it is encourages these types of initiatives. She added that she has contacted some of the researchers on the CFIDSAA website and others to encourage them to look at this initiative and submit proposals. The institutes are required to contribute 2% of their funding to it.

Dr. Patarca then discussed why many researchers do not submit proposals. He said it is a huge leap for an unknown researcher to get involved in the field; someone may come up with a great marker for a hypothesis on CFS but might not be near to or know of any specialists. As a result, the grant may be out of reach.

Dr. Hanna responded that they do have a number of researchers in the field who have expertise and could collaborate to provide structure to build on. Dr. Patarca asked why this is not happening, and Dr. Hanna responded that she did not know but noted that the Roadmap Initiative is new this year.

Dr. Reeves commented that he has spent a large part of his career creating banks and that it is not very straightforward. He explained that an underlying issue is determining the sample, since not all of the patients are the same. Would they include people coming to Dr. Klimas's or Dr. Natelson's clinics or people from CDC population studies? How long would they have to have been sick? What kinds of studies did they come from? He said that they have dozens of people who contact them and want to send specimens to CDC to test their messenger RNA. Specimens can disintegrate in minutes, so for proteomics, they have to be processed in very specific ways. He explained that the specimens collected for the Wichita study are no longer suitable to the current proteomics assays. There are a myriad of severe technical problems that must be considered to collect specimens for future studies.

Dr. Patarca asked if Dr. Reeves agreed that this is a major obstacle in getting researchers to do the right research and to enter the field. Dr. Patarca acknowledged that if they have a sample, regardless of the approach being used, they do not know what medications the patient used and other factors that greatly affect biomarkers. He asked what the framework should be. He noted that a key question is how to stratify patients. Should they leave it to the researchers who have very specialized clinics and patients who are already going through several treatments?

Dr. Mohagheghpour responded to Dr. Reeves and Dr. Patarca by referring back to her presentation and noting the importance of standardized methodology. She said that they need to have identification for anything they bank. She added that the CRC in New Jersey, for example, is stratifying the data and are at least addressing this issue. She said that for a blood bank, they would not blindly accept samples; the samples would be from centers, such as CDC or CRCs, and researchers would know what they are dealing with.

Dr. Reeves responded that he personally agrees with the concepts. He noted, however, that things are moving very rapidly, particularly for hypothesis-driven research such as proteomics; the way they collect blood samples now differs from how they were doing it

last year. He explained that for neuroendocrine samples, blood must be collected and separated in the dark at 4 degrees, or it will degrade. If someone is currently doing a study specifically in this area, then it is not a problem, but for someone following the same pathway later, how the sample was collected determines if the sample is usable.

Dr. Patarca commented that if someone collects the sample in the dark at 4 degrees for their study and keeps the sample, then others could validate the results later internationally with the given methodology; this is not happening readily now. He explained that there is so much controversy with every little result because there is no way to validate what is published for these reasons.

Dr. Reeves responded that this is how science moves forward. When people cannot repeat a study, it does not mean these studies were bad or have no meaning. There are some extremely good observations that are correct but are not generalized. He explained that there are subsets of patients. Patients with sudden versus gradual onset, for example, have very different gene profiles, risk factors, and outcomes. He noted that the NIH model of investigator-led protocols helps to sort out the controversies as the understanding of the disease is developed.

Dr. Bell suggested that they put the banking issue on hold temporarily and asked if there were other issues regarding funding.

Ms. Fitzpatrick asked if most of the symposia have taken place on the East Coast of the US. She referred to the symposia sponsored by government agencies and the International Study Group discussed by Dr. Reeves. She proposed that CFSAC promote symposia or other opportunities for researchers to come together and share their work.

Dr. Reeves responded that most of the meetings have been held internally with sponsorships provided for people's attendance. The NIH workshops were held at NIH, and CDC held many meetings in Atlanta. He noted that they are also involved in other meetings, including CDC-sponsored symposia held in Cold Spring Harbor with invited international researchers. He added that both CDC and NIH have sponsored workshops almost yearly at the AACFS meeting. When this international meeting was held in Seattle, for example, CDC sponsored a half-day workshop on the case definition. CDC participated in a meeting in Stockholm last year and will also be involved in the next Psychoneural Immunology Society meeting in Scotland,.

Ms. Fitzpatrick then asked if there were any presentations on CFS at the American Medical Association (AMA) or major pediatrics meetings. Dr. Bell responded that this information would not be available through CDC and that CFSAC has an option to invite these organizations to discuss CFS. He noted that one of the challenges is that they do not advise these organizations. Ms. Fitzpatrick agreed but added that they could promote submissions of CFS presentations to their meetings to ensure that CFS is on their agenda, even if they just do a poster session.

Dr. Reeves responded that CDC has booths and posters at many meetings, including meetings focused on PAs and nurse practitioners, the Public Health Association, and the Infectious Diseases Society of America. He added that they also contract with various speakers bureaus to have presentations on these issues. He explained that information on whom is doing CFS research and where they want to present their data is not readily accessible to them. Dr. Reeves shared that CFSCC held a very good session in which they invited AMA and other similar organizations to share their perceptions of CFS.

Dr. Patarca responded that he would address this issue during his presentation on education. He noted that since CFS is an "orphan" illness, they do not have many specialists educating people and promoting the field.

Mr. Sterling noted that NIAID decided to stop funding CRCs since they believe that this research is outside of their domain. Dr. Bell responded that this issue was discussed at the last meeting, noting that Dr. Hanna believes that other methods will generate better research.

Dr. Hanna agreed. She added that CRC researchers have been asked to collaborate and apply for the Road Map Initiative; much of the research would benefit from doing hypothesis-driven studies submitted as RO1s.

Mr. Sterling explained that the CRCs did not coordinate very well among themselves. He added that compared to illnesses of similar prevalence and severity, CRCs were not funded at the same level, which was a factor in their results. He added that based on the experience with CFSCC, one helpful tool, which Dr. Lapp had alluded to, would be a project-level breakdown of what is being funding with the investigator, title, funding amount, and period of funding. He wondered why CRISP could not be used to provide these data as NIH had previously done.

Dr. Hanna responded that CRISP does not provide these data and that CFSCC received the list because GAO requested it. She spoke to the NIH Budget Office, and generating the list would require a special request. Dr. Hanna would have to coordinate the break up of the list and send it to the Budget Office, who would then send it to all of the institutes that are funding the research. These institutes would then report the same amount of funding that they report to the Budget Office every year.

Mr. Sterling asked how CFSAC could recommend and coordinate research between various government agencies without knowing what is being funded. Dr. Hanna responded that the total is $7.5 million and that she provided a breakdown by institute. Mr. Sterling noted that the list does not provide a budget breakdown by project, and Dr. Hanna responded that even she does not have access to this information because it is only reported to the Budget Office.

Dr. Fields noted that this issue was raised at the last meeting and that they may want to make a note of it for future discussion and action. Dr. Bell agreed, adding that this topic will be revisited many times as long as CFSAC is active. He explained that CFSAC's

greatest responsibility is to do whatever is necessary to encourage good and appropriate research. Dr. Bell suggested that they continue with the other presentations.

Before moving on, Dr. Lapp asked for clarification on the NIH process based on Dr. Hanna's presentation in the previous minutes; he noted that as a private practitioner, he does not interact at that level. He noted that the minutes say that the announcement has been available for the last 2 years and that in this period, 67 proposals were received but only 15 were reviewed, which is less than 25%. He explained that as a board member of AACFS, he knows that many of the researchers in that group are concerned because they have submitted excellent proposals that were turned down due to low scoring. They have submitted a letter to NIH regarding this issue. He asked Dr. Hanna how long the process takes and if reviewing 15 proposals is standard. He also shared that his understanding is that no CFS projects were approved within a 12-month period. He asked if this was correct and if so, why this was the case.

Dr. Hanna responded that this was not correct since NIH funded 32 studies in FY 2003, in addition to the CRCs. She explained that many researchers have issues with scientific review, since when someone submits a good proposal, there is usually someone who does not like it. These proposals go back to the researchers, and some of them take the criticisms, rework the proposal, and resubmit it, while others choose not to. She gave and example of a Chicago project that received a poor score but got funded after it was resubmitted. She noted, however, that some resubmitted proposals are still not funded.

Dr. Lapp said he would explore the issue further since he did not have the facts in front of him. Dr. Hanna responded that she understands how these researchers feel, noting that they often call her with their concerns.

Dr. Lapp asked for clarification about the 67 proposals received and the 15 reviewed, since Dr. Hanna had mentioned 32 studies. Dr. Hanna responded that 32 studies were funded but not necessarily reviewed; two or three were new studies. Dr. Lapp asked if the 32 studies were applied for before 2002, and Dr. Hanna responded that many of them were, since projects apply for multi-year funding.

Dr. Lapp commented that they need the dates of when proposals were submitted and approved, since it appears that there may be a bottleneck somewhere; part of CFSAC's role is to understand where that bottleneck is and to make recommendations that address it.

Dr. Hanna explained that there are four council reviews every year. Grants are submitted to councils, and they are assigned to independent reviewers who come to the council meeting. If a majority reaches a consensus that a proposal scores beyond 500 — meaning that it has no chance of being funded — they do not review the proposal at the meeting. They then review the proposals that could be funded; three to four reviewers review and discuss each one very carefully. Sometimes they rate them before and after the discussion, so that people are free to change their opinions. Then the proposals are given

percentiles and priority scores, which are then given to the individual institutes to decide where the proposals fit in terms of the funding level.

Dr. Lapp asked if researchers have an opportunity to revise and resubmit their proposals if they are turned down, and Dr. Hanna responded affirmatively. Dr. Bell suggested that they collect more information and return to this issue in some detail at the next meeting.

