CHRONIC FATIGUE SYNDROME ADVISORY COMMITTEE

Meeting

Monday, November 20, 2006
9:00 a.m. to 5:00 p.m.

Tuesday, November 21, 2006
9:00 a.m. to 3:45 p.m.

Room 800, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Agenda Monday, November 20, 2006

9:00 a.m.	**Call to Order** **Opening Remarks** **Roll Call**	Dr. Anand Parekh *Designated Federal Officer, CFSAC*
9:30 a.m. .	**CFSAC Community/ Organizational Updates**	Dr. Mary Schweitzer *CFS Advocate* 2nd CFS Advocate –Meghan Shannon
10:30 a.m.	**Break**	
10:45 a.m.	**Updates from the Federal Partners**	*Ex-Officio* Members, CFSAC
12:00 Noon	**Lunch**	
1:00 p.m.	**Updates from the Federal Partners**	*Ex-Officio* Members, CFSAC
1:45 p.m.	**Provider Group Testimony on Enhancing Provider Education**	Dr. Lucimar Cose-Cannon *Pan-American Health Organization*
3:00 p.m.	**Break**	
3:15 p.m.	**Discussion on Enhancing Provider Education/Awareness**	CFSAC Members
4:45 p.m.	**Closing Remarks**	Dr. Anand Parekh
5:00 p.m.	**Adjournment**	

Agenda Tuesday, November 21

9:00 a.m.	**Call to Order** **Opening Remarks** **Roll Call**	Dr. Anand Parekh *DFO, CFSAC*
9:15 a.m.	**Review Response of HHS to CFSAC Recommendations**	
11:15 a.m.	**CFS Public Awareness Campaign** **Press Conference Video (from 11/03/06)**	
11:45 a.m.	**Committee Business/Discussion**	
12:00 Noon	**Lunch**	
1:00 p.m.	**Committee Business/Discussion**	
3:00 p.m.	**Public Comments**	
3:30 p.m.	**Closing Remarks**	Dr. Anand Parekh
3:45 p.m.	**Adjournment**	

U.S. Department of Health and Human Services

CHRONIC FATIGUE SYNDROME ADVISORY COMMITTEE Meeting

November 20-21, 2006

Room 800, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Members in Attendance

CFS Advisory Committee Members

Chair (Absent)

Dr. Nahid Mohagheghpour	Term: 09/29/03 to 09/29/06

Voting Members

Rebecca Artman	Term: 12/01/05 to 12/01/08
Dr. Lucinda Bateman	Term: 12/01/05 to 12/01/08
Jane Fitzpatrick	Term: 09/29/03 to 09/29/06
Dr. Kenneth Friedman	Term: 09/29/03 to 09/29/06
Kristine Healy	Term: 12/01/05 to 12/01/08
Dr. Anthony Komaroff	Term: 09/29/03 to 09/29/06
Jason Newfield	Term: 07/01/06 to 07/01/09
Dr. James Oleske	Term: 12/01/05 to 12/01/08
Dr. Morris Papernik	Term: 12/01/05 to 12/01/08 – ABSENT
Staci Stevens	Term: 09/29/03 to 09/29/06

Ex Officio Members

Centers for Disease Control and Prevention (CDC)

William C. Reeves, MD, PhD *(Primary)*
Chief, Viral Exanthems and Herpesvirus Branch
National Center for Infectious Diseases

CDR Drue Barrett, PhD (*Alternate)*
Deputy Associate Director for Science
National Center for Environmental Health

Food and Drug Administration (FDA)

Marc Cavaille-Coll, MD, PhD
Medical Officer Team Leader
Division of Special Pathogens and Immunologic Drug Products

Health Resources and Services Administration (HRSA)

William A. Robinson, MD, MPH *(Primary)*
Director, Office of Minority Health and Health Disparities
Chief Medical Officer

CAPT Deborah Willis-Filinger, MD *(Alternate)*
Senior Medical Advisor
Center for Quality

National Institutes of Health (NIH)

Eleanor Hanna, PhD
Associate Director for Special Projects and Centers
Office of Research on Women's Health

Social Security Administration (SSA)

Laurence Desi, Sr., MD, MPH *(Primary)*
Office of Medical Policy
Office of Disability and Income Security Programs
Office of Disability Programs

James Julian, Esq. *(Alternate)*
Director, Office of Medical Policy

Executive Secretary *(Designated Federal Officer)*

Anand Parekh, MD, MPH
Senior Medical Advisor
Office of Public Health and Science

Invited Speakers

Dr. Mary Schweitzer, CFS Advocate
Meghan Shannon, CFS Advocate
Dr. Lucimar Cose-Cannon, Pan-American Health Organization
Dr. John O. Agwunobi, HHS Assistant Secretary for Health

Monday, November 20, 2006
Call to Order/Opening Remarks

Dr. Anand Parekh

Dr. Parekh called the Chronic Fatigue Syndrome Advisory Committee (CFSAC) meeting to order and introduced himself as the panel's new DFO and Executive Secretary.

Dr. Parekh came to the Department of Health and Human Services (HHS) 15 months earlier as Special Assistant to the Science Advisor to HHS Secretary Mike Leavitt, focusing on public health emergency preparedness. Dr. Parekh's background is in medicine and public health from the University of Michigan—Ann Arbor and Johns Hopkins Hospital.

During his first year at HHS, Dr. Parekh focused on public emergencies, including bioterrorism and pandemic flu. Several months before the CFSAC meeting, he accepted a position with Dr. John Agwunobi, HHS Assistant Secretary for Health, that encompasses a broad medical and health portfolio including coordination of HHS advisory committees.

Roll Call

Dr. Anand Parekh

Roll call found nine of 11 voting Committee members present, which constitutes a quorum. Absent were the chair, Dr. Nahid Mohagheghpour, and Dr. Morris Papernik, who could not attend due to a death in the family. All *ex officio* members were present.

In discussing the meeting agenda, Dr. Parekh noted that he had attempted to schedule a representative from the American Medical Association during provider group testimony but had been unable to do so.

Dr. Parekh noted that Tuesday afternoon's agenda was devoted largely to provider education, an important topic that had already warranted a CFSAC Education Subcommittee report and a Committee recommendation to the HHS Secretary. Dr. Parekh encouraged the Committee to decide during the Tuesday afternoon session whether to initiate further actions to address the issue.

Dr. Parekh next reviewed the contents of the Committee's meeting packet:

- A revised Committee charter that will be in effect until September 2008.
- Testimony and three handouts from Dr. Mary Schweitzer, CFS advocate (handouts listed separately below with Dr. Schweitzer's testimony).
- A letter to Dr. Mohagheghpour from Dr. Agwunobi, with an attachment describing the department's responses to the 11 CFSAC recommendations.
- The June 2004 reports from the Education, Research, and Disability Subcommittees.
- Minutes from the CFSAC April and July 2006 meetings.

Other documents were handed out during subsequent presentations to the Committee; these are listed below preceding each individual's testimony.

Dr. Parekh opened discussion on approving the CFSAC meeting minutes for April and July 2006. Members expressed concern that the minutes have been chronically late in both distribution and web posting, and inquired what can be done to produce minutes within the statutory 90-day deadline. A request was made that all minutes consistently include the meeting date in the document title and appear on the CFSAC website in PDF format for ease in downloading. Dr. Parekh promised prompt production of the minutes in the future and resolution of formatting issues.

The Committee agreed to table further discussion of the minutes until the following day so that all members had a chance to review them thoroughly.

Dr. Friedman requested an overview of how the Committee is to operate under its new charter. He noted that members made assumptions about operations in the past, particularly the fact that all CFSAC recommendations go directly to the HHS Assistant Secretary of Health. Dr. Friedman said that members have received conflicting information from past Executive Secretaries about whether or not recommendations can be held back if deemed inappropriate. He said that members were also told that although they approve the minutes, the Chair and Executive Secretary have the ultimate say over contents.

Dr. Parekh suggested that members discuss charter issues during Committee Business the following day, but noted that the panel's purpose has not changed in the new charter. He said that he will transmit all CFSAC advice and recommendations directly to the Assistant Secretary "in a very unfiltered way." Dr. Parekh emphasized that there is no reason for editing the minutes to remove material and that he will work with the Committee in a coordinated and collaborative manner "that meets all of your expectations". Dr Friedman urged him to maintain a frank and open dialog with Committee members about future operations.

Meghan Shannon, CFS advocate, noted that her comments from the December 2005 CFSAC meeting were incomplete and attributed only to a "woman". Ms. Shannon added that she had purposely read people's names in order to place them in the official record. She asked that the situation be rectified in future minutes so that they reflect what actually took place.

Dr. Reeves suggested that all speakers be encouraged to provide copies of their remarks and presentations to the person taking the minutes.

CFSAC Community/Organizational Updates

Dr. Mary Schweitzer, *CFS Advocate*
My History with ME/CFS
Handout 1 – *The Clinical Features of Myalgic Encephalomyelitis* – Melvin Ramsay, M.D., 1986
Handout 2 – Bibliography for the *Canadian Consensus Document for Diagnosing and Treating ME/CFS (2003) Overview* – Bruce M. Carruthers, M.D. and Margorie I. van de Sande, Bed

Handout 3 – *U.S. CDC CFS Website – Bibliography*
***Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Clinical Case Definition and Guidelines for Medical Practitioners – An Overview of the Canadian Consensus Document* – Bruce M. Carruthers, Marjorie I. van de Sande**
(Note: These documents are posted on the CFSAC Website.)

Dr. Schweitzer opened her remarks by complimenting the NIH Office of Research on Women's Health website.

She then presented a summary of her history with ME/CFS, describing how her "charmed life" as a successful 44 year old Villanova University professor married for 20 years to the love of her life "changed forever" on Oct 24, 1994. Dr. Schweitzer was struck with full-blown ME/CFS while grading tests and lapsed into a fog that lasted several hours. When she awoke, she could not understand one word in the blue books in front of her and was in such pain that she could not turn her head to check before merging into traffic on the drive home.

Dr. Schweitzer was diagnosed early in her disease, and assumed that with sufficient rest and treatment, she would recover by April, 1995 and be able to do light research. She did not improve. While it may have appeared that she was "resting", Dr. Schweitzer was actually using enormous exertion and concentration to accomplish the simplest task. She could not read print or knit—her two previous activities during recovery from illness. Months and years went by in this state as she continued to deteriorate. No one but her immediate family saw her at her worst, as she lay in a dark room watching movies because it was the only way she could bear the pain.

Dr. Schweitzer told the Committee that for four and a half years, "morning coffee was the biggest thing I did." In her former life, she read three daily newspapers, the *New York Times Book Review*, and the *New York Review of Books*, all from beginning to end. "I finally realized how bad it had gotten when I could no longer read comic strips," she said. "By the time I got to the fourth panel, I couldn't remember what was in the first…It would be years before I could read again.

"This is what made me disabled—not fatigue, not being tired. My brain was broken, as my son put it." Writing one email might take hours, with a rest required between each sentence. "It's a bit of a blow to your self to disappear so much," she said. On bad days, she would lie under the covers "feeling like somebody had hit me in the back of the head with a baseball bat and someone else had unscrewed my eyeballs with pliers…I did not experience a single day in four and a half years without that pain on some level and without confusion on some level—the feeling that it's three o'clock in the morning all the time.

"Expressive aphasia was a very difficult thing with my family because we had always talked everything out. My husband said he had lost his best friend, and he meant it. This was very difficult for him. I could not stay in a conversation long enough to be a participant. If I did, I couldn't express what I was thinking. So I began to just disappear, like it is to be deaf around people who can't sign.

"Here's what I want to get across--This was hard, hard work. Getting through every day was hard work. I was not resting. I was working as hard as I could to make it from

morning to sundown…I don't think I coped so well with the disease; my family had to cope. They're the ones who had to make things work.
"Early on, Dr. Schweitzer had tested positive for the autonomic nervous system defect NMH/POTS, Hashimoto's thyroiditis, fibromyalgia, and restless leg syndrome, four conditions for which she continues to be treated. Everything changed, however, in the fall of 1998 when Dr. Schweitzer tested positive for an immune defect called 37kDa Rnase-L Factor as well as the "truly vicious" Human Herpes Virus 6 (HHV-6A). These are two of the three biomarkers that seem to be useful predictors of success with an experimental drug called Ampligen, an asymmetrical double-stranded synthetic RNA. She began taking Ampligen in February 4, 1999, and that spring, attended her first CFSAC meeting, walking on her own.

Dr. Schweitzer went off Ampligen after 20 months and a year later, HHV-6A came back again, causing another collapse. By the time she went back on the drug seven months later, she had to be taken to her treatments in a wheel chair wearing sunglasses because the lights in the ceiling hurt so badly. During the first years of her Ampligen treatments, Dr. Schweitzer paid $40,000 per year cash. Since 2003, she has paid $20,000 per year, almost precisely her after-tax disability income. Most people with CFS cannot afford testing and treatment. "Where would I be if I didn't have my family? Where would I be if I never got disability insurance?"

At the conclusion of her personal story, Dr. Schweitzer turned to the three handouts accompanying her testimony. She applauded the CDC for differentiating ME from CFS on its website. She explained that Handout 1 is the classic Melvin Ramsey definition of ME from his 1986 textbook, revised in 1988. Dr. Schweitzer then critiqued the CDC website for including neurasthenia, noting that the American Psychiatric Association does not recognize it as a disease.

She complimented the CDC's public information campaign, but expressed concern that when people access the toolkit on the CDC website, they are referred to a bibliography that contains only CDC research. She said that this bibliography does not allow people to learn about the breadth of the disease and should be expanded to include the seminal articles in each area.

