



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

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TO: House Committee on Appropriations

Subcommittee on Labor, Health and Human Services, Education and Related Agencies

United States House of Representatives - FY 2011

Agencies: DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) - Secretary of Health Kathy Sebelius - Desired Funding Level: **\$25 million – 5-year funding allocation**

Dear Chair of the Subcommittee on Labor, Health and Human Services and Distinguished Committee Members,

Herein, I present a matter of great importance to our patient advocacy community. 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). For 6 years our organization has attended and provided input during CFSAC meetings, and yet not one single crucial recommendation has been implemented or enacted. The current CFSAC charter is due to expire on September 5, 2010. The Committee is governed by the provision of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Here, we clearly stress it is a matter of national importance and why it is crucial that this congressional appropriation committee provide funding for research, patient care, physician education, and clinical trial under a DHHS regional centers format. Since September 2005, the CFSAC has consistently, year after year, recommended the following:

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 for 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.”

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 for 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.”

November 20-21, 2006: The Committee’s **Recommendation 3:** “The committee recommends that CFS be included in the Roadmap Initiative of the NIH.”

May 16-17, 2007–Recommendation 1: “There have been basic scientific advances that should be leading to new treatment strategies, yet progress in translating these advances into effective treatments has been slow. This is due, in large part, 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 five regional clinical care, research, and education centers which will to provide offer care to this critically underserved population, educate providers, provide outreach to the, and provide effective basic science as well as translational and clinical research on CFS.** The advisory committee understands that fiscal exigencies have, to date, prevented the formation establishment of these previously recommended centers, but it is our hope that the Secretary will use the full weight of office to effectively fund this program through existing funding mechanisms that might be available or new programs.”

November 28–29, 2007: The 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 of the to CFSAC effective immediately, but at least in advance of the next CFSAC meeting. ... 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.”

May 5–6, 2008: The committee unanimously recommended four 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 patients with CFS. HRSA should further inform these groups that the CDC offers a web-based continued education program (CME) 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.”

October 28–29, 2008: Several recommendations were made. For the purpose of this testimony, I quote Numbers 1 and 4: “1) It is recommended that DHHS solicit M: COOPERATION BY the Department of Education ~~Cooperation~~ on issues relating to pediatric CFS ... 4) CFSAC recognizes that much can be done to ensure every child with CFS has the best possible access to support and treatments 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.

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 recommendations are being made, and yet there has not been any progress for the past six years in the most important recommendation from the CFSAC to the Secretary of Health regarding chronic fatigue syndrome: “The establishment of Centers of Excellence or Regional Centers funded by DHHS for clinical care, research, and education on CFS.”

Therefore, we urge you—our congressional leadership—to ensure funding for the Neuroendocrineimmune (NEI) Center,[™] a patient-driven community initiative in the state of New Jersey (and we hope in Florida as well), that will address all of the issues mentioned in the CFSAC recommendations in addition to addressing quality of life issues for patients. We also ask you to provide continuing funding to the Whittemore Peterson Institute for Neuro-Immune Disease (WPI), which is located Reno, Nevada. 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 M: IN THE CFS POPULATION.

On February of this year, the North Carolina state Mountain Area Health Education Center (MAHEC) official was put in the awkward position of reneging on his original agreement to be a CME provider for a pediatric family mini-conference with our organization. The conference included physician training on NEIDS. The MAHEC official

informed us that in an “impromptu meeting with the local Medical Board overseeing the MAHEC programs,” a board comprised of local physicians from the Black Mountain, Asheville, Buncombe County Area expressed that **“In general, they feel the diagnosis and treatment of CFS is a gray area.”** We were told that they felt they should not be involved in training medical providers on NEIDs and much less with our organization. The fact is that, unfortunately, some of the MAHEC physicians were involved in the Baldwin family plight, which involved a child previously diagnosed with CFS and other NEIDs who was taken from his parents after an allegedly and (unconfirmed) anonymous physician report was made to the Buncombe County Department of Social and Senior Services (DSS). It resulted in DSS charges of Munchausen syndrome by proxy leveled against the mother. After a 10-month court case, the judge ruled that the family had “simply failed to provide the minor child with the care of a primary physician.” It is, however, ironic that we can factually state that, as it currently stands in the MAHEC medical system, the MAHEC does not have primary physicians (or any specialists) capable of diagnosing, much less treating, a child with CFS and/or several other NEIDs in the 16 county areas that MAHEC oversees in North Carolina. Our organization spearheaded a nationwide community advocacy outcry. The child is now back with his parents, but during the whole time that the child was shuffled between three foster families during a 9.5-month period, DSS never once provided him with the specialized medical care he needed. The irony is that this particular child had already been approved for Social Security disability due to his illnesses and had access to two electric wheelchairs, which during the court case were taken away from him, placing him at a significant physical risk. I urge you to stand by the side of millions of Americans who presently do not have a voice. Their future depends on your compassion and vision. Help us to restore their health and hopes. This committee has the power. 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 regional centers for clinical care, research, and education for CFS and other neuroendocrineimmune disorders. Thank you!

