SOLVE**CFS**

The Chronicle of the CFIDS Association of America

Fall 2010

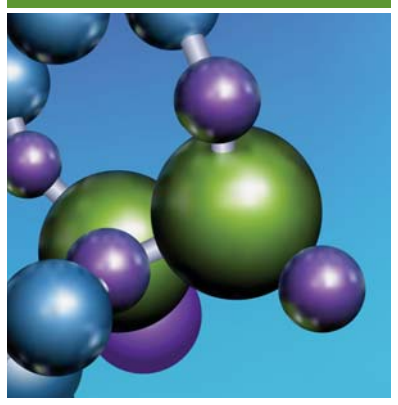
XMRV One Year Later

It has been one year since the first publication linking CFS to a gammaretrovirus called xenotropic murine leukemia virus-related virus or XMRV. This high-profile report in *Science* and subsequent studies of XMRV have helped keep CFS in the headlines, attracted new scientific interest and deepened engagement by federal agency policymakers and researchers. Too often in the history of CFS promising leads have not been followed by larger studies or independent confirmation, so it's very encouraging that so many study results have been published or presented in the past 12 months, even if they don't yet resolve basic questions about risks, diagnosis and treatment.

Many of the people studying XMRV gathered at the 1st International XMRV Workshop on Sept. 7–8, 2010 to share data and establish consensus about methods and research priorities. (See an excerpt of our report on pages 4–5.) The research team led by theWhittemore Peterson Institute remains the only group to have found XMRV in samples obtained from CFS patients and healthy controls, but two groups have now reported finding sequences consistent with other members of a larger family of murine leukemia virus-related viruses (MLVs) in CFS patients and healthy controls. Ten groups from eight countries have reported studies in which they could not detect XMRV (and/or MLV sequences) in CFS samples.

There are important differences between the methods used by the various groups that may account for the results obtained. There are a variety of laboratory techniques being used and some may prove to be better suited to detecting these new agents than others. A study being led by the National Heart, Lung and Blood Institute is attempting to standardize sample collection, storage and processing methods that may be important to comparability of results. Because laboratories are vulnerable to artifacts arising from exposure to mouse DNA through a variety of direct and indirect routes, groups are focusing on ways to fully address this potential confounding factor. Different case definitions for CFS, differences in the geographic distribution of viruses and diversity of viral strains are other possible factors contributing to discrepant results.

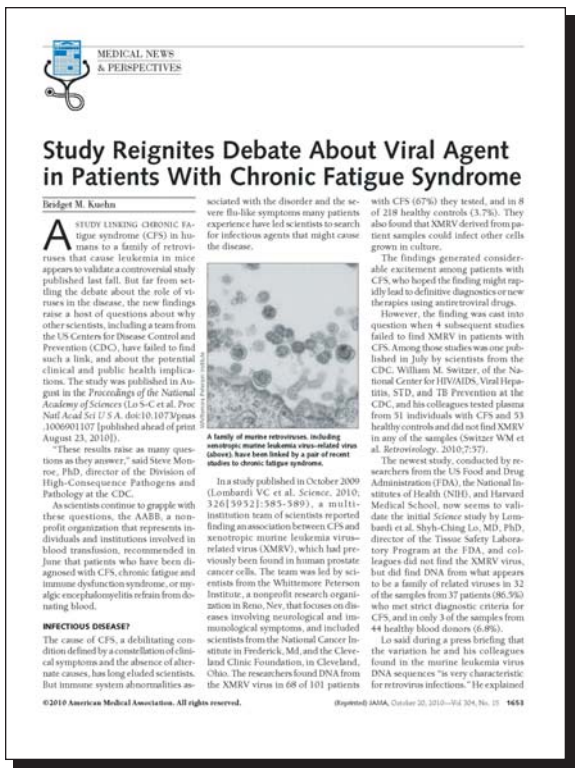
One point of universal agreement is that more study is needed to understand the prevalence and role of gammaretroviruses in humans, considering the array of study results obtained in CFS and prostate cancer, the other condition associated with XMRV in multiple publications. With many more follow-up studies in the pipeline, there is much more information to come. ■



High-Profile Media Coverage Reaches Diverse Audiences

Another peak in news coverage about CFS occurred in the weeks before and days following publication of an August 23, 2010 study titled, "Detection of MLV-related virus gene sequences in blood of patients with CFS and healthy blood donors," by Shyh-Ching Lo and colleagues. (See page 3 for more details.)

Although news articles focused mainly on the results of this study and/or the controversy that surrounded its delayed publication, CFS was uniformly described as a serious and disabling medical condition. Stories appeared in top daily newspapers, including the *New York Times*, *Washington Post* and *Wall Street Journal*; high-impact science journals, including *Science* and *Nature*; wire services, including Reuters and Bloomberg; magazines, including *Scientific American*, *New Scientist* and *DISCOVER*; and specialty outlets including WebMD and HealthDay. Stories were also carried on radio and by French, Spanish, Italian, Greek, Dutch, German, Austrian and Russian-language news media as well.



MEDICAL NEWS & PERSPECTIVES

Study Reignites Debate About Viral Agent in Patients With Chronic Fatigue Syndrome

Bridget M. Kuehn

A STUDY LINKING CHRONIC FATIGUE syndrome (CFS) in humans to a family of retroviruses that cause leukemia in mice appears to validate a controversial study published last fall. But far from settling the debate about the role of viruses in the disease, the new findings raise a host of questions about why other scientists, including a team from the US Centers for Disease Control and Prevention (CDC), have failed to find such a link, and about the potential clinical and public health implications. The study was published in August in the *Proceedings of the National Academy of Sciences* (Lo S-C et al. *Proc Natl Acad Sci U S A*. doi:10.1073/pnas.1006901107 [published ahead of print August 23, 2010]).

"These results raise as many questions as they answer," said Steve Monroe, PhD, director of the Division of High-Consequence Pathogens and Pathology at the CDC.

As scientists continue to grapple with these questions, the AABB, a nonprofit organization that represents individuals and institutions involved in blood transfusion, recommended in June that patients who have been diagnosed with CFS, chronic fatigue and immune dysfunction syndrome, or myalgic encephalomyelitis refrain from donating blood.

INFECTIOUS DISEASE?

The cause of CFS, a debilitating condition defined by a constellation of clinical symptoms and the absence of alternate causes, has long eluded scientists. But immune system abnormalities associated with the disorder and the severe flu-like symptoms many patients experience have led scientists to search for infectious agents that might cause the disease.

A family of murine retroviruses, including xenotropic murine leukemia virus–related virus (above), have been linked by a pair of recent studies to chronic fatigue syndrome.

In a study published in October 2009 (Lombardi VC et al. *Science*. 2010; 326[5952]:585-589), a multiinstitution team of scientists reported finding an association between CFS and xenotropic murine leukemia virus–related virus (XMRV), which had previously been found in human prostate cancer cells. The team was led by scientists from the Whittemore Peterson Institute, a nonprofit research organization in Reno, Nev, that focuses on diseases involving neurological and immunological symptoms, and included scientists from the National Cancer Institute in Frederick, Md, and the Cleveland Clinic Foundation, in Cleveland, Ohio. The researchers found DNA from the XMRV virus in 68 of 101 patients with CFS (67%) they tested, and in 8 of 218 healthy controls (3.7%). They also found that XMRV derived from patient samples could infect other cells grown in culture.

The findings generated considerable excitement among patients with CFS, who hoped the finding might rapidly lead to definitive diagnostics or new therapies using antiretroviral drugs.