For comparison, she pointed to Handout 2, a short version of the Carruthers and van de Sande bibliography from their summary of the Canadian definition of ME/CFS. She called attention to an article by Dr. Komaroff from the year 2000 that calls for the recognition of CFS as a serious disease, and noted that research has doubled since then.

Other articles in the bibliography that are essential to physicians' understanding of CFS include the 1995 Bouholaigah/Rowe/Kan/Calkins *Journal of the American Medical Association* piece that sparked interest in the relationship between autonomic nervous system dysfunction and CFS, and Peckerman's *American Journal of Medical Science* piece showing that CFS could be dangerous to the heart health of CFS patients. Handout 3, the CDC toolkit bibliography, could be improved by CFSAC forming a subcommittee to compose a more well-rounded version, Dr. Schweitzer suggested.

She also objected to a sentence in the toolkit that reads, "There are no tests and there are no treatments." She countered that she represents at least four subgroups of CFS—ME, NMH/POTS, 37kDa Rnase-L Factor and HHV-6A—for which there are

treatments, and noted that insurance policies cover some of the drugs prescribed for CFS. She said that the sentence discourages patients from finding out what they have and getting treated.

The Canadian consensus document was written by clinicians, concluded Dr. Schweitzer, and gives instruction to physicians treating CFS patients. She urged the Committee to "get a document like that out to the public" along with a bibliography that includes a representative body of literature.

Dr. Parekh commended Dr. Schweitzer's courage for sharing her personal experiences and her suggestions.

Committee Members Q&A

Ms. Fitzpatrick: Is there any part of the treatment that you seek that's covered by insurance?

Dr. Schweitzer: Blue Cross/Blue Shield and/or Medicare covers IV nurses and IV equipment for twice-a-week infusions, with a $25 co-payment. Insurance covers a liter of IV saline for NMH/POTS, but does not cover Ampligen, and does not pay for some of the tests. I pay $16,000 cash for Ampligen, about $4000 in testing co pays, and bills for other medications and doctors.

Ms. Fitzpatrick: Has that improved? Do they recognize your diagnoses?

Dr. Schweitzer: They do not recognize the experimental tests for Rnase-L and HHV-6A.

Ms. Artman: What are your medical expenses for a year as someone who has a private insurance policy?

Dr. Schweitzer: $25,000-$30,000.

Dr. Friedman: One of the reasons that CFS research "is in the dismal state that it's in" is that people do not realize the significance of chronic fatigue. There has never been a longitudinal study on CFS. You know a lot of people. I'm wondering if you could document what diseases these people end up with and try to categorize them to produce at least an informal summary of what CFS leads to. That's important in documenting the effects of CFS. It's not just an illness that goes on forever. I am sure that it does end up with certain morbidities that contribute to a premature death. The sooner we can document it, the more attention and funding will go to CFS.

Dr. Schweitzer: That's what the CDC should be doing. I'm finishing a book on my experience with the disease that is also an analysis called *Slightly Alive*. At one point I put together a data set for another purpose that had 55,000 people with 20 observations. I got one article published from that. I know how much trouble it would be to put an unbiased survey together correctly and I really want to go back to my first love and finish the research I was doing when I became disabled by CFS.

Meghan Shannon, *CFS Advocate*
***Presentation, patterns of myocardial damage, and clinical course of* – Mahrholdt, et al, Oct. 10, 2006**
T-cell alternations in late post poliomyelitis – Ginsberg, AH, et al, *Archives of Neurology*, May 1989
Fluctuations of CD4+ T-cell subsets in remitting-relapsing multiple sclerosis –Rose, LM, et al, *Annals of Neurology*, August 1988
Benign Myalgic Encephalomyelitis (Iceland Disease) in Alaska – J.B. Deisher, M.D., *Northwest Medicine*, December 1957
Passage on CFIS/ME from Special Concerns for Women, *Our Bodies, Ourselves*, p. 665
(NOTE: These documents are posted on the CFSAC Website.)

On Dec. 8, 2003, I swore that I would never come back here again. I'm crying now because I'm tired. I drove by myself from California to Pottstown, Pa., less than a month ago. I'm not one of the lucky ones—I live by myself. I was 31 when I got CFS. I was saving children's lives on an emergency response team, and I was proud that I could rescue these children. Then I got sick at the very place that I was working. My healthcare profession that I was so proud to be a part of turned its back on me.

[Ms. Shannon showed the Committee her IV equipment, which is necessary for her to receive electrolytes.] Normal saline will kill me. I have an oncologist's letter stating that I need fluid support on a weekly basis, sometimes biweekly. I get chest pain and it goes through my backbone and up my jaw and feels like a woman's heart attack, although it is not. I will not go to an emergency room (ER) without an invitation. If you have CFS on your chart, you get put in a back room and they turn the light out and they don't come back and see you.

[Ms. Shannon described her experience with being unattended by an ER doctor as Ms. Shannon exhibited a blood pressure of 80/60 and a pulse barely at a 30. Her blood work indicated dehydration even though she had taken two liters of fluid the day before. She said that she was "shoved out the door at midnight".] I walked out, went home (two blocks away) and went to bed. I thought I slept one night, but I slept two. I was awakened by my seven pound cat that walked up and down on me until I woke up. I drove to my doctor's office 20 minutes away. I got to where I needed to be to be taken care of.

In 1982 the adenovirus number 2 went through Children's Hospital in San Diego where I worked. It killed six kids. In those times, we didn't wear goggles. The child I took care of was 18 month old and had been sick with the virus since the day he was born. People who wore glasses were more protected than I was. I got conjunctivitis three years later and ended up with an immune system that "looked like AIDS". She also found during her years of testing for CFS that she has had polio, although not the paralytic variety. Ms. Shannon said that the actual bout of occurred when she was six.

I actually thought yesterday morning, I'm not going to attend this meeting. I've been doing this for 22 years. I'm trying to make a life of my own in Pottstown, Pa., on horses. Neurologically, when you're sitting on a walking horse, you're repatterning the brain. I'm trying to make a change. I'm angry and it's not at you. I'm glad you're here because you seem like you're going to do something.

[Ms. Shannon referred the Committee to an article that accompanied her testimony on adenovirus and noted that while she was working at Children's Hospital, the virus was

being used for gene therapy for cystic fibrosis. She said that Canada and European nations refuse to use the adenovirus for this purpose.

She also referred the Committee to two more articles on the CD4+ and CD8+ T-cells and the fact the multiple sclerosis and post-polio patients have the same results that AIDS people have. Ms. Shannon next referenced a 1957 article on benign ME in Seward, Alaska. The author, Dr. J.B. Deisher, noted that people were coming through his port town with an ailment that did not look like polio.] Why is this not on the NIH and CDC websites? Why are we not talking about the fact that there is benign ME evidence in the United States? The conclusion of this doctor's report discusses how he spoke specifically to Australia, Great Britain, Europe, and Alaska about the explosive scattering of this disease in the '50s in the United States.

[Ms. Shannon read a passage from Chapter 29 in the book, *Our Bodies, Ourselves* covering CFIDS/ME that includes material from herself, Dr. Schweitzer, and other CFS patients.] The woman who edited the book knew this disease and the politics of this disease. The sidebar in the chapter notes that CFIDS/ME is not rare and affects 422 out of 100,000 people ages 18 to 69, or about 800,000 people in the United States. It is three times more common than the HIV infection in women and 25 times as common as AIDS among women. The risk of getting it is considerably higher than a woman's lifetime risk of getting lung cancer.

CFIDS was brushed off as the yuppie flu, or an affliction of upper middle class white women even though Latinos and African Americans appear to be disproportionately affected. CFIDS has also been attributed to midlife crisis and boredom. The chapter notes that the "difficult, unreasonable, and hysterical" women leading patient advocacy were held up as evidence that CFIDS patients need cognitive behavioral therapy, graded exercise, and anti-depressants, even though the effectiveness of these treatments are the subject of debate.

Committee Members Q&A

Ms. Artman: You talked about ER treatment in England and the United States. Have you as a patient noticed a consistent lack of ERs' ability to respond to your needs as a CFS patient?

Ms. Shannon: If say I the words CFS, yes.

Ms. Artman: If you say post-polio syndrome?

Ms. Shannon: …and if I come in with my ID bracelet and my letter from the oncologist, who's well-known, I get treated. But not as well as others.

Dr. Bateman: As a clinician, I advise my patients not to mention CFS when they go to the emergency room. I think they'll get better care. People turn their brain off and do not give ordinary, acute medical care when they learn someone has CFS.

Ms. Shannon: But if it's in your record, there's nothing you can do.

Dr. Friedman: Pandora, which is the Florida CFS patient advocacy group, is attempting to write a manual for emergency physicians and I have been appointed to the board, so there is hope and the situation has been recognized. The New Jersey CFS Association

holds two patient-physician conferences a year and we have an attendance of about 100 people at each of those conferences, so we appreciate the demand. I believe my role here is to stimulate the Federal government to pick up the slack.

Ms. Fitzpatrick: An emergency room is not a good place for CFS patients to go without an advocate.

[**Ms. Shannon** contended that ERs often ban advocates from accompanying CFS patients and requested that the Committee also recognize this issue, concluding, "We need somebody with us when we're sick."]

[Dr. Parekh called a five-minute break.]

Updates from the Federal Partners

Dr. Marc Cavaille-Coll, FDA
Food and Drug Administration Update
(NOTE: This document is posted on the CFSAC Website.)

Dr. Cavaille-Coll noted that his written testimony summarizes FDA actions concerning CFS, particularly in the area of provider education, and referred his colleagues to the agency website for more details. He then highlighted several actions:

FDA's labeling review process for prescription drug products – Labels are one of the ways that the agency communicates with physicians and healthcare providers. The review process will change based on revised labeling rules published this summer that require the package insert to be written in a way that is more helpful to healthcare providers. Inserts will be smaller, better structured, and include a half-page of highlights with references to other sections if people want greater detail. The rules apply to products that are coming to market or are on a new drug application. Although there are deadlines for transforming all package inserts to this format, companies can voluntarily submit labeling changes earlier. For more information, search the FDA website for "physician labeling rule".

Med Watch System – This online system has existed for almost 10 years and allows healthcare providers to submit information about prescription drug safety problems. The program also has a list of Med Watch partners who get notified whenever a new labeling adds information about safety. Website search word: Med Watch.

Office of Special Health Issues – The office was created more than 10 years ago to address serious and unmet health needs in areas such as AIDS, cancer, and CFS. It also assists the Office of Advisors and Health Consultants' to find people who can serve as patient advocates or on FDA advisory committees. Website search words: Office of Special Health Issues.

Pre-IND Program – Any drug being investigated for human use that is not classified as a lawfully marketed product needs to be investigated under an IND (Investigative New Drug) exemption. The pre-IND program is for investigators who want to study a new drug to treat a serious condition. The program allows them to get the information

needed for a successful application that will meet review conditions. Website search word: IND

Safety Board – This board has existed at FDA for a year and includes members from all agency centers as well as representatives from other public health service agencies. The body acts as an oversight board to examine how FDA is handling drug safety issues and communicating safety through notices directed toward physicians or the public. Website search words: Safety Board.

Committee Member Q&A

Ms. Artman: Is Ampligen on a fast drug approval track or on a regular track?

Dr. Cavaille-Coll: I cannot comment on the status of any product that is under an IND, but I can tell you that if the product is made by a publicly held company, it has to communicate this type of information to shareholders and to the community in general. Such information would appear in a company's Security and Exchange Commission report.

Dr. Friedman: Am I correct that there is not one drug that is FDA-approved for the treatment of CFS?

Dr. Cavaille-Coll: There is no product approved for the treatment of CFS, but there are quite a number of lawfully marketed products that are used to manage CFS patients.

Dr. Oleske: There's a problem with that. Some managed care companies won't cover the medications because they are not designated. It is important that some pressure be brought when the manufacturers of these drugs know that they are being used for CFS. We need clinical trials. It's hazardous to say that you can use a drug for an unapproved indication because in the long run, patients aren't benefited when there aren't legitimate clinical trials to address an illness. It is a reflection of people not taking this disease seriously that there are no pharmaceutical companies willing to fund studies to treat the disease. It's never going to change until we have some pressure brought for clinical trials. FDA needs to suggest that if a manufacturer knows that a drug is being used for CFS, it should support a clinical trial.

Dr. Cavaille-Coll: FDA cannot really initiate this type of research. We are aware that there are a number of products such as thalidomide that are being used for CFS, and we would welcome anyone who wanted to submit an IND to conduct clinical studies. I would say they should contact our pre-IND program.

Dr. Parekh: There are a host of medications that we use for CFS. There are at least eight or 10 classes of medications that we find useful. I guess it gets down to the post-marketing surveillance of off-label uses for chronic fatigue and determining the public and private responsibilities and roles.

Dr. Oleske: It's not so easy for an individual clinician to get an IND to study a drug.

Dr. Friedman: I just want to reiterate that without the establishment of drugs that are effective in the treatment of CFS, there are two problems. One is cost recovery and the other is the reluctance of patients to try drugs that are not indicated for their condition. There has to be a lot of trust on the part of the patient, and sometimes it does not work

out as well as might be expected. I'm hoping that there's something that this Committee can do to establish the acceptable level of care in terms of drug treatment for these patients.

Dr. Oleske: What's frustrating to me is that there are drug companies that will encourage a study for CFS, but these are mostly for antidepressants and other psychiatric drugs. The problem is that I think that most of those drugs are not effective for CFS. Patients sometimes enter a clinical trial out of desperation for drugs that I don't recommend.

