



P.A.N.D.O.R.A.- PATIENT ALLIANCE FOR NEUROENDOCRINEIMMUNE DISORDERS  
ORGANIZATION FOR RESEARCH & ADVOCACY INC. – [www.pandoranet.info](http://www.pandoranet.info)

RESPONSE TO REQUEST FOR INPUT – April 27, 2009

CDC FIVE-YEAR Strategic Plan

Prepared by K.J. Friedman, Ph.D., Director, Public Policy, Marly C. Silverman, Founder & Public Policy & Community Advisor, and Rebecca Artman, Public Policy & Community Advisor

The purpose of the public meeting is to solicit input from interested parties **on issues that CDC will consider as it develops a five-year strategic plan for its CFS research program.** Input is sought only on the CFS strategic research plan, not on CDC's overall CFS program. As CDC is one of many institutions conducting research on chronic fatigue syndrome, the strategic plan will only address research that is within CDC's purview.

**Topics Include:** The objective of the five-year strategic plan is to conduct public health research leading to the control and prevention of medically unexplained chronically fatiguing illnesses, in particular CFS. The agenda will focus on the goals and objectives of CDC's CFS research program in five major categories:

### ***Studies of Defined Populations***

Our organization supports the CDC's continuance of studies of defined populations. However we see several flaws in the current CFS definition used by the CDC. Current and future studies, however, are critically dependent upon the diagnostic criteria used to define individuals with CFS as opposed to those without. We express concern over the CDC's unilateral change in inclusionary diagnostic criteria for patients with CFS. In recent years, the CDC has broadened its definition of CFS and, in so doing, has raised its estimate of the number CFS patients within the United States from approximately 1 million to 4 – 6 million. We caution the CDC, and express our concern, that by altering the inclusionary criteria for CFS, the previously accumulated population

data is no longer compatible with the current CDC data. It is our preference that the CDC adopts the increasingly more popular & scientifically well received Canadian case definition for its current and planned 5-year strategy.

We suggest that the CDC expand its studies of defined populations. We suggest that both morbidity and mortality data be included. We suggest that long-term, longitudinal studies be incorporated into the plan. We suggest that data be obtained not only for adult populations but for pediatric and adolescent populations as well. We affirm our position on the need for a return to biomarker and evidence based medicine.

With regard to long-term studies, we specifically suggest that the CDC also return to Lyndonville, NY, and Incline Village, NV for follow-up studies to determine the fate of individuals in the populations which the CDC has previously studied in order to indentify who, why, how and if these individuals have experienced remission, remain disabled or have died of the potential consequences of CFS.

With respect to longitudinal population studies, we suggest long-term studies with a commitment, both in principle and financial support, for long-term studies such as a 30-year study.

### ***Provider-based Patient Registries***

We do not favor provider-based patient registries. Our organization does not understand the rationale, or wisdom of proposing provider-based patient registries and we assume that it comes to a considerable financial cost that could be applied to more efficient ways to gather information on patient population. It is the CDC's own data and assertion that as little as 15 percent of the CFS patient population is identified and treated and it is done through medical diagnosis. Moreover, the CDC recognizes and has made the public painfully aware of the lack of physician and other healthcare provider knowledge of CFS. To that end, the CDC has launched a number of programs to educate physicians and other healthcare professionals (Train-The-Trainer, Spark-Awareness, The Physicians' Toolkit, The Healthcare Provider Toolkit) concerning diagnostic and treatment protocols for CFS. Until such time as the providers are calibrated and experienced in using the same diagnostic criteria for accepting registrants into the data base, we see little value in using healthcare providers as the gatekeepers of any CFS registries.

Our organization does support and suggests that patient registries be established. One suggestion we have is that online patient self-reporting be established as a viable tool and cross-referenced with patient's medical providers. It is also our suggestion that teams of CDC-trained healthcare providers visit hospitals and medical practices in areas throughout the United States and, by reviewing patient charts and interviewing patients as they seek admission to healthcare through physician offices or hospital admission desks, identify patients who should be included in patient registries. The reason we need to cross reference these steps is because often when CFS patients reach an emergency room, and describe their health challenges and diagnosis, hospital

medical personnel quickly dismisses them as having a serious health issue. The treatments approaches change and their demeanor towards the patient changes as well. (Vide In-hospital Clinical Studies below.)

In addition, to rely on non-calibrated health-care practitioners for the assessment of patients and the decision as to whether or not those patients should be included in the CFS registry seems to compromise the very data the CDC seeks prior to the collection and entry of that data.