Dr. Mohagheghpour shared that she did not want to leave CFSAC with the impression that the CRCs are not functioning well. She noted that she supports the work of at least two of the CRCs. They have multidisciplinary teams of researchers, and some of these investigators have submitted R01 proposals and were funded. She added that she supports funding hypothesis-driven research by independent investigators nationally and possibly internationally.

Dr. Bell said that many people have been very pleased with the research from the CRCs and that he was personally disappointed that their funding is being discontinued. He said that it remains to be seen if the next phase of research will be better.

Dr. Marc Cavaillé-Coll

Dr. Cavaillé-Coll said he did not have anything specific to present to CFSAC at this time but asked CFSAC if they had any issues that they would like him to address. He noted that at the last meeting he described their activities and provided information and links on their website.

Q & A and Discussion

Ms. Fitzpatrick noted that Dr. Cavaillé-Coll's had shared that they had not received much for CFS recently; she asked if there was anything new since the last meeting.

Dr. Cavaillé-Coll responded that it is very challenging to develop a therapeutic agent for CFS in the absence of any in vitro or animal tests to screen drugs, which is true for any illness. He referred to AIDS as an analogy, explaining that discovering the virus allowed researchers to develop animal models, understand mutations and the biology of the virus, and ultimately, screen thousands of molecules to determine their potential activities. He said that the lack of understanding of CFS makes it difficult for drug companies to screen the volume of molecules that they normally do before they find one to develop. He explained that this situation will not change until more progress is made in the basic science.

Mr. Sterling said that he has received several emails and phone calls because physicians can no longer access Kutapressin, since the producer, Schwartz-Pharma, no longer manufactures it. He asked Dr. Cavaillé-Coll if he was aware of this situation and had any information that he could share.

Dr. Cavaillé-Coll said he could not comment on investigational new drug products that are actively under investigation. He noted that Kutapressin was one of many other

products that can be lawfully marketed when used by physicians in clinical investigations; they do not require an IAD and consequently, do not come to their attention.

He explained that they have a group that works with the rest of the organization to find solutions to drug shortages. The solutions may involve finding alternative sources or manufacturers, and if there are sufficient applications, they may be able to expedite the approval process to avoid the shortages. He noted, however, that FDA is not the only player in this process. The cooperation of the manufacturer is also required. He explained that the medical necessity must be evaluated and possible manufacturers identified, noting that they can go outside of the country to encourage more manufacturers to produce the drug. These manufacturers would be evaluated with the same standards as US-based companies.

Dr. Lapp then responded to Mr. Sterling's question. He explained that he spoke to the Director of Medical Information for Schwartz-Pharma on December 4, who informed him that the company decided to no longer manufacture Kutapressin. They had a single source supplier for this drug, and for the last year, they had tried to locate another source. Though several companies applied, none could manufacture the drug satisfactorily.

Mr. Sterling asked if there were alternatives for doctors. Dr. Lapp responded that the company was not aware of any alternative that came close to the same quality, though there were other products that came from the same derivative — pork liver.

Dr. Gantz shared that he had gotten a call from Schwartz-Pharma several years ago because they wanted to distribute one of his articles that mentioned their product. He asked them if they were interested in a control study that examined advocacy, and they had no interest.

Dr. William Robinson

Dr. Robinson explained that he deferred his time for Dr. Patarca's presentation. Similar to Dr. Cavaillé-Coll's comments, he shared that HRSA is ready to assist CFSAC and that he has had discussions with the Director of the Bureau of Health Professions. He asked that recommendations to HRSA be as specific as possible and noted that CDC's budgetary support has made their accomplishments possible to date.

Dr. Bell thanked Dr. Robinson and noted that Dr. Partarca's presentation would be given later in the meeting.

William Anderson

Mr. Anderson explained that they have a new education effort. He noted that SSA uses interactive video training, utilizing two-way audio and one-way video, and they plan to have a 1-hour interactive session on CFS and FM in March. The primary audience will be the Office of General Counsel and the administrative law judges, but the adjudicators

will also participate. He noted that though the training is directed at a particular audience, it will provide a good reminder of SSA policies and how to evaluate disability for people with CFS. Mr. Anderson then invited any questions from CFSAC.

Q & A and Discussion

Mr. Lieberman commented that the training Mr. Anderson described sounds great, especially if goes out to the state agencies. He explained that although administrative law judges have long followed the SSA rulings, it has been difficult for state agencies to follow them, even with process adjudication training. This is a good reminder that they can adjudicate these cases at the lower level.

Mr. Anderson explained that they notify everyone about these types of events. SSA provides 100% funding to the states, but they operate under a regulatory approach; as long as they process applications according to guidelines, SSA and most government agencies do not get involved in their day-to-day work. Mr. Anderson explained that with trainings, most state agencies will have one or two people participate and then decide how to disseminate the information.

Mr. Anderson explained that when they held process adjudication training, they did not shut down operations but mandated that everyone attend the training. As a result, they had a mix of physicians, administrative law judges, people in the disability network, and others, which allowed them to achieve better cross-cooperation because people understood each other's intentions and challenges.

Mr. Anderson noted that states process approximately 4 million claims each year and that getting states to focus on issues that do not represent a majority of cases is a major challenge. They do something on CFS at least every other year to address this challenge. He shared that they have worked hard in the past 3 to 4 years to educate people on CFS, FM, and other illnesses that involve subjective symptoms. He added that adjudicators follow rules that are clear-cut, but it gets more challenging with cases in gray areas.

Dr. Bell noted that he was struck by the fact that only 500 claims that were approved by SSA last year for an illness that affects up to 800,000 people in the country. According to these numbers, CFS is not a very disabling disease. He asked if Mr. Lieberman could be charged with examining the pertinent issues in this area. He shared, for example, that many of his patients that have disability have it under the wrong diagnosis. He asked if there is a way to look at this and to change the directives suggested to SSA.

Dr. Reeves added that according to the Wichita study and Dr. Leonard Jason's study in Chicago, only about 20% of people who meet the CFS case definition in the community have been diagnosed and treated by a health care provider. He noted that this complicates the issues with SSA.

Mr. Lieberman agreed to take the charge but noted that when people at SSA know that a person is disabled but cannot competently categorize them for CFS, they will place them

under another equivalent impairment listing. In other cases, a medical expert may say that the illness is equivalent to another listing due to the fatigue.

Dr. Bell asked if this is a good or bad practice, and Mr. Lieberman responded that it is particularly bad on the mental side. Many patients will have long-term disability from an insurance carrier, which limits disability for 2 years if it is based on a mental impairment.

Mr. Anderson said CFS is not different from a lot of other diseases. When people apply for disability, they try to collect information on anything that may be affecting their health, often resulting in a list of six to seven alleged impairments; SSA is not concerned with which impairment is particularly disabling. He noted that there is still a great deal of disagreement in the medical community about many aspects of CFS; when a doctor cannot find anything physically wrong with a patient, they send the person to a psychiatrist. The problem is that many of the symptoms are consistent with the depression category, and it is easier for SSA to adjudicate these individuals under depression. Mr. Anderson said they know that this happens, which is part of the challenge of the education process.

Mr. Anderson added that they have specific rules for when a disability determination is made. However, their electronic system only captures primary and secondary conditions, and there is a lot of confusion about what are primary and secondary causes of disability. He also noted that approximately 2,500 claims that were paid last year, not 500. He acknowledged that SSA has problems and that any help would be appreciated. He believes that educating people who are filing and physicians who treat them would be helpful, noting that SSA identifies disability based on the treating or examining source. He added that for the most part, physicians and professionals in their program never see the people who file for disability.

Dr. Bell noted that it is an important issue because of the sensitivity of how you label or name the illness. Clinicians need to deal with this issue because it impacts patients' self-esteem and other things. Dr. Bell moved that they consider this issue at the next meeting with Mr. Lieberman taking the charge. He encouraged Mr. Lieberman to ask for assistance from other members, if necessary. Mr. Lieberman agreed.

Ms. Fitzpatrick asked if there is a way to determine if a person receiving full disability for CFS has given it up and gone back to work. Mr. Anderson responded that they probably could provide these numbers but that less than 0.5% go off of disability to return to work regardless of the disease. He explained that this is why they worked closely with Congress to get the Ticket to Work in place. He noted that this is not his area of expertise, but SSA worked very hard to come up with ideas. When people receive disability or SSI, they get both cash benefits and health care, which are driving factors for people returning to work.

Dr. Friedman asked what is a reasonable time to wait to for a final disability determination. Mr. Anderson responded that of the people who are allowed disability, 80% of the benefits are paid by state agencies for both initial and reconsideration

determinations. For initial determinations, the process takes approximately 100 days. Once people are denied, they have 60 days to appeal, and if they appeal, they receive reconsideration, which probably would not require much more processing time. The time frame can be 3 to 6 months, but a large percentage of claims are paid within the first 60 days.

Mr. Anderson noted, however, that for illnesses that are more complex like CFS, many end up going through the administrative law judge level, which can be very time consuming because OHA has backlogs. After 6 or 7 months, these patients may be denied at the initial and reconsideration levels and then file for a hearing, which often requires waiting 1 year. As he mentioned at the last meeting, the commissioner is privy to this slow process, and proposals to improve the process have been developed.

Mr. Lieberman noted that he does not know the statistics on which Mr. Anderson is relying but shared that he has represented over 10,000 clients in his practice. He explained that most of the successful cases are at the administrative law judge level and that of the initial and reconsideration levels, approximately 30% of the cases are allowed.

Mr. Anderson responded that 30% is a very large number. Mr. Lieberman agreed and noted that some decide not to reapply. He added that at the administrative law judge level nationally, 54% of the cases are allowed for all cases and that there are many other levels of appeal that follow.

Mr. Lieberman noted that the people who toil at the initial and reconsideration levels — the adjudicators and the physicians who work with them — are the unsung heroes and not just the "rubber stampers." He said that they have low wages compared to their level of responsibility, noting that the average social security case is for approximately $200,000. He knows that many of them would like to make decisions, but by law, their decisions would be kicked back by quality assurance.