However, the finding was cast into question when 4 subsequent studies failed to find XMRV in patients with CFS. Among those studies was one published in July by scientists from the CDC, William M. Switzer, of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention at the CDC, and his colleagues tested plasma from 31 individuals with CFS and 53 healthy controls and did not find XMRV in any of the samples (Switzer WM et al. *Retrovirology*. 2010;7:57).

The newest study, conducted by researchers from the US Food and Drug Administration (FDA), the National Institutes of Health (NIH), and Harvard Medical School, now seems to validate the initial *Science* study by Lombardi et al. Shyh-Ching Lo, MD, PhD, director of the Tissue Safety Laboratory Program at the FDA, and colleagues did not find the XMRV virus, but did find DNA from what appears to be a family of related viruses in 32 of the samples from 37 patients (86.5%) who met strict diagnostic criteria for CFS, and in only 3 of the samples from 44 healthy blood donors (6.8%).

Lo said during a press briefing that the variation he and his colleagues found in the murine leukemia virus DNA sequences "is very characteristic for retrovirus infections." He explained

©2010 American Medical Association. All rights reserved.

(Reprinted) JAMA, October 20, 2010—Vol 304, No. 15 1653

The October 20, 2010 edition of the *Journal of the American Medical Association* (*JAMA*) included in its print edition a two-and-a-half page article about CFS and the XMRV/MLV link. *JAMA* is the most widely circulated medical journal in the world and it reaches more physicians than any other. Reporter Bridget M. Kuehn writes, "The cause of CFS, a debilitating condition defined by a constellation of symptoms and the absence of alternate causes, has long eluded scientists. But immune system abnormalities associated with the disorder and the severe flu-like symptoms many patients experience have led scientists to search for infectious agents that might cause the disease." The article reviews the research on XMRV and MLVs in CFS and concludes with quotes from Vanderbilt professor and secretary of the Infectious Diseases Society of America, William Schaffner, MD, calling for more studies, NIH to recruit more qualified researchers to the field, and empathy for patients and their families.

Find links to all the latest news and news coverage at www.cfids.org/SolveCFS/fall10.asp. ■

IN THIS ISSUE

Validate. Innovate. Eliminate.

Expanding Research: Building on Your Investment

When the CFIDS Association of America launched the **Campaign to Accelerate CFS Research**, a year-long, $1-million initiative to expand its research program in 2008, a committee of board members and other scientific experts recommended five distinct and specific evaluation criteria for proposals received from researchers. Among those five criteria was this question: "How likely is it that the proposed research will be fostered and will succeed in securing greater funding from larger funding sources (like NIH)?"

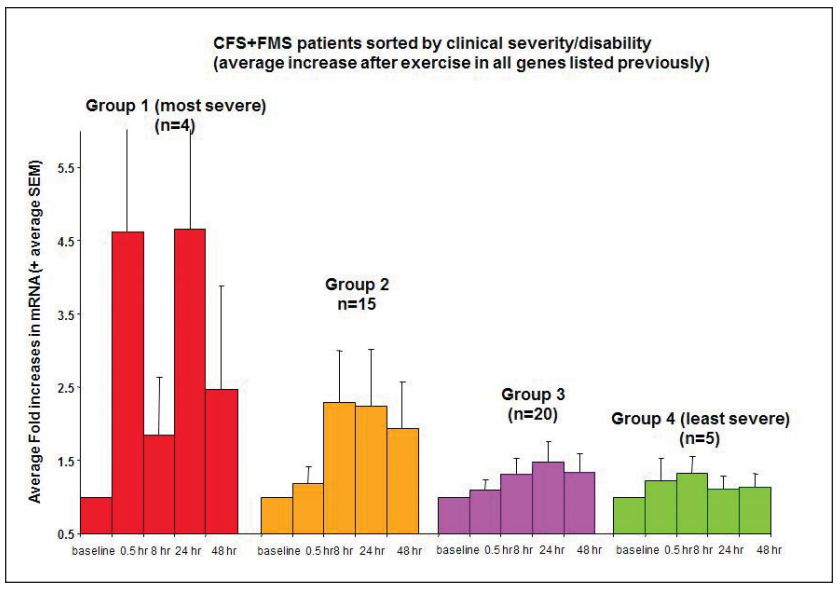
This important question underscores how the Association views its research program: the grants we make, made possible through your generous gifts, are investments in the future of CFS science. We don't expect your bucks to stop here — we expect them to grow and spread throughout the research community until, one day, CFS is widely understood, diagnosable, curable and preventable. The six projects selected for Association support are already demonstrating success.

"We had previously shown in a small sample that following 25 minutes of moderate exercise, patients with CFS have increases in expression of several genes beginning as soon as 30 minutes later and lasting for 48 hours that correlate with worsening fatigue and pain," says the University of Utah Health Services Center's **Dr. Kathleen Light**. "The goal of our study was to test 30 additional patients with CFS (including those who did and did not meet diagnostic criteria for fibromyalgia as well) and 30 healthy controls, to reconfirm our original findings and to see if our post-exercise gene expression markers can differentiate CFS patients with and without fibromyalgia pain. Our original findings were reconfirmed with support from a major pharmaceutical company; we will extend this research to see if treatment with an FDA-approved pain medication helps to normalize these abnormal gene expression patterns in CFS patients who also have fibromyalgia. We are also seeking support from NIH to verify that CFS patients can be differentiated from patients with clinical depression using this same post-exercise gene expression profile."

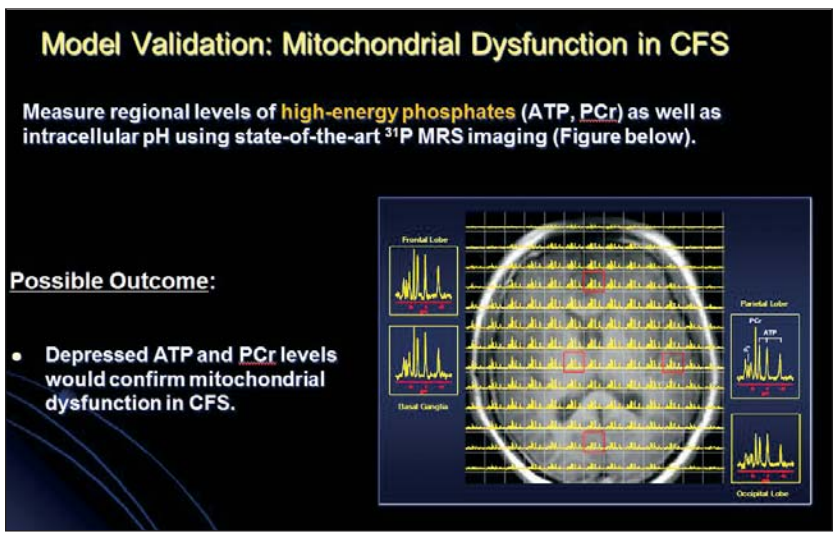
Gordon Broderick, PhD, of the University of Alberta, directed a cross-disciplinary team from four institutions to study adolescents who became ill with CFS after contracting infectious mono-nucleosis. Using a very specific and well-defined group of patients, he investigated the immune and endocrine responses of the study subjects from initial infection through the first 24 months of illness. Put very simply, their immune cells were not "communicating" the way that healthy people's cells do. Dr. Broderick parlayed these results into three additional grant awards, totaling more than $4.5 million, from the National Institutes of Health and the Department of Defense. He and colleagues will focus on the neuroendocrine and immune systems, using molecular profiling and examining the systems' dynamics to explore ways to "re-set" them to normal functioning.

Broderick (left) has engaged medical students, including Andrea Kreitz (right) and Landon Berger, in CFS studies. The team has leveraged its Association pilot grant for $4.5 million in new funds.