### **In-hospital Clinical Studies**

Our organization supports the CDC's goal of conducting in-hospital clinical studies. Nonetheless we are concerned that such studies would be difficult to implement. We are also concerned about the quality and significance of the data obtained.

CFS patients who rely on hospital admission for any part of their care, report anecdotally that it is "a mistake" to indicate to hospital staff that they are CFS patients. According to these reports, an admission of being a CFS patient dramatically alters the acceptance of the patient's symptoms by the medical staff and alters the care from being procedural to being psychological. Under such circumstances, it is difficult to forecast the value of in-hospital clinical studies.

CFS patients react differently to medications and to procedures. Unless CFS patients are matched to controls both in age and gender, it would be difficult to quantify or characterize the differences between CFS patients and controls.

Clinical studies are only as valid as the constancy of their data. There is much variation amongst the patient population of CFS patients. There has been, and continues to be – particularly at the 9<sup>th</sup> International Meetings of the IACFS/ME held in Reno, NV, March 8-11, 2009 – of identifying sub-populations of CFS patients. It would be our recommendation that in-hospital clinical studies be cognizant of the emerging sub-groups of CFS patients if such studies are undertaken.

Clinical studies are only as valid as the proficiency of the investigator in accumulating the data. Our organization suggests that before any such studies are undertaken, the researchers involved in the study be calibrated as to the procedures and data analysis necessary to competently collect and report the data.

The two items above suggest, in our mind, that such in-hospital studies are best conducted in facilities trained and dedicated to the treatment of CFS patients. In our mind, such facilities would be reminiscent of the now defunct CFS Centers of Excellence, but armored with new and updated scientific research that is showing great promise. It is, therefore, our recommendation that the CFS, Clinical, Centers of Excellence be re-established or created anew. P.A.N.D.O.R.A. appreciates the concept of the Neuroendocrine-immune Institute (Research Centers) and in our mind; it is only in such

Centers that clinical, in-hospital studies could be conducted with the assurance of appropriate attention to the CFS patients, and the confidence of accurate data collection and interpretation.

## **Laboratory Studies**

Our organization supports the CDC's goal of conducting laboratory studies. In our opinion, the CDC's laboratory studies have been the most promising of its CFS studies to date. We do believe, however, that CDC laboratory studies should not be a citadel of research but rather be a partner in the world's laboratory studies of CFS.

It is our suggestion that the CDC's laboratory studies be more cooperative in nature: sharing both specimens and data with researchers outside of the CDC.

It is our suggestion that the CDC use existing case definitions for CFS patients and for obtaining samples and data from this population.

It is our recommendation that the CDC adopt a pre-existing case definition and rely on that case definition for the duration of its 5-year strategic plan.

It is our recommendation that the CDC train researchers outside of their Department to conduct and confirm studies not only within other regions of the United States but throughout the world.

It is our recommendation that the CDC's laboratory studies program be sufficiently facile so as to be capable of reacting and responsive to the needs and developing research priorities of the CFS community nationally and internationally.

It is our recommendation that the results of the CDC's laboratory studies program be published promptly in easily obtainable, open access journals.

It is our recommendation that the CDC designs its laboratory studies in such that the results of these studies can be interpreted unambiguously and has direct and immediate application to the needs of CFS patients.

It is our recommendation that CDC studies which require multiple, outside agencies to interpret their data, and whose interpretations are at variance with each other, should be avoided. It is our belief that such studies and the results of such studies have little present and little future impact on the lives of CFS patients.

## **Provider and Public Educational Intervention Research**

Our organization supports the concepts of both provider and public education for CFS. Our organization supports efforts to increase the efficiency of both lay public and healthcare professional education for CFS.

Our organization supported and successfully used the CDC's trainer-trained CFS CME program. Our organization views the discontinuance of that program to be an error. It our suggestion that the program be reinstated. We believe it is an extraordinarily effective way of training healthcare professionals about CFS.

It is our further suggestion that the trained-trainer program be expanded so as to include all healthcare professionals involved in the diagnosis and treatment of CFS.

It is our suggestion that CFS Awareness and Diagnosis programs be expanded so as to include allied healthcare professionals more frequently visited by CFS patients than physicians: dentists, chiropractors, massage therapists, physical therapists, and other integrative and holistic providers.

Our organization is aware of the belief by the CDC that its on-line CFS Diagnosis and Treatment Course is an effective mechanism of training physicians. We are aware that the CDC cites a comparatively high number of CME certificates being issued for this web-based course. Unfortunately, it has not translated well to the available pool of physicians willing to treat CFS patients nor making any significant impact in the quality of life for CFS patients. Our organization recognizes that the number of CFS treating physicians remain quite low in the U.S. To this date, we are not aware, however, of any data indicating the impact of these CME certificates on the diagnosis and treatment of CFS either. It is our suggestion, therefore, that studies to determine the significance of the CDC's educational programs on the diagnosis and treatment of CFS be undertaken.

