

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY - 1 2000

Ms. Judy Norsigian
Executive Director
Our Bodies Ourselves
5 Upland Road, #3
Cambridge, MA 02140

Dear Ms. Norsigian:

Acting Secretary Charles Johnson has asked me to thank you for your letter encouraging the Administration to take action to further the understanding and treatment of chronic fatigue syndrome (CFS) and reply directly to you.

CFS poses a difficult diagnostic challenge because there are no characteristic physical signs or diagnostic laboratory abnormalities, so definition relies on self-reported symptoms and ruling out or treating medical and psychiatric conditions that cause fatigue. CFS was first defined by CDC in 1988, and as the illness was increasingly recognized, Australia published a definition in 1990, which was followed by a UK definition in 1991. In an effort to standardize these similar definitions, CDC convened an international panel of CFS research experts, and in 1994 this group published the current internationally recognized CFS case definition for use by both researchers studying the illness and clinicians diagnosing it. According to the 1994 case definition, in essence, in order to receive a diagnosis of chronic fatigue syndrome, a patient must satisfy two criteria:

1. Have severe chronic fatigue of six months or longer duration with other known medical and psychiatric conditions excluded by clinical diagnosis; and
2. Concurrently have four or more of the following symptoms: post-exertional malaise lasting more than 24 hours, unrefreshing sleep, substantial impairment in short-term memory or concentration, muscle pain, multi-joint pain without swelling or redness, sore throat, tender lymph nodes, and headaches of a new type, pattern or severity.

The symptoms must have persisted or recurred during six or more consecutive months of illness and must not have predated the fatigue.

Because of the complexity of CFS and the inherent difficulty of clearly placing patients into a confirmed diagnosis with the 1994 definition, researchers and clinicians wanted a more standardized and measurable case definition that could be used universally. In 2000, CDC organized an International CFS Study Group comprised of experts in CFS, epidemiology, infectious diseases, endocrinology, immunology, neurology, psychology, psychiatry, biostatistics, and patient advocacy to consider difficulties in applying the

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1994 CFS case definition. The group met for a series of three day workshops in 2000, 2001 and 2002, and developed recommendations for use of the definition, standardization of classification instruments and study design issues that are intended to improve the precision of case ascertainment. The International CFS Study Group also identified ambiguities associated with exclusionary and co-morbid conditions and reviewed the standardized, internationally applicable instruments used to measure symptoms, fatigue intensity and associated disability. More information on the case definition is available on CDC's website at <http://www.cdc.gov/cfs/cfsdefinition.htm>.

The Chronic Fatigue Syndrome Advisory Committee (CFSAC), supported by the Office of Public Health and Science, will take your concerns under consideration. Please provide any additional comments to the CFSAC via email at CFSAC@hhs.gov.

The next public meeting of the CFSAC is scheduled for May 27 and 28, 2009, from 9:00 a.m. to 5:30 p.m., at the Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, S.W., Washington, D.C. You are welcome to attend.

Again, thank you for your letter.

Sincerely yours,

/s/

Steven K. Galson, MD, MPH
RADM, USPHS
Acting Assistant Secretary for Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY - 1 2009

Ms. Cynthia Pearson
Executive Director
National Women's Health Network
514 10th Street, N.W., Suite 400
Washington, D.C. 20004

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Steven K. Galson, MD, MPH
RADM, USPHS
Acting Assistant Secretary for Health

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NATIONAL
WOMEN'S
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NETWORK



OUR BODIES
OURSELVES

January 2009

To the Obama Administration Health Care Team:

We are two women's health advocacy organizations with a longstanding interest in medical conditions that solely or disproportionately affect women. We are writing today to encourage the Obama Administration to take action to further the understanding and treatment of the illness known as Chronic Fatigue Syndrome (CFS). CFS, which is also known as Chronic Fatigue Immune Dysfunction Syndrome (CFIDS) and Myalgic Encephalomyelitis (ME), is a poorly understood, variably debilitating illness of uncertain causation. CFS primarily affects women.

Despite the prevalence and severity of this illness, it has garnered far too little attention and research money. Chronic fatigue syndrome is a devastating illness that often leaves its victims unable to work and with a greatly diminished quality of life. While the exact number of people with CFS is difficult to determine, the CDC estimates that this illness affects between 4-7 million people in the U.S.