Cornell University's **Dr. Dikoma Shungu** extended early Association funding into an additional grant to expand his research into brain lactate levels. He explains, "Following our first CFIDS Association-sponsored brain imaging study that found significant elevations of ventricular cerebrospinal fluid (CSF) lactate in CFS compared to matched patients with anxiety disorder and to healthy control subjects, we received additional support from the Association to try to understand the cause(s) of this increase of CSF lactate in CFS. Our overall hypothesis is that the increased lactate is the result of a secondary brain energy production problem due to mitochondrial dysfunction that arises from accumulation of toxic chemicals known as free radicals. Increased levels of free radicals lead to a condition known as oxidative stress that can damage the mitochondria, leading to a brain energy production problem and associated increases of CSF lactate." He continues, "A decrease in brain blood flow can also lead to increased lactate. To test this overall model, we're using a number of advanced brain imaging methods to replicate our finding of increased lactate in new CFS patients, document decreased brain energy production to establish mitochondrial dysfunction, measure brain blood flow and document the presence of increased oxidative stress. If successfully completed, this research could significantly advance our understanding of some of the causes of CFS."



The Light team has identified biomarkers that provide objective measures of illness severity in patients who have CFS and fibromyalgia pain.



Shungu has been studying levels of various chemicals in the brain that could unify other observations of mitochondrial dysfunction in CFS.

The teams shared these outcomes during a webinar moderated by scientific director **Suzanne Vernon, PhD**, on Oct. 5, 2010; you can link to the recording from www.cfids.org/SolveCFS/fall10.asp. All three teams of researchers have added publications to the peer-reviewed literature and made presentations at professional meetings around the world that have helped raise awareness and deepen understanding of CFS among their scientific colleagues.

In our next issue, we will report on the other three funded research projects led by Marvin Medow (New York Medical College), Bud Mishra (New York University) and Sanjay Shukla (Marshfield Research Foundation). We plan to issue a new request for proposals to stimulate studies that will validate biomarkers to advance objective diagnosis and effective treatment. The timing of this announcement will depend upon our success in raising funds to support new studies and other aspects of our research program. Your continued support will help acceleratethe unprecedented momentum and speed better diagnostics and treatments. ■

SolveCFS BioBank Gets Rolling!

This spring we launched the **SolveCFS BioBank**, the first initiative of its kind to create a repository of clinical data and biological specimens collected from well-characterized CFS patients and controls that can be accessed by approved researchers to discover and validate biomarkers. In the first six months, we have enrolled 549 participants and established several collaborations with researchers.

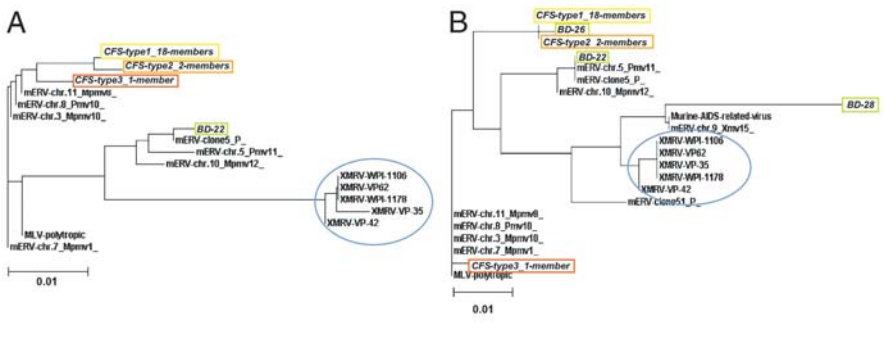
We are now in the process of converting from a paper-based system of collecting extensive medical history and symptom information from participants to one that is completed online directly by the participant. Individuals who don't have Internet access or can't complete the online questionnaire can still use paper forms, but this new system will facilitate regular updates from participants to collect information about the course of illness. Ultimately, we envision collecting blood samples at various time points to create a bank of specimens for longitudinal studies.

For more information about participating in the **SolveCFS BioBank**, please visit our website at www.cfids.org/SolveCFS/fall10.asp or contact our BioBank Coordinator, Gloria Smith, at 704-362-2343.

FDA/NIH/Harvard Study Takes New Turn

On Aug. 23, 2010, a much anticipated report from a group of researchers led by Shyh-Ching Lo of the Food and Drug Administration (FDA) with collaborators at the National Institutes of Health (NIH) and Harvard Medical School was published online in the *Proceedings of the National Academy of Sciences* (PNAS). This study reports a strong association between CFS and polytropic murine leukemia virus-related viruses (MLVs), with 32 of 37 (86.5%) CFS patients testing positive for MLV sequences compared to 3 of 44 (6.8%) healthy blood donors. In all, there were six variants of MLV found. The sequences for four of those variants are described in detail, with corresponding figures to illustrate the relationships of those variants to other known strains of MLVs. The authors write, "…our analysis revealed three different types of MLV-related sequences in CFS patients. In all three groups, the sequences were more closely related to the sequences of polytropic mouse endogenous retroviruses (mERVs) than to XMRVs..." (Polytropic refers to the agent's ability to infect both mice and other species, while the "X" for xenotropic refers to the agent's ability to only infect non-murine species.)

CFS samples were obtained by Dr. Lo from Anthony Komaroff, David Bell and Paul Cheney in the early 1990s for a study of mycoplasma. Eight of the 25 patients from Dr. Komaroff's practice provided fresh samples in early 2010.



This figure from the *PNAS* paper shows the position of the sequences found by Lo et al. in comparison to XMRV and other murine gammaretrovirus. ("BD" stands for blood donor.)

The study was covered widely in the press both before and after its publication (see page 1). A media leak of a presentation that promised results confirming the original XMRV finding was followed by allegations that the positive study was being withheld by Department of Health and Human Services officials because an unpublished study conducted by Centers for Disease Control & Prevention (CDC) researchers had not found XMRV. The negative CDC study was published in *Retrovirology* on July 1, 2010; Dr. Lo's group voluntarily withdrew its manuscript and conducted more tests. The two groups have shared some samples, and Dr. Lo's tests of 34 CDC samples came up negative for XMRV and MLV sequences. Both groups are part of the blood safety study working to align detection methods.

In the days following publication of the Lo paper in *PNAS*, we enlisted a group of experts to help answer Frequently Asked Questions about the study. Here are a few of the Q's and A's; the complete set is available at www.cfids.org/SolveCFS/fall10.asp.

Harvey J. Alter, MD, MACP of the NIH

Question: Do you consider the *PNAS* study to have been designed as either a validation or replication study of the Lombardi et al. study?

Answer: The *PNAS* study was stimulated by the *Science* publication and by the negative studies that followed. We tested our cohort of CFS patient samples and controls without bias. That is, we did not have an expectation in either direction, but simply wanted to know whether or not we could find XMRV in our samples. As it turned out, we did not find XMRV, but rather, closely related polytropic murine leukemia virus-related viruses (MLVs). The strong association of the MLVs with CFS identified in our patient population was similar to the strong association of XMRV and CFS reported by Lombardi et al. However, the role of MLVs in the CFS disease process is still not clear. — **Harvey J. Alter, MD**, MACP, Chief, Clinical Studies & Associate Director for Research, Department of Transfusion Medicine, National Institutes of Health and **Shyh-Ching Lo, MD, PhD**, Medical Officer, Division of Cellular and Gene Therapies, Federal Drug Administration

Question: The FDA has posted a Q&A on its website, stating that Dr. Lo tested 34 CFS patient samples from CDC and that there were "no XMRV-positive" results. Did he test for the broader group of MLVs? Will these results be published when all 82 samples from the CDC's negative study have been tested?