Dr. Bell then adjourned the meeting for lunch. When he resumed the meeting, he introduced Dr. Patarca and his presentation on education.

Dr. Roberto Patarca

Dr. Patarca explained that his presentation would focus on provider education, though some of the issues have more general applications. He defined "provider" as anyone who provides general services to the patient population, including physicians, nurses, psychologists, and those providing reimbursement and legal services. Dr. Patarca explained that he worked with others to gather as much data as possible to analyze past experiences.

Provider Education Challenges

He noted that CFIDSAA and other studies have confirmed a number of provider education challenges. The primary challenge is that 70% of primary care physicians are frustrated with CFS care and the challenging patient population. CFS educators are not

meeting the expectations for educating their peers and students in the health care field due to the limitations in content and format. In the era of evidence-based medicine, people are looking for statistics and the right data, which Dr. Reeves noted are missing. He explained that there has also been a large attrition of these educators, scientists, and specialists.

Dr. Patarca explained that another provider education challenge includes limited outreach of the educational activities. They need to address how to reach out to more specialties, geographic areas, psychologists, adjudicators, and others dealing with CFS. In addition, Dr. Patarca noted the limited funding for CFS education and the need to determine if this funding is adequate and how the available funds should be applied.

Educational Materials and Trainers

He noted that the NIH, CDC, and CFIDSAA websites cover similar information and shared some specific data based on the CFIDS Foundation's 5-year grant, which is renewable each year and is funded through HRSA by CDC at $500,000 annually. CFIDSAA is charged with developing educational materials for providers. Dr. Patarca presented data on the use of video, print, and the web to deliver self-study modules. Overall, they have achieved a 19% impact or 132 certificates of completion out of 684 requests. He noted that the web-based method was most effective, with 28% receiving certificates (115 out of 408 requests). Video achieved 3.1% (one out of 32 requests), while print achieve 6.6% (16 out of 244 requests).

Examining the CFIDSAA project and the train-the-trainer program, the number of core trainers is also decreasing. These numbers decreased from 62 people who were trained to be trainers in 2001, and only seven or 10% of these people remain. He said that 23 new people have been recruited, but there is still a decreasing trend. The 85 trainers who went through the program have given a total of only 33 presentations from 2001 to 2003.

Speakers Bureau

Dr. Patarca said that the American Association of Chronic Fatigue Syndrome (AACFS) created a speakers bureau in 1994; it has 11 members, including some CFSAC members. The bureau's mission is "to provide patients and providers with accurate and timely information on CFS, as well as to generate funds for the ASCFS." In reviewing the website (aacfs.org/html/spk-bur.htm), Dr. Patarca noted that the content had not been updated since 1996, though the web page was revised in 2003; they have not been very active in education.

Conferences and Meetings

Dr. Patarca explained that conferences and meetings are another strategy that has been used. He noted that their main limitation is that they are more oriented to CFS specialists and primary care providers. He then reviewed some of the major conferences and meetings, noting that they mainly attract people already in the field and are not venues for raising broader awareness about CFS:

- CFIDSAA (with CDC funding) has had CFS programs at major conferences. In 2002, two were held at the large biannual AACFS conferences, one for the Nurse Practitioner Associates for Continuing Education (NPACE), and one for National Medical Association (NMA). In 2003, two ground rounds were held by the same doctor in Oregon. In addition, they had modular displays at six national conferences.

- AACFS holds a Biennial Research, Clinical And Patient Conference and a Biennial Patient Symposia.

- NIH held the CFS State-of-the-Science Consultations in 2000 and 2003 to update people in the field. Reports are available on the NIH website (http://www.niaid.nih.gov/dmid/meetings/cfsreport.htm).

- HRSA held a satellite conference in 1997

Bibliography and information

Dr. Patarca named bibliographies and general information as another education venue. Noting that he is not criticizing anyone in particular, he noted that most of these materials are outdated, too specialized, or too general. He mentioned that the AACFS bibliography is current as of October 1997 (http://222.aacfs.org/html/educmatertoc.htm), but they now have a webmaster who is updating it. He added that the *Journal of Chronic Fatigue Syndrome* periodically has Literature in Review sections, which last appeared in volume 11, number 2, 2003 and is available online; this material includes abstracts and some commentary and is very specialized. He explained that general information can be found on the websites and newsletters of many organizations such as NIH (http://niaid.nih.gov/factsheets/cfs.htm), CFIDSAA, CDC, and AACFS. He noted, however, that the newsletters go mainly to the constituency of these organizations and that the websites do not provide physicians with solid information for treating patients.

Needs to Address

Dr. Patarca explained that there are four areas that must be addressed: content, impact, format, and funding.

He began by discussing content needs and the need to formulate treatment guidelines that address issues such as evidence levels required for various treatments, tests patients have undergone, how patients are stratified, effectiveness for various groups, and symptoms. As Dr. Reeves discussed, Dr. Patarca noted the need to standardize the case definition and ensure that it is empirical and clinically useful. Finally, they need to study CFS's natural course, epidemiology, and nosology, which involves the symptoms present and how they develop and progress.

For impact, he noted the need for increased participation in educational activities in terms of numbers and specialty mix; they need to engage neurologists, endocrinologists, and those involved in the legal and reimbursement fields. In addition, they must broaden the settings, as Ms. Fitzpatrick mentioned earlier, as well as the geographic outreach of these

efforts. He added the need to follow up and determine the qualitative and qualitative impact of these activities; it was very challenging to gather data on the impact of past activities. The involvement of diverse professional organizations, such as AMA and those for different specialties, is necessary since CFS is an "orphan" disease. He also noted that involving journals that already have a high impact would be helpful.

For format, Dr. Patarca described the need to test more ways to disseminate the information, including the web, video, print, and telemedicine and other methods. Practical publications and reference guides are also scarce; people in the different professions tend not have the time to read a whole volume to get the information they need.

Lastly, in the funding area, he noted that there are limitations in the efforts to recruit from the public and private sectors as well as from different specialties; they need as much support from as many sources as possible.

Possible Recommendations

Dr. Patarca proposed recommendations to begin the discussion.

In the content area, Dr. Patarca recommended that the focus be on raising contextual awareness and using lessons-learned. He explained the need to educate people on what fatigue is as a symptom. They have many lessons from pain, nausea, and other symptoms that were unspecific and not appropriately addressed in the context in which they appeared. He explained that once the awareness of the symptoms was increased, then their diagnosis, management, and assessment improved. He noted that CFS has opened the "fatigue revolution" era, where people are aware of fatigue as an important symptom in many diseases, such as cancer, diabetes, rheumatoid arthritis, and autoimmune diseases; fatigue is the most prevalent complaint among cancer patients (70%).

Dr. Patarca noted the need to educate providers on how to diagnose fatigue and treat chronic fatiguing illnesses. There is a plethora of oncology literature that addresses treating fatigue in cancer patients, and though the same treatments may not work entirely for CFS, they could involve oncologists and attract new researchers to the field. They could then address the peculiarities of CFS within a context that is meaningful to physicians and applicable to many different specialties. He added that this strategy would involve different specialties and their societies, noting that they could form a fatigue society similar to the pain society.

Dr. Patarca explained that there are poorly understood illnesses in each specialty and that they can learn from these experiences. There is a Cardiac Syndrome X where a category of patients experience chest pain that cannot be explained by any available test. He also discussed Metabolic Syndrome X in endocrinology, which took some time to understand, as another example.

For the impact area, Dr. Patarca recommended increasing outreach, recruiting help, and following up. Educational programs could be taken to diverse settings nationwide, such

as schools and specialists in health care, reimbursement, and legal fields. He referred to Ms. Butler's suggestion that they raise awareness of CFS in elementary schools, high schools, and nursing schools.

He also recommended recruiting the interest and help from professional organizations and high impact journals; AMA's journal, for example, has an education section in each issue. In addition, Dr. Patarca suggested implementing means to collect qualitative and quantitative data on the impact of funded activities, which would allow them to better focus educational activities.

In the format area, Dr. Patarca proposed diversifying the means for communicating the information and emphasizing practicality. This could be achieved by expanding the use of the internet and other means, as well as by generating practical publications and reference guides. He noted that the people who need this information are very busy and that every professional society has guidelines for diagnosis and treatment.

Finally, in the funding area, Dr. Patarca described the need to raise awareness about the importance of funding, not only for CFS but for all of fatigue. He noted that overlap exists with other illnesses, as Dr. Reeves indicated in his discussion of the case definition. He added the need to involve the private and public sectors as well as diverse specialties.

Dr. Patarca acknowledged that they have several obstacles but that they need the content and materials to educate providers; they cannot wait until they discover the exact disease. He explained that they could start by addressing fatigue as a symptom and chronic illnesses. They can emphasize to societies and in medical school curricula that fatigue is important, and as more information becomes available, they can shift the focus of educational efforts to diagnosis and treatment.

Q & A and Discussion

Dr. Bell thanked Dr. Patarca and asked if he could translate his recommendations into specific recommendations for the Secretary. Dr. Bell suggested that maybe they could develop them for the next meeting.

Dr. Patarca responded that they had discussed inviting people, such as AMA. He suggested that they could invite these organizations, present the issue, and see if they are interested. He acknowledged that CFSAC's role is to make recommendations but noted that his recommendations are general because he cannot speak for AMA or these other organizations. He said that it may not be their role to mention specific organizations and asked how far CFSAC's role should go.

Dr. Friedman noted that approximately 2 years ago when the CFS manual was produced by the Academy of Medicine in New Jersey, getting CFS into the medical school curriculum was raised as an issue. Dr. Friedman shared that he wrote letters to AMA and the Association of American Medical Colleges (AAMC) to request their assistance in this project and received no responses. Given the importance of CFSAC, they could invite these organizations and others to get their help in educational efforts. He noted that there

are no data that CFS is included in any of the medical school curricula but that this is the best place to produce a generation of physicians who know about CFS.

