



PATIENT ALLIANCE FOR NEUROENDOCRINEIMMUNE DISORDERS
P-A-N-D-O-R-A
ORGANIZATION FOR RESEARCH AND ADVOCACY *inc.*

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FROM:

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TO:

Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
United States Senate - FY 2011

Agency:

DEPARTMENT OF HEALTH AND HUMAN SERVICES - Secretary of Health Kathy Sebelius

Dear Chairman of the Subcommittee on Labor, Health and Human Services,

On behalf of our organization I want to share with you a matter of great importance to our patient advocacy organization. It is related to the CFS Advisory Committee (CFSAC), a congressional committee overseen by the Department of Health and Human Services established to provide science-based advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on a broad range of issues and topics pertaining to chronic fatigue syndrome (CFS). It has been at least 6 years since our organization has attended and provided input during CFSAC meeting and yet not one single crucial recommendation has been implemented or enacted. Currently the CFSAC is due to expire on September 5, 2010.

We need to call you attention why is so important that this appropriation committee provide funding for research, patient care, physician education and clinical trial within a center of excellence format. The CFSAC has consistently year after year as far back as September 2004 recommended the following:

In September 2004 – Recommendation 1: “We would urge the DHHS to direct the NIH to establish five Centers of Excellence within the United States that would effectively utilize state of the art knowledge concerning the diagnosis, clinical management, treatment and clinical research of persons with CFS. These Centers should be modeled after the existing Centers of Excellence program, with funding in the range of \$1.5 million per center per year for five years.”

In August 2005 - Recommendation 1: “We would urge the DHHS to direct the NIH to establish five Centers of Excellence within the United States that would effectively utilize state-of-the-art knowledge

concerning the diagnosis, clinical management, treatment, and clinical research of persons with CFS. These Centers should be modeled after the existing Centers of Excellence program, with funding in the range of \$1.5 million per center per year for five years.”

In November 20-21, 2006 - The Committee skipped recommending again because it was told that it needed to wait till the Secretary of Health could reply on the earlier recommendations therefore CFSA then provided **recommendation 3** – “The committee recommends that CFS be included in the Roadmap Initiative of the NIH.”

In May 16-17, 2007 – Recommendation 1 - ...There have been basic science advances which should be leading to new treatment strategies, yet progress in translating these advances into effective treatments has been slow. This is in large part due to a complete lack of clinical care centers and research centers. Investigators are frustrated by a lack of access to representative patient populations, and patients are frustrated by a lack of accessible expert clinical treatment centers. Funding mechanisms to develop new centers for either clinical care or centers for research are shrinking, but the needs of this underserved very ill patient population are unmet and growing.

Therefore, the CFSAC recommends that the Secretary use the resources and talent of the agencies that make up the HHS to find ways to meet these needs. **One starting point is our request that the HHS establish 5 regional clinical care, research, and education centers, centers which will provide care to this critically underserved population, educate providers, outreach to the community, and provide effective basic science, translational and clinical research on CFS.** The advisory committee understands that fiscal exigencies have to date prevented the formation of these previously recommended centers, but it is our hope the Secretary will use the full weight of his office to effectively fund this program through existing funding mechanisms that might be available or new programs.”

In November 28-29-2007 - CFSAC voted unanimously to send the following recommendations to the Assistant Secretary for Health for transmittal to the Secretary:

- It is recommended that a representative of AHRQ be added as an ex officio member to CFSAC effective immediately, but at least in advance of the next CFSAC meeting. The next CFSAC meeting is scheduled to be held in May 2008.
- It is recommended that the CDC effort on CFS be restructured to reflect a broader expertise on the multifaceted capabilities required to execute a comprehensive program that incorporates the following elements:
 1. an extramural effort directed by the Office of the Director;
 2. sufficient funds for a program for which the authority and accountability is housed at the level of a coordinating center director;
 3. a lab-based component that maintains the current search for biomarkers and pathophysiology;
 4. the recommendations of the external CDC Blue Ribbon panel, including developing, analyzing, and evaluating new interventions and continuing support for longitudinal studies; and
 5. an expanded patient, healthcare provider, and family caregiver education effort that is managed by staff with appropriate expertise in clinical and public education strategies.