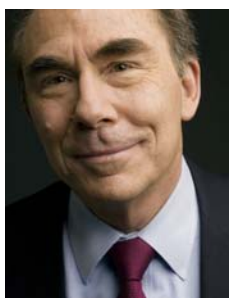
Answer: The CDC samples were tested for the broader group of MLVs. While we did not find any of the 34 CDC CFS samples to sequence as MLV, there were three samples that were indeterminate in that they had weak PCR-positive signal, but could not be confirmed by sequencing. These samples are now being further amplified and cloned for resequencing. CDC and FDA/NIH will continue to work to understand the disparities, but there is no current plan to publish the results of this sample exchange. It was not critically designed to be a study for publication, but larger coded panel testing conducted by NHLBI in which both CDC and FDA, as well as other labs, are participating will be published when the data are complete. — **H.J. Alter, MD, MACP** and **S-C Lo, MD, PhD**

Question: You've been at this a long time and have seen evidence that associates several different infectious agents with CFS. What are your thoughts on this particular study?

Answer: Based on my experience talking to the patients, and examining them, I think that the most likely explanation of their illness in most of the patients with CFS is that they are suffering from some kind of chronic infection. I think it is very plausible that the infection is of a type that cannot be fully cleared by the immune system, although that has not been proven. I think it is very plausible that the key symptoms of CFS are caused by the immune system's attack on the infectious agent(s) that may be involved, although that has not been proven. Finally, since symptoms are experienced in the brain, I think it is very plausible that the immune system molecules that may cause the symptoms are either produced in the brain (because the infection is there) or reach the brain through the circulation, although that has not been proven.

This study found strong evidence that a group of retroviruses that were first discovered to infect mice may also be infecting many patients with CFS, and also a few healthy blood donors. However, other studies—both published and unpublished—have not found that. All of the laboratories that have studied this question need to work together to try to understand why they have gotten different results. The PCR techniques that were the basis of most of these studies are very tricky: they can be falsely positive, and they can be falsely negative. Dr. Lo's laboratory took great pains to rule out various types of falsely positive results, as explained in our paper. We also proposed some reasons why other studies might have obtained falsely negative results, but that is just speculation.

In summary, our study does not and should not settle the question as to whether mouse retroviruses may be associated with CFS. It is one study, one piece of evidence. Scientific conclusions require multiple studies, and multiple types of evidence. More work needs to be done, particularly among those laboratories already engaged in the study of this question, to understand why their results are different. Even if it is concluded that these viruses are often present in patients with CFS, that will not prove that the viruses are a cause of CFS. So we are a long way from the finish line in getting solid answers to these important questions. — **Anthony L. Komaroff, MD**, The Simcox/Clifford/Higby Professor of Medicine, Harvard Medical School; Editor in Chief, Harvard Health Publications, Harvard Medical School; and Senior Physician, Brigham and Women's Hospital



Anthony L. Komaroff, MD of Harvard

Question: Do the three variants of MLV sequences found in the CFS patients from your practice correlate to any particular CFS symptoms, type of onset, age, illness severity, etc.?

Answer: Not that we can tell, but the total numbers are small. We need much larger studies to answer this important question. — **A.L. Komaroff, MD**

Question: Some media reports referred to murine leukemia virus-related viruses (MLVs) as "cancer-causing agents." This description refers to some MLVs being cancer-causing in mice, but what does it mean for humans?

Answer: The MLV family of viruses has never been shown to cause cancer in humans. There are lots of animal viruses that cause tumors in other species. These viruses are also related to feline leukemia virus and porcine leukemia virus. Similarly, it is often possible to cure tumors in mice and rats, but the same agents are ineffective for human tumors, so it is both inaccurate and misleading to suggest that these viruses cause human tumors. — **Harvey G. Klein, MD**, Chief, Department of Transfusion Medicine, NIH Clinical Center

Answer: Human T-lymphotropic virus (HTLV) was the first human virus linked to cancer, followed by hepatitis B virus (HBV) and hepatocellular carcinoma. Mouse viruses while having the capacity to infect human cells, have not been associated with any human cancers. — **Susan L. Stramer, PhD**, Executive Scientific Officer, Scientific Support Office, American Red Cross ■

International XMRV Workshop Convenes Experts

Dr. Francis Collins, director of the National Institutes of Health (NIH), gave the opening address of the 1st International XMRV Workshop, held Sept. 7–8, 2010 in the Lister Hill Building on the NIH campus. In the 10 plenary talks and 20 data presentations that followed, 225 participants from 11 countries and 57 institutions heard new, but sometimes discordant, data about the structure and properties of these viruses of probable mouse origin, assay methods used to detect them, their prevalence in different populations (healthy and ill) and possible therapeutic and control measures. Twenty-three posters supplemented the oral presentations, although the program did not include a summary or critical review of posters. This report is an excerpt of a more comprehensive summary available on our web site at www.cfids.org/SolveCFS/fall10.asp.

CFS Presentations

A total of nine (six oral and three poster) Workshop presentations offered data examining the prevalence of evidence of murine leukemia virus-related viruses (MLVs) in CFS cohorts. The study from **Shyh-Ching Lo** at the Food and Drug Administration (FDA) was the only presentation that repeated published data, aside from **Francis Ruscetti's** lecture on CFS in which he discussed the National Cancer Institute's studies of XMRV in CFS, including the one reported in *Science*. Eight of the nine studies reported on samples collected for the explicit purpose of testing for XMRV/MLVs, an advance from reliance on banked samples of convenience in earlier studies. Three of the six oral presentations found evidence of XMRV and MLV-related DNA in CFS (**Maureen Hanson** of Cornell University, **Lo** at FDA and **Judy Mikovits** of the Whittemore Peterson Institute); two did not (**Norbert Bannert** of Robert Koch Institute in Germany and **Jonas Blomberg** of Uppsala University in Sweden); and one concluded that positive results were due to contamination (**Brigitte Huber** of Tufts University).

Of the three positive studies, all reported some diversity of sequences found, although Dr. Mikovits stated that the predominant variant detected by WPI was XMRV. Two of the three positive studies classified CFS patients using Fukuda criteria and the third used Carruthers (Canadian) criteria. The rates of positivity varied. Dr. Hanson's study tested samples obtained by **David S. Bell** from 20 CFS patients, 10 of whom reported having recovered but still demonstrated lower physical activity levels than the 10 healthy control subjects as measured by seven instruments employed by Dr. Bell. Of these 20 CFS patients, 11 (55%) were positive; 8 (80%) of the 10 patients currently meeting Fukuda criteria and 3 (30%) of the individuals who had recovered tested positive, compared to 1 (10%) of the 10 healthy controls. The *gag* sequences found by Dr. Hanson were more similar to those reported by Lo et al., than to the *gag* sequences for XMRV, although all are part of the same gammaretrovirus family. Her group is working to sequence the *env* sequence and the entire virus genome(s) now that they have external funding support from NIH. Thirty-two (86.5%) of the 37 patient samples tested by Dr. Lo, as published in the *Proceedings of the National Academy of Science* on Aug. 23, 2010, were positive for MLV sequences. He responded to several questions about possible contamination and indicated that they had used sodium citrate tubes for sample collection in the 1990s and for the follow-up samples collected earlier this year. Dr. Mikovits reported on a cohort of 50 ME/CFS patients recruited from the London area; 24 (48%) of 50 were positive using PCR and 39 (78%) of 50 were positive using a DERSE cell assay described in another session by **Kyeong Lee** of the National Cancer Institute (NCI). Dr. Collins asked Dr. Mikovits about the rate of positives among healthy controls, to which she replied, "6–8% have antibodies with some indeterminant results and we're able to isolate virus from 11%." Following another question, she noted that the healthy blood donors used as controls were not matched by age or sex to the patients, but all came from the London area.