Dr. Parekh: I think you're right. I think that those are the ones being studied because those are the blockbuster drugs that there's a big population for, and they sell well.

Dr. Cavaille-Coll: I'd just like to add that one of the big challenges for developing drugs for CFS is that we don't have a laboratory model, an animal model, or an *in vitro* model that would allow us to sort through the tens of thousands of molecules that are likely to benefit a person with CFS. I think it's very much like where we were with AIDS more than 20 years ago—until the virus was identified there really weren't any good therapeutics.

Ms. Artman: As a patient, it's very difficult for me to go to my specialist and get my off-market CFS drugs, then go to my family practitioner and give my list of medicines and why I'm taking them. It is especially difficult maintaining a list of drugs not labeled for CFS. I really don't know all of the reasons behind the drugs.

Dr. Reeves: We do not know what the lesion is in CFS, so we can't treat the lesion. The treatment is largely aimed at the alleviation of symptoms. Antidepressants have powerful anti-inflammatory properties which take care of some of the pain. They also have muscle relaxant properties, and they aid with sleep. In our population studies, we review every medication that every patient with CFS is on. Fewer than 50 percent of them have seen a doctor for their fatigue and fewer than 20 percent have been diagnosed with CFS. The physician registry, which I will briefly describe, will enroll as many healthcare providers as we can in one area, and it will track how they treat their patients and how their patients fare. One of the things that one sees is that the medications that people with CFS take are sometimes causing as many symptoms as they are relieving. Patients see various practitioners, don't tell one about the other, and end up getting drug cocktails. Each medication is probably prescribed for good reasons, but in a vacuum.

Dr. Parekh: Drug interactions and side effects could potentially worsen the symptoms of a CFS patient.

Ms. Shannon: Psychiatric drugs are the ones that are causing patient blood pressure to drop and hearts to race. Psychiatric drugs have been a problem for over 18 years.

Dr. Robinson: I would like to question Marc about the FDA orphan drugs program. We had individual drugs for relatively small populations and FDA sat down with the manufacturers to talk through how it could be mutually beneficial for companies to invest in products that didn't have a large market.

Dr. Cavaille-Coll: The Orphan Drug Act allows us to give exclusivity for seven years to a drug by indication and by molecule. It really applies to conditions for which the

prevalence in the country is less than 200,000 patients. I believe that the estimates of the prevalence of CFS are in excess of 200,000. So it might be difficult unless the company can make an argument that its drug is intended to treat a specific subpopulation of CFS. However, if a product is already qualified under the Orphan Drug Act, its designation would not change if the prevalence of the disease increased.

Dr. Parekh: The CFS patient population is so diverse that we may be able to stratify the population and determine the subgroups that might have a common biochemical etiology, then target potential drugs to that particular population. But you need the research first to identify those subgroups.

Dr. Hanna: The clinicians who use these off-label meds are free to do their own clinical trials or to form consortiums to do this and submit funding applications to NIH. I realize it's difficult, but it is possible, and when they get those papers published, they can build up at least some evidence for these different drugs.

Dr. Parekh: If private physicians can pool patients and data, I think it's a good point.

Dr. Komaroff: It's very unusual, though, for NIH to fund drug trials. So are there any particular circumstances where it's easier to get NIH funding given that pharmaceutical companies are also candidates to fund drug trials?

Dr. Hanna: One of the studies that we're funding for the RFA (request for applications) could be looked at as a drug trial. It's an examination of how different classes of anti-depressants work on brain mass cells. Any well designed study with good justification has a chance. I've seen NIH funding for studies of different medications just as there are studies of different treatments such as cognitive behavioral therapy.

Dr. Oleske: I've been involved for 20 years in clinical trials, and I've been trying to get an NIH clinical trial network for CFS following the model of HIV. Such a network could study medications' long-term effects and treatments for palliative care that improve quality of life. Because there was a clinical trial network specifically looking at HIV, we were able to make some fairly rapid advances in its prevention. With a network for CFS, we could at the very least put to rest some of the things that don't work. A clinical trial network would try to bring some controls over huge amounts of money being spent on unnecessary lab studies. A clinical trial network would also bring real science as well as compassion to addressing these problems. Remember, we're not being compassionate by having a committee like this that just listens to patients talk to us. The real commitment to doing something about this disease will be recommendations that establish a way of addressing this problem appropriately. We spend an inordinate amount of money arguing over whether a syndrome is real or not instead of just accepting that it's real and doing some research.

Ms. Fitzpatrick: This discussion is leading me to think that this is certainly an area in which the Committee will want to consider making a recommendation. Another aspect of this is that if we really want to be advocates for patients, we should facilitate finding a treatment that is payable by somebody and is not labeled experimental. I consider that one of our most important obligations.

Dr. Cavaille-Coll: Is there a separate budget line for the AIDS clinical trial centers and are there any other diseases for which there is a budget line for collaborative clinical trials?

Dr. Hanna: I don't know the answer off the top, but I do know that there was a special line for AIDS. And as I said at the last meeting, the entire NIH is being reorganized, so whatever is going to happen is up for grabs. We're all sort of unclear about where things are going to go and how money will be distributed.

Dr. Eleanor Hanna, NIH
(NOTE: This document will be posted on the CSFAC Website if it is available.)

We just passed out all of the awards that were made to the RFA. You have all the details and the summary and the actual abstracts are on the website. I won't spend time going over these except to again recount that these were in response to the RFA that was developed out of the workshop that we had on neuronal mechanisms for CFS. We did the RFA so that we could try to understand better what the etiological aspects of CFS might be, how markers could be developed, and how treatments could be studied if you looked at these underpinnings of the disease. I think that the seven grants that came in and that we're funding are going to help immeasurably in answering some of these questions. I am hopeful that these studies will help us understand the mechanisms better, including why antidepressants may provide some relief. I am also hopeful that the studies will shed light on the genetic component that I think the CDC has gotten at in their large scale studies, including the data mining studies.

Getting back to the clinical trial network…one of the plans that I have is to require the RFA investigators to meet here in Washington once a year. It is my hope to build a consortium for CFS out of these investigators, and that's going to be the purpose of the meeting—to get them to collaborate with each other and develop plans for the future that include applying for further NIH monies.

We tried to develop the website to reach physicians, the lay public, patients, and researchers. I do think we have a comprehensive website. You can go on there and get anything you want out of Pub Net. The search is already there for CFS. You can pull up 2500 - 3000 articles, and you can also tailor it to any particular subjects within CFS.

Another thing that we're planning on is the development of a Roadmap initiative. When the CFS Working Group reconvenes in January, I'm hoping to get cooperation to develop a Roadmap initiative to fund the centers that people have been asking about. What I have in mind is developing a center that would train clinician investigators and foster senior investigators who go from basic to translational clinical work. To get the funding, it would have to be accepted as one of the Roadmap initiatives by the Roadmap Committee and be put out for public comment.

Committee Member Q&A

Ms. Fitzpatrick: Would a stronger recommendation from this Committee help in any way towards that?

Dr. Hanna: I really don't know. I'm not in charge of money, everything's being reorganized, and budgets are being cut, so it's hard to say whether it would really make a difference. We still have to function within the resources we have, and that's why I'm trying to be inventive in thinking how I could get some of the other resources that are

available. I don't think I can get much more money out of Women's Health than I've already gotten, and the Institutes will only fund things that fall within their missions.

Ms. Artman: Those patient groups that are here will take whatever information comes out of here to lobby Congress. Even if we make a recommendation for money that isn't there, lobbying groups may use it to get more funding out of Congress. I have a question on the 2000 State of Science meeting recommendations, which appears on the CDC website – I would hope that more recommended study areas, especially cardio, would include CFS.

Dr. Hanna: If you look at research funding, there is a lot that is specific to CFS in the cardio and neurological areas. Those recommendations were used when we wrote the first PA and they're still in there. There will be three separate applications—one for the R01, one for the R21, and one for the R03. Those same recommendations are still there except in newer versions, and we're asking for interdisciplinary research.

Ms. Stevens: [Thanked Dr. Hanna for often "going it alone" at NIH with pushing CFS to the forefront.] Committee members began with the suspicion that the agencies weren't being responsive to our recommendations, and they have shown that they are. You're hearing that we want a Center of Excellence, which is our number one recommendation. This is the first meeting that we've heard that response. That's a huge step forward.

Dr. Parekh: Finding avenues of funding is difficult. Eleanor, in terms of the Roadmap initiative, you can keep others informed where that is going. I'm assuming that there will be other initiatives competing to be funded.

Dr. Hanna: Once we develop it, I will certainly circulate the first draft to the Committee. Anybody who has ideas, feel free to email your comments/suggestions.

Dr. Friedman: Are you keeping statistics on the CDC web page for number of hits—specifically the number of physicians logging on?

Dr. Hanna: Yes, we do have the number of hits. We've just changed website contractors. I'll be sure that we can get them specifically for the CFS page. Last year I told you that it was the number one hit on the Women's Health website. There is currently no way to distinguish physicians from patients, but I can discuss that with the new contractor.

Dr. Friedman: I am concerned that government in general overestimates the effectiveness of physicians accessing web pages. The state of Vermont posted the New Jersey CFS Association's consensus manual with the option for physicians to get a hard copy. I suspect that physicians don't access the information online as often as they do when they have a hard copy. I would like to encourage that some statistics be kept in terms of trying to determine whether or not that program is effective and if not, perhaps we should consider an alternative.

Dr. Hanna: Most of the publications on the website are all available in hard copy and people order them. In fact, the neuroimmune mechanisms were the number one request.

Dr. Friedman: My second, broader question concerns the fact that most of the CFS research being done is more or less basic research. I'm wondering what this Committee could do to promote research that will be of more immediate benefit for CFS patients.

Dr. Hanna: I'm hoping that some of the studies that we just funded will do exactly that. For example, the study that's being done in Miami will be looking at a phone-based intervention for stress management, which has been proved to be effective, but they'll be looking at all the physiological changes. We should be able to develop something out of that in terms of treatment.

Dr. Friedman: What can we do to stimulate this research that has a more immediate effect for patient care?

Dr. Hanna: I think that until you have the basic research, you can't do that. We came to this critical mass and were able to put out this RFA and get this high quality research. There's potential here now to develop an animal model. We need to have those answers first. But I think now there's enough of that that people can try to translate them.

Dr. Friedman: I was hoping for a different answer. In medical school the trend is evidence-based medicine, and I'm wondering if NIH grants could incorporate some of that concept—establishing clinical trial groups to have physicians or groups of physicians report to NIH so that we could use evidence-based medicine to further CFS treatment.

Dr. Hanna: It depends on how you define evidence-based medicine. At the NIH that's defined through a consensus conference and a key part of that is an AHRQ report, which collects all the treatment literature out there. I think you would find almost the same thing right now that we found the last time that there was an evidence-based report on CFS. That's why I'm hoping that these studies will help move us off that page. I don't think we're ready to have another consensus conference.

Dr. Friedman: I agree we're not ready for a conference, but how could we stimulate the research that will cause a conference to occur sooner?

Dr. Robinson: The Agency for Healthcare Research and Quality is the one that uses evidence-based medicine at its mantra. It might be good to invite a representative from that organization. The other critical partner could be CMS in terms of some of what they may be supporting directly or indirectly.

Dr. Parekh: Is there interest from the rest of the Committee?

Dr. Cavaille-Coll: I think that when we were a CFS coordinating committee we did invite AHRQ to put together a report. That's been published. We've had some consensus conferences organized by NIH. I was reading through the grants that have been funded. We're seeing, I think, the results of those types of activities and I hope that we'll be looking at this research a few years from now and using that to revisit the state of the science in CFS. It's cyclical, and I think right now we need to see the results of this work before we can move forward.

Dr. Parekh: Eleanor, how many applications were submitted?

Dr. Hanna: Twenty-nine were submitted, so seven out of 29 were funded.

Dr. Laurence Desi, SSA

We're continuing our education on CFS as part of the training for administrative law judges, Federal review officials, and disability examiners. The training is developed at the central office. We sent out a memorandum to state DDs advising them of the CDC/CFIDS free continuing medical education (CME) credits for physicians on the CDC website to encourage both medical consultants (physicians who review the case files at the DDs) and consultative examiners (physicians who actually see the patients) to get this kind of education. We also do annual literature reviews to update our understanding of CFS.

[Dr. Parekh called a break for lunch.]

Dr. William Robinson, HRSA
Letter to HRSA Centers re CFS information resources
Letter from Asst. Surgeon General (1999) to community health centers
CFSAC Education Subcommittee Report, June 2004
(NOTE: These documents are posted on the CFSAC Website.)

[Dr. Robinson introduced his HRSA alternate, CAPT. Debra Willis-Filinger. She will serve as the HRSA representative until someone permanently replaces Dr. Robinson, who is retiring from his position.]

HRSA has no specific programs or appropriations that address CFS. HRSA's involvement began in the late 1990s when HHS formed a CFS coordinating committee under the Assistant Secretary for Health and the group began to address providers and their role. Patients were having difficulty finding primary care providers who took the disease seriously. The problem was nationwide, not specific to any region or specialty. HRSA looked at how we could help support a solution, particularly through the Bureau of Health Professions, because this was the entity that was providing primary care support. HRSA staff partnered with CDC and the CFIDS Association of America. As they would help put up resources for collaboration, we had a particular vehicle called area health education centers (AHECs), which was a group of centers funded under Title 7 of the Public Health Service Act that trained health care providers as teams as opposed to one discipline at a time.