SUMMARY, BACKGROUND, AND FACTS ON NEUROENDOCRINEIMMUNE DISORDERS

The concept of Neuroendocrineimmune Disorders (NEIDs) applies to illnesses such as chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis or encephalopathy (ME) and also known as chronic fatigue immune deficiency syndrome; fibromyalgia (FM); chronic Lyme disease (CLD); environmental illness (EI); and multiple chemical sensitivity, Alzheimer’s, Lyme disease induced-autism, and Gulf War Illness (GWI). The scientific rationale is that the consistently and well-recorded overlapping of symptoms, medical protocols and biomarkers, indicate that discoveries and advances made in any one of the neuroendocrineimmune illnesses will be applicable and beneficial to other neuroendocrineimmune illnesses, thereby bringing us closer to a cure.

LATEST SCIENTIFIC RESEARCH SUPPORTING THE NEIDs CONCEPT - According to the Whittemore Peterson Institute, “The spectrum of neuro-immune diseases including: Myalgic Encephalomyelitis (ME/CFS), Atypical MS, Fibromyalgia and Gulf War Syndrome, share common abnormalities in the innate immune response, which result in chronic immune activation and immune deficiency. We have detected the retroviral infection XMRV (xenotropic murine leukemia virus-related virus) in greater than 95% of the more than 200 ME/CFS, fibromyalgia, and atypical MS patients tested. The current working hypothesis is that XMRV infection of B, T, NK, and other cells of the innate immune response cause chronic inflammation and immune deficiency, resulting in an inability to mount an effective immune response to opportunistic infections. (See [XMRV paper](#) in *Science*. (DOI: 10.1126/science.1179052). This discovery opens an entirely new avenue of Neuro-Immune Disease related research, and our discovery has brought to this field world-renowned immunologists and retrovirologists building our team of collaborators to translate our discoveries into new treatments as soon as possible. Because retroviruses are known to cause inflammatory diseases, neurological disease, immune deficiency, and cancer, the discovery of XMRV has far-reaching implications for the prevention and treatment of not only lymphoma, one of the potentially devastating complications of ME/CFS, but prostate cancer and perhaps many others.”

U.S. BLOOD SUPPLY IS POTENTIALLY TAINTED -Of great urgency to our nation is that the Whittemore Peterson Institute reported that the XMRV virus was also found in 3.7 % of those without CFS, bringing to the forefront the issue that our nation’s blood supply is potentially tainted.

POTENTIAL OVERLAPPING OF XMRV WITH CHRONIC LYME DISEASE - According to Dr. Joseph Burrascano, a Lyme disease researcher, the XMRV virus finding has implications for Lyme research because it is possible that patients who carry this virus when co-infected with Lyme go on to have persistent symptoms because a) of activation of the latent virus; b) infection with Lyme or another tick-borne disease lowers the immune surveillance, making the individual more susceptible to "catch" the virus; or c) the presence of the virus and the spirochete together act synergistically to induce an array of illness symptoms or to prevent eradication or control of either organism. In a paper 'Inflammation and central nervous system Lyme disease' published in the journal *Neurobiology of Disease*, Fallon, Hardesty, Levin, and Schweitzer 2009) discussed their finding that neurologic manifestations of Lyme disease occur in 10 to 15% of individuals with untreated Lyme. The researchers discussed the symptoms of neurologic Lyme and reviewed experimental studies that provide insight into the possible mechanisms of inflammation following *Borrelia* infection and contributing risk factors.

DEMOGRAPHICS It is estimated that 20 million Americans are stricken with NEIDs. It crosses barriers of social status, age, and gender. The CDC figures for CFS are now over 4 million Americans. The DOD has stated that 800,000 veterans are stricken with Gulf War illness. It is stated in the CDC website that for Lyme disease “State health departments reported 28,921 confirmed cases and 6,277 probable cases of Lyme disease to CDC in 2008.” This represents a 5% increase in confirmed cases since 2007. NIAMS states “Scientists estimate that fibromyalgia affects 5 million Americans 18 or older.

ECONOMIC IMPACT -It is estimated that NEIDs cost our nation \$75 billion annually.