Mr. Sterling shared that he was also involved in creating the consensus physician manual and that it was organized by symptoms. The people were not CFS specialists but people such as rheumatologists and gastroenterologists. He referred to Dr. Patarca's point on formulating clinical guidelines and suggested that they could do something similar to AIDS, which has a clinical trials group. He suggested that they could recommend a CFS clinical trials group composed of doctors across the country who would coordinate their efforts; this would provide a clearer picture of what works and does not work, provide the information for the clinical guidelines, and provide a better context for how to manage CFS.

Dr. Patarca agreed with this idea, noting it goes beyond the education area and into other issues, such as how to fund clinical trials. He explained that different specialties that are affected by the problem could be involved in the clinical trials, which is why he sees a tiered, temporal structure to their approach. They would begin by raising awareness about CFS, and the other components would flow into place. He added that he did not think that they should rely on government agencies to raise all of the funds, noting that there are patient group representatives and people who have spent many hours on CFS. He said that his presentation was meant to "shake the ground" and start with something different, since they are all frustrated with being stuck despite their best efforts.

Dr. Gantz shared that he was involved in developing practice guidelines for FM and chronic fatigue for the Department of Defense (DoD) a year ago. He added that they should be available to all of the VAs and DoD. Dr. Patarca asked who knows about this project, and Dr. Gantz responded that he did not know. Dr. Gantz added that they also did a session for the American College of Physicians at a symposium on chronic fatigue approximately 3 to 4 years ago. He also mentioned the American Academy of Family Physicians as another possibility.

Dr. Patarca responded that all of this information should be on the major websites but it is not; persons that do not know what is happening in the field would have no way of knowing about these presentations and resources. Dr. Gantz responded that some of this information was published on different websites.

Dr. Bell noted that CFSAC's role is to take the information presented and to make practical recommendations. He added that two issues emerged in the discussion. The first area involves the larger world of the AMA, American Academy of Pediatrics, and other organizations, and the second is whether the ex officio members and their agencies participate in this process.

Dr. Patarca responded that the agencies are very active, noting that CDC and HRSA funded a contract with the CFIDSAA. Dr. Bell then referred back to Dr. Hanna's question about what NIH can do if researchers do not apply for grants, emphasizing the

need to turn this information into something practical beyond what is currently being done.

Dr. Patarca responded that these agencies have contractors and asked how they are following up and handling the facts that are already there. He noted that CDC has the funding and that everyone who is providing funding is indirectly funding education; the question is whether they doing it the right way. He noted that he presented the issue and would like to hear how the agencies could use it. Dr. Bell suggested that this issue be addressed very specifically by each of the ex officio members at the next meeting. He acknowledged that they discussed this issue to some extent at the first meeting but asked that they return to it.

Dr. Barrett shared that the DoD guidelines that Dr. Gantz mentioned are available on DoD's PDHealth.mil website. She added that they also funded DoD and involved VA to develop a centralized website that was a library of information on Gulf War Syndrome; it made it easier for people to go to one place to find the information. Dr. Gantz responded that this information needs to be publicized.

Ms. Fitzpatrick then shared a number of hours of continuing education credits are required to keep her license, noting that she would like some credits on CFS. She did not know about the materials on CFS. She explained that she went to American Physical Therapy Association (APTA) website and reviewed a list of activities that she could do online. She added that her state has increased the number of allowable online credits from 6 to 12, which is a trend with these courses. She noted that they would have to ascertain if the speech, physical therapy, and other associations would certify the course first, but it could easily be publicized in a journal. She said that she has not seen the CFS course publicized and suspects that many people would sign up for it, especially if it costs under $200.

Dr. Robinson responded that these kinds of specific recommendations are what HRSA would find useful, though it would require another conference call to strategize on these issues. He added that they would not be best serving CFSAC if the ex officio members developed their own suggestions without any discussion and feedback.

Dr. Robinson then responded to Dr. Friedman's point about the AAMC and AMA. He explained that one of the biggest problems with the medical school curricula is that they tend to be reactive out of necessity; schools say that they do not have open space when they are trying to stay abreast of current challenges such as bioterrorism, anthrax, and SARS. Schools have to be responsive to new issues over time. He described obesity as an issue that has existed for some time, but with the more recent media attention and community-driven efforts, schools are discussing changes to their curricula. He noted that medical schools will likely continue to decline changes that CFSAC proposes, despite the importance of the illness, and that they need to continue going to providers already in the field. He added that he is not sure if the best use of CFSAC's time would be to bring different organizations in one-by-one. He said he welcomes continuing the discussion of these strategic activities.

Dr. Patarca responded that there are likely many other examples of past attempts that had different degrees of success. He noted the importance of institutional memory on these efforts and having similar data to determine what strategies are most effective; this would allow CFSAC to make more specific recommendations. He asked that other members share any data they have on the various activities that have been done so that they can be incorporated into the presentation; he emphasized the need to be evidence-based in their approach.

Ms. McLaughlin thanked Dr. Patarca for his presentation. She referred to the $500,000 funding that CDC and HRSA provided to CFIDSAA for physician education. She explained that she did not understand why a private lay organization should be doing provider education and asked who makes these decisions. She added that this funding has been provided for some years but that Dr. Patarca's presentation indicated that it has not been very effective.

Dr. Bell responded that CDC has a long history of hiring private consultants, noting that this is separate from the global issue of reaching more providers.

Dr. Reeves responded that he made the decision because CFIDSAA was the only organization that developed this idea and applied for a competitive contract; they are an organization doing a concerted educational campaign that they competed for. He noted that the most important question is how to get the message out regardless of other issues, emphasizing that fewer than 20% of CFS cases have been appropriately diagnosed and managed. This continuing education course is advertised in journals and on their website. Unfortunately, there is a dearth of interest among primary providers in dealing with CFS.

Dr. Reeves explained that the issue is not the quality of the course curriculum, which is CDC-certified, but how to get providers motivated to learn about CFS. This is an issue CFSAC can address. According to CFIDSAA focus group data from primary care providers, CFS patients are the last people they want to see. These problems need to be understood to build this interest. He shared that CDC faced a similar challenge when they developed excellent guidelines for treating people with opportunistic infections with AIDS. When they asked physicians if they had read the guidelines, few of the AIDS primary care providers had.

Ms. McLaughlin responded that the curriculum is important and that it has not been effective. Patients still cannot get medical care.

Dr. Lapp shared that he is one of the trainers for this program and has been doing it for years. He noted that the data presented did not reflect the impact that they did have. He explained that they trained 150 medical professionals over a period of 2 to 3 years. Each of these professionals was then to go back and present to 40 other medical professionals; 33 of these individuals did go back and speak to other groups, training 1,200 professionals on how to diagnose and treat CFS. He noted that there is not another source that has done this well, with the exception CDC.

Dr. Lapp then noted the 168 people who responded and received certificates. The website has only been up for a year, and advertising began in June. He added that their advertising strategy was designed to determine which journal produces the most responses, which was the *New England Journal of Medicine*. In this respect, they have taught 1,200 people how to diagnose and treat and certified 168 people as knowledgeable. He noted that this has been a major success.

Ms. McLaughlin responded that it was not useless but that it is a large sum of money. Dr. Lapp responded that these were primarily production costs, since it took 2 years and hundreds of hours to produce the course. He added that the website is up and requires minimal cost to maintain; now anyone who wants to be certified in CFS can do it.

Dr. Patarca responded that these data are needed to make decisions, noting that the 1,200 trained professionals Dr. Lapp mentioned did not appear in the report they received. They need that information with data to make better recommendations.

Dr. Fields noted that CFSAC's position should be evidence-driven regardless of what that position might be; if they find that something is not effective, then is should be based on a body of evidence. He added that it would be useful to get more input quickly about what has been accomplished.

Dr. Patarca responded that his presentation was also meant to provoke more data collection. Dr. Fields noted that he succeeded and encouraged the completion of the data set to determine the effectiveness of these efforts. Dr. Fields added that the fact that the data exist is important, since they did not exist before.

Dr. Patarca explained that there are many ways to get data, even if they are approximations. DoD, for example, could provide the number of hits that the website received.

Dr. Bell noted that this is clearly an ongoing issue. He added that Dr. Patarca presented a good beginning and that a lot of work still needs to be done. Dr. Bell suggested that Dr. Patarca recruit other CFSAC members and divide the tasks. Dr. Patarca shared that Ms. Butler volunteered to assist with the school perspective, which is an important area in which she has expertise, and invited other members to participate.

Ms. Fitzpatrick noted that the media does not want to deal with CFS, but now that Dr. Reeves has put a dollar amount on the cost to the US, they may be able to get more interest from the women's magazines and other media. She suggested that this is a way to develop patient-driven efforts to reach the providers. She added that women's magazines write about FM frequently.

Dr. Patarca responded that they focused on provider education but that educating the general population is also important. He noted that this issue was brought up at the last meeting in their discussions of recognizing certain individuals like Laura Hillenbrand. Dr. Bell then asked Ms. Fitzpatrick to work with Dr. Patarca on this issue.

Ms. Fitzpatrick noted that she is being interviewed by the APTA for an article on her and her involvement with CFSAC; she wanted to wait until after this meeting to do the interview so that she would have more to share. She suggested that all CFSAC members try to get the local media to write stories about their work.

Carryover Issues

Dr. Bell moved the discussion to the mission statement, goals, and priorities.

CFSAC Mission Statement

Ms. Fitzpatrick began her discussion by reading two portions of the Federal Advisory Committee Act:

- "The function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved." She noted that this statement clarifies CFSAC's function.

- "No advisory committee shall meet or take any action until an advisory committee charter has been filed with…with the head of the agency to whom any advisory committee reports." She noted that specific components of the charter are also listed, including the committee's scope of work and objectives.