There was a contract let with the University of Illinois, and a project was designed to come up with curricula and case models that could be made available to other primary care providers across the country. AHECs served as distribution points so that practitioners who were in training—medical students, dental students, nurses, interns, residents, and practicing physicians—could learn more about CFS. The group also decided to have a national teleconference linked into the AHEC sites. The conference went to 75 downwind sites in 20 states. It didn't work quite as well as had been hoped. We shifted focus to target providers in smaller groups rather than do something nationally to try to come up with a way for training physicians who would be peer trainers for other physicians, using the network that practitioners already had.

[Dr. Robinson referred Committee members to his second handout, a 1999 letter from then Asst. Surgeon General Marilyn Gaston to HRSA community health centers for underserved populations.] The letter provided various resources for information about CFS. There are thousands of these centers nationally.

[Dr. Robinson sent a similar follow-up letter in August 2006 to update information, including websites.] The idea was that if you could take practitioners who had a sense of community who could then go out and train their peers, we would have a way of people getting credible information from people they respect about a disorder that has been poorly appreciated. This train-the-trainer program was begun in 1999. www.cfids.org/treatcfs includes the provider education project that has continued after HRSA dropped out.

The CFS coordinating committee went out of existence and CFSAC took its place in 2003. CFSAC created an education subcommittee to target all providers, not just physicians, with the idea that nurse practitioners, physician's assistants, and others would also be working with CFS patients.

Committee Member Q&A

Dr. Friedman: Can you provide a list of AHECs? They may be useful contacts.

Dr. Robinson: Due to budget difficulties, HRSA is not going to be able to continue to include those in the budget packages that go to the Hill. There have been a number of different cuts that have hit some of the health professions programs rather hard, including the ones for primary care training. I'm hoping that most of those organizations are going to be able to get continued support outside of Federal funding. I'll get in touch with the program and try to get the information back for those that we have—in the form of a URL or hardcopy.

[Members of the Committee thanked Dr. Robinson and wished him well in his future endeavors.]

Dr. William Reeves, CDC

CFS Health Behavior and Education Update

(Note: This document will be posted on the CFSAC Website if available.

[Dr. Reeves said that he would give a quick update of progress in the CDC CFS research program, then deal with primarily education and how it fits into a model for control.]

- We have finished and I have presented previously a survey of CFS in metropolitan urban and rural populations in Georgia. A manuscript describing the prevalence is submitted and in review.

- A manuscript looking at formal measures of cognitive function is ready to be submitted with a larger number of better characterized patients than the Wichita study. We are finding some significant changes in cognitive function. What we had found previously is that cognitive function was relatively unimpaired, but

fatigue increased as the tasks went on. That is still true, but some areas of higher cognitive function are also minimally impaired.

- Other manuscript topics in process include: medication use and the severity of illness, a formal economic evaluation, allostatic load and metabolic syndrome in people with CFS, and analyses of access to and utilization of health care.

- Further in the future are formal analyses of subgroups or clinical types of CFS and whole genome analysis of CFS. What is nice about these is that they are observations within a population that are confirming and honing results that have been shown in a variety of other studies that did not always connect together well.

- We have a heavy program in mathematical modeling of the HPA axis.

- We are well into OMB clearance for a follow-up study to look at the clinical course of CFS in Georgia and for a pilot registry of CFS as seen by providers in urban Georgia.

- We have in review by the IRB an in-hospital clinical study slated to start in January or February that will evaluate cognitive function at the same time as functional magnetic resonance imaging that looks at neural pathways and brain architecture.

- We are in the last year of the first iteration of the provider education study before we put it up for renewal.

Everything that we are doing in the program applies to the control of CFS– reducing the prevalence and duration of the illness, the amount of impairment that people suffer, and the economic impact. Those are all things that we are measuring in the population so that as we put the control program to work, we can measure changes. I'm not talking prevention, I'm talking about reducing morbidity.

Less than half of those with CFS see a doctor; less than 25 percent get diagnosed and treated for it. A quarter of the people with CFS in the population are out of work or on disability. The average affected family loses $20,000 per year in earnings and wages.

[Dr. Reeves presented his CFS logic model:

CFS--medical care--control—reduction of prevalence, duration, impairment, and economic impact

If people with CFS seek medical care, it leads to control, which reduces the four listed effects of the disease.]

It's a simple logic model, but people must get medical care. That means they have to have access to medical care, then they have to use it. These we can measure in our population studies. The public awareness campaign targets this. Once a patient is appropriately evaluated and diagnosed, he or she can get appropriate treatment. I feel strongly that we don't want to put together a cookbook to diagnose CFS; we need to deal with sick patients. Forty-eight percent of people in Georgia who meet the case

definition of CFS have other serious illnesses as well, such as hypothyroidism, diabetes, or hypertension.

Providers' knowledge, attitude, and beliefs are critical. One has to understand what they are, then modify them. Our whole research program involves that logic model with those components. Measuring outcomes is at the basis of the education program. We can talk all we want about materials development and dissemination, but if they don't change knowledge, attitudes, and beliefs, it's a waste of time. The research component is critical.

[Dr. Reeves updated the Committee by listing several CDC public outreach efforts]:

- We have updated and revised the HHS/CDC/CFS booklet. It's available to all members of the public. It took a year to get it updated, approved, and printed—it's obviously also available online. Most of what we are doing in education is through contract with the CFIDS Association of America.

- We have finished the third edition of a resource pocket guide for healthcare providers with three sections – background, diagnosis, and management.

- We have revised and received approval for the second version of the Continuing Medical Education Curriculum. CDC offers an updated certification for physicians, nurse practitioners, and physician's assistants. The materials are available in print, USB stick, and web format. It includes an appendix of evidence-based instruments that assist healthcare providers in making a diagnosis of CFS and other resources for consultation. Ongoing and complete bibliographies also are available.

- We have just received approval for a newly developed allied health continuing education certification. These materials were developed specifically for allied providers such as physical therapists, occupational therapists, and psychologists.

- The public awareness campaign was launched November 3.

- For physicians, our focus groups and research indicated that grand rounds teaching forums was one of the preferred formats for continuing education. This lets us target CFS education at all levels of training—the student, the house officers, the faculty, and the allied people who come. We are trying to present a minimum of seven grand rounds programs during the academic year. We're targeting those places with family practice programs.

- Our provider education staff attends conferences to raise awareness by giving talks and sponsoring booths. The conferences we attend are aimed at primary care providers, nurse practitioners, and physician assistants. The booths we sponsor provide diagnostic guides, fact sheets, bibliographies, CDC and HHS booklets. Attendees are offered the opportunity to get CME credits.

- The contract with CFIDS illustrates the value of the government working with a patient advocacy group to increase recognition and diagnosis of CFS. We have proposed collaborations with the Universities of Michigan and Colorado and the Medical Research Council in England that is putting into practice a national treatment program for CFS.

- The measurement of CFS knowledge, attitudes, and beliefs among healthcare providers through research is extremely important. We collect data to do this during the grand rounds, we collect information as part of the CME certification, we have anonymous surveys of providers at conferences, we conduct focus groups with healthcare providers as part of our pilot registry, we have a manuscript in review reporting on the findings of the train-the-trainer study, we have another manuscript that we are finalizing for peer review that documents the findings of the CME initiatives, and we have a third manuscript for which we're just finishing the data collection for our populations in Georgia that will examine the differences in provider attitudes based on professional occupation.

Committee Member Q&A

Dr. Komaroff: Has lack of funding affected your ability to follow through with any of your ongoing research?

Dr. Reeves: There has been payback funding that allowed us to operate at the level of about $9 million a year. That's how we were able to do the population surveys, initiate the registry, etc. That funding ended a year ago. We have funded the first follow-up study in Georgia, the physicians' registry, and the GCRC (General Clinical Research Center in-hospital) study with remaining monies from that. When our current allocation is gone in 2007, we will cease doing population studies.

Ms. Artman: I have already discussed with other Committee members via email the possibility of NIH and CDC working with other organizations to have conferences and other educational opportunities that do not require government funding, but instead use agency names with private funding. I was told that this would involve a director's level discussion. I think that's something worth looking into.

Dr. Bateman: I want to hear more about the CFS pilot registry.

Dr. Reeves: We have started a pilot registry in Macon, Ga., an urban population, with the idea of seeing how this will work. We have contacted essentially all health care provider in this urban area—there is a medical school and two HMOs in addition to having private practitioners, school nurses, chiropractors, occupational therapists, physical therapists, etc. We've contacted all of these people and we're just at the end of doing focus groups with them. They will refer us all of their patients that have an unexplained "chronic unwellness". We will then evaluate those individuals in a clinic and go through the exact same procedures as with those who took our telephone survey. The problem with the registry is that it will be only people who are seeing doctors. I will get a large number of people, but it won't be a representative sampling. More importantly than that, it gives me access to the providers' knowledge, attitudes, and beliefs; it gives me insight into how they're treating the patients.

Dr. Komaroff: What about the funding issue?

Dr. Reeves: The research will stop without more funding after 2007 when this cycle of contracts is over.

Kim McCleary, *a public attendee*: I want to add one other outcome measure that we have as part of the national awareness campaign. CDC annually does a set of omnibus surveys. One goes to the general public and is called Health Styles Survey; the other is

called Doc Styles and goes to physicians. We were able to get 12 questions about CFS embedded in the surveys, which went out last summer. The National Center for Health Marketing has the initial data for what will be considered a baseline survey of public and provider knowledge and attitudes about CFS that we'll be able to reevaluate in the summer of 2007 to determine the effectiveness of the public awareness campaign.

Dr. Reeves: We now have measures on a national level and on a regional level, and if they don't add up, it will give us ideas for research.

Provider Group Testimony on Enhancing Provider Education

[Next **Dr. Parekh** introduced the guest speaker, Dr. Lucimar Cose-Cannon, special assistant to the director of the Pan-American Health Organization (PAHO) and a certified gynecologist and obstetrician by training in Brazil. Dr. Cose-Cannon has worked over the past 25 years for the government of the Federal District of Brazil hospital system as a consultant and as director of several health centers. She worked for the Ministry of Social Security of Brazil and the Ministry of Health of Brazil before earning a masters degree in public health and a PhD at the University of Dundee in Scotland. She joined PAHO in 2000 and has extensive international experience in adolescent health and chronic disease prevention and control.

Dr. Lucimar Cose-Cannon, Special Assistant in the Office of the Director of PAHO

I would like to explore how CFSAC and PAHO/WHO (World Health Organization) can work together. I'm not an expert on CFS, but I think in the last 48 hours I got to know a lot, and based on my experience and the knowledge of my organization, possibly we could explore some work together. I want to know more about your needs and how PAHO can help the Committee.

Dr. Parekh: How does PAHO approach diseases about which the organization thinks there needs to be more awareness in the provider community?

Dr. Cose-Cannon: We have a counsel on which all member countries sit and direct the work of PAHO. The organization was started 104 years ago and maintains the largest data base on health in the Americas. We issue a document called Health in the Americas every four years. When we notice that something is becoming a growing public health problem, we start to talk with member states about how to address it.

In the case of CFS, we don't have anything very specific. It is competing with many other priorities. Funds are needed to address public health issues and there are limits. I had a health economics professor at New York University who started all his classes by saying that we must be efficient because there are three things of which we can be sure: we are born, we will die, and there will not be enough money for health. This struggling with funds is everywhere in the world. There is not a homogeneous definition of CFS.

[**Dr. Cose-Cannon** provided a list of ideas for collaboration between the CFSAC and PAHO/WHO]:

- As a member of PAHO, the United States can request action from the organization to address CFS.

- PAHO could put a CFS link on its home page. It would help boost CFS on the agenda of the United State as well as the world.

- PAHO is in the midst of an organizational shift in knowledge management and information, with more tasks performed electronically. CFSAC could create a software CFS Checkpoint within PAHO, then post documents and create a link to them. PAHO could provide software "keys" so that those on CFSAC could enter and post comments in the members-only area. PAHO has found Checkpoint safer and more practical than email for such discussions.

- CFSAC could propose changing and clarifying the definition of CFS within the Family of International Classification, where it now appears under both brain disorders and mental health.

- A proposal could be made to PAHO's research committee to expand CFS research in Latin America and Caribbean countries.

- PAHO/WHO has a large number of collaborating centers. CFSAC could work with PAHO to find out which of these centers are interested in CFS or start the process of designating a new collaborating center.

- CFSAC can explore with PAHO's unit on non-communicable diseases the possibility of adding CFS as a topic.

- CFSAC and PAHO could approach the WHO European office about expanding CFS work, since the disease gets more press in Europe.

Committee Member Q&A

Dr. Friedman: What is the relationship of WHO and PAHO?

Dr. Cose-Cannon: PAHO was created before WHO. We are the health agency of the Organization of American States. When WHO was created in 1946, it needed to have an office in each of six regions. PAHO became the regional office of the WHO. We have two budgets—a small one for OAS and one for WHO, which comes from the United Nations. The programs of PAHO are basically those of WHO.

Dr. Friedman: Do WHO and PAHO both recognize CFS as an illness?

Dr. Cose-Cannon: We recognize it because it is in the International Code of Disease. We can't establish the cause, but we understand something about treatment. We think that health professionals should be well informed about the disease.

Dr. Friedman: How does CFS rate in your priorities?

Dr. Cose-Cannon: There are many Americas. We have a well-developed America, we have an America that has a medium level of development, and within the countries we have pockets of incredible poverty with communicable diseases prevalent. The first priority is to tackle poverty and the diseases of poverty. The emergence of disease and

poverty rise hand in hand. As you are trying to put CFS in the agenda, we could try to do it together.

