

Testimony by Kim McCleary

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CDC Stakeholder Meeting on the 5-year Strategic Research Plan

My name is Kim McCleary and I am the president & CEO of the CFIDS Association of America, the nation's largest and most active organization working to make CFS widely understood, diagnosable, curable and preventable. This is my 19<sup>th</sup> year of service to the organization, and in all that time, I have missed just one public meeting on CFS. I am deeply familiar with the CDC's research program and CDC staff is quite familiar with me. I've got just 5 minutes so I'll cut to the chase and focus on five areas of concern as the CDC develops its 5 year strategic plan for CFS research.

The 4 goals CDC has provided us are certainly worthy and closely match our organization's goals. If that was all we had to discuss, we could end the meeting early and be on our way. But a strategic plan requires more than that. (Dr.) Steve (Monroe) has just told us that the swine flu cases in the U.S. make it a national "public health emergency." With 4 million cases of CFS in the United States alone, what does it take to have CFS declared a public health emergency?

I will agree with the four peer reviewers who met in November of last year that at one time, this program was doing good work and contributing to the field and to our understanding of CFS. But the CFS research group has lost its mojo. The CDC's CFS research group receives half of the (meager amount of) money that the U.S. spends on CFS. Half. CDC has provided extensive financial information on its CFS spending between FY2005-2008, during which time expenditures totaled about \$23 million. Since 2000, CDC has spent about \$71 million on CFS and it has published 115 peer-reviewed articles in the same time. I doubt most academics could survive with that record. There is a tremendous amount of data housed in this program that needs to be widely shared so we as taxpayers and as advocates yield a better return on our investment than CDC can produce on its own.

Second, by virtue of the plan outline posted on the CDC's website for a CDC RESEARCH plan, it does not seem that three of the four goals are consistent with a research plan for a branch housed in the Coordinating Center for Infectious Diseases. Using organizational information contained in the CDC's 2008 Congressional Justification document, Goal 2 of the research plan, clearly an education-related activity, appears much better suited to either the National Center for Health Marketing or the National Center for Chronic Disease Prevention and Health Promotion. The same is true of goal 4. But these tasks are not logically part of a research strategic plan and are not well-suited to the individuals and leadership currently working in the Chronic Viral Diseases Branch. Even Goal 3 seems an odd fit. This group has become increasingly isolated and insular and is not currently collaborating with any clinical investigators, yet it proposes to develop international consensus on the management of CFS. Note that its clinical recommendations on the web site focus on UK guidelines that are very controversial in that country. How does CDC expect to replicate the success of the clinics in Bibb County, Georgia, that Dr. Royal (from Abt Associates) described? Educating health care professionals is necessary and worthwhile, but it's cost prohibitive to go town to town with the approach used in Macon. How will CDC address that?

Third, this group named the "Chronic Viral Diseases Branch" is currently doing little if any research on viral (or other biological triggers) of CFS. Although they supported the landmark Australian Dubbo Infection Outcomes Study, there is no current work to evaluate EBV, HHV-6, enteroviruses and other agents as triggers of CFS, despite the finding that 10% of these and other acute infections do not successfully resolve and result in a CFS-like state. Instead, the group is focused on early life psychological stressors, a risk factor in most chronic illness, and proposes to study whether the

economic crisis will result in a higher rate of CFS among respondents in the next phase of the Georgia surveillance study. So, why is this psychosocial dimension the focus of research in the NCVZED and the CVDB? So much opportunity has been lost to study the rates of CFS occurring in the wake of outbreaks of West Nile Virus, avian flu and now swine flu, and other acute infections or chronic exposures like toxins and molds. There is great opportunity cost to the choices that branch leadership has already made in an apparent vacuum within its own center.

Fourth, you can't build a sustainable structure on a weak foundation. Yet, it is the strong belief of many in the CFS community – researchers and patients alike (with all due respect to the four individuals who served as peer reviewers in November) – that the empiric criteria is a weak foundation. It is used only by CDC and defines a different patient population and make its studies difficult – if not impossible – to compare to all other studies. So how much of the \$25 million or so that will be dedicated to CDC over the next 5 years will be wasted as a result of this shaky methodological foundation?

Last, the clear consensus message at the two most recent international research conferences on CFS has been the need to establish CFS subsets to facilitate research, objective diagnostics markers and more effective treatments. Yet the research outline makes no reference to this need and focuses on the need to identify biomarkers only for “incident CFS” which may leave out all longer duration periods of illness, and most of the patients who are already ill. This is an unacceptable goal for our nation's public health agency.

CDC alone has the resources and infrastructure to understand the long-term health consequences of CFS and we underscore the importance of CDC conducting longitudinal follow-up studies to track patients for several years, but this is not included in the research plan. Right now we don't know what happens to patients with long-term illness. I can tell you from having known many patients over almost 20 years now that there are some strange and troubling things that occur. We don't know whether this is due to an acceleration of aging, consequences of long-term disability, or aspects of the normal aging process that are exacerbated in some patients, but CDC is the only agency that can study it.

Finally, for any strategic plan it is necessary to address performance milestones, accountability measures and transparency, especially since President Obama made these priorities in the earliest days of his presidency. I know that these values are held by CDC more broadly and hope they will be enforced at the branch level through this plan.