

**TESTIMONY TO THE
DHHS CHRONIC FATIGUE SYNDROME ADVISORY COMMITTEE**

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My name is Kim McCleary and for nearly 18 years I have served as the chief staff executive of the nation's largest and most active organization dedicated to conquering chronic fatigue syndrome, the CFIDS Association of America. I had hoped to share with you ideas for strengthening public/private partnerships to advance CFS research and education, based on successes for other complex health issues.

Instead, I feel I must use my time before the committee to inform you about a situation of deepening and widening concern to all of us at the CFIDS Association, including my colleague Dr. Suzanne Vernon, a former CDC staff scientist. I regret that this testimony is necessary, as we have been here – here in this very room – before, talking about this very same topic. In spite of my calm demeanor, I am outraged that we are again forced to confront serious funding issues with the CDC research program, just as we were 10 years ago, in April 1998. At that time, it was Bill Reeves who took the courageous step to provide evidence of funding irregularities in the CFS program; a year later the Inspector General confirmed that \$12.9 million had been reported to Congress as CFS expenditures, but actually was spent by CDC on other programs between 1995 and 1998. Now it is Dr. Reeves at the center of these problems as chief of the CFS program. The headlines on these *Chronicles* might be the same as they were in 1998. Only my hairstyle has changed.

Based on information we have obtained directly from CDC officials (thank you to Sarah, Mike and Steve for the improved transparency over the past 5 months) and available on public information sites, the “boom” of CFS research that occurred during the “payback” phase from 1999-2005 has eroded to a “bust” of shameful scientific leadership, zero accountability, invisible outcomes and millions and millions of dollars stuck in suspended animation, if not wasted. At least in the 1998 scandal, science was being conducted that would aid discoveries in other diseases. This time, only the government contractors seem to be benefiting from millions spent for which there are no worthwhile outcomes for American taxpayers, or CFS patients.

You're all familiar with the infamous “Bridge to Nowhere.” Let me introduce you to what I call the “Research to Nowhere.”

Please allow me to share to an analysis of the data we have compiled. I understand that you have received from CDC copies of some of the information from which I draw my analysis. (It should be in your notebooks – indicated documents.)

In 2004, CDC began funding a new series of contracts with Abt Associates, a for-profit business and research consulting firm with gross revenues of \$225 million. CDC's CFS research program has contracted with Abt every year since 1989, with most contracts being “sole source” awards – kind of like those no-doc mortgage loans we've heard so much about lately. On September 1, 2004 (29 days before the end of its fiscal year), CDC obligated \$632,174 to pay Abt to “conduct field operations for follow-up of persons with CFS, chronic unwellness and well [sic] that were identified during baseline surveillance” – the “Georgia Study” about which Dr. Reeves presented regular updates to this committee. These studies were designed to “measure clinical course of CFS, evaluate changes in

population morbidity and evaluate economic impact of CFS.” More funds were obligated to this contract on August 9, 2005, August 31, 2006, September 4, 2007 and August 18, 2008. The total allocated to this contract **so far** is \$3,167,516, although only \$1,542,449 has been spent – less than the first two years’ obligations. \$1.6 million in funds directed to this contract have essentially been in limbo since 2007, signaling a lack of strategic direction, accountability and performance by CDC management and the contractor. Information provided by Sarah Wiley indicates that CDC anticipates needing to spend more on this contract, but they do not know how much more or over what time period the expenditures will continue.

You may recall this is the study that utilized the “empiric” definition for CFS about which you expressed concerns this morning and on other occasions, out of concern that the empiric definition captures a different, and perhaps broader, population of patients than does the 1994 definition. So far, there have been just three papers published as a result of this study that has consumed \$3.2 million of CDC’s programmatic budget.

This was not the only project begun during this timeframe with Abt. On August 20, 2005, CDC entered into another task order with Abt to “assess logistics inherent in identifying, contacting, and enrolling subjects into a CFS patient registry.” The first obligation for this effort, which Dr. Reeves has presented to this committee on several occasions, was for \$1,413,940. On August 14, 2006 and September 5, 2007 additional obligations were made, for a total of \$2,187,467. These funds covered protocol development, development of a statement of work, submission of approvals, staging focus groups in Macon, Georgia, and further revising the statement of work and OMB package. In a nutshell – paperwork. The OMB package was not submitted until 2007 and was not approved until August 2008, so the registry has enrolled just one patient in the three years since funding began. Yet \$2.2 million has already been obligated and Ms. Wiley states that CDC anticipates needing to put more money into this contract in future years. Of this amount, just \$975,290 has been spent, leaving another \$1.1 million in limbo, unavailable for other studies or activities.

The third project is the clinical study being conducted in collaboration with Emory University, which also involves contracted services through Abt. The Abt portion alone, begun on September 13, 2005 with an obligation of \$1,213,231, continued with additional obligations by CDC on September 5, 2007 and August 18, 2008, for a combined total of \$2,638,882. This sum has paid for Abt to “provide logistic services to screen participants for an in-hospital study at Emory University, schedule them at the General Clinical Research Center (GCRC), and manage data.” Emory also received multi-year payments for this study, the first one obligated on August 31, 2005 for \$183,381 and payment for intergovernmental personnel services for 14 staff totaling \$345,120 that year and another \$393,041 for 9 staff in 2008. Subsequent years’ payments, 2006-2008, result in a grand total paid to Emory of \$1,843,084. So combined funding for the Emory GCRC study to Emory and Abt is \$4.48 million. \$800,000 of the amount given to Abt is unspent; CDC did not provide data on the expenditures made for the Emory portion of the project. These figures do not count the NIH support that funds the GCRC study at Emory.

There are four major problems with the GCRC study. First, the study did not begin enrolling patients until late April **2008**, according to a “CDC In the News” story circulated by CDC’s press office. Second, only 30 CFS patients (defined by the empiric definition) will be studied, along with 60 controls. Third, the psychiatry group at Emory with whom CDC is working is the same group now under close scrutiny because its (former) department chairman, Charles Nemeroff, was found to have taken at least \$1 million from pharmaceutical companies without disclosing these payments to the university. Senator Grassley has recently widened his investigation of such abuses (see *Nature* magazine, October 2008).

Finally, this \$4 million study being conducted at a per subject cost of \$49,800 (or \$149,000 per CFS subject), is largely designed to examine the response to psychological stressors in CFS.

I provided you with the dates on which these obligations occurred because they are consistent with a pattern of spending commonly referred to as “use it or lose it.” All obligations for these contracts were made in the last few weeks of each fiscal year. And although progress was not being made on the studies per the milestones Dr. Reeves regularly discussed with this committee, more money was committed to the contractors for these projects, even when no reasonable outcomes were generated. In spite of your stated concerns and ours, payments for these contracts have been made as recently as August 2008, even though most all of the work completed so far could have been paid for with funds obligated in 2005. This \$2-plus million “reserve” created for their favored contractors has resulted in program management coming often to this committee and telling other investigators that no funds are available for new projects or collaborations.

In conclusion, when this committee convened last May, you sent a strong “no confidence” signal to DHHS and CDC about the leadership, direction and pace of CFS research at CDC. In light of next week’s peer review of the CFS program, I urge you to send an even stronger signal to the Secretary and CDC’s leadership to decisively address this irresponsible management of the CFS program.