Dr. Friedman: Would it be fair to say that the prevalence of CFS in South American countries is relatively unknown?

Dr. Cose-Cannon: I think so. We could see if we could contact ministers of public health and conduct some surveys, especially in the more developed countries such as Argentina, Brazil, Mexico, and Colombia.

Dr. Friedman: The first study that would need to be done is a prevalence study to determine the magnitude of the problem, and I suspect it would have to be done on a country-by-country basis. Are you aware of any programs for CFS in either PAHO or WHO?

Dr. Cose-Cannon: I didn't have time to search for programs. I just talked this morning with a consultant said who said that neither the non-communicable disease office nor the mental health office has a program—it's a new thing for us.

Dr. Parekh: Does that include funding research in member countries as well?

Dr. Cose-Cannon: Yes.

Dr. Parekh: Is there any WHO or PAHO funding for ongoing CFS research?

Dr. Cose-Cannon: We could mobilize some funds, but I would have to talk to my director. I think that we have to bang the drum—say that this something that is growing and becoming a health problem. We could work together to disseminate that information.

Dr. Cavaille-Coll: I would say that as much as one-half of the new drug applications contain foreign data, which leads to my question. I thought I heard you say that within your organization there's a divergence in the definition of CFS—it this true?

Dr. Cose-Cannon: It's not about the countries; it's my review that I've done. I notice that there is a Barraca definition that is more complete, and when I look at the International Code of Disease, it's not the same. We need to standardize the methodology and definition, and then you can compare the data.

Dr. Reeves: There are people doing research on CFS in Latin America. The problem is that there are a lot of people—20 million in Mexico City alone—and the terminology is not simple. This isn't the big public health problem in Latin America when people are dying of vaccinable diseases. Health programs want to prevent things where they can get a big bang for the buck rather than try to conduct studies in places where there are no telephones. It's premature to be really thinking seriously about that.

Ms. Fitzpatrick: What about getting something into the Health in the Americas chapter on the United States?

Dr. Cose-Cannon: The deadline for contribution to the 2007 version is already past.

Dr. Bateman: What is the attitude of providers in Latin America towards CFS?

Dr. Cose-Cannon: There is a need for more education. There is a long way to go in creating an attitude of acceptance. We have an association of public health schools, and PAHO could help you put into their agenda a discussion of an investigation of hospitals, centers, and doctors' attitude. PAHO and the CDC are already partners on some other programs.

[Dr. Parekh called a five-minute break.]

Discussion on Enhancing Provider Education/Awareness

Dr. Parekh introduced the afternoon session by underscoring the important relationship between provider awareness of CFS and the advancing of research and effective treatment. He opened the floor for Committee discussion by dividing provider education/awareness into two parts:

Part 1 – What should we tell the provider community?

Part 2 – How do we get that message out?

He invited Committee members to brainstorm about future actions to improve provider education/awareness.

Measuring Provider Interest

Ms. Fitzpatrick asked whether any new patterns have emerged in the way in which physicians take an interest in CFS, such as rheumatologists treating fibromyalgia or oncologists treating CFS. **Dr. Reeves** replied that CDC has not formally measured this in the past, but is measuring it now in provider focus groups. The information will be baseline. Right now, he said, there is probably anecdotal information on who's interested in CFS, but no long-term statistics on whether this is changing or expanding.

Dr. Parekh wondered whether the evaluation of the CDC's national CFS outreach program might include measuring physician interest. **Dr. Reeves** confirmed that physician interest will be measured nationally in the outreach program evaluation, but won't give the same sensitivity as the information collected from the analyses and registry in the local Georgia study.

School Curricula

Dr. Oleske supported the idea of getting CFS better covered by medical school curricula, especially now that more schools are recognizing the value of humanism in medicine. He urged the Committee to focus on how it can use the humanism movement to introduce CFS into curricula, perhaps through a scholarship, as the New Jersey CFS Association has done. He said that physicians become interested in CFS only if there is support for doing chronic fatigue work. This type of support could be generated through a clinical trials network with sites at medical schools.

Dr. Reeves: The Committee has discussed how to get CFS into medical school curricula several times, and it's not simple. Both New Jersey and Pandora have scholarships. Graduates should be tracked to see what they do when they get out of

medical school so it can be determined if these scholarships are an efficient use of the money. The grand rounds presentations were started to get CFS into the curricula. The other way that it enters is due to general interest and scientific credibility. To some extent, it's what faculty members are reading about in the literature and get interested in themselves.

Speakers/Booths at Medical Conferences

Dr. Bateman: If there are a million Americans with CFS, and each specialist treats 1000 people with CFS, it would take a thousand providers to offer any kind of standard of care. This Committee needs to think about how to get information quickly to a huge number of providers. If we think that each primary care provider should see 20 CFS patients, 50,000 providers would be needed to treat a million individuals. How do we get the word out to 50,000 primary care physicians that the CDC toolkit exists for them?

Ms. Fitzpatrick: Getting some speakers trained to present at conferences and getting speakers to submit papers to those conferences. That reaches providers, and it doesn't tell them what has to be in their curriculum.

Dr. Reeves: That's one of the things that we're already doing aggressively, although people might say not aggressive enough. Each one of those things costs money. What is in fact the outcome? What difference would it make if I presented and set up a booth at each conference? How many people would I attract? We are just beginning to figure out what conferences to go to and what information is best to get out in a group. The amount of money to do that exceeds our budget. We need to evaluate the most effective method and see what works.

Patients as Educators

Ms. Artman: There tends to be a lack of looking to the patients to be educators. I go out and see doctors. I have no problem taking the toolkit and putting in their hands. You look at the membership of the CFIDS association; you look at the membership of the Dallas-Fort Worth group. If you can get patients doing this at no cost, you're reaching people who see first hand someone who has this illness. I think this is one of the best tools we have available, and the cost is printing and shipping to patients.

Dr. Friedman: I want to reinforce what Rebecca said. The New Jersey CFS Association produced a consensus manual in 2003 and distributed it to every physician in the state. The Academy of Medicine of New Jersey distributed it under contract with a state health agency. One of the unexpected byproducts was that some copies fell into the hands of patients, which validated their illness. They took that manual to their treating physicians. In many cases, it was the event the turned the tide by inducing the physician to read the manual and give appropriate treatment.

Ms. McCleary: We're using what is called in social marketing a push-pull strategy with health care professionals in the CDC national awareness campaign. Patients recognize themselves in the ads, and then do the educating with the providers. Although physician focus groups say that they don't like when patients come in armed with materials, we know that that's the way things happen in the consumer savvy marketplace.

Medical School Scholarships

Dr. Friedman: When education is provided to practicing physicians, it is more of an uphill battle to gain that practitioner's acceptance. The longer they are in practice, the more they are convinced that they've seen it all and know it all. If a patient comes to them with some vague illness, it can be dismissed by that practitioner.

The New Jersey CFS Association Medical Student CFS Scholarship does not compete with school curricula in order to avoid the appearance of animosity or lack of cooperation. The program runs in the summer between the first and second years of medical school—the only summer that students are not involved in class work. Students submit essays on an assigned topic relevant to CFS, those submissions are judged, and one award will be made in the fall. All applicants learn about CFS. We feel that they learn more than during grand rounds presentations. This is the first year that we have done it. If we can mount a $25,000 endowment, the University of Medicine and Dentistry will rotate the scholarship through all three New Jersey medical schools.

Due, I think, to the state association's informal PR campaign to raise CFS awareness in medical schools, a new component called "patient behavior in unexplained illnesses" is being added as part of the third year clerkships. The state association has been invited to send speakers to explain their illnesses and how that has modified their behavior.

Dr. Bateman: Is there some way in the Federal system to augment that by sending the word from the top down to physicians that this is a big public health problem and we have this resource [the CDC toolkit] to access? Physicians have all the tools they need to take care of this illness. They just need three things: information on how to diagnose, an understanding that it's OK to treat patients symptomatically, and access to our state of knowledge.

Teacher Resources

Ms. Healy: In undergraduate medical and other professional education, a professional will access information when he or she feels the need. One way to create that interest in the medical curriculum would be to create teacher resources. If we could create objective, structured, clinical examination kinds of cases ready to go to an educator, it may help them see this as a chronic illness model that can be used in various ways in curricula. When creating a case, it takes hours and hours to write the script, then train the TAs. If someone could do the script part, it would really help a lot of people.

Top-Down Message from HHS

Dr. Robinson: It may not be appropriate for the HHS Secretary or Assistant Secretary to write a letter to individual providers, but such a letter might be sent to the Federation of State Medical Boards, or to each of the 50-plus members of the federation, asking them to share information. It might carry some weight, since physicians are licensed through those boards. Another group is the American Board of Medical Specialties. If your specialty board forwards something to you, there's a tendency to give it more credence. The Committee may want to consider crafting such a letter that could be sent to the Secretary or Assistant Secretary.

Ms. McCleary: We used the top down approach at the press conference launching the CFS national awareness campaign by having Dr. Agwunobi and the CDC Director at the

podium to signal the importance of the message. The conference generated 140 news articles of what was said at the podium, including those in the AMA newspaper, WebMD, and a series in the specialty journals of the International Medical News group.

Dr. Reeves: Part of the campaign is to drive people to the CDC website for more information. We will send as many hard copies as somebody wants. We'll be able to track that, which we are doing now.

Dr. Hanna: One of the results of the follow through on the press conference is that I have had several calls from people who have not been able to get through to CDC. They know the material is on website, but they want human contact. There should be someone there who can talk. [Dr. Reeves noted that only three people are available at CDC to answer questions, while Dr. Hanna replied that she is the only one who can handle the calls at NIH.]

Dr. Friedman: I have had a concern over infrastructure for the campaign. If it successfully generates interest from patients for getting diagnosed and treated, they'll want to know how in their local area. The infrastructure to do that has to be generated as quickly as possible so that people can be treated as quickly as possible.

Dr. Hanna: Based on my experience in dealing with alcoholism from the time it was generally considered a crime until it was recognized as a disease, I wonder if you could get state public health departments to license some of the major hospital clinics to distribute toolkits. CDC already collects much of its data through the states. No matter what you do to change attitudes, you have to keep doing it, because when you stop doing it, everything goes back the way it was.

Dr. Friedman: If you [Dr. Reeves] want to put together a package that you want a state department of health to have, I would pilot it with the Department of Health of Vermont because the Vermont CFS Association has a working relationship with the state and they are willing to work with us to disseminate information to physicians.

Dr. Reeves: A group requests that we send them the material, and then the group deals with it. If I have the idea of distributing this to every state health department in the country, that is not a trivial bureaucratic decision. HHS must determine that it will be sent. It's much easier to respond to a request. But I think that it is a strategic move that we can keep in mind. Another strategic move on which we have not acted is aggressively going to insurance companies, third party providers, and big HMOs.

Dr. Friedman: We obviously can't do all of that at once. How should we begin to implement these plans? Can we make the assumption that one good plan would be to divide up the country on a state basis and try to disseminate information within states?

Dr. Reeves: I think it's a plan that's worth considering, along with how it will be done and who will do it. There also has to be some measure of what I have gotten for my money. What is the outcome that I can measure by distributing these to every state health department in the country? Who in the health department is interested in receiving them? What are their knowledge, attitudes, and beliefs before and after they got them? It would be a serious campaign.

Dr. Friedman: Is it CDC's job to come up with a plan?

Dr. Reeve: With the resources that I have, I wouldn't make it one of my priorities.

Ms. Artman: What about state medical associations? I know that my state association in Florida treats everything from the CDC as the end all be all. It can be done via email so it doesn't have to cost you anything.

Dr. Reeves: We had all kinds of buy-in from one medical society about distributing the toolkit, with four meetings, including one with the executive director. At the end of all of it, they asked for $4 million to do it. That's what becomes the problem—making the ideas operational.

Third Party Payers

Ms. Fitzpatrick: I'm interested in third party payers. I don't see why a family physician would want a CFS patient in the practice, because they don't pay very much. You order a medication for somebody, and they come back and say they can't afford to buy it because their insurance won't cover it. Could we get a letter like Bill Robinson's letter tailored to third party payers that provides some CFS information and asks them what their policies are on CFS? We could then invite them to a meeting. I would like this Committee to be proactive in this regard. The Education Subcommittee did send out letters of inquiry.

Dr. Bateman: Being a veteran of dealing with third party payers, I hate to be cynical, but unless you can convince them that they can save money by diagnosing and treating patients, they won't be interested.

Dr. Reeves: There is a growing body of evidence that early intervention is associated with shorter duration of illness. Seeing primary care providers is associated with a shorter duration of illness. That data is not as good as it could be. It's something we'll be looking at in Georgia and will be quantifying this year. But how do I get to Blue Cross/Blue Shield and Kaiser to get them the information and start a dialog?

Dr. Komaroff: They have organizations. But I think that Cindy's point is right. It's not only being able to get to them, its having a message that they want to hear.

Dr. Bateman: But this message is strong. It would be a good project to show third party payers that they would save money, and maybe we should be thinking about that kind of a recommendation for funding.

Mr. Newfield: Practically speaking, one of my concerns is that the providers who are paying for the medicines and those handling the disability claims are often different. The disability claims are dealing with patients' ongoing monthly benefits, and providers want to minimize that. Then you have the providers that pay for medication, and they don't see any cost savings from getting the person back to work. Each type of insurance company is out for its own benefit. I don't think you're ever going to get the insurance companies to come to this forum unless you leverage one of the Federal organizations to emphasize the increasing recognition of CFS.