Ms. Fitzpatrick explained that she followed the charter in writing the mission statement and proceeded to read the proposed HHS CFSAC Mission Statement.

Dr. Bell asked if there were any questions or comments on the mission statement. Ms. Fitzpatrick said that her only question was whether they wanted to adapt this statement or stick to the charter. Dr. Bell responded that he thinks it is a reasonable statement and follows the charter.

Dr. Lapp motioned to accept the mission as it is written; the motion was seconded and all voted in favor. Dr. Bell noted that the first portion of the document had been accepted.

CFSAC Goals and Priorities

Dr. Bell then asked Ms. Fitzpatrick to present the CFS goals that follow the mission statement in the document. Ms. Fitzpatrick proceeded to read the goals to the committee. She noted that they identified these areas of interest at the last meeting, which they may decide to advise on or not, and acknowledged that others could be added.

Dr. Lapp proposed focusing on three areas because they cannot do all of them. He proposed that two of the areas be paragraph 2, to increase community awareness, and paragraph 3, to increase funding for CFS research. For the third area, he motioned that

they add a paragraph on promoting the education of health care professionals on the management and diagnosis of CFS. He suggested that the other goals take lesser priority.

Dr. Patarca noted that the second paragraph mentions health care providers. Dr. Lapp responded that diagnosis and treatment are not mentioned; it focuses on raising awareness and not training.

Dr. Bell noted that this is not a time sensitive issue and asked CFSAC for their comments. Ms. Fitzpatrick responded that this document was developed for discussion purposes, so adding and deleting portions of it would be a simple process. Dr. Bell asked that the goals be reworked and presented again at the next meeting, noting that the prioritization of the goals is an important issue.

Ms Fitzpatrick asked if it would be necessary to work on all of the goals listed, particularly if they want to focus on the three areas proposed by Dr. Lapp. Dr. Bell responded that he prioritized the last paragraph that refers to listening to the concerns of the community impacted by CFS; he said this is essential to CFSAC and would suggest making it the first goal.

Dr. Bell noted that CFSAC had two invited guests for this meeting, Mr. Sterling and Ms. McLaughlin. He asked that Mr. Sterling work directly with CFSAC as a consultant in developing the goals and priorities. Dr. Bell added that an area in which they need to improve is increasing contact with patients, groups, and communities with CFS; he asked Ms. McLaughlin to also assist in this process. Ms. McLaughlin agreed, adding that the patients could also be contacted directly.

Name Change

Dr. Bell noted that the name change issue has been very controversial and will likely continue to be. He explained that CFSAC received the recommendations from the CFSCC Name Change Workgroup (NCW) at the last meeting and have since reviewed the issue. Dr. Bell then read a proposed position statement for CFSAC on the name change matter.

Mr. Lieberman responded that he was won over by this proposal. He said that they have found in representing many of these people that the vagueness of the definition has caused some resistance with the administrative law judges. He noted that now that "the snow ball is rolling down the hill," they are changing the definition anyway. Mr. Lieberman said he concurred with everything in the proposal.

Ms. McLaughlin noted that NCW recommended that NDS be used as an umbrella term and that the existence of subgroups be recognized. She acknowledged that Dr. Reeves is examining the case definition, but based on his presentation, individuals with endocrine problems, infectious problems, and sleep disorders would be thrown out. She asked what would be left in the definition, adding that autoimmune dysfunction happens across the

board, and as a result, CFS patients have these ongoing infections. She added that this is not a hypothesis and that the publications address these issues.

Dr. Bell noted that everyone on the committee has their own feelings. He shared that as a primary care physician and a specialist, he is in contact with a lot of physicians who refer patients to him. If he were to suggest to them that there was a new name for this illness, they would have a very difficult with it; they are already struggling with CFS. He added that he agreed that the term is not appropriate but that changing it now would cause a great deal of harm, despite the good points that Ms. McLaughlin has raised.

Ms. McLaughlin responded that she did not know if any amount of education would overcome the name.

Dr. Bell responded that the disrespect to the patients is not just caused by the name. He explained members of the medical community, of which he is a part, are rushed and do not want to spend a lot of time with certain patients. He added that in medical school they would always joke that they knew who would become different specialists because physicians do not enjoy treating all illnesses. He acknowledged that there has been disrespect towards patients but noted that changing the name to another vague term would not correct this problem at this time.

Ms. McLaughlin noted that the proposed name is not a vague term. Dr. Bell noted that the recommendation was to change the name to NDS. Ms. McLaughlin explained that the proposal was to use NDS as a general category for the other subgroups.

Dr. Bell asked if other CFSAC members would like to comment on this issue, noting that there would also be a public comment period shortly. Some members of the public asked why only one or two were allowed to speak. Dr. Fields noted that they have time reserved for public comments. Dr. Bell explained that Mr. Sterling and Ms. McLaughlin were invited guests.

Dr. Bell asked if any members would like to make a motion concerning the name change issue. Dr. Friedman motioned to adopt the position statement, and the motion was seconded. Ten members voted in favor, and Dr. Lapp abstained as a member of CFSCC.

Dr. Bell acknowledged that this will be a difficult issue for the patient community, noting his great admiration and respect for Dr. Klimas and Dr. Jason who both advocated for the name change. He said that all CFSAC members are sensitive to patient needs and difficulties. He noted that at the present time, however, the committee does not think that they should adopt this.

Dr. Bell asked if there were any new issues before the committee.

Dr. Lapp commented that it would be helpful to know what specific recommendations were made and what questions were raised by CFSCC. He suggested that it might be helpful to review those minutes. Dr. Fields responded that this is the first advisory

committee to the Secretary and the first opportunity to make recommendations; he noted that CFSCC was a coordinating committee. Dr. Lapp asked what kind of files or final reports were completed by CFSCC.

As the former non-federal co-chair, Mr. Sterling responded that he would have to look at the previous minutes to determine the exact date but recalled that it was in late 1999 or early 2000 when CFSCC committed to examine the name change. At that point, the committee chair, which he believes was Dr. Donna Dean, asked that CFSCC members form a workgroup.

Dr. Lapp clarified that he was asking about the whole CFSCC process and whether a summary of their discussions is available and if so, where. He added that he did not want to rehash old issues but in an effort to not "reinvent the wheel," wondered if the accomplishments and recommendations of CFSCC were summarized succinctly in some place and available to CFSAC.

Mr. Sterling responded that they made several recommendations to the Assistant Secretary of Health regarding a broad range of issues, which should be available through HHS. Dr. Fields responded they should be able to pull them from the files. Dr. Bell asked if Dr. Fields could obtain copies of these documents, and Dr. Fields responded that he would. Dr. Fields asked if the CFSCC recommendations were formally submitted into the record. Mr. Sterling responded that to the best of his knowledge, they were.

Dr. Patarca asked about follow up and data on the impact of any recommendations that were implemented. Dr. Sterling responded that he could only speak in terms of the few actions that were taken. He shared that CFSCC recommended that the Surgeon General create a PSA on CFS, and it was completed even after CFSCC was dissolved. There was also a recommendation that a name change WG be formed; their work also continued and was shared with CFSAC at the last meeting. He added that the ex officio members would probably be able to tell CFSAC what recommendations were acted on.

Dr. Hanna responded that each person from the different agencies could share this information. The recommendations to NIH were to hold the State-of-the-Science Symposium and to write a program announcement based on it; NIH acted on both of these recommendations.

Dr. Reeves suggested that these recommendations may not be as relevant as CFSAC may think. He noted that the CFSCC last met approximately 2 years ago at the height of the "troubled times" and that many of the recommendations dealt with those problems. He said that in many ways they now have different questions and have moved far beyond those issues. Dr. Bell said they do not want to revisit anything that will not be of practical value.

Dr. Sterling noted that Dr. Lapp and Dr. Patarca raised good points and that CFSAC may benefit from learning from CFSCC's mistakes. He explained that it took CFSCC some time to realize that their actions were really their recommendations and that their

discussions should have led to applications. As a consultant, the advice he would provide CFSAC is to state their priorities as positive recommendations.

Dr. Patarca responded that he wanted guidance on the scope of work for CFSAC. He shared that he is not sure how far they are expected to go. He tried to think from the perspective of the Secretary about what recommendations he could make and implement with impact. For the education recommendations, for example, he asked if they should recommend a physical therapy course on CFS or focus on the global issues. He explained that he tried to take a global perspective in examining these issues but senses that they are expected to go down to the minutia level and into areas where he is not as comfortable. If CFSAC's role is to advise the Secretary, then they should be providing all encompassing measures and recommendations that will have an impact; he added that the agencies have the expertise to develop specific plans.

Dr. Fields responded that Dr. Patarca is correct. The goal is to move in a direction that results in the outcome of recommendations, based on CFSAC's experience and expertise, that the Secretary can consider. In terms of specificity, he also agreed with Dr. Patarca in that the agencies and offices have the ability to develop the specific plans. If the Secretary decided, for example, to implement a CFSAC recommendation to educate providers and other specific groups, then there would be a process that would involve the agencies and set the recommendation into motion.

Dr. Patarca said that from an administrative point of view for the Secretary, they can procure data and act as a catalyst to bring the data to the right place. Dr. Fields added that this is why their work must be evidence-based.

Mr. Sterling responded that sometimes the specific actions come out the recommendations made. He shared, for example, that the State-of-the-Science Symposium was created out of a recommendation to increase the pace and amount of CFS research. He explained that NIH took the recommendation and implemented it in a very good and unique way. They brought together representatives from the patient, clinician, and research communities to plan the conference; they decided the speakers, venue, and format together. It was successful and branched out into broader areas. He noted that this is one of the best examples of how the CFSAC and the agencies worked together to positively implement a recommendation.