With regard to the CDC's general education programs, we are unaware of any outcome data suggesting that the general public is more aware of CFS or that the general public is more accepting of CFS as a multi-organ-system disorder.

Our organization is only aware of one media campaign (Spark Awareness) intended to educate the general public about CFS. We are aware of no outcome measures of the effectiveness of this campaign. We are aware of the intent of the marketing program to have a presence in larger, metropolitan areas. We are also aware that the marketing program did not reach many, more rural areas. We are routinely told of cases where parents with CFS children in rural areas are being charged with Factitious Disorder by Proxy (FDP), medical neglect, child abuse, and dependency. Cases where when the parent is ill with CFS, these parents may also face dependency charges by the school system, county or state. Thus, in our opinion, its geographic impact is/was limited. We suggest that alternative educational strategies for educating the general public throughout the United States be identified and tested.

# Strategic Research Plan General Outline

Objective: Conduct public health research leading to the control and prevention of CFS and to improve the quality of life of persons with the illness.

## **Goal 1: Refine understanding of the etiologic pathways involved in CFS in order to improve diagnosis and to identify therapeutic targets.**

- Identify psychosocial, clinical, and laboratory biomarkers associated with incident CFS and with the clinical course of the illness.
- More precisely identify risk factors as related to clinical attributes.
- Measure psychoneuroendocrinologic and immune characteristics of CFS to identify potential diagnostic and therapeutic targets.
- Elucidate pathophysiologic mechanisms associated with symptoms.

Our organization supports the CDC's goal of increasing our understanding of the etiological pathways involved in precipitating CFS. Understanding the etiological pathways is critical to diagnosis and treatment of CFS. It is our suggestion that understanding the etiological pathway be a primary and critical goal of the CDC's 5-year plan. Without understanding the multiple etiologies of CFS, it will not be possible to differentiate the complex overlap of biomarkers, risk factors, neurological, immunological and psychological factors that are precipitated by CFS. It is our opinion that the identification of subgroups or subtypes of CFS is critical to understanding the etiology and complex symptom presentation of the illnesses that are currently grouped as one illness: CFS.

## **Goal 2: Improve clinical management of CFS patients by providing evidence-based educational materials that address evaluation and clinical management of CFS**

- Provide current evidence-based information on diagnosis and management of CFS to health care providers, persons with CFS and their caregivers, and evaluate associated outcomes.
- Evaluate effects of access, utilization, and quality of health care on clinical course of the illness that would enhance the overall quality of life of CFS patient and their families.

In our opinion, it will be difficult if not impossible to disseminate educational materials that assist in the evaluation and clinical management of CFS until such time as the CDC and the healthcare provider population appreciate the existence of sub-types of CFS. Until sub-types of CFS are identified, patients now and until then need to be treated on an individualized treatment plan with implementation of new therapies proceeding cautiously and slowly.

In our opinion, it will be difficult for primary care physicians inexperienced in the diagnosis and treatment of CFS to effectively manage CFS by relying on educational materials.

In our experience, the participation of primary care physicians in the treatment of CFS is best and most efficiently achieved when there is an experienced CFS physician who serves as a consultant to the primary care physician.

It is our belief and therefore suggestion that improvement in the clinical management of CFS patients would be better achieved by the establishment of a nationwide network of CFS specialists to whom patients could be referred for diagnosis (or confirmation of diagnosis) and the establishment of a preliminary treatment plan with the subsequent participation of more local, cooperating primary care physicians.

It is our further suggestion that the nationwide network of CFS specialists be associated with a network of CFS centers, which could then participate in the production of the evidenced-based materials that the CDC wishes to create.

It is our further suggestion that the physicians specializing in the treatment of CFS be the individuals who would evaluate or participate in the evaluation of healthcare access, utilization, and quality of care provided to patients in all stages of this illness.

### **Goal 3: Clinical intervention trials**

- Develop international consensus regarding management of CFS.
- Collaborate to conduct clinical intervention trials.

It is our organization's view that the development of an international consensus regarding the management of CFS is premature at this time. Discussions amongst members of the IACFS/ME as well as scientific papers presented at the IACFS/ME 9<sup>th</sup> International Meeting suggest that CFS is treated differently in different regions of the world. For example, the approach in England differs with that in the United States. The conceptualization of CFS in Japan differs from that in the United States. China has not participated in the IACFS/ME nor is there a presence of Chinese physicians or researchers in the "western" literature.