Dr. Robinson: One reason for earlier suggesting the Agency for Healthcare Research and Quality is that whether it is cost effectiveness or medical evidence, those are areas handled by AHRQ. Also, is CMS spending any money on CFS, either through Medicaid or Medicare? Do they have any vested interest in saving money on costs by looking

into some of these questions? We need to get each of these groups, including insurance companies, to look at what their best interests are, then approach them individually rather than as a monolith.

Dr. Bateman: It would be a great study for Medicare to look at patients and see if early intervention makes a difference and how many people collect disability insurance.

Dr. Parekh: I think insurance companies to a large extent follow Medicare in terms of payment policies. As Medicare tries to take a more chronic approach to CFS given the demographics, by framing it in a way that early intervention reduces costs, it's certainly something in CMS's interest even if it's just in the Medicare population. I think it would be interesting for someone from CMS—and potentially representatives of the various health plans—to come here and describe how they view CFS. Let's become aware of how insurance companies are paying for various therapies for their CFS patients. We should know where they stand.

Dr. Hanna: I wonder how many patients are actually given a diagnosis of CFS and how many are getting treated under other diagnoses in which they're treating symptoms and that's why they're getting reimbursed. They might not get reimbursed with a diagnosis of CFS. We've had research for 20 years that shows that it's real, but it's not going to make any difference to the insurance companies. HHS agencies have regional offices—don't they have contact with state agencies and insurance companies? Maybe it could be explored regionally.

Dr. Parekh: HHS certainly does use the regional offices, particularly CMS and the Assistant Secretary's office. One operating division that does not have a full regional office is the CDC, which is in the lead for provider education. I see one pathway where CDC is the lead assisted by the Association of State and Territorial Health Organizations, and one where the regions contact the state and medical societies. And maybe it's all of the above, including a letter from the Surgeon General to certain groups.

Ms. Healy: Is there any way that some part of the continuing care of a patient with CFS can be incorporated into some of these bodies that are overseeing accreditation and other issues? That's one way to change behavior—make it be measurable.

Dr. Robinson: It's going to sound like a broken record, but I'm going to go back to CMS and AHRQ. One of the things that the Secretary has been pushing as he goes out to talk to groups is that the quality of care in this country is going to become even more important as it's related to reimbursement for care. Right now we don't have standard mechanisms for CFS that call for certain kinds of care for certain kinds of conditions. What's going to happen in terms of pay for performance is that people will be expected to meet certain standards if they are going to continue to receive funding, under CMS in particular. The reason that I keep encouraging the group to listen to CMS and AHRQ is to hear from them what they are looking for in terms of quality of care for patients with CFS. If CMS is currently paying for it, why not get them to come and say what they consider to be value? What is it that they're looking for that would allow them to start paying for CFS if they're not doing so now? If insurance companies do come here, without putting words in their mouth, ask them what their experience with CFS patients is and let them be forthcoming.

Ms. Fitzpatrick: I think that's part of what our real mission is, to gather information on all aspects of this disease so that we can make recommendations and find and plug the holes where information is missing.

Dr. Bateman: I think that third party payers have a lot more information than we know. They just don't have the motivation to release it. There was a study done in Salt Lake City about fibromyalgia using Blue Cross/Blue Shield data that I thought was stunning and changed the way we look at the disease in terms of the demographics. That information is out there if we can motivate them to share it in a non-threatening way.

Dr. Friedman: I'm not sure that the information out there is accurate. My experience in talking to patients is that if they want to get billed, they have to use other diagnoses and other codes.

Dr. Robinson: What I'm saying is just get the information on the table.

Dr. Friedman: If the physicians treating patients do not acknowledge that CFS is an illness, you're not going to get CFS as a diagnosis.

Dr. Bateman: That information would still be useful to us.

Dr. Robinson: All I'm saying is get all those perceptions on the table. First find out what seems to be their perception of reality so that you have a basis for determining how you want to respond to it.

Ms. Artman: If we invite CMS should we then provide them with the long list of the codes that are possibly used to diagnose CFS?

Dr. Bateman: Just see what they have to say first. I bet they are much more savvy than we think about cross-over of these codes and related codes.

Dr. Hanna: Bill is exactly right—you need to know what their criteria are. What do they need to know about CFS to pay for it and what will they pay for it?

Ms. Fitzpatrick: It's something we haven't touched yet that could help us as well as the patient community. I would like to see CMS and invite one of the heads of the insurance associations. I don't know that they would attend.

Mr. Newfield: There are a few companies that do cross over and do both the medical and the disability [Signet, Aetna]. If you can position them as the leaders so that their press release says, "We're championing the issue," that may be one way to get them. You're not going to get it from somebody who doesn't do both the disability and the medical. There's no benefit to them. But I can't imagine either Signet or Aetna wanting to participate in this forum.

Committee members listed as possible speakers for the spring 2007 meeting representatives from AHRQ, CMS, and AMA, as well as Annette Whitmore, who is developing a center of excellence for CFS in Reno, Nevada, using private and state funding.

Mr. Newfield: Reimbursement and provider education are separate issues. I think that at this point we should consider a subcommittee on third party payers so that we can

explore some of the insurers that we may want to invite, how we go about bringing them to the table, and what we're seeking to illicit from them.

Dr. Parekh: I think that reimbursement is tied to providers given the way that the health care system is set up. If primary care providers know that they're not going to get reimbursed for treating a segment of the population, they're likely not to be very interested.

Dr. Parekh amended his earlier division of provider education/awareness into three "idea buckets":

Provider Education (med schools and continuing medical education)

Provider Outreach (how do we get what we have to the provider?)

Physician Reimbursement

Dr. Komaroff brought up the idea of pursuing CDC outreach from a purely electronic standpoint. CDC would contact state health departments and medical organizations about putting a link on their home pages to the CDC's web information and a survey that the person can answer about how useful he or she thought the information was and how it changed his or her practice. Dr. Komaroff said that "the rest of it is so expensive to distribute—paper information and polling people by paper questionnaires. I despair of it ever being cost effective."

Dr. Parekh: CDC has weekly and monthly partners calls on a variety of topics. Would this be appropriate on one of the regular calls to bring up the issue of CFS provider outreach?

Dr. Reeves: Good idea.1

Ms. McCleary: We're actually doing some of that through the National Center for Health Marketing. We have some of the partners who have already signed on to the campaign printed on the back of the toolkit. [**Dr. Reeves** suggested that Ms. McCleary might want to explore further the use of these partnerships to increase provider awareness.]

End-of-the day discussion led the Committee to determine that it would take the PAHO presentation as informational only and not follow up with outreach at this time.

Dr. Cavaille-Coll questioned whether the CFSAC website was being kept up to date and suggested a link to the CDC toolkit.

Closing Remarks

Dr. Parekh tabled further Committee discussion and recommended that members consider how to implement their ideas, either through recommendations or action items. He noted that no decision has been made on whether or not the five Committee members whose terms expired will be able to return for one more meeting. He said that

a decision on that as well as other Committee logistics—including who will chair the panel—will be made before Christmas break.

Dr. Bateman inquired how subcommittees could be formed if five members are rotating off the Committee. **Dr. Parekh** replied that two voting members and one *ex-officio* adviser are required to form a subcommittee. The six remaining voting members are enough to form subcommittees.

Adjournment

A motion for adjournment was made, seconded, and approved by Committee members.

Tuesday, November 21, 2006

Call to Order/Roll Call/ Opening Remarks

Dr. Parekh called the meeting to order and took roll call, then opened the floor to discuss minutes from the April 24, 2006 and July 17, 2006 CFSAC meetings.

Dr. Parekh explained that detailed minutes are provided through extensive notes taken at CFSAC meetings backed up by tapes of the meetings. He said that providing word-by-word transcripts may not be possible under current contracts. He pledged to ensure that future minutes are produced in a timelier manner.

Dr. Friedman requested a definitive answer to the issue of whether Committee recommendations are filtered, or go directly to the Secretary of Health, and if they are filtered, who does so, and why. Dr. Friedman referred to a telephone conversation between Howard Zucker and the Committee in which he stated that one of the recommendations was not being forwarded to the HHS Secretary because it was deemed inappropriate. "To this Committee's knowledge, all of our recommendations were appropriate," said Dr. Friedman. "We had sought the advice of our exec sec (Larry Fields) when we wrote them. To have someone say in a phone conversation a year later that one of them was inappropriate and then not identify it prompted my inquiry. We never got a response."

Dr. Parekh told the Committee that all of its recommendations will go to the Secretary's office and that no filtering will take place.

Committee members discussed specific changes to the April 24 and July 17 minutes. Motions to approve the minutes as amended were seconded and approved. Committee members also made the following requests for future minutes:

- Inclusion on the CFSAC website of written material accompanying the testimony of invited speakers. Guests should be informed in advance to provide written materials electronically if possible. Material that is not available electronically should be archived in some way and a note placed in the minutes about the availability of items by speakers.

- Putting minutes on the website in PDF format.

- Producing minutes in a timely fashion. The chronic late posting of minutes reflects poorly on the seriousness of the Committee and causes repetition of discussions.

Recognition of the Service of Rotating CFSAC Members

Dr. John Agwunobi, *Assistant Secretary of Health*

Dr. Agwunobi praised Dr. Parekh as a "very honest, committed, highly educated professional" whom Dr. Agwunobi brought onto his team "to help keep us connected to what it's all about." Dr. Agwunobi noted that Dr. Parekh practices at night and on

weekends in an emergency ward and told the Committee that "I'm hoping you will see in him some of our enhanced commitment to this issue" of CFS.

Dr. Agwunobi also recognized the volunteer service of Committee members "who sacrifice to be here. In recognition of that, I will try to at every opportunity to attend each of your meetings, if only for a few minutes—if only to say thank you".

Dr. Agwunobi proceeded to specifically recognize the service of *ex-officio* member Dr. Robinson, "a great source of counsel…respected by us all", as well as the voting members who will be rotating off the Committee (the Chair, Dr. Nahid Mohagheghpour; Ms. Jane Fitzpatrick; Dr. Kenneth Friedman; Dr. Anthony Komaroff; and Ms. Staci Stevens). He continued that Committee members serve "not because we ask them to, but because they are passionate and because they are committed", adding that "some may be asked to stay for an extra meeting just to help with the transition."

Dr. Agwunobi assured the Committee that "we will have a full membership at the next meeting…and a chair…It is actually because we are taking this very seriously that we haven't just pulled the trigger and thrown some names on the Committee." He thanked the rotating members for serving on the panel during its early evolution. "We will nurture and strengthen this baby that you have helped keep alive and helped grow. I know there are many out there in the community and I know all of you around this table feel this Committee should do more and should be heard more. I intend to try and make that happen in the two years I have left to serve."

Rotating members were recognized individually with a plaque and a letter. Individual photos were taken, and Dr. Agwunobi said that the letters of recognition will go on the HHS website. "I would advise each individual who rotates off the committee to stay involved," Dr. Agwunobi concluded. "I worry that the community that understands and that recognizes this issue is still a fairly small community. We'll be calling on you for second tours of duty, I have no doubt, either on this Committee or in other settings. Your work is done for now, but not forever, I would hope."

Committee Member Q&A

Dr. Agwunobi applauded the work of advocacy groups and the CDC for launching a public awareness campaign that will help fix "once and for all in the minds of science and in the minds of practice the fact that this is a condition that is a real condition that needs to be taught, that needs to be discussed, that solutions need to be sought for." He called the release of the CFS Toolkit a "watershed event". He thanked advocates who have often "shouted from the wilderness in the middle of the dark and refused to stay quiet, because I sense there's movement."

Dr. Friedman: I have two concerns. Our charter was not renewed, it was rewritten, and in the rewriting, the number of meetings has been reduced from four per year to two per year. I am concerned that the length of time between meetings will actually reduce the productivity of this Committee. I think that two meetings a year are inadequate. I am also concerned about the reduction in the Committee's budget to less than half of what it was. While we speak of renewed support and endeavor, my concern is that the restrictions of the new charter will prevent or impede the level of productivity and momentum that this Committee has achieved.

Dr. Agwunobi: Time will prove the point that I'm about to make. I'm committed to having this Committee over the next year be more productive than it has ever been before. Much of the work that needs to be done needs to be done between meetings, with the chair, with the community, and with our staff. Meetings need to be about focused discussion on issues that have been charged to the staff and pulled together prior to each meeting. I'm going to be monitoring very closely and reporting to the Secretary whether or not it's working. I'll be seeking the Committee's thoughts as I go along as to whether or not it's working for you. Our hope is that we can begin to make these meetings intense, productive, and satisfying to you and productive and impact to the community.

In terms of money, I urge you to recognize that I'm not sure that the sign of a good committee is how much it spends. I recognize that below a certain amount, it becomes ineffective. If we're not spending enough, we'll spend more. I'm committed to spending what it takes to get the job done. I have a high bar in terms of efficiency and expectations of staff. Our staff wasn't entirely efficient in the way it was managing the Committee in the past. Hold me to the fire, watch me closely, and tear me up if you think I'm failing.

Ms. Artman: Two day meetings are very difficult for CFS patients and it's important for patients to participate because it's how they know that government does care about them. While a two-day meeting is productive, it might be something to address down the road if we see that patients are not coming out as much.

Dr. Agwunobi: Duly noted—that is an important consideration. We're trying to find the right balance. We recognize that people travel to these meetings. Traveling four times a year is sometimes harder for the patient community than traveling two times a year. We may well find that we end up with a balance of three times a year. As much as a charter is a formal document that moves you forward, it is not a ball and chain restriction on what we should or can do. I would urge those living with the condition to give us feedback on how the process is working.

[Dr. Parekh called a five-minute break.]