The two negative studies presented orally also used Fukuda criteria to select CFS patients and a variety of assay methods to detect XMRV and MLVs. The study presented by Dr. Bannert included patients with multiple sclerosis (MS) but did not find any evidence of virus in the 36 CFS patients, 50 MS patients or 17 healthy individuals. Dr. Bannert was able to demonstrate that the peripheral blood mononuclear cells (PBMCs) from CFS patients could be infected experimentally with XMRV. Dr. Blomberg reported some weakly positive results, but stated that they were ultimately unable to recover virus from any of the samples tested, which included 35 CFS patients, 15 fibromyalgia patients and 200 healthy controls. Additionally, he reported finding viral sequences in 3 of 5 XMRV-positive samples received from the WPI. These two negative studies came closer to using the methods reported in *Science* than the four earlier negative attempts and a study from Hong et al. in China that all relied solely on polymerase chain reaction (PCR) assays (published Sept. 13, 2010).

Dr. Huber reported on two separate cohorts tested in her lab, the first of which included 111 patient samples collected by **Susan M. Levine**, only one of which was positive and was later determined to be a false positive result. In the second cohort, consisting of 3 CFS patients and 36 healthy controls, 2 (67%) of 3 patient samples were positive, but so were 17 (47%) of 36 control samples. Dr. Huber's laboratory conducted additional tests, including an assay for mouse intracisternal A-particles (IAP) that had been described the day before by **Oya Cingöz** of Tufts University, to look for minute traces of mouse DNA and RNA. Dr. Huber concluded that the results were likely due to contamination of a common lab reagent, but had not yet identified the particular contaminant. During the question and answer session that followed Dr. Huber's presentation, some participants suggested heparin in the tubes used to collect samples might be to blame for the results; however, the original report in *Science* from WPI also described the use of heparin tubes for sample collection in that study. Discussion did not address which suppliers' tubes were used in either study.

Three posters reporting positive findings were from investigators associated with WPI, using the WPI lab or its subsidiary, VIP Diagnostics, for testing. Rates of positives ranged from 35.5% among 640 samples from individuals with a variety of conditions who paid to have their samples tested at VIP Diagnostics, to 74.5% in 47 consecutive patients seen by **Paul Cheney** at his private practice specializing in CFS. Two of the posters also reported results from other populations tested. Dr. Cheney reported that 50% of "exposure controls" were positive, while the WPI poster study authored by **Max Pfost** reported on a cohort of adults and children with a variety of neuroimmune diseases (including CFS, FM, Lyme, autism spectrum disorder and Neimann-Pick C) and healthy parents or siblings of those individuals. Overall, 55% of the 66 samples were positive for XMRV. While Pfost et al. suggest that the "significance of these findings is not clear," these results add another level of complexity to discerning the meaning of positive (and negative) data presented at the meeting and in the literature.

Another poster reporting results of XMRV testing, although not specifically oriented to prevalence, was from **David Strayer** at Hemispherx, manufacturer of the experimental drug Ampligen. Banked samples collected before a 40-week trial of Ampligen were tested for XMRV. Of the 208 Ampligen-treated CFS patients meeting Holmes, Fukuda and other severity criteria, 33.7% were positive for antibody to XMRV in testing conducted by WPI.

NIH Director Francis Collins Delivers Opening Remarks


Francis S. Collins, MD, PhD

"Prostate cancer and chronic fatigue syndrome (CFS) are of enormous medical importance. Both are relatively common and the identification of a viral component has increased interest in both conditions. Over many years, CFS has been buffeted back and forth, leaving individuals with it wondering if they have been forgotten. So, this is a timely meeting, at a timely moment when science is at an interesting crossroads," Dr. Collins observed. He briefly recapped the discoveries leading up to the meeting, noting the conflicting data about the association of XMRV to both prostate cancer and CFS. Laying out questions that need to be answered, he underscored that differences between "X" (xenotropic) and "P" (polytropic) murine leukemia virus-related viruses (MLVs) might matter. As one of the steps being taken by NIH, he announced that **Anthony Fauci**, director of the National Institutes of Allergy and Infectious Diseases (NIAID), had tapped **Ian Lipkin** of Columbia University to conduct a multicenter study of the role of XMRV and PMLVs in CFS patients and matched controls with broad geographic distribution as a "critical next step." He reminded the 225 participants gathered that "association does not equal causation" and suggested the possibility that some underlying problem with the immune systems of patients with one or both of these conditions might make these viruses more easily detectable. He urged participants to maintain a healthy skepticism and to demand rigor of the studies. He defined the synergistic efforts that would be required by researchers working on prostate cancer and CFS and from different disciplines of science and medicine to uncover clearer answers. Concluding his remarks, he called the assembly a "brain trust" and reminded people that the suffering endured every day by patients with these conditions can only be overcome by strong science. Dr. Collins left shortly after making these introductory comments and returned the next day to participate in the sessions focused on prostate cancer and CFS.

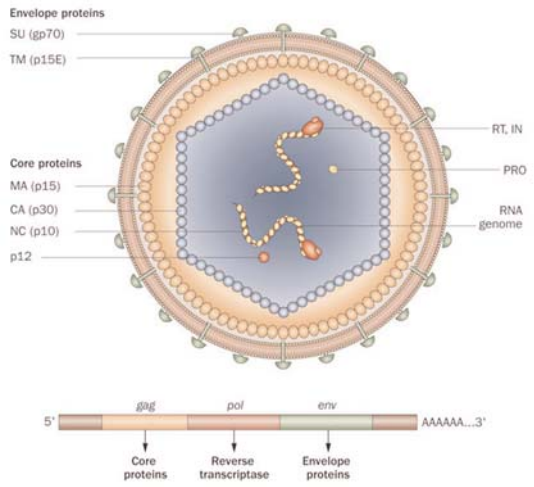
Dr. Strayer reported that an analysis of data following 40 weeks of therapy indicated that Ampligen patients who were XMRV-antibody negative had lower (worse) activity of daily living (ADL) scores and lower overall activity levels than the Ampligen patients who tested positive for XMRV.

The final presentation of the two-day Workshop was a report on the study being led by the National Heart, Lung and Blood Institute (NHLBI) through a collaboration established as the Blood XMRV Scientific Research Working Group. A four-phase study has so far compared the performance of XMRV assays using an analytical panel of samples, showing that investigators at NCI, CDC, FDA (two groups), WPI and Blood Systems Research Institute (BSRI) have similarly effective means of detecting XMRV RNA in blood and plasma. These results were reported at the July 26, 2010, meeting of the FDA's Blood Products Advisory Committee. Just days before the XMRV Workshop, the six laboratories participating in the study shared results of phase II experiments; however, there was sufficient ambiguity about the interpretation of results that the group determined it would be better not to report them until after additional experiments are completed. **Graham Simmons** of BSRI indicated that additional tests are being conducted to discern how sample collection and processing might affect assay results and how well assays performed against panels containing validated pedigreed XMRV-negative samples and samples from XMRV-positive patients supplied by WPI.

Q&A Session

A one-hour question and answer session with a panel led by **Jonathan Stoye** of the U.K.'s National Institute of Medical Research was webcast live to the public and archived for later viewing. Joining Dr. Stoye on the panel were **Donald Blair** of NCI's extramural division, **Jerry Holmberg** of the Department of Health and Human Services, **John Coffin** and **Judy Mikovits**. Before taking questions from participants, Dr. Stoye reminded everyone that this was a scientific session and not a political one, a reference to a pointed question posed in the earlier session about the lack of governmental pursuit of XMRV research prior to publication of the paper from WPI. This had been the only tense moment in a meeting where those with differing perspectives and discordant data addressed one another with collegial respect. As **Stuart LeGrice** said during his introductory remarks at the beginning of the meeting, "This isn't the frenzy some in the media have portrayed. We're just doing what we're trained as scientists to do." But by the end of second day, with many puzzled by the conflicting data and complex array of information that didn't present any obvious solutions, frustration was more palpable. Cameras located around the bowl-shaped auditorium were reminders that a larger audience was watching too.