The name of the illness and the illusory nature of its biological underpinnings have contributed to the common misperception that people with this illness are simply tired, as so many others are, or worse, that the illness is caused by psychological distress. However thousands of peer-reviewed research articles have noted biological abnormalities in people with this illness, and subgroups of patients have been defined through objective testing such as biomarkers, SPECT scans, and specific types of stress tests.

Almost a decade ago, Harvard physician Anthony Komaroff reviewed the research on CFS and wrote:

In summary, there is now considerable evidence of an underlying biological process in most patients who meet the CDC [Fukuda] case definition of chronic fatigue syndrome. ... [This evidence] is inconsistent with the hypothesis that chronic fatigue syndrome involves symptoms that are only imagined or amplified because of underlying psychiatric distress – symptoms that have no biological basis. It is time to put that hypothesis to rest and to pursue biological clues. ... in our quest to find answers for patients suffering from this syndrome.

Moreover, Dr. Philip R. Lee, who served as Assistant Secretary for Health in the Department of Health and

¹ Komaroff, A. "The Biology of Chronic Fatigue Syndrome." Am J Med 108: 169-161, 2000.

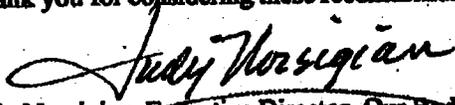
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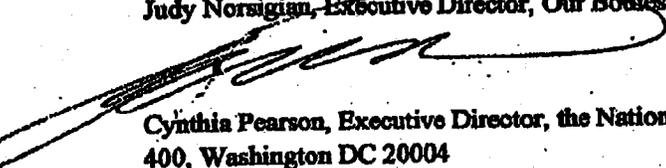
Human Services during the Clinton administration, also shared this viewpoint.² Unfortunately, the little research conducted by the NIH and CDC has too often focused on psycho-social issues and failed to focus on the biomedical aspects of this illness. The Obama Administration needs to ensure that government agencies take an evidence-based approach to find the causes of this illness and to discover treatments that will meet the needs of the many Americans suffering with this illness.

We urge the Obama Administration to take the following steps:

1. Adopt the recommendations of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) (see <http://www.cfids.org/advocacy/cfsac-recommendations.pdf>). This special committee advised the Department of Health and Human Services (DHHS) on policy regarding chronic fatigue syndromes. It brought together officials representing various health agencies with seven appointed members of the public to improve coordination of federal CFS programs. The CFS Advisory Committee grew out of this committee and in 2004 created 11 recommendations for the Secretary of DHHS. These recommendations have thus far not been implemented.
2. Adopt the definition of the illness from the Canadian Consensus Document, created by a committee of experts selected through Health Canada, to diagnose and treat CFS. Other definitions of CFS were created for research purposes; this is the only definition designed for clinical use. It offers a means of recognizing the complexity of the condition at the same time it presents options to begin treating it. The adoption of this international Consensus Document by the United States would aid greatly in the efforts to find and treat those who suffer from this devastating and confounding disorder. A summary of the Canadian Consensus Document is available online at <http://www.mefaction.net/Portals/0/docs/ME-Overview.pdf>.

Thank you for considering these recommendations.


Judy Norsigian, Executive Director, Our Bodies Ourselves, 5 Upland Rd, #3, Cambridge, MA 02140


Cynthia Pearson, Executive Director, the National Women's Health Network, 514 10th Street NW, Suite 400, Washington DC 20004

² Following are excerpts from Dr. Lee's acceptance speech for the Rudy Perpich Award presented at the Bi-Annual Research Conference of the American Association for Chronic Fatigue Syndrome (AACFS) on October 10-11, 1998 (Cambridge, Massachusetts): "I also want to take this opportunity to express myself on an issue that you will be considering at a forum on Monday evening - the change of the name of chronic fatigue syndrome. It is time for a change... First and foremost, most physicians have no respect for the name and it sends the wrong message. Second, the approach to CFS is now dominated by the biopsychosocial approach that gives excessive emphasis to the social, behavioral, and emotional factors in the presentation and perpetuation of symptoms. The "bio" seems to be missing....

Finally, the overlap of symptoms with Gulf War Syndrome, fibromyalgia, and multiple chemical sensitivities merit a thorough re-examination and the development of a comprehensive strategic plan for research. We owe it to the thousands of individuals who suffer from these chronic debilitating diseases to place these issues squarely on the national research agenda."



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WOMEN'S
HEALTH
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A VOICE FOR WOMEN, A NETWORK FOR CHANGE

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Secretary-designate Thomas Daschle
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200 Independence Avenue, S.W.
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