Review Response of HSS to CFSAC Recommendations

Dr Parekh opened the review session by pointing to a November 3 letter included in the meeting packet with a five-page summary from Dr. Agwunobi to Dr. Mohagheghpour outlining actions that HHS has taken on the Committee's eleven recommendations. Dr. Parekh credited the efforts of *ex-officio* members for the fact that many of the recommendations are being addressed. Committee members agreed to discuss the recommendations one by one.

Ms. Artman noted a point in Dr. Agwunobi's letter that CFSAC recommended a permanent NIH review committee for CFS-related applications. CFS has not yet made the 25-application threshold per session for formation of a permanent review committee. Ms. Artman inquired how many CFS applications were received by NIH last session. **Dr. Hanna** replied that eight had been received, but that the 25-application threshold for a permanent committee had been reached by combining CFS with fibromyalgia and

TMJ. The head of the review committee happens to practice in the field of dentistry, noted Dr. Hanna, but also "brings in the right scientists for the job."

Dr. Parekh asked a general question about review committee member qualifications. Dr. Hanna replied that many applications involve basic science, so the committee requires highly skilled members who may not necessarily be CFS experts, but who are experts in their field. Also taken into consideration are conflict of interest and availability of the reviewer, but there is a huge stable of people from whom to chose. The chair of the review committee for the RFA was a CFS expert.

Dr. Friedman: How can CFSAC, the scientific community, and the public be informed about the upcoming organizational changes at NIH?

Dr. Hanna: The changes are happening gradually. There are many items on the Director's web page. In terms of the review process, when there is a definite plan of action that will be made public too. If I hear anything beforehand that's in the offering, I'll be happy to share it.

Recommendation 1 (Establish five CFS Centers of Excellence within NIH)

Dr. Parekh: We discussed some of this yesterday in terms of the Roadmap initiative. Eleanor will keep us informed about the possibilities for funding.

Dr. Hanna: There are Roadmap initiatives available that researchers can apply for now. What I was talking about yesterday was getting Roadmap money specifically for CFS, but that doesn't preclude CFS researchers from forming their own consortium.

Recommendation 2 (Expedite issuing an RFA for CFS)

Dr. Parekh noted that this had been accomplished with NIH's recent award of seven research grants. **Dr. Hanna** added that although the RFA is a one-time event, there's a PA that covers the same things and at its reissue, more emphasis has been placed on the interdisciplinary nature of the research in order to attract multidisciplinary teams. **Dr. Komaroff** asked whether having a PA improves the possibility of research funding as opposed to a standalone R01. Dr. Hanna answered yes, because not only is the PA updated as the science changes, each of the representatives from the Institutes puts in items that are of specific interest to their Institute. Dr. Hanna put links to all of the Institutes on her office's homepage so that applicants can see what's being prioritized.

Recommendation 3 (HHS should fund an international Network of Collaborators for multidisciplinary CFS research)

Ms. Artman asked Dr. Hanna whether the model presented by CDC to the trans-NIH Working Group will be reevaluated since it was found not to be robust enough. Dr. Hanna replied that "that's just a nice way of saying that the committee wasn't eager to get involved in that kind of collaboration, and I think they'd be more receptive to the one I presented yesterday."

Recommendation 4 (HHS should fund an intramural staffed laboratory for CFS research)

No Committee discussion

Secondary Recommendations (5-11)

Recommendation 5 (HHS should fund research directed toward pediatric and adolescent CFS)

Dr. Komaroff asked if substantial effort has gone into designing a study of this population that won't be completed due to lack of funding. **Dr. Reeves** replied that the most promising is the registry, which is going into schools. Funding is available for the first phase of the registry, but without further appropriations, the registry will be cancelled. **Dr. Hanna** said that NIH is funding prospective studies on adolescents.

Mr. Newfield noted that the July meeting minutes state that the registry is fully funded. Dr. Reeves explained that under a contracting task order, the first phase of the registry is fully funded. Subsequent phases would have to be funded on a year-to-year task order basis.

Recommendation 6 (HHS should continue sponsoring CFS workshops for interested investigators)

Dr. Hanna repeated her plan to convene a meeting of the researchers awarded a grant under the RFA with the intention of getting them to work on a collaborative alliance.

Dr. Reeves added that CDC is planning a March 2007 workshop involving the international collaborative group to consider problems in CFS detection, evaluation, diagnosis, and treatment. Workshop content will rely heavily on the British experience. "We're going to try to identify those public health research areas related to the logic model I put out," he explained. The next Cold Spring Harbor-type meeting will be at the conclusion of the GCRC study. CDC is also sponsoring a workshop in March at the Society for Behavioral Medicine. He clarified that GCRC stands for general clinical research center, which is an NIH-funded center at a university that conducts in-hospital research.

Recommendation 7 (HHS should pursue making CFS a training topic for healthcare providers at Department-sponsored conferences)

Ms. Fitzpatrick noted her concern that the allied health professional program was not deliverable, but was reassured by **Ms. McCleary** that the web-based version is up and available and the print-based version is at press and currently has 700 pending requests. Ms. Fitzpatrick asked about plans for a train-the-trainer program, and **Ms. McCleary** replied that there are no plans at present to do the train-the-trainer format.

Dr. Parekh inquired about data on what percentage of people with CFS who are diagnosed and being managed were diagnosed and are being managed by physicians versus to allied non-physician providers. **Dr. Friedman** suggested that "I don't even think that is a fair question to ask" because the diagnosis of CFS is a process, and it usually takes more than one healthcare provider to raise the possibility. CFS is a gradual diagnosis that comes about by seeing multiple healthcare providers.
Dr. Parekh noted that he was asking in relation to figuring out who the target groups should be for provider education efforts. Dr. Friedman said that he has personally modified the CDC curriculum and given it to allied healthcare professionals, the caveat being that the organization sponsoring the seminar must be able to provide continuing

healthcare professional education credits. Dr. Friedman said that it is certainly feasible that if an organization wants such training and can provide the credits, the curriculum can be modified for the members of that organization. **Dr. Reeves** noted that the CDC has accredited the course through the CDC Accredited Continuing Education Units.

Ms. McCleary clarified that the train-the-trainer program was an effort to build a core group of people who could give CFS talks to their peers. There are members of the speakers' bureau who are giving the curriculum to audiences when identified or upon request. There is, however, no plan to set up a training mechanism. **Ms. Fitzpatrick** asked how speakers qualify. **Ms. McCleary** replied that the speakers' bureau has just begun to be built, and those giving the curriculum are people who went through the train-the-trainer program of several years ago. Her group has also partnered with other organizations to find qualified individuals.

Dr. Reeves: Most of the people in the speakers' bureau are internationally recognized experts, including myself, Dr. Klimas, and Dr. Bateman.

Ms. Fitzpatrick pointed out that there are meetings in the allied health field where it would be appropriate for a therapist to give the program, and inquired how a person could get trained to provide the course? It was noted that CFIDS has given the course at meetings of physical and occupational therapists and for social services professionals and a multidisciplinary allied health audience at Lake Forest University. It was noted that the speakers' bureau has been able to take care of requests. Ms. Fitzpatrick asked that for the next meeting, the minutes include how a person can become qualified to give this presentation.

Dr. Reeves: Reaching allied health professionals is something that CDC has worked on for over a year. The key question is who do people with CFS see? Who takes care of them? We have an article in review on utilization of complementary/alternative medicine. We are disturbed by the fact that only 16-20% of those with CFS have been diagnosed and are being treated for the disease. They are being treated for something else. When we find out who is treating them, we can then modify the training program accordingly. Georgia is really the site for determining who is using allied health professionals without a physician. A lot of the targeting and testing is going to be done in that population, and we'll have some results. We can discuss that in detail at the next Committee meeting.

Dr. Oleske brought up the fact that no one on the Committee represents the Veterans Administration or anyone knowledgeable about the Gulf War Syndrome, with the exception of Dr. Reeves. He asked whether members want the panel's work to be more inclusive of that issue. **Dr. Reeves** replied that the CDC wrestled with the issue and a major part of its research portfolio is looking at unexplained fatiguing illness in the military. He noted, however, that it is a CFS Advisory Committee "and if you begin to get outside that illness, no matter how similar they are, you begin to dilute your mission". **Dr. Robinson** also noted that the predecessor to the CFSAC had VA and Department of Defense (DOD) speakers make presentations and that this information should be made available to Committee members before they decide to bring in another presenter.

Dr. Oleske: It is very possible that sometime in the future, a voting panel member will have an interest in the Gulf War. I didn't know if a better response might be to have an

official representation from the VA system or DOD. I didn't know if the panel thought we were being short-sighted and not inclusive, or as Bill said, we're just trying to stay within the limits of what our name is.

Dr. Reeves: I have mixed feelings. It might be more valuable to engage the VA and SSA from the standpoint of how they treat medically and psychiatrically unexplained disabling illnesses.

Dr. Oleske: Should we recommend that we seek out a panel member from the VA? It looks like this Committee doesn't have a voice for the veterans who suffer CFS illnesses whether we call it by any other name. I think the VA is further along with rehabilitation for CFS. There is a wealth of research and educational outreach that goes on in that world that we don't know about.

Dr. Reeves: I think the whole decision is going to be on what the Committee's priorities are and if this fits into the strategy. It looks to me to be the education and treatment aspects of CFS. What would the VA contribute to this process?

Dr. Oleske asked advocates in the audience to address the issue**. Ms. McCleary** noted that the CFSAC advises HHS, and the VA is a completely different entity. The HHS Secretary can't impose anything on the VA. "We have to be careful of those sorts of turfing issues. But I see tremendous opportunity in taking the educational materials that we've developed and distributing them to their tremendous network of providers and to vets' family members."

Dr. Parekh echoed Dr. Reeves in saying that resolution of the issue depends on the Committee's strategy and the direction in which it wants to head.

Ms. Artman reminded the Committee that Dr. Nancy Klimas, president of the International Association for CFS and a speaker at the July 17 meeting, practices from the VA, "so we do get some voice from the VA". She continued that the subject of a speaker from the VA was discussed at that meeting. **Dr. Freidman** reminded the Committee that the July 17 minutes contain some discussion of including the VA, with the panel concluding that it would be an excessive broadening of its mission and open the door to discussing other illnesses such as fibromyalgia and Lyme disease. He suggested that the Committee stick to chronic fatigue. Any of the other information can be learned from subcommittee reports, he said. No one is precluding subcommittee members from learning how the VA creates its models and treats its patients and reporting back to the Committee.

Ms. Fitzpatrick pointed out that under Recommendation 11 "the Committee voted not to expand the scope of the Committee to non-CFS diseases at this time" and to hold off on inviting representatives from VA and DOD until a framework is developed for their participation. **Dr. Parekh** asked when the VA last made a presentation on treating Gulf War-like illnesses, and **Ms. McCleary** recalled that a VA representative named Mark Brown made a presentation in 1998 or 1999. **Dr. Reeves** maintained that more presentations would not support the panel's priorities. **Ms. Artman** suggested that CDC encourage VA to use the toolkit, but Dr. Reeves replied that VA should take the initiative to request and make use of the resource.

Recommendation 8 (HHS should encourage continuing education for SSA reviewers and adjudicators)

Dr. Desi expressed concern that the memo wording makes it sound as if SSA training efforts were a one-time occurrence in 2005-2006. In fact, the reviewer and adjudicator training programs are ongoing, including web-based training, he said.

Recommendation 9 (HHS should conduct a public awareness campaign)

Dr. Komaroff asked how often HHS public awareness campaigns are ongoing, as with the anti-smoking effort, and how they receive one-time funding. He inquired if it is reasonable to ask for ongoing support for the CFS campaign. **Dr. Parekh** pointed out that funding issues are often tricky, with many projects funded for a year or two in hopes that people will continue to advocate on its behalf. **Dr. Reeves** noted that the CFS campaign is a $4 million allocation directly from the Director's level and is the first major campaign of the National Center for Health Marketing. It is a one-shot allocation. This is why the evaluation is so important, he said, recommending that it remain high on the list of Committee priorities. **Ms. Fitzpatrick** urged the Committee to keep the issue a high priority for the afternoon's discussion about recommendations.

Recommendation 10 (The CFSAC encourages classifying CFS as worded in the ICD-10 G93.3)

Dr. Komaroff expressed surprise at the memo's conclusion that not enough evidence-based research exists to warrant revision of the CFS classification. He countered that while the full physiology of what is going on in the central and autonomic nervous system is by no means worked out, there is abundant evidence that there is a dynamic pathological process going on in the central nervous system. **Dr. Reeves** said that the CDC agrees in principle, but the agency does not decree what goes in ICD-10 and taking up the issue is "not worth it right now".

Dr. Friedman inquired about what standard needs to be met. Dr. Reeves said that the first step would be to find out the ICD process for determining that CFS is a nervous system disease. "This is a mind-body interaction involving brain physiology, but I do not know what the lesion is and I do not have a treatment," he said. "The standard to me is that there is a consistent replicated literature showing that same lesion; it all points in that direction. But I still do not have anything definite in that direction."

Dr. Schweitzer: The international body has its codifications. If a disease is not in those codifications, we can put it where we want. The CDC is the North American distribution center. But if a disease is codified in a chapter by the international organization, we can leave it out if we want, but we can't put it in a different chapter. ICD-10 already has CFS under G93.3 under neurology. You cannot have the same disease in two chapters.

Dr. Bateman: I'm sure that the decision to use the current code was based on a lot less evidence than we have now.