Dr. Patarca asked if they were to hypothetically recommend creating a special center for chronic illnesses and the Secretary goes to NIH to implement it, would NIH then come back to CFSAC to be involved in the implementation. Dr. Bell responded that whether recommendations are acted on or passed on is not CFSAC's concern; CFSAC's role is to come up with the best recommendations possible.

Dr. Patarca asked if they should make the recommendations as general as possible. Getting into minutia may dilute their purpose. Dr. Bell responded that if there are specific recommendations, then they may consider those as well.

Dr. Fields agreed that CFSAC should focus on the key direction to go in for education. He added that the more informed the recommendation, the more likely it will be implemented with a meaningful outcome. He said that they should be careful of getting bogged down in details. There are many competing priorities in HHS.

Dr. Patarca added that based on experiences with AIDS and other diseases, a lot of passion and pressures tend to exist, but they need to focus on objective evidence. He explained that is why they need to prompt the collection of the data so that they can ensure it goes to the right place. He added that it is a lot of work for CFSAC and the ex officio members to put together these presentations, despite the fact that the data look scant. He explained that he just wanted to make sure that they all had the same understanding of the expectations from the beginning of their efforts.

Dr. Bell responded that additional feedback can come from other members and that they will continue to discuss ideas.

Dr. Fields noted interest in recommendations that are informed and reflect the patient and research communities. Dr. Patarca added that it is important to communicate with the patient community and the public.

CFS Public Service Announcement (PSA)

Dr. Bell noted that the PSA was available to review and discuss, noting that he saw it for the first time on the website. Dr. Fields proceeded to show the PSA.

After the PSA was shown, Dr. Bell asked Dr. Fields if he had a sense of how often it was aired. Dr. Fields noted that two of the principals might know the answer. Dr. Bell then asked if there were any comments and if members thought this is something that they should pursue or not.

Ms. Butler responded that PSAs are very pertinent to getting information to both patients and the community at large; the more people see a message from an official representative of the government, the more people will respect CFS patients. She said that as part of the educational efforts, she would like to see something like this PSA run more often during the times when people would watch it and to make it available to other organizations such as the Rotary Club.

Dr. Friedman agreed and suggested that it be done on the radio. Mr. Sterling responded that it had been. Dr. Friedman suggested that it be done again. He added that having it come from more than one source would have a great effect and suggested that other organizations distribute it. Dr. Friedman explained that the more the message is said, the more effective it will be; it will also assist them in addressing the patient community's concerns about the name by communicating the severity of CFS to the public.

Dr. Bell noted that someone had suggested contacting Laura Hillenbrand about possibly doing another PSA. He asked if CFSAC thought this would be beneficial.

Before answering Dr. Bell's question, Dr. Lapp agreed with Dr. Friedman's comments and asked if the PSA was developed and paid for by CFIDSAA. Mr. Sterling responded affirmatively. Dr. Lapp asked what the cost of doing something similar would be. Mr. Sterling did not recall the exact cost and said that there would need to be government funding not only to produce the PSA but also to get it aired.

Dr. Lapp asked what is required to get a PSA aired at popular viewing times. He shared that in his past experience, PSAs had to be aired during donated times and asked how things have changed. Mr. Sterling explained that there are distribution costs, adding that a letter from the Secretary could be written to explain the importance of CFS and to ask that the PSA be aired at optimal times. Dr. Lapp asked if there would be a charge for doing this, and Mr. Sterling responded that he did not know.

Dr. Bell asked the ex officio members who pays for the smoking campaign. Dr. Hanna shared that their sleep campaign was a special initiative for which they made videos. She was not sure how much the government paid for and how much was volunteered, but she did know that they paid a contractor to put the information together. The rest was public service. She added that they need prominent people to get the message out and push the education.

Dr. Patarca responded that private philanthropy could be approached for this purpose, and Dr. Hanna noted that they might consider approaching the Robert Wood Johnson Foundation since CFS is a health issue. Dr. Fields noted that if CFSAC recommends this to the Secretary, then these details could be worked out.

Mr. Sterling explained that CFSCC stopped functioning in January 2001 and that the PSA was not completed until October 2001, which was during the time of 9/11 and anthrax. He added that if CFSCC had continued, then they would have needed money to implement the PSA campaign.

Ms. McLaughlin said that doing a PSA is good but acknowledged that she did not know about the cost and feasibility. She asked if they could recommend a national awareness day, similar to what is done for diabetes and other diseases. She explained that the cost would be low and could be publicized by a press release.

Dr. Patarca responded that they need the right infrastructure to make an awareness day work. They would need the right speakers and recognizable people to participate. He added that this is why they need a tiered structure to determine what efforts need to be done first. Ms. McLaughlin responded that if they issued a press release, others could come in and build on the efforts.

Dr. Patarca noted that local CFS days and events exist and that data on how they have had an impact beyond the patient population would be helpful. He asked Ms. McLaughlin if she had any data on these events, and Ms. McLaughlin said they do not have generalizable data because they fund research. She added that HHS has more clout

and would have a different impact; an awareness day could also be done immediately rather than waiting for a PSA to be produced.

Dr. Reeves commented that CFSAC is having a lot of discussion about branding, advertising, and PSAs. He noted that these are tactics and not CFSAC's function. Rather than discussing what the Surgeon General or Secretary should be doing, they should be discussing the overall strategies for enhancing public awareness. He noted that the national awareness day, the PSA, and asking Laura Hillenbrand to be involved are part of this strategy and that the agencies will be working through the tactics of implementing it. He added that CFSAC could then review the tactics and comment on them.

Dr. Bell asked if there was any other new business.

Ms. Fitzpatrick mentioned that there was a press release that was available after the last meeting and asked if there would be others. Dr. Fields responded that there would not be but that the press release is available as a handout. She asked for a contact person for interviews since she may send the release to some organizations.

Dr. Patarca asked if it would be helpful to provide guidelines for how they go about CFSAC business, such as how they want to discuss and present on issues in the future.

Dr. Patarca asked if everyone was comfortable with how they are communicating. Dr. Bell asked Dr. Fields if this is how other committees function. Dr. Fields explained that they want to ensure that CFSAC functions like other committees. He noted that this is why they make it clear upfront that the output is recommendations. He added that there may be recommendations that are not practical to implement, and CFSAC will have to decide if it should be a priority over something else in the same general area. He said that the committee will have to go through a learning process and that they have already made a lot of progress.

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

Public Comments

Dr. Fields said that they received a number of requests for the public comment period, including a written statement from Nancy Hall. He explained that the policy provides each individual with 5 minutes to speak, including those speaking on behalf of others. He added that if extra time remains, then they would allow other comments to be shared.

Dr. Mary M. Schweitzer

Dr. Schweitzer noted that she distributed a copy of her comments. She introduced herself, sharing that she has a PhD from Johns Hopkins University but that she has not been able to practice as a professional for 9 years. She explained that she was fortunate to

be diagnosed by Dr. Marsha Wallace and alleged that there are no general practitioners in the Delaware Valley who understand CFS.

She thanked CFSAC for showing the urgency of this issue by scheduling the meeting so close to the last one and for allowing her to speak. She shared her appreciation for the positive direction of the meetings and in particular, Dr. Bell's leadership.

She shared that since the name "CFS" is not working, she suggested going back to myalgic encephalomyelitis (ME), which has been used internationally. She expressed her concern as a scholar that the research is highly polluted because a lot of the research that has been done does not use the CDC definition.

Dr. Schweitzer said that she wishes CFSAC would address the issue of the polluted literature and that the only solution she can suggest is to use CFS-CDC and CFS-UK to distinguish the different definitions. She added that the international community has already come up with a name, noting that the US should not be isolated.

She noted that if CFSAC looked around, they would see a lot of people who are very sick or very tired because they are caring for people who are very sick. She explained that they do not have the same care as HIV/AIDS patients.

She then discussed the seriousness of chronic illnesses, noting that measles and smallpox have conquered empires. She predicted that there would be CFIDS outbreaks after the worst flu season in recent history and the second Gulf War. She suggested that CFSAC address these issues because they will happen in the next 12 months.

She referred to the CDC study on the economic impact of CFS and shared that she had done the same study while she was ill, noting that her second specialty is economics. Based on Dr. Jason's estimate of 800,000 CFS patients, she said that this country loses $15 billion in goods and services each year. She added that $5 billion a year is lost in income tax revenue and $1 billion to FICA.

She also said that they do not need another demographic study since they already have the data.

Dr. Fields thanked Dr. Schweitzer for her comments.

Peter White, Board, Central Virginia CFS/FM Association, Inc.

Mr. White thanked CFSAC for the opportunity to present to them. He shared that he has two daughters with CFS.

Mr. White then shared that his organization welcomes the potential progress with CFS. He noted that two major CFSAC actions are necessary for a substantive move forward. He noted that CFS and related illnesses have a history and that this is an opportunity to recognize that history. The first expected action is a fundamental change in the approach

to CFS. He explained that they must have a solution-focus with measurable goals and processes to achieve these goals. The second action is to utilize and integrate the broad range of government and private/nonprofit resources, including implementation organizations, academia, and health industry organizations.

He explained that progress with CFS also requires established schedules and roadmaps. CFSAC must establish at least three working groups that address research assessment, diagnosis and treatment methods, and information programs. He added that CFSAC must meet at least quarterly.

He proposed that CFSAC conduct an assessment of all current and relevant research funded by the government, private, and non-profit sector by June 2004. A research roadmap must be developed and executed, and CFSAC must take an impartial approach to maximize potential opportunities and maintain a solution-focus.

Mr. White also recommended that diagnosis and treatment methods be integrated with epidemiology and risk factor research assessments. He explained the need for full disclosure of research and study results related to treatments and to recognize conflicting diagnosis and treatment approaches.

Mr. White also explained the need to implement targeted information programs that address the needs of all communities and have an integrated solution-focus. This should result in multi-source information that could then be distilled into a researcher/physician information-sharing network, similar to the Gyn-Oncology network for rare cancers. He explained that these information programs must have measurable goals and benchmarks that are prioritized with the consensus of government and all private and non-profit entities. The attitudes of health care and insurance industries and some government agencies need to change, from medical schools to front-line health providers, to all levels of government.