Questions about what to call the different sequences that had been reported and how to prove they were transmissible were met with long answers that can be summarized as, "We need more research and classical virology before we'll know." The blood safety study was offered as a near-term indicator of how different sample collection and processing protocols might be contributing to discordant results. It was also cited as an effort by several labs to test samples from the same patients collected under standardized conditions, although some pushed for expanded efforts to do this outside the context of blood safety to resolve discrepancies between the groups. There was consensus that greater collaboration and coordination was needed, and an offer to arrange the sharing of XMRV-positive samples was tendered by **Judy Mikovits** and accepted by **Myra McClure**, one of the authors of the first paper that found no evidence of XMRV in CFS samples. There was also consensus that stand-alone PCR was not sufficient for detection of the virus in clinical samples. Several questioners noted the vast differences between groups, in that some found high rates of positive cases in CFS cohorts while others found zero, suggesting that differences in case definition alone would be more likely to yield a range of positive rates rather than such extremes. Host genetics, background influences and restriction factors were offered as unknowns that still needed to be sorted out, in addition to technical differences in sample handling and assay methods. The need for funding to support this research was another point of strong consensus, with even intramural NIH researchers noting that the work done so far had largely been carved from other budgets and would need to be sustained by larger, dedicated sums. **Don Blair** noted that the number of research applications on XMRV was still small, in spite of the capacity crowd attending the workshop. Some questioners sought to understand the connection between prostate cancer and CFS, beyond the first link suggested by similar defects in the RNaseL antiviral pathway. Immune defects that suppress the immune system to allow viral infection or presentation of latent viruses were suggested, while others stated it might be more advantageous not to consider prostate cancer and CFS together since different mechanisms might be at work. The idea that XMRV might be a passenger virus and that the immunosuppressive state associated with disease might result in the viral infection (rather than the virus possibly causing disease) received some attention. Participants named lessons learned from other retroviruses like gibbon ape leukemia virus (prevalent among healthy gibbons in U.S. zoos) and HTLV-1 (one agent causing two distinct diseases). At a few different points, including the discussion of XMRV as a possible passenger virus, the discussion shifted to using clinical trials of antiretroviral agents as a means to learn about the virus itself, as well as to treat individuals who had tested positive. This was by far the most contentious point of the meeting, with great caution expressed about the off-label use of HIV drugs, while others stated that controlled trials of agents shown to have some utility against XMRV could be instructive. In the end, there was some agreement that a small study of patients identified as XMRV-positive by standardized tests, with close monitoring using a quantifiable assay for viral load could be conducted when appropriate methods were available to follow the individuals receiving therapy. Questions about issues deemed by the panel chair to be political (rather than scientific) were deferred, including a repeated question about why CDC selected the subjects it did for its study and why it used a lab that had reported negative results in prostate cancer for confirmation of its own negative results.



Reprinted by permission from Macmillan Publishers Ltd: *Nature Reviews Urology*. Silverman, R. H. et al. (2010) The human retrovirus XMRV in prostate cancer and chronic fatigue syndrome. doi:10.1038/nrurol.2010.77

The Q&A session led by an expert panel was webcast to the public.

Inconclusive Conclusions

The Workshop was brought to a close without definitive answers to questions about the origins of MLVs in humans, disease associations, testing, transmissibility, therapeutic approaches or preventive measures. Renowned retrovirologist **John Coffin** characterized the state of current knowledge as a "zone of chaos." There were no easy answers offered, and the discrepant data presented so far in CFS and prostate cancer are unlikely to be resolved by one simple explanation. However, there was considerable optimism among speakers and panelists about the accelerating pace of progress and that accord on key issues is likely less than a year away. While that timetable is little comfort to people whose lives have been derailed by any of the conditions linked to this family of retroviruses, this meeting demonstrated that XMRV has rallied scientific interest unmatched in the history of CFS. ■

What's Next?

- Refinement and reporting of data from the Blood XMRV Scientific Research Working Group's Phase II and Phase III studies that will help optimize sample collection and processing for detection of XMRV/MLVs.
- Details of the study supported by NIAID in which "microbe hunter" Ian Lipkin of Columbia University will test samples collected from CFS patients in distinct geographic areas for MLVs.
- New publications from groups attending the workshop and others.
- A State of the Knowledge conference for ME/CFS being planned by NIH for spring 2011.

CFS Advisory Committee Elevates Network and Name

The federal **CFS Advisory Committee** (CFSAC) is one of relatively few disease-specific advisory committees that exist to make policy recommendations to the Secretary of Health and Human Services (HHS). The CFSAC was formally chartered under the Federal Advisory Committee Act in 2003 and its charter was most recently revised and renewed on Sept. 5, 2010. The recent renewal expanded the committee's scope to include quality of life issues, added representatives from two more HHS agencies and changed the requirement for meetings to "at least" two per year, rather than "no more than" two per year. A call for nominations to fill scheduled vacancies arising in April 2011 provided an opportunity for the Association to submit the names of seven highly qualified candidates for consideration.

On Oct. 12-14, 2010, the CFSAC held its second meeting of the year. The first of three days was dedicated to the science of CFS, and was structured to provide the committee, federal agency representatives and the public with an update on the latest developments in etiology, natural history and clinical studies. Six presentations covered the immune system, Epstein-Barr virus infection, XMRV, genetic and genomic markers, other markers of change and antiviral therapies.

Day two's agenda focused on issues related to documenting vocational disability and other employment-related issues that fall under the CFSAC charter. On day three, the committee heard and challenged federal agency presentations and subcommittee reports. Three hours were dedicated to public testimony given in person, by telephone and via video by CFS patients, family members and advocates, including Association CEO Kim McCleary. During the final session, three recommendations to the Secretary of Health were presented, debated and approved. The entire meeting was webcast live to public and has been archived on the CFSAC's web site. You can find links to CFSAC-related materials at www.cfids.org/SolveCFS/fall10.asp. ■

Recommendations by the CFS Advisory Committee — Oct. 14, 2010 (abridged)

ONE: Following other successful networking models for complex diseases, we propose the development of a national research and clinical network using regional hubs serving as a patient care/education/research hub to fill a crucial need for the ME/CFS community. This network would link multidisciplinary resources expanding access to expert patient care, assisting patients in disability assessment, developing educational initiatives and certification programs, providing the core support for a much-needed research and clinical trials network, and providing experts to develop health care policy.

TWO: HHS leadership should engage the expertise of the CFSAC as it moves forward in developing policy and agency responses to the health crisis that is ME/CFS.

THREE: That HHS use the term ME/CFS.

Senate Directives Reflect CFS Research Priorities

Expanding sources of research funding is central to the CFIDS Association's mission and is its core strategy to make CFS widely understood, diagnosable, curable and preventable. In addition to the direct support of research studies (see page 2), the Association annually submits its requests to the U.S. Congress to expand research and education on CFS and diligently shepherds those requests through the lengthy bi-cameral appropriations process.

Appropriations bills are the legislative means by which Congress apportions the federal budget to executive branch agencies, providing large-scale budget divisions to the agencies as spending plans. The report that accompanies each spending bill spells out Congressional priorities for funding.