Dr. Reeves: Of all of the things that this Committee has to worry about that are going to affect controlling, preventing, and taking care of people with CFS, my personal belief is that this is trivial. This is going to change over time. You're getting into coding issues, which I don't think should be a high priority level for advising the HHS Secretary.

Dr. Bateman: I beg to differ. As a clinician I have to tell you that we deal with these codes every day. You form your opinions about a disease by the classification of the code. The insurance companies make a decision about the severity of an illness or how they're going to reimburse. It's a way of teaching people what we know about the illness. It is not a trivial issue and maybe a recommendation would be to do a little investigation into what the coding process would be and then make a decision.

Dr. Oleske: It isn't trivial, but I agree with Bill that I don't think it necessarily needs to be in our agenda, except to recognize that coding determines how much a physician gets paid and which physician can see a patient. It has billing implications that would require a lot more homework. If we want to do it, we probably need to table it and look into what the implications would be.

Dr. Friedman: I think it is a legitimate concern and part of the disability/patient treatment discourse to consider what the implications of the ICD code are on both. But we're not ready to do that today. It's a subcommittee charge.

Dr. Hanna: I think about the possibility of classifying it as a nervous system disease—eventually I think everything is going to be classified that way because the brains winds up being in charge of everything. Then if you say it's a stress response, where does that go? You're still in the same kettle of fish.

Ms. Stevens: We did have a presentation a couple of years ago by the National Center for Health Statistics. It might be helpful to review the minutes from that presentation.

Dr. Friedman: There's a whole new system that's going to replace the ICD.

Ms. Fitzpatrick: What you just mentioned is one reason why this recommendation was put in here, to say that we support the U.S. government getting behind changing to the new code system.

Dr. Friedman: My recollection for the specificity of the recommendation is the fear that CFS would be branded a psychiatric illness and if so, insurance companies would exclude treatment.

Dr. Oleske: Before I voted on something like this, I would want to have much more information on what that means. [Dr. Parekh noted that this is the general feeling of the entire Committee.]

Recommendation 11 (HHS should consider CFSAC *ex-officio* membership for DOD, the VA, AHRQ, and the National Institute of Disability and Rehabilitation Research)

Dr. Parekh noted that members can invite any representatives from these agencies to the next meeting.

Dr. Friedman asked that the recommendation response letter and memo be posted on the CFSAC website, and Dr. Parekh responded that he would look into it. **Dr. Reeves** noted that the recommendations are not set in stone. These are ongoing topics, including Committee membership and ICD coding. The important thing is continuity as new members come in. Do the recommendations continue to express Committee priorities and is there progress on them?

[Dr. Parekh called a five-minute break.]

Committee Business/Discussion

Dr. Parekh announced that Olga Nelson will be available during lunch to answer committee member questions about an honorarium, email contact information for members, and conflict of interest and waiver issues.

Committee members agreed to break for a shortened lunch during which they would brainstorm ideas for recommendations, then view the video of the CDC CFS public awareness campaign and take up recommendations and other business topics.

Ms. Artman noted that she heard a rumor that CDC is providing $800,000 in funding for a research project with Simon Wesley's group. Dr. Reeves said that although he met with Simon Wesley the week before, the funding rumor is completely incorrect.

[Dr. Parekh called a break for lunch.]

CFS Public Awareness Campaign Press Conference Video (from 11/03/06)

Following lunch, the CFSAC was photographed as a group and viewed the CFS awareness campaign video. It was noted that the campaign's public service announcement and script are on the CDC website, and the audio file will be put up as well. The agency is working out distribution of video tapes and will keep members informed. **Ms. Healy** suggested that the information be made available in the form of a decision-making tool for PDAs, since clinicians use these widely.

Dr. Parekh thanked Diana Martinez-Fonts for her assistance with the video presentation and throughout the meeting.

Dr. Friedman noted that a successful public awareness campaign will generate patient inquires and asked for assurance that CDC and CFIDS can handle the volume of requests about diagnosis and treatment. Dr. Parekh said that distribution infrastructure can continue to be a topic of discussion. He next introduced Dr. Schweitzer, who had requested to provide her public comments at this point in the agenda to accommodate her travel schedule.

Dr. Schweitzer: I am concerned that in the CDC toolkit, an entire page is devoted to cognitive behavioral therapy, which is very disproportionate to how this therapy is used in clinical practice. I'm concerned about what message that is going to give doctors who may say, "CFS is psychological after all." I'm glad you mentioned NMH/POTS in the toolkit, but I'm wondering if you can also get across that there are other cardiac issues. It's unfair to people who are enormously sick to state that the bedridden need to start slowly, and then they can go about their daily functions. This is not necessarily true. I could have started really slowly and I never could have done my daily functions. There needs to be a sentence clarifying that some CFS patients are so sick that graded exercise will not work.

Committee Business/Discussion

Dr. Parekh opened the floor to discussion about recommendations as well as activities over the next several months relating to staff assignments, *ex-officio* members, subcommittee formation, and the spring 2007 meeting agenda.

Ms. Artman said that members decided at lunch to brainstorm over general recommendations, then pick their priorities and craft the wording. **Mr. Newfield** expressed concern that members will spend unnecessary time on specific wording when the ideas and concepts are more important. He suggested that the Committee focus on ideas and refine wording between meetings. **Dr. Komaroff** supported fleshing out the actual language by the end of the meeting, if possible.

Other discussion points of note:

- The November 3 launch of the CDC national CFS awareness campaign was its most intense phase. Paid advertising will roll out in December and last for about three months. After that, the campaign will consist basically of earned media and publicity generated by the traveling CFS photography exhibit. The target market is women aged 40-60, because that group exhibits the highest prevalence of CFS. To make the campaign longer and more intense and to reach a greater variety of people, more funding is needed.

- Several Committee members expressed concern over what will happen if the CFS awareness campaign generates a large response from patients. Some felt that patients need what amounts to a referral service to direct them about how to find a physician to treat CFS. Others found it impractical to expect this of a government agency and thought that the Internet could fulfill this need. Some members noted that not all CFS patients are Internet savvy and need telephone contact to get more information so that they can approach their physician.

CFSAC Structure

The Committee discussed the need for an active CFSAC chair, especially to drive the work between meetings and assure that draft recommendations end up on the HHS Secretary's desk. Members also expressed an urgency for formulating recommendations promptly before current members rotate off the panel and cannot participate. **Dr. Parekh** explained that the CFSAC chair is appointed, not elected and that the members rotating off the Committee can likely still function as advisers.

He continued that six current CFSAC members are returning. He promised that the Committee will have a chair, a full 11 members, and the November 20-21 meeting minutes completed before Christmas. Dr. Parekh then read Committee guidelines for forming subcommittees:

- The subcommittee provides advice to the parent advisory committee and recommendations for action.

- Formation of a subcommittee requires the majority approval of advisory committee members.

- A subcommittee must include at least two voting advisory committee members.

- The chair, with the approval of the advisory committee, designates members of the subcommittees.

- The CFSAC chair, with advice from the DFO, designates subcommittee chairs and an *ex-officio* member to serve on each subcommittee as a technical resource.

Dr. Parekh noted that CFSAC has had three subcommittees in the past on the topics of education, research, and disability and asked members if they wanted to form additional panels. Although new CFSAC members will not attend their first meeting until spring, they can still become involved in subcommittee work, pending review of the charter and FACA rules and regulations, he said. Members agreed on three subcommittees: Research (to include the issue of a CFS clinical trial network), Education, and Patient Care/Quality of Life (to include reimbursement and third party payer issues).

Dr. Friedman proposed a fourth subcommittee based on communication. He maintained that CFSAC has operated in an insular manner, unaware of other Federal advisory committees and how they operate and the process of Congressional oversight. He proposed a subcommittee to ensure that CFSAC is operating in parallel and being treated in the same manner as other Federal advisory committees and to establish a relationship with those on Capitol Hill providing oversight.

Dr. Parekh told the Committee that he will take on the role of solving operational problems and keeping members apprised of what is going in Congress. **Dr. Oleske** noted that he has attended one and a half meetings under three executive secretaries. Dr. Parekh urged members to observe Committee operations over the next six months before deciding on the need for a ways and means-type subcommittee. **Ms. Fitzpatrick** pointed out that a good relationship between the CFSAC executive secretary and chair builds confidence among members that operations are running smoothly.

Ms. Artman moved, then later withdrew the motion in favor of an informal suggestion that those members rotating out write confidential letters about their experiences on the Committee. Members discussed the benefits of learning what those who are departing see as “the pitfalls and peaks” during their service.

Ms. Healy suggested establishing a subcommittee that would function as a welcome committee to orient new members. **Dr. Robinson** noted that the executive secretary serves that role. He added that current members can also write memos informing Dr. Parekh of problems with Committee operations as soon as possible.

It was moved and seconded that the Committee create the Education, Research, and Quality of Life Subcommittees.

Dr. Friedman suggested that the Committee institute an informal mentoring program that pairs experienced and new members. Dr. Robinson said that such mentoring is also a subject for the executive secretary to investigate.

CFSAC unanimously approved the following subcommittees, then agreed on membership assignments:

Research – Dr. Oleske (chair), Ms. Artman, Dr. Hanna (*ex-officio* adviser)

Education – Ms. Healy (chair), Dr. Bateman, Dr. Deborah Willis-Filinger, Dr. Hanna (*ex-officio* adviser)

Patient Care/Quality of Life – Ms. Artman (chair), Mr. Newfield, Dr. Oleske, Dr. Desi (*ex-officio* adviser)

Dr. Parekh made a note to confirm with Dr. Desi his assignment as *ex-officio* adviser to the Patient Care/Quality of Life Subcommittee and to ask Dr. Reeves about serving as *ex-officio* adviser for the Research and Education panels.

Recommendations and Subcommittee Topics

CFSAC voted unanimously to send recommendations 1-4 to the Assistant Secretary of Health and the Office of the Secretary:

1. The Committee recommends that the FY08 and 09 budgets of the CDC for research be restored to or increased beyond the FY05 level in order to sustain the CDC's remarkable momentum including the ability to finish the Georgia Study (especially the longitudinal portions).

2. The Committee recommends that the FY08 and 09 budgets of the CDC for CFS public awareness education be restored to or increased beyond the FY06 level based on the positive initial response to the November 2006 campaign launch.

3. The Committee recommends that CFS be included in the Roadmap Initiative of the NIH.

4. Based on the positive response to the NIH's Request for Applications (RFA) issued in July 2005 (funded in 2006), the Committee recommends equivalent funding for a second RFA.

Topics 5-16 will be assigned to the appropriate subcommittee by the Executive Secretary:

5. A letter from the Surgeon General sent to state and national organizations for physicians, PAs, nurses, and other allied health professional groups informing them about the CDC toolkit and other resources.

6. Establishment of a CFS clinical trials network patterned after the HIV clinical trials network.

7. Agency for Health Care Quality Research development of guidelines for the treatment of CFS using the CDC toolkit as a start.

8. Investigation of new methods of provider outreach and education (primarily for the physician community)

9. Investigation of how to put new technology to use for inexpensive outreach, particularly linking state health departments, medical associations, and various other groups to information on the CDC's website.

10. Consideration of enhancing and enriching the CDC program to train physicians along the lines of a three-hour interactive presentation to impart skills in diagnosis and treatment. Finding more qualified people to give the presentations.

11. HHS should explore resources to provide incentives for all health care providers to train in the area of CFS (research and treatment).

12. Expansion of third party providers' CFS knowledge base through community education programs.

13. Development of teaching resources to be used in medical/nursing education – outline diagnosis, treatment, etc.

14. Addition to the FDA website of a section on supplements and drug interactions where patients are encouraged to report to physicians what medications they are taking.

15. Exploration of whether HHS can provide web or pod casts of CFSAC meetings.

16. Exploration of ways for patients to access CFS campaign materials and information other than the on the CDC web site.

Members agreed that further discussion of the spring 2007 meeting agenda would occur post-meeting via phone and email communication with the Executive Secretary.

Dr. Hanna suggested that members access the Office of the Director's page on the NIH website and click on the page for OPASI to see the latest information on the NIH restructuring, including future directions and the agency's reauthorization legislation.

The Committee approved a motion to open the floor to public comments.

Public Comments

Ramona Hahn, CFS patient since 1993

Ms. Hahn told that the Committee that she worked for the IRS for 18 years and has been on Federal disability since 1997. She explained that she wants to return to part time work for the Federal government, but is prevented from doing so by a policy that permits only current fulltime workers to switch to part time employment. She asked that the Committee promote part time Federal positions for CFS patients and that the Patient Care/Quality of Life Subcommittee take up the issue, specifically with the Office of Disability Employment Programs in the Department of Labor.

Dr. Oleske asked whether making accommodations for the disabled is a legal requirement. Ms. Hahn replied that she is told that positions for which she has applied require a fulltime employee. She added that agencies often have no part time positions for which she can apply. She clarified that she would have to be accommodated had she requested part time employment while working at a fulltime job, but the same accommodation is not required for those on disability.

Dr. Friedman noted that Ms. Hahn's experience is not unique for CFS patients. He said that the Quality of Life Subcommittee could look into encouraging the Federal government to provide incentives for either the private or public sector to provide opportunities for people in her situation. **Ms. Artman** said that as chair of the subcommittee, she would be happy to look into the issue. Committee members noted that lack of part time employment impedes recovery and leads to the stereotyping of CFS patients as not wanting to improve. Opportunities allow those with CFS to stay connected to the mainstream and maintain a sense of self worth.

Closing Remarks

Dr. Parekh thanked Committee members and members of the public for "two very good days of productive meetings".

Adjournment

A motion for adjournment was seconded and unanimously approved.