Mr. White concluded his presentations with recommendations to consider:

- Integrate government and private actions by NIH, CDC, and private and non-profit organizations.

- Establish a funding plan for FY 2005 and beyond for the research recommendations and targeted information programs.

- Establish goals and benchmarks for assessment of all activities.

Meghan Shannon, Wisconsin State CFS Association

Ms. Shannon questioned the 5-minute limit and expressed her appreciation for CFSAC and recognized that Dr. Fields is trying his best with the challenging circumstances.

She began her presentation by sharing that she had two points to make. The first point was that this is an international problem, noting that CDC and CFSAC actions affect the whole world. Her second point was the need to legitimize the disease.

She shared that she now knows that she got CFS from polio when she was 5 years old in 1956. She discovered this 2.5 years ago. ME/PPS cannot be distinguished unless there is a history of polio in a family.

She explained that the name issue as an international problem. She asked that the name change workgroup be supported as an arm of CFSAC and that the development of a clinical definition should be an international effort. Ms. Shannon referred to different documents, which she said Dr. Bell and Dr. Fields were given or would be given later. She proceeded to read comments from several different individuals, including:

- A doctor suggested requiring the use of the new term in federally sponsored publications and education efforts as a condition of support. He added that widespread acceptance and understanding of the term can only be accomplished through a massive, multi-year education campaign.

- A woman in Denmark expressed her respect for CFSCC efforts and their recognition of CFS and ME; she hoped CFSAC would continue this work. She explained that ME is not well financed and is recognized by few.

- Doris Jones in England noted that certain psychologists have distorted ME, which has been classified as a neurological disorder since 1959.

Ms. Shannon also referred to the following documents:

- A portion of Pat Fero's article "Must We Dummy Down to Understand CFS and ME?"

- Several documents by doctors who describe the problems of CFS and ME terminology and definitions.

- Statements from Parliament that describe ME and patients' experiences.

- An article by Dr. Cooper, et al, entitled "What is CFS? What is ME?"

- Dr. Elaine Dupree's testimony to Congress, which says that as many as 1.25 million people are affected by CFIDS and have not been diagnosed.

Ms. Shannon shared that she nearly lost her life in August when she went into neurogenic shock. She said that she has cardiac problems and that her blood pressure and heart rate drops. She described how she has lost days of her life and how health care providers would not treat her. She alleged that in one case, a doctor did not give her an IV infusion even when her pulse fell to 40.

She said that CFSAC needs to hear these stories; no one is treating CFS patients. She said that CFSAC needs to overcome the institutional memory loss.

Dr. Fields thanked Ms. Shannon for sharing her views and experiences, emphasizing that they want her and other patients and members of the public to provide input.

Lois Ventura

Ms. Ventura introduced herself, sharing that she is from Southwestern Pennsylvania and a patient representative. She thanked the people who have supported people like her for many years. Her first request was that Ms. McLaughlin, Mr. Sterling, and other patient representatives continue to be given invited status with CFSAC.

She shared an example of how the "f" word (fatigue) has impacted so many people. Before she was ill, she knew what fatigue was, and it was not what she is experiencing now, which is disabling. She said that the "f" word made her dismiss her symptoms as just fatigue, so she continued to fight the fact that she had CFS and searched for answers on what her serious disease might really be. Doctors and tests came and went, and she would make some gains and then get worse again. She then looked at ME criteria and began to understand more than her doctor.

Relieved as she was to find out what she had, her providers did not tell her that forced bed rest provided the best prognosis; she wished her doctors knew about this even before she got the illness. They all told her that she would never get disability benefits from the "f" word, so she never wasted her energy or pride to try to get paid. Uninsured, she said she stopped going to doctor visits and getting expensive tests. She struggled for survival, noting that she struggled to pay her taxes for 7 years.

She said that the lack of information and the little knowledge doctors have on CFS must be addressed by CFSAC. She said the because of the "f" word, her health got worse and that it is still happening to too many CFS patients. She said that her productivity could have been 70% to 80% of what it was compared to the 30% to 45% that it is now.

She wrote to her Senator last spring to ask for more CFS funding. The first response that she received thanked her for contacting him regarding a "mental health" issue and the second called it a "medical liability insurance" issue. Ms. Ventura attributed this misunderstanding to the "f" word and urged CFSAC to consider NCW's recommendations so that they can get the needed recognition.

She applauded Canadians for their clinical case definition for ME/CFS and thanked CFSAC. Dr. Fields thanked her for her remarks.

Tom Hennessy, Jr., President RESCIND, Inc.

Mr. Hennessy shared that 11 people who he has never met sent him their testimony to read today, and he has only 5 minutes.

He read the CDC mission statement to CFSAC and noted that the CDC definition does not even look at patients until they have been disabled for 6 months. He questioned what CDC has told Congress about the illness. He noted that the name "CFS" is an obstacle to advancement.

He said that they have had checklists that Dr. Carol Jessup, Dr. Bell, and others have used for years. Dr. Jessup had over 1,500 patients with over 200 different symptoms with a range of severities. He said that they have the extensive data that Dr. Patarca is looking for. He referred to the formation of the American Bowel Movement Association. He added that they changed the name of Chronic Epstein-Barr to CFS.

He quoted Louis Pasteur. He referred to Mr. White's presentation, noting that there have not been organized meetings until now. He said that for years they have discussed what was happening in England and in Canada and added that what they do here affects the rest of the world. He noted that people are losing their homes.

He noted that he had a petition with 6,417 signatures demanding the recognition of MEitis. He said that they want nothing to do with fatigue or chronic fatigue.

He shared an excerpt from a woman who is 80% non-functional and has FM and other disorders. She explained how her life and the lives of her family have changed because of the immense pain that she experiences. She said that the name has caused her relationships with her friends, family, physicians, and health care providers to deteriorate, noting that she does not tell them that she has chronic fatigue. She asked CFSAC to give patients "at least some dignity."

He noted that Dr. Klimas and Dr. Jason have been dismissed after working very hard for 3 years. Mr. Hennessey said that he proposed 14 years ago on the *Larry King Live* show that that the Gulf War illness sounded very similar to CFS patients. He added that Dr. Reeves stated that Gulf War Syndrome was identical to CFS 6 years later. He said that $2.3 billion have been given to investigate the 159,000 sick Gulf War veterans. He noted that this was the largest cohort of sick patients from veterans of any war in history. He then referred to a study that compared how 29 symptoms of Gulf War Syndrome relate to CFS. The study found overlap for 28 of these symptoms.

Mr. Hennessy then noted that the NIH budget went from $19 billion to $39 billion. He noted that CFS was given $6 million and that the largest single grant ever given was for depression.

In conclusion, Mr. Hennessy stated that all truth goes through three stages: ridicule, vehemently denied, and accepted as being self-evident. He noted that they are currently at the second stage.

He noted that insurance companies provide only 2 years of lifetime disability for mental illnesses. He shared that 23 people have died within his 400-person group and that none

of them died because they were fatigued. He also noted that patients are tired of being sick and not sick of being tired.

He added that they have an internet relational database, which is not being used. He noted that doctors and patients are burned out.

He shared that because his father has full-blown Alzheimer's disease, he can no longer attend the CFSAC meetings.

Dr. Fields thanked Mr. Hennessy and allowed additional people to speak and asked them to please introduce themselves. He explained that if they still had time remaining that they would cycle back to those who have already spoken and who wish to share additional comments.

Sandy Solomon

Ms. Solomon shared that she had some comments that might be helpful based on her professional experience. Her son has had CFS for 8 years, and she shared some of the challenges that he has faced with doctors who do not believe in CFS and the inability to work.

She shared that she retired last January and that she worked on computer systems for research projects. She referred to earlier discussions about information CFSAC was seeking from NIH on specific research projects. She noted that the process described by Dr. Hanna on how to get the information is not unusual and that $7.5 million for 32 projects are low numbers. She said that what CFSAC is asking for is reasonable and urged CFSAC to pursue the information. Ms. Solomon noted that it would be difficult to make research decisions without it.

Ms. Solomon suggested that they ask for additional information, even if it is not in a computer system. She said if CFSAC wants to get accurate information about the level of interest in research, then they need to get information on the number of grants submitted and the process, such as how many are submitted and rejected and how many are reviewed and rejected. She noted that this would provide baseline data.

She also explained that not filling the vacancies for CFS positions is damaging and that losing FTEs is even worse. She encouraged CFSAC to support these efforts.

Dr. Bell commented that there was no resolution on the funding issues that were discussed during the meeting. He shared that he agreed that the amount of money provided for CFS is inadequate. He added that it is helpful to pinpoint problems like the unfilled and eliminated FTEs in CDC, noting that these are issues CFSAC can address. He noted that he would like to pursue some of the NIH funding issues, acknowledging that it may be difficult.

Albert Donnay

Mr. Donnay introduced himself as an independent environmental health engineer, the founder of the nonprofit MCS (Multiple Chemical Sensitivity) Referral and Resources, and an investigator at Harvard School for Public Health on a study of the overlap of carbon dioxide poisoning and CFS. He added that he brought some articles to share with CFSAC.

He noted that if patients are not stratified for the overlap of CFS, FM, and MCS, then they do not know what illnesses they are studying. He referred to Dr. Reeves's discussion of exclusions and comorbid conditions as points of stratifications. He suggested encouraging this in the literature and the agency's RFA process. He noted that it would be a waste of money to fund CFS research without requiring researchers to determine the percentage of the population that is purely CFS, CFS/FM, and CFS/MCS. He added that these are not the same diseases since none of the studies show a 100% overlap; they can and should be distinguished, which would bring in a larger group of researchers who are studying these diseases.