For the first time, the Senate Appropriations Committee for the Department of Defense has included CFS as an eligible topic for the $50 million **Congressionally Directed Medical Research Program** (CDMRP) for fiscal year 2011. The Association was instrumental in justifying the relevance of CFS to military and civilian health, a requirement for a research topic to be deemed eligible for funding.

The Senate Appropriations Committee for the Departments of Labor, Health and Human Services, Education and Related Agencies also includes CFS-specific recommendations submitted by the Association. Recommendations made in collaboration with the Overlapping Conditions Alliance and the Campaign to End Chronic Pain in Women are reflected in the report as well.

Unfortunately, Congress as a whole was unable to reach agreement on any fiscal year 2011 funding bills before the session recessed for the election. A stopgap "continuing resolution" will fund programs until Dec. 3, 2010. We will be working to protect all the CFS-related funding priorities as work on the funding bills is completed by Congress. We'll post updates on our website at www.cfids.org/SolveCFS/fall10.asp. You can also find links to the funding justifications submitted as part of the request process. ■

Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Bill Report Language for Fiscal Year 2011

Centers for Disease Control and Prevention:

Chronic Fatigue Syndrome — The Committee urges the CDC to follow recommendations made by the CFS Advisory Committee and the 2008 peer review panel to prioritize laboratory efforts aimed at the identification of diagnostic subtypes and therapeutic biomarkers with increasing efforts in viral etiology. Intervention, including vaccination studies, against pathogens with known associations with CFS should be pursued in collaboration with other agencies and investigators to support genetic, genomic and intervention studies. The Committee continues to support efforts to make data accumulated since 1984 by the CFS research program available to outside researchers to maximize the value of this data.

Chronic Pain Conditions in Women — The Committee encourages the CDC to build on its previous related epidemiological work to undertake a study of the prevalence, overlapping nature, and shared risk factors of chronic pain conditions which solely or disproportionately impact women, including vulvodynia, TMJ disorders, endometriosis, fibromyalgia, interstitial cystitis, and chronic fatigue syndrome. The Committee further encourages the CDC to educate the public about the seriousness and societal costs of these conditions; make available and promote sources of reliable information on the symptoms, diagnosis, treatment, and overlapping nature of the conditions; and make available information to women with chronic pain about how to communicate effectively with their health professionals about these conditions.

National Institutes of Health:

Chronic Fatigue* — The Committee is aware that in October 2009, a group of researchers announced that it had performed blood tests on patients with Chronic Fatigue Syndrome [CFS] and found sufficient evidence of the presence of xenotropic murine leukemia virus-related virus [XMRV] to suggest a correlation between XMRV and CFS. While the work has not yet been replicated, the reported research warrants further discussion and investigation. The Committee is aware that NIH will host an international symposium on XMRV in September 2010 to address the pathogenesis and clinical and public health implications of the XMRV virus and to obtain input in developing a coordinated strategy for XMRV research. The Committee also is aware that the second State of the Knowledge Conference is being planned by the Trans-NIH Working Group on Chronic Fatigue Syndrome for 2011 and is encouraged that this conference will likely make additional recommendations about future funding opportunities for XMRV and CFS research.

Overlapping Chronic Pain Disorders — The Committee again notes the growing body of evidence demonstrating considerable overlap among chronic fatigue syndrome, endometriosis, fibromyalgia, headache, interstitial cystitis, irritable bowel syndrome, temporomandibular joint and muscle disorders, and vulvodynia. These poorly understood and neglected conditions impact millions of Americans and cost the Nation tens of billions of dollars each year. The Committee requested last year that the Director coordinate a trans-NIH research initiative, and the NIH responded that this work would be carried out by the Trans-NIH Working Group for Research on Chronic Fatigue Syndrome [CFSWG]. The Committee is not satisfied with that response, as the scope of the proposed initiative spans well beyond the purview of the CFSWG, and strongly urges the NIH to take a more comprehensive approach to these conditions. The Committee urges the NIH to promptly develop and coordinate, with all relevant ICs, a trans-Institute research initiative to support studies aimed at identifying etiological pathways of these overlapping conditions with the goal of identifying potential therapeutic targets.

Agency for Healthcare Research and Quality:

Chronic Pain Conditions in Women — The Committee notes that up to 50 million American women suffer from one or more poorly understood and often overlooked chronic pain conditions. The Committee urges AHRQ to analyze the healthcare expenditures associated with chronic fatigue syndrome, endometriosis, fibromyalgia, interstitial cystitis, temporomandibular [TMJ] disorders, and vulvodynia. The analysis should quantify costs associated with the failure to promptly and adequately diagnose and treat these conditions, as well as those incurred by employers due to lost productivity, increased number of sick days and increased disability claims.

*Note: This is actual the text from the Committee; only "material differences" will be considered as the bill moves forward. According to Congressional staff, making a revision to include "syndrome" won't rise to the level of material since CFS is used correctly in the paragraph.

Article Series Explores Post-Exertional Malaise/Relapse

Muscle wilting meltdown, air gulping short of oxygen feeling, brain blood vessels flayed on a laundry line in the wind, metal rods in the back of head…someone crushing your ribcage, limbs giving out, mesh bag constricting head, "pingers": those first small headaches that warn of bigger headaches, "back of head clamp" headache, increased gravity feeling, being pushed backward into bed, temple-to-temple headache, weak arms as if bound down by stretchy ropes, eyes and brain blanking with a kind of pulse through the head…Harm and damage often come from these collapses, though on the outside they may look like "malaise."

Post-exertional malaise or relapse (PEM) is a hallmark symptom of CFS and may be the symptom that best distinguishes it from other conditions. In the June 2010 issue of our monthly e-newsletter, CFIDS*Link*, we launched a four-part series of articles to explore this disabling, and relatively unique, aspect of CFS. Writer Jennie M. Spotila, J.D., compiled research and experience to offer breadth and depth of understanding.

- **Unraveling Post-Exertional Malaise** — Part one examines the definition of PEM and how CFS patients experience it.
- **Post-Exertional Malaise: Perception and Reality** — Part two reviews objective evidence of PEM and how it differs from fatigue in other illnesses.
- **Post-Exertional Malaise: Cause and Effect** — Part three delves into the topic of kinesiophobia (excessive fear of physical movement) and what mechanisms may cause PEM.
- **Post-Exertional Malaise: Power to the People** — Part four explores what patients can do to cope with and avoid this incapacitating symptom.

You can find links to the article series at www.cfids.org/SolveCFS/fall10.asp. If you'd like to receive a printed copy, contact us by e-mail, phone or mail; our contact info is listed on page 8. ■

Webinar Series Archive Preserves High-Interest Programs

Our 2010 Webinar Series has now logged 16 programs, featuring leading experts speaking about a wide range of topics from Association-funded research to XMRV. In addition to the "live" online events, we've been able to archive recordings of 15 programs on our *SolveCFS* YouTube channel, expanding the audience to more than 18,000 viewers and creating a valuable library of sought-after information.

The most popular program (based on views of the recording) features Dr. Peter Rowe of Johns Hopkins University discussing **Management of Orthostatic Intolerance**, a disabling condition that frequently co-occurs with CFS. The largest "live" attendance was for a program on **CFS & the Viral Connection** delivered by Harvard Medical School's Dr. Anthony Komaroff. The highest ratings were given to Dr. Louis Katz of the Mississippi Valley Regional Blood Center for his program on **XMRV & Blood Safety**. Across the series, we've attempted to balance "hot" research topics with information that has a longer shelf life, like documenting disability.

