

December 12, 2005

Dr. Vivian Pinn  
Director, Office of Research on Women's Health  
National Institutes of Health  
Building 1, Room 201  
9000 Rockville Pike  
Bethesda, MD 20892-0161

*Susan Jacobs, Esq.*  
Chairman of the Board

*K. Kimberly McCleary*  
President & CEO

Dear Dr. Pinn,

We are deeply appreciative of your efforts and those of Dr. Eleanor Hanna that culminated in the July 15, 2005 release of the Request for Applications titled, "Neuroimmune Mechanisms and Chronic Fatigue Syndrome" (RFA-OD-06-002). We understand that 30-40 applications were received in response to the RFA and that the review of these applications will take place late next month.

Over the years we have, on multiple occasions, expressed to you and others at NIH our concern about the composition of the Special Emphasis Panel (SEP) for chronic fatigue syndrome (ZRG1 CFS 01) and the consistent lack of significant expertise in CFS among panel members. After reviewing the credentials of panelists appointed by Dr. Terry Hoffeld for the November 11, 2005 meeting of the SEP, it is evident that these expressed concerns have been largely ignored. While several of the panelists study fibromyalgia and related conditions, only one (Jian M. Ding, PhD) has been funded to study CFS. While research expertise in sleep, pain and other domains may contribute valuable insights to the review of individual grants, it is very difficult to understand how a fair and thorough review of CFS applications can be accomplished in the total absence of dedicated expertise in the condition itself.

We have conveyed to you the feedback we receive from investigators after their applications are reviewed by the SEP. Pink sheet comments frequently reflect limited understanding of CFS on the part of reviewers. I am aware that within the Center for Scientific Review (CSR) it is common for staff to receive complaints from applicants about the marks and remarks they get back from reviewers. However, problems with the CFS SEP have been reported to us consistently for several years, including by senior investigators with strong track records in securing R01 support in other areas of science.

As we look ahead to the review of applications submitted in response to the RFA, we remain seriously concerned about the prospect of a similarly constituted panel of reviewers. This past August, Dr. Nancy Klimas, president of the International Association of Chronic Fatigue Syndrome (formerly the American Association of CFS), met with you to articulate these concerns in the context of the selection of

reviewers for RFA applications. Following this meeting, she asked us to submit names of potential reviewers to her for inclusion on a list she had been invited to submit to Dr. Hoffeld. We were happy to do so and anticipated that this list would also be a resource for other review panels, not just the one constituted for the RFA-related applications. It's also worth noting that we have submitted lists of potential reviewers to Dr. Hoffeld in the past. Yet, very few of these prospects have been appointed to the CFS panels over the years. We recognize that CSR must observe firm conflict of interest rules that affect the eligible pool of candidates for each round of reviews, but based on the very limited amount of information available to the public about past reviews, these rules don't entirely explain the composition of past panels.

As you know, the CFIDS Association worked for several years to secure an RFA for CFS. In our analysis, one of the greatest benefits of the RFA mechanism (as compared to a Program Announcement) in addition to the availability of set-aside funding, is the opportunity for the review panel to be assembled independent of CSR, a provision we understood to be unique to the RFA mechanism. Given the problems we have observed for so long with the CFS panels constituted by CSR, you can understand that it was an enormous disappointment to learn that CSR would manage the RFA review process instead of the Office of Research on Women's Health. In light of the unacceptable composition of the November 11, 2005 panel, it would be tragic for the same lack of CFS expertise to characterize the panel appointed to review the applications submitted in response to the RFA.

In our interaction with NIH in general and your office in particular, we have sought to support every request with credible, well-researched facts and substance. We have been reasonable in our expectations for growth and positive change. We have attempted to work collaboratively with staff and to offer and provide resources when appropriate. We have tried to propose viable solutions, not just point out problems.

In this spirit, we request an update on the process by which reviewers are being selected for the RFA-submitted grant proposals and the timeline for this panel to be finalized. We would like to know how the list of prospective reviewers is being used by CSR. We also request an opportunity to explore with you other means (as an alternative to the existing SEP) to fairly accomplish the ongoing review of CFS research applications, and ways in which we can work together to achieve the most highly qualified pool of experts to review CFS grant applications. I look forward to your reply.

Sincerely,

K. Kimberly McCleary  
President & C.E.O.  
The CFIDS Association of America

cc: Dr. Antonio Scarpa, Director, NIH Center for Scientific Review  
Dr. J. Terrell Hoffeld, Program Officer, NIH Center for Scientific Review  
Dr. Howard Zucker, Executive Secretary, Department of Health and

Human Services CFS Advisory Committee  
Dr. Nancy Klimas, President, International Association for Chronic  
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