He then discussed issues outlined in a document he distributed on redefining CFS. He noted that the 1994 CFS research definition allows but does not distinguish the diagnosis of CFS in cases that overlap with the following comorbid conditions: depression, FM, MCS, neurasthenia, and somatoform disorders. He noted that these conditions have a published prevalence that is 10 times greater than CFS. He said if they think CFS is a distinct condition, then they have to be able to distinguish it from these conditions. If it cannot be distinguished, then it should be classified as a subtype of these disorders.

Mr. Donnay added that any new definition of CFS should be distinguished from carbon monoxide poisoning, which can cause many of the same symptoms. He noted that Dr. Reeves and the International Study Group did not discuss this.

He then recounted a recent encounter with a woman who was diagnosed with CFS and FM by one of the leading specialists; she shared that her symptoms sounded like carbon monoxide poisoning. He said he also observed some of the "telltale" signs of carbon monoxide poison, a drooping eye and mouth, as seen in pictures of Edgar Allan Poe. Mr. Donnay asked her if she has multisensory sensitivities, which are a hallmark of MCS, and she responded affirmatively. He asked her if her doctor asked her about MCS or carbon monoxide (CO) poisoning, and she responded negatively. The woman then shared that 2 years after she got sick, a workman had gone into a coma because of CO poisoning from her furnace. Mr. Donnay proceeded to take a CO sample, and she showed elevated levels. He added that it is the most common form of toxic poisoning in the US.

He congratulated Dr. Lapp for identifying CO poisoning in his patients. He noted that he heard CFS mentioned in a CO presentation in which the researcher said that most of patients that have seen him for CO poisoning were previously misdiagnosed with CFS, FM, or MCS. He noted that once someone is diagnosed with CO, they cannot have CFS by the proposed definition.

Christine Gaffey

Ms. Gaffey introduced herself as a member of CFIDSAA and shared that she has had CFIDS since 1989. She said that NIH funding is not enough and that there are not questions about why they are not getting funded. Patients are just lying in bed waiting for NIH to do more testing. She noted that they have the ability and obligation to gain a stronger scientific understanding of CFS and that over 800,000 Americans are counting on CFSAC. Without adequate effort and support from NIH for scientific inquiry in this field, the research effort will wither, and the small number of CFS scientists will be forced to study other fields. She said that the lack of funding and intensive research at NIH and CDC is a very sad story for CFS patients and their families.

In conclusion, she asked if individuals could talk to the network affiliates in their cities to help get a PSA aired and start building a network to get the word out. She then thanked CFSAC.

Pete Ventura

Mr. Ventura introduced himself as Ms. Ventura's husband. He referred to Dr. Lapp's comment that there were 1,200 providers trained on CFS. He asked if a list of providers was available to the public, noting that they had a major problem finding physicians who understood the disease and how to treat it.

Dr. Lapp said that there have been approximately 1,200 medical personnel trained on the diagnosis and management of CFS but that not all of them have been certified. He explained that he and Dr. Jason are the two instructors who provide the course and that each course has 20 to 40 health care providers in it at a time. These individuals are supposed to go back and teach the course to an average of 40 additional providers, which totals 1,200 people trained. He noted that the certification does not mean that a provider is an expert in CFS but that they have received 2 to 3 hours of learning on CFS for continuing education credits.

Mr. Ventura responded that even with 3 hours of training, these doctors would be better prepared than other doctors. He added that they are from Pittsburgh area and wondered how broad the network is.

Dr. Lapp agreed. The trainers are required to take 2 days of intensive training with either Dr. Jason or himself and must be motivated to take the course. He explained that a test and a certain grade point average are required.

Mr. Ventura asked if the list of more knowledgeable providers could be place on the CFSAC website, and Dr. Lapp responded that Mr. Sterling should be asked, since CIFIDSAA supervises these efforts and has all of the records, which may be public or not. Dr. Lapp noted that they also stay in contact with these trainers.

Mr. Ventura then shared that they are disappointed by CFSAC's decision on the name change because the name causes trivialization of CFS. He added that he believes the name is a factor in why CFS funding is so small. He shared that he his wife was once very active and no longer is.

He then referred to CFSAC's statement on the name change about trivialization and disrespect not being corrected solely by the name change. He noted, however, that the name change would be a start. He thanked CFSAC for the opportunity to speak.

Dr. Bell commented that Mr. Ventura made some eloquent points. He explained how he has been an advocate for changing the name and even wrote a book 15 years ago that addressed this issue. He said he was somewhat skeptical of the process in 1988 when the original criteria related to CFS came out. However, he has been impressed with each subsequent refinement of the definition, noting that their approach to the work is becoming unique. He added that there is more involvement in other countries, including some interesting papers from Japan. He acknowledged that there are challenges but explained that things are moving faster than what Dr. Patarca's presentation may lead some people to believe.

Dr. Lapp suggested that the patients change the name themselves, noting that CFIDSAA changed name in 1991 and that many physicians use CFIDS instead of CFS. He noted that another term could be popularized and that CFS could be used for scientific research.

Dr. Beverly Bugos

Dr. Bugos shared that she has CFS and has a PhD in technology policy and R&D management from MIT. She explained that she was previously in the pre-medicine field, noting that she conducted research at the Bascom Palmer Eye Institute.

She noted that the case with medical terminology is similar. She explained that the term CFS is not comprised of medical terms, causes problems for patients, and does not have international medical usage. She shared that it is important to use appropriate medical language to describe this condition. She added that they can refine the definition all that they want, but they need to have the proper term.

Dr. Bugos explained that Congress will not understand what kind of support CFSAC is looking for, which is important. Because it is so misunderstood, people try to use things like cognitive therapy to treat these medical conditions.

She shared that she finished her dissertation in 6 months at MIT and is highly driven. She said that she desperately wants to work but cannot and that patients who have these problems now need to be involved in CFSAC's decision making. She added that CFSAC should do outreach to the patient community and seek ways to allow people to read other people's statements to the committee.

She noted that patients need help and will not get it until research is done in the proper scientific manner by people who want to find the answers.

Ms. Butler responded that she wanted the public know that she is a CFS patient and encouraged them all to participate and be constructive and helpful in what CFSAC is trying to do. She explained that CFSAC believes the name is a critical issue, but currently, they need to focus on other goals. She said that all of the members are hearing their comments and that they care about the patients.

Dr. Bugos responded that the name change is the top priority for CFSAC before they do anything else, since it is the top from which everything else falls.

After Dr. Bugos's comments, Dr. Fields apologized for the need to have time limits, and since more time remained, he indicated that Dr. Schweitzer had more time to speak.

Dr. Mary Schweitzer

Dr. Schweitzer began by sharing some of the illnesses with which she has been diagnosed over the last few years and how she had problems finding doctors to treat her. She noted that she is on Ampligen again, which has helped her condition improve in the past.

She commented on the institutional memory issue, noting that people testified to Congress and CFSCC over the past 15 years. She explained that she started an organization called We Can, which has since been dissolved, and that she used to bring documents with these patients' stories to these meetings; she described these individuals as too sick to do anything and expressed her sadness and disappointment that these stories have been lost. She shared that she was "living death" when she was very ill.

She alleged that the CDC and NIH websites have inaccurate information on CFS. She explained that someone who wants to know how many people are affected by CFS would likely turn to the CDC website, which says that 500,000 have a CFS-like condition and is based on a 1988 bulletin. She noted that this would translate into 50,000 people who have CFS. She suggested that if Dr. Reeves does not want to publish the current numbers that CDC has, then they should use Dr. Jason's 800,000 number, which appeared in a top-tier, peer-reviewed journal. She said that this information should be on the home page. She also alleged that NIH's information comes from the old physician's guide.

Dr. Schweitzer then listed several illnesses one by one, such as FM and MCS, and asked the people in the room to raise their hands if they or their child has the illness. She described how there are so many CFS symptoms and how she is on several medications. She noted that CFSAC needs to know data about patients' illnesses, determine the correlations between them, and understand how patients are dying besides suicide.

In conclusion, she shared that she thinks CFSAC is a great group and that they can accomplish a lot.

Dr. Fields concluded the public comment period. He shared that they all wish that they had more time and acknowledged the awkwardness of having to limit each speaker's time. He emphasized that CFSAC very much values the input they receive from the public.

Wrap Up

Next Meeting

Dr. Bell asked for suggestions for the next meeting. Dr. Mohagheghpour suggested that since they agreed to meet four times a year that they meet in late March or early April. Mr. Lieberman noted that he will be traveling during his granddaughter's spring break but was not sure when that would be.

Dr. Bell asked if there were any suggestions on how to handle the public comment period for the next meeting, such as requesting comments or inviting people to address specific topics or issues. Dr. Fields suggested that CFSAC could propose topics but should be open. Dr. Bell asked if there were any issues that they should suggest for public comment, such as education.

Dr. Bell asked if there were any other issues. Ms. McLaughlin noted that December is a difficult month for most people to attend meetings and asked that future meetings be moved earlier. Dr. Bell responded that they have some flexibility with scheduling.

Dr. Bell noted that they have not made any specific recommendations that they all agree on and that they need to think about these topics over the following months. He added that they have not established formal workgroups but encouraged people to seek help from other CFSAC members.

Ms. Shannon raised the issue of the name change. Dr. Bell explained that at this point, the committee feels that substantial new information is required before they can try to develop a new name or go back to an old one. He acknowledged that this is unsatisfactory for many people but that they do not know how to pursue this issue in a practical manner. He added that CFSAC would continue to think about this issue as they move forward.

Mr. Sterling asked if the issue would be reopened if any CFSAC members believed it was necessary to revisit it, and Dr. Bell responded affirmatively.

Dr. Bell asked if there was other new business, and no one responded.

Adjournment

Dr. Bell motioned to adjourn the meeting, and his motion was seconded. He adjourned the meeting and thanked everyone for attending.