

The CFIDS Association of America

Working to conquer chronic fatigue and immune dysfunction syndrome

Report on the May 16-17, 2007 Meeting of the DHHS CFS Advisory Committee

The [CFS Advisory Committee](#) (CFSAC) to the Department of Health and Human Services (DHHS) met on Wednesday, May 16, and Thursday, May 17, in Washington, D.C. This was the Committee's first meeting with its [current membership](#) and its 12th overall since being chartered under the Federal Advisory Committee Act in 2002. Committee chairman Dr. James Oleske opened the meeting and welcomed new five new members. Executive Secretary Dr. Anand Parekh, representing the Department's Office of Public Health and Science, reviewed the agenda and assisted the committee to understand its role and clarify procedural issues. All 11 Committee members were in attendance on day 1; Kris Healy was unable to participate on day 2 and others had to leave before the ending time due to scheduling conflicts.

Three invited guests delivered prepared remarks on the morning of the first day. The Committee heard first from Linda Milne, a board member representing the Organization for Fatigue and Fibromyalgia Education and Research (OFFER), based in Salt Lake City, Utah. Ms. Milne described OFFER's mission and services provided to regional patients, caregivers and providers. Next, Patricia Fennell, MSW, gave a presentation about the four phases of illness experience that most CFS patients cycle through, and the needs that they have at each stage. She detailed her approach to case management and identified gaps in services that patients often encounter in attempting to deal with the multiple medical, economic, relationship and social effects resulting from CFS. The final invited guest was Joseph John, M.D., who reviewed CFS management and research approaches. All three speakers were warmly received by the committee and answered numerous questions from committee members.

Following a break, Dr. Oleske asked to hear progress reports from the federal agencies. Representing the National Institutes of Health, newly appointed director of the newly created Office of Portfolio Analysis and Strategic Initiatives ([OPASI](#)), Dr. Alan Krensky, made a presentation about this new organization within NIH that was codified under the NIH Reform Act of 2006. OPASI will undertake initiatives that strive to build greater cross-disciplinary research infrastructure and capacity, utilizing innovating funding mechanisms supported by a "common fund" for research established by Congress. His organization will be prioritizing initiatives that fall under the NIH director's "Roadmap Initiative" (launched in 2002) and will explore new ways to handle the peer-review of investigator-initiated studies; the current process has come under fire by applicants and reviewers. Dr. Krensky stated that CFS could benefit greatly from the new research approaches being pursued through OPASI, but he was clear that little of their work would be disease-specific. He also addressed numerous questions and comments before the committee adjourned for lunch.

After the break, Dr. William Reeves of the Centers for Disease Control and Prevention (CDC) provided an update on research and education activities led by his group, including community-based studies in Georgia, a clinical study being planned in collaboration with Emory University, a pilot registry being launched in Bibb County, Georgia, and laboratory studies. He also briefly reviewed provider education efforts conducted in collaboration with the CFIDS Association of America. Dr. Joanne Cono, chief science officer for the Coordinating Center for Infectious Diseases in which the CFS program is located, described an ongoing reorganization of CDC and recent meetings held with internal and external groups to consider where in the new structure the CFS program would best be located. She indicated that reports on these meetings had recently been submitted to CDC leadership and that a decision would be forthcoming in the next few months. Drs. Reeves and Cono addressed questions, including several related to current, past and future funding levels for the research program. Dr. Reeves

indicated that his budget had fallen to approximately \$4.3 million for FY07 compared to an FY05 level of \$8 million while Dr. Cono considered this to be “steady” when “payback” funds were omitted from the earlier year totals. Concern was expressed by several committee members that several studies, particularly lab efforts, were in jeopardy due to the reduction of nearly 50% support. Completing presentations from CDC was Dr. Fred Fridlinger, the project officer for the CDC’s public awareness campaign, for which the CFIDS Association of America is the primary contractor. Dr. Fridinger provided an update on the campaign and statistics related to TV/radio PSAs, print ads, earned media, web site traffic and the traveling photo exhibit, which was on display at the HHS building for the two days of the meeting. He also addressed questions about campaign funding and future plans.