In May 5-6, 2008 – The committee unanimously recommended 4 items. For the purpose of my testimony I quote :... “CFSAC recommends to the Secretary of Health and Human Services that the Administrator of HRSA communicate with each Area Health Education Center (AHEC) regarding the critical need for provider education of CFS. HRSA has the potential to disseminate information on CFS to a wide range of providers, communities and educational institutions. HRSA should inform these groups that persons with CFS represent an underserved population and that there is a dramatic need for healthcare practitioners who can provide medical services to CFS patients. HRSA should further inform these groups that the CDC offers a web based CME program on CFS at www.cdc.gov/cfs; and encourage AHEC providers to

participate in this CME program. Additionally, HRSA should alert AHECs of the availability of a CDC CFS provider toolkit.”

In October 28-29, 2008 – Several recommendations were made. For the purpose of our testimony we quote: ...”

1. It is recommended that DHHS solicit the Department of Education’s cooperation on issues relating to pediatric CFS.
2. It is recommended that the Transition report to the new Administration and Secretary include the background of the CFSAC and CFS and a list of the recommendations that have been developed by this Committee over the past two chartered periods, with any action taken on each point.
3. CFSAC endorses the planned State of the Knowledge Conference to be developed by the NIH.
4. CFSAC recognizes that much can be done to ensure that every child with CFS has the best possible access to support and treatment and asks that the Secretary facilitate a taskforce or working group to establish an ongoing interagency and interdepartmental effort to coordinate school, family, financial, and health care support for children and young adults with CFS.

In October 29-30, 2009 – Recommendation 1 - Establish Regional Centers funded by DHHS for clinical care, research, and education on CFS. **(Resubmitted from May 2009)**

As you can see, year after year, the same recommendation is being made, and yet there has not been any progress for the past 6 years in the most important recommendation from the CFSAC to the Secretary of Health regarding chronic fatigue syndrome. Therefore we urge you – our congressional leadership - to ensure funding for the Neuroendocrineimmune (NEI) Center™ & to the Whittemore Peterson Institute. Please allocate funding for scientific research, clinical trials, patient registry, physician education, public education and social services to an estimated 20 million Americans stricken with neuroendocrineimmune disorders such as chronic fatigue syndrome (CFS) and related illnesses. Throughout the U.S. , day after day we witness great suffering being inflicted on individuals, children, teenagers, adults and the elderly. We witness children being taken from their families simply because they “have failed to find a primary physician to treat their child” (Baldwin Family vs. DSS Buncombe County, North Carolina). Too much suffering because it seems that no one in our government cares to take courageous step and stand up for individuals with CFS.

We urge you to provide funding to The NEI Center™, a patient-driven community initiative in the state of New Jersey (hopefully in Florida as well), which will address all of the issues mentioned on the CFSAC recommendation in addition to addressing patient’s quality of life issues. The cornerstone of the NEI Center™ (www.neicenter.com) is that discoveries and advances made in any one of the neuroendocrineimmune illnesses: chronic fatigue syndrome (CFS), myalgic encephalomyelitis or encephalopathy (ME), fibromyalgia (FM), Gulf War syndrome/illness (GWS/GWI), multiple chemical sensitivity (MCS), environmental illness (EI), chronic or persistent Lyme disease (CLD-PLD), Alzheimer’s Disease (AD), and autism, will be applicable and beneficial to other neuroendocrineimmune illnesses, thereby bringing us closer to a cure.

I ask you why hasn’t this crucial issue be addressed promptly? Why has our government failed to address such injustice? I urge you to stand by the side of millions of Americans who presently do not have a voice. Their future depends on your vision. Help us to restore their health and their hopes. Please provide funding to the NEI Center™ and or similar efforts in the U.S. This committee has the power. You can do it! And as one of the many individuals stricken with CFS, I thank you for this opportunity to share the plight of so many. We need a hero, and you have the opportunity to demonstrate vision, courage and foresight by allocating funding for future centers of excellence for CFS and other neuroendocrineimmune disorders. Thank you!