It is our suggestion, therefore, that rather than develop an international consensus concerning the management of CFS, that an effort be undertaken to determine the procedures and philosophies used to treat CFS in the various regions of the world.

Our organization supports collaborative clinical interventional trials. Such trials, by their nature, must involve multiple sites. The CDC, therefore, must be willing to support the clinical trials at multiple sites. It is our suggestion, that such clinical trial sites should be housed in CFS Centers of Excellence. Physicians and healthcare practitioners who are experienced CFS healthcare providers are best able to participate in clinical trials and accumulate the data derived from such trials.

It is our organization's further suggestion that, to the extent possible, an effort be made to include international clinical trial sites as well.

#### **Goal 4: Move CFS into the mainstream of public health concerns**

- Provide current evidence-based information concerning CFS to federal, state, and local public health authorities, related government agencies, and HMOs.
- Evaluate outcomes associated with dissemination of public health information.

Our organization supports the dissemination of evidenced-based CFS educational materials to federal, state and local public health authorities. We support dissemination of these materials to related government agencies and the inclusion of health insurance companies.

We suggest that such materials and training be provided to adjudicators of social security disability benefits in all states nationwide. We are aware of large discrepancies in rejection rates of CFS patients for Social Security Disability Insurance (SSDI) benefits amongst states suggesting the use of different criteria in states determining the disability of these patients.

We suggest that a mechanism or tool be placed in the Social Security Disability system that would track denial & approval rates for CFS. We also suggest that while at it, why not keep the same types of records for the overlapping number of neuroendocrineimmune disorders such as fibromyalgia, persistent Lyme disease, Gulf War syndrome, multiple chemical sensitivity and environmental illnesses be tracked too.

We suggest that a clearing house-paper trail be established, so records that include, gender, age, ethnic group, and rates of morbidity and co-morbidity are kept.

We suggest that prevention, short and long-term health maintenance should be addressed by properly identifying the crucial requirements that CFS patients have in the area of community social services. We suggest that solutions for the delivery of social services be implemented while monitoring their actual delivery

to the CFS community; as they should be part of illness prevention, relapse prevention and deterioration of the overall health of CFS patients.

We suggest the development of an educational program for private disability insurance companies and the establishment of a mechanism to monitor the honoring of disability benefits to CFS patients of these companies.

We suggest the development of programs involving Area Health Education Councils (AHECs) throughout the country for the various components of our healthcare delivery system. In our experience, AHECs are an underutilized resource in the dissemination of CFS educational materials.

We suggest the development of pediatric and adolescent CFS programs for state and county welfare agencies and for both public and private school systems. We are aware of legal proceedings being instituted against parents who are seeking healthcare for their children who suffer with CFS. Parents are being accused of inflicting Munchausen's Syndrome By Proxy in their children and the children are then removed from their homes causing additional physical, financial and emotional strain within families that are already in the brink of collapse. We are also painfully aware of many difficulties that children and their parents experience within their school systems generated by CFS. Children are being punished for high absenteeism generated by their CFS traumatic health challenges. Parents are charged with contributing to truancy because of the high absenteeism of children with CFS.

We suggest the development of educational programs for school systems so that relevant personnel are aware of the signs and symptoms of CFS. Such a program exists in the State of New Jersey. The justification for such programs is that quite often, children spend more time in school than with their parents. Therefore, it may be easier for teachers to observe the signs of CFS in a child than the parent because the teacher spends more time with the child than the parent.

We suggest that immediate priority be given to provide grants to state and or counties to address how they can better serve the CFS patient (and their families) population in their respective geographical areas.

We suggest that the CDC include in the area of public education the inclusion of health insurance companies which are known to keep track of their risk management programs, health prevention and service provider disbursements; as well as using technology for the homebound. Since these services are already being provided to the elderly client population, there will be minimum cost in implementing them.

We suggest to use individuals trained in the symptoms of CFS, as test patients to determine the physician's ability to diagnose CFS.

We suggest to measure the improvement of quality of care of CFS patients managed by the physician, not only through patient feedback, but also by the use of medical services that are crucial to the CFS patient. This tool is already being used extensively by hospitals, medical practices and other medical related businesses.

We suggest that before a physician takes the CDC training course, a before questionnaire be given, and a year later a follow-up questionnaire be sent to the physician as well to gauge whether his ability to diagnose CFS patients is in place, and if the number of CFS patients he currently sees has also increased or decreased.

Built on Hope – Strong on Advocacy – Finding a Cure through Research