Following a short break, Dr. Marc Cavaille-Coll from the Food and Drug Administration (FDA) gave a brief report on agency activities, indicating that the number of products under review for CFS was still small (fewer than 20). He responded to questions about whether the “lumping” of several conditions by pharmaceutical companies would be permitted as a strategy to extend patent rights for products vulnerable to losing exclusive marketing rights, by stating that the marketing approval would only be granted if safety and efficacy were demonstrated for a particular patient population. Dr. Deborah Willis-Fillinger, representing the Health Resources and Services Administration, reviewed the agency’s mission and major program areas. She discussed the special services created to serve the HIV/AIDS community to meet the rapidly increased demands for patient care and provider education, which prompted a discussion about the similarities to the current situation with CFS. For the Social Security Administration (SSA), Dr. Laurence Desi reported on the ongoing efforts to educate adjudication staff about CFS and informed the committee that the new SSA commissioner was considering changes to the adjudication process for disability applications. Dr. Eleanor Hanna of the National Institutes of Health added a final report, noting that the CFS Program Announcement would be renewed in November and she solicited comments by July as part of the renewal process.

Committee discussion capped the first day, with questions from new members about the process for developing the agenda, determining invited guests and soliciting additional ex-officio representatives from other DHHS agencies and other departments, such as Veterans Affairs (VA). The issue of access to meetings was raised, with Dr. Parekh committing to exploring cost-effective ways to make the meeting more accessible to patients unable to travel to Washington, D.C.

The second day began with a report from each of the three subcommittees that had been formed at the November meeting. The Patient Care and Quality of Life Subcommittee, led by Rebecca Artman, reported first on efforts to identify and prioritize the myriad issues that could be addressed to improve the illness experience for CFS patients. Discussion centered on quality of life studies being conducted by CDC and an HHS-wide planning group’s work to develop standardized measurements and definitions for studying quality of life in various disease states. Jason Newfield recommended surveying third-party payors about reimbursement issues and Dr. Klimas suggested that the VA be invited to share information about how it educates providers about medical issues of emerging importance, since 30% of adults receive their healthcare through the VA system. Data on Social Security disability benefits approved for CFS was sought by the committee.

The Research and Education subcommittees also gave reports and a long discussion about the value of the committee recommending support for clinical/research centers ensued. Centers of

Excellence, CTSA (Clinical and Translational Science Awards), AETC (AIDS Education and Training Centers), BIRCWH (Building Interdisciplinary Research Careers in Women's Health awards) and SCOR (Specialized Centers of Interdisciplinary Research) funding models were considered, with the primary interest being a group of regionally dispersed locations where clinical care, research, training and outreach would occur, linked by virtual and other systems to augment communication and data sharing. Dr. Arthur Hartz expressed reservation, stating that these centers would need to be located where sufficient patient populations exist, and that this might crowd-out other approaches and squeeze funding for investigator-initiated studies that need to continue.

After a lunch break, public testimony was delivered by the following individuals: Mary Schweitzer, PhD (of Delaware), Marly Silverman (of Florida), Eileen Holderman (of Texas), Barbara Soliday (of Florida), Angela Linford (of Utah), Pat Fero (of Wisconsin) and Cort Johnson (of California). Kim McCleary had registered for testimony, but ceded her time to allow other advocates, not usually able to be present, to deliver their remarks. This meeting had the best attendance from members of the public for at least two years, due largely to people staying over from the CFIDS Association's annual Lobby Day activities held on May 14-15.

Following the comments from the public, the committee returned to its discussion and formulation of recommendations to the Secretary. Two formal recommendations were voted on and sent to the Secretary. The first, passed by a vote of 8-1, recommends that due to the magnitude of CFS and the public health priority it warrants, the Secretary fund a network of five regional research/clinical/training centers for CFS. The second, passed by a vote of 7-0, recommends that the Secretary instruct the Surgeon General to send a letter to the following entities about existing educational materials to train providers about the diagnosis and management of CFS: state health departments, health professional education programs and national organizations for physicians, physician assistants and nurse practitioners.

The committee discussed additional information-gathering steps on other issues of primary concern, including the handling of CFS claims by insurance companies and alternative review processes for CFS grant applications submitted to NIH. They asked Dr. Parekh to gather funding information from CDC on the various research, education and awareness programs being supported for CFS. Dr. Parekh stated that the next meeting would likely take place in November and he reiterated support to assist the subcommittees with their interim meetings. At 2:45 p.m. a majority of committee members were no longer present (due to travel schedules and other issues), so the meeting was adjourned.