In November and December we'll host programs on **Communicating with Your Health Care Professional**, **Pacing Yourself Through the Holidays** and **Spirituality & Health**. We hope to extend the popular series into 2011. We recognize that some of our SolveCFS readers have very limited internet access, so making you aware of this "on demand" archive is important. You can view the schedule of upcoming programs and find links to program recordings and slides at ww.cfids.org/SolveCFS/fall10.asp. ■

CFIDS Association Receives BBB Accreditation

The Better Business Bureau's (BBB's) Wise Giving Alliance helps donors make informed giving decisions and advances high standards of conduct among organizations that solicit contributions from the public. In October 2010, the Wise Giving Alliance conducted its biannual evaluation of the CFIDS Association of America according to its 20 Standards of Accountability for Charitable Organizations and reported that the Association is fully compliant. The Wise Giving Alliance standards seek to encourage fair and honest solicitation practices, to promote ethical conduct by charitable organizations and to advance support of philanthropy. The CFIDS Association is the only CFS-focused organization to have received this designation from the Wise Giving Alliance. ■

Legacy Fund Grows

Planned gifts are the ultimate expression of confidence in the CFIDS Association of America. A planned gift is one that is made as part of your overall financial and estate plan. We have created The Legacy Fund to honor patients, families and friends who have established a planned gift. The Legacy Fund helps you help the Association carry on until its mission is fulfilled.

To date, 72 people have joined The Legacy Fund. Over the years, the Association has received a cumulative total of more than $1.1 million in planned estate gifts, a vital source of support for crucial programs. Think about your legacy and help us achieve our mission to make CFS widely understood, diagnosable, curable and preventable. For more information, contact Ashley Comstock, major gifts officer, at aacomstock@cfids.org or 704-364-0016, ext. 101. ■

2010 Annual Fund Under Way

The Association's annual fund provides the support needed to fuel research, policy and communications. We have set an ambitious goal to raise $5 million by Dec. 31, 2010 for programs that will stimulate research aimed at the early detection, objective diagnosis and effective treatment of CFS through expanded public, private, and commercial investment. Funds raised will sustain existing programs and enable the CFIDS Association to:

- issue a new **Request for Applications** for research that moves biomarkers for diagnosis and treatment to the next level of validation, taking advantage of increased scientific interest in CFS;
- craft **CFS-specific legislation** to define a comprehensive federal response to CFS, leveraging the heightened political awareness about CFS;
- expand the **SolveCFS BioBank** to include more CFS patients and healthy (contact and non-contact) control subjects and samples to build this robust research asset; and
- extend our webinar series to keep you up-to-date with all the latest news and help you with the everyday challenges of living with CFS.

The CFIDS Association of America is the only organization working across so many fronts, led by volunteers and staff who share a broad scope and depth of experience, command of the issues and commitment to the mission, working with a vibrant network of researchers, physicians, advocates, policymakers and thought-leaders to effect change and **make CFS widely understood, diagnosable, curable and preventable.**

We deeply value your continued participation and support. Please make a donation to the 2010 Annual Fund today! ■

Ways to Donate:

Use the enclosed envelope

www.cfids.org (secured by PayPal)

Facebook cause: SolveCFS

Join the Chairman's Circle monthly giving program

Blood Donation Discouraged

The AABB (formerly the American Association of Blood Banks) issued guidance to its international membership on June 18, 2010 that blood collection centers should actively discourage individuals with CFS from donating blood. Educational materials and a poster were distributed with the advisory bulletin. Since then, the American Red Cross and many independent community blood centers in the U.S. have implemented these recommendations. Centers are using materials to inform every potential donor about CFS and are monitoring the number of individuals that acknowledge past or present diagnosis.

As of Nov. 1, 2010, the U.K. will permanently defer persons with a past or present CFS diagnosis. A statement from the National Health Service indicates that the change is being made "on the grounds of donor safety, as ME/CFS is a relapsing condition. It brings practice for ME/CFS into line with other relapsing conditions or neurological conditions of unknown or uncertain origin, such as MS and Parkinson's Disease." Canada, Australia and New Zealand indefinitely defer individuals who volunteer having a past or present diagnosis of CFS.

The CFIDS Association has long advised people with CFS not to donate blood, tissue or organs. Our statement and the latest regulations from government authorities are available at www.cfids.org/SolveCFS/fall10.asp.

NONPROFIT
ORGANIZATION
US POSTAGE
PAID
CHARLOTTE, NC
PERMIT NO. 2989

The CFIDS Association of America
PO Box 220398
Charlotte, NC 28222-0398
Resource line: 704-365-2343
Fax: 704-365-9755
Website: www.cfids.org

Address Service Requested

Not One Alone

We are witnessing an extraordinary time in the fight to solve CFS, and the most important word in this sentence is "WE."

Scientific interest in CFS is at an all-time high. Sustained media coverage by top outlets reaching the public and the scientific and medical communities has consistently presented CFS as a serious, life-altering condition that affects millions and warrants more attention. Activism in the patient community has been energized by new efforts spurred by individuals and small groups to engage policy makers and remind them of the harsh realities that CFS presents. Thought leaders within science, medicine, policy and government are responding and meaningful change is beginning to occur.

The convergence of these events proves a powerful and essential point: CFS will not be solved by one person or one organization alone.

Not one patient alone can give voice to the suffering inflicted by CFS.

Not one researcher alone can supply the evidence needed to objectively diagnose and effectively treat CFS.

Not one clinician alone can treat the one million or more Americans afflicted with CFS.

Not one government agency alone can deliver the services needed by people with CFS.

Not one policymaker alone can allocate the research funding necessary to solve CFS.

Not one organization alone can exert the necessary pressure or provide the essential knowledge to the patients, researchers, clinicians, agencies, and policymakers that must coordinate efforts on all fronts to defeat CFS.

We need a diversity of strategies and tactics. We need a chorus of voices and opinions. We need coordination of effort, sharing of expertise and collaboration on a level greater than the CFS community has ever attempted.

At this critical time in CFS history, the CFIDS Association stands with you, firm in our resolve to stimulate research aimed at the early detection, objective diagnosis and effective treatment of CFS through expanded public, private, and commercial investment. None of us is in this fight alone.

The Board of Directors
The CFIDS Association of America

Above: At the October CFSAC meeting (see page 6), Robert Miller (center) and other advocates demonstrated solidarity in calling for government action.

Right: The group stood behind several others giving public testimony, including CEO Kim McCleary.

The CFIDS Association of America

BOARD OF DIRECTORS

Bruce Allshouse
New Castle, DE
Treasurer

Christoph Bausch, PhD
St. Louis, MO

Diane Bean
Bethesda, MD

Katrina Berne, PhD
Seattle, WA

Vicki Boies, PsyD
Chicago, IL

Amy Divine
Boulder, CO
Vice Chairman

Stuart Drescher, PhD
Salt Lake City, UT

Adam Lesser
San Francisco, CA
Chairman

K. Kimberly McCleary
Charlotte, NC
President & CEO

Dimitris Papanicolaou, MD
Rahway, NJ

Robert Raidt
Chicago, IL

Brian Smith
Omaha, NE

Jennie Spotila, JD
King of Prussia, PA
Secretary

Amy Squires
Alexandria, VA

Patrick Venetucci
Park Ridge, IL

PROFESSIONAL STAFF

President & Chief Executive Officer
K. Kimberly McCleary

Chief Financial Officer
Kristina P. Hopkins

Scientific Director
Suzanne D. Vernon, PhD

Public Relations & Events Manager
Sara L. Collins

Major Gifts Officer
Ashley A. Comstock

Operations & Network Administrator
Kim A. Almond

Office Manager & BioBank Coordinator
Gloria E. Smith

CONTACT INFO

The CFIDS Association of America
PO Box 220398
Charlotte, NC 28222-0398

E-mail: cfids@cfids.org
Websites: www.cfids.org and www.SolveCFS.org
Resource line: 704-365-2343
Fax: 704-365-9755