



Bergen ME/ CFS-FM Support Group Newsletter

Meeting

The January Holiday Party was a resounding success with well over 20 people in attendance! It was so successful that we are considering permanently switching our Holiday Party month from December to January, in order to not interfere with the already stressful December month. We would like to thank everyone enormously for all of the wonderful and delicious food that was brought! We had a buffet table fit for a king with lots of food and desserts for everyone! We also had the opportunity to meet and discuss ME/CFS/FM issues with our attendees, including four new members, as well as several supportive family members and friends. It is always heartening to see family members and friends attend, showing support for their loved one who is suffering with these debilitating illnesses. Thank you to all who attended! Let's keep the momentum going in the months to come!

In the News

Public Citizen is a national, nonprofit consumer advocacy organization founded in 1971 to represent consumer interests in Congress, the executive branch and the courts. On January 20th, they submitted a letter to U.S. FDA requesting the withdrawal of Savella from the market. Below is an excerpt of that letter. The complete letter can be found at the following link.

<http://www.citizen.org/publications/release.cfm?ID=7723>

January 20, 2010

Margaret Hamburg, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hamburg:

Public Citizen, representing more than 65,000 consumers nationwide, hereby petitions the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug, and Cosmetic Act 21 U.S.C. Section 355(e)(3), and 21 C.F.R. 10.30, to immediately remove from the market the drug Savella (milnacipran; Cypress Bioscience, Inc. and Forest Laboratories, Inc.) because it has highly questionable clinical efficacy and has been found, in randomized controlled trials, to cause a large number of potentially serious adverse reactions including hypertension, increased heart rate, and increased suicidal ideation. On July 23, 2009, milnacipran's approval for fibromyalgia was denied in the European Union for these very same efficacy and safety reasons.

Sincerely,

Elizabeth Barbehenn, Ph.D. - Research Analyst

Sidney Wolfe, M.D. - Director, Health Research Group, Public Citizen

In the News – Part 2

The CFIDS Association of America [cfidslink@cfids.org]

Alert: Change of leadership announced for CDC's CFS Research Program

The U.S. Centers for Disease Control and Prevention (CDC) has announced that Dr. William C. Reeves, head of the agency's CFS Research Program, will be taking a new position within the agency effective Feb. 14, 2010 and that he will no longer lead the agency's CFS research. Dr. Elizabeth Unger will serve as acting chief of the Chronic Viral Diseases Branch, the unit within CDC that houses the CFS Research Program. On Feb. 14, Dr. Reeves will begin an assignment as Senior Advisor for Mental Health Surveillance in the Public Health Surveillance Program Office within the CDC's Office of Surveillance, Epidemiology, and Laboratory Services.

The CFIDS Association of America, other organizations and advocates have vocally supported new program leadership to effect a more robust research effort at CDC. This staffing change has the potential to significantly advance CFS research beyond the agency's intramural program and to seize scientific momentum generated by recent discoveries. We are fully dedicated to making rapid progress in this new era of collaboration and discovery in CFS research.

K. Kimberly McCleary
President & CEO
The CFIDS Association of America

Info on XMRV

The CFIDS Association of America <http://www.cfids.org/cfidslink/2010/010603.asp>

MRV Negative Results Emphasize Need for Robust Replication Study

Suzanne D. Vernon, PhD
Scientific Director

A study testing for evidence of XMRV infection in CFS patients in the United Kingdom has reported negative results. This is the first publication following the article in the top-ranked journal *Science* from researchers at the Whittemore Peterson Institute, the National Cancer Institute and Cleveland Clinic that garnered worldwide attention from the media and scientific community. [The new report](#), published Jan. 6, 2010, in the open access online journal *PLoS ONE*, failed to detect XMRV in CFS, but should not be considered a valid attempt to replicate the findings described by Lombardi et al., in the [Oct. 8, 2009 Science article](#).

The *PLoS ONE* paper by Otto Erlwein, Steve Kaye, Myra O. McClure, Jonathan Weber, Gillian Wills, David Collier, Simon Wessely and Anthony Cleare is titled, "Failure to Detect the Novel Retrovirus XMRV in Chronic Fatigue Syndrome." The investigators tested peripheral blood DNA from 186 routine clinic attendees who met 1994 (Fukuda) CFS case definition criteria and were well-characterized from participation in prior neuroendocrine and cognitive behavioral therapy studies. These 186 CFS patients were reported to be unwell for a median of four years with high levels of fatigue and disability.

This team of researchers used a special type of DNA "xeroxing" called nested [polymerase chain reaction](#) (PCR) reaction to amplify specific segments of the XMRV proviral DNA from the genomic DNA obtained from these 186 CFS subjects. In essence, they were looking to see if XMRV genetic material had integrated into human genetic material, which is a key characteristic of retroviral infection. The experiment included positive, negative and contamination controls, but did not test any samples taken from healthy subjects. The samples were coded so that the origin of the DNA was not known to the

person conducting the PCR assays. XMRV was not detected in any of the 186 samples.

Can this study be considered comparable to the results published by Lombardi et al., in *Science*? In short, no. Both studies included CFS patients defined by the 1994 case definition criteria, but this is where the comparability ends. Here are some of the ways the *PLoS ONE* and *Science* methods differ:

- The blood was collected from CFS patients in different types of blood collection tubes.
- The genomic DNA was extracted and purified using different techniques.
- The amount of genomic DNA included in the amplification assay was different.
- Different primer sequences were used that amplified different regions of the XMRV proviral DNA.
- The conditions of the PCR amplification assay were different – from the numbers of cycles, to the type of polymerase used.

Should these differences affect an investigator's ability to detect XMRV? To a microbiologist with experience handling samples and studying various infectious agents (as I am), these variances in procedure could make the difference between detecting XMRV or not.

It very well could be true that XMRV is not present in the U.K. as Erlwein, et al. suggest in their discussion, but it is also possible that the technique used in the *PLoS ONE* paper was suboptimal due to the different methods employed, when compared to the original experiments conducted by Lombardi, et al.

The U.S. Department of Health and Human Services [Blood XMRV Scientific Research Working Group](#) is conducting a rigorous study to detect XMRV. Multiple laboratories will standardize methods to optimize sensitive detection of XMRV proviral DNA and viral RNA and then, once methods are standardized, these same laboratories will test coded panels of blood samples obtained from healthy blood donors and CFS patients. We look forward to the results of this study and urge that it be completed expeditiously, especially in light of this report from the U.K. In the meantime, be prepared to read about more studies with conflicting findings. Rather than simply accept or dismiss new information, we will help make sense of why discrepant results occur.

Perhaps the most important statement in the *PLoS ONE* paper is the acknowledgement by this group of investigators that CFS is an incapacitating organic disease affecting millions of people worldwide. Once XMRV detection methods are optimized and made widely available, we encourage this group of researchers to take another look at XMRV as a possible explanation for the organic basis of CFS in the U.K.

Citations:

Erlwein O, Kaye S, McClure MO, Weber J, Willis G, Collier D, Wessley S, Cleare A. (2010) Failure to detect the novel retrovirus XMRV in chronic fatigue syndrome. *PLoS ONE* 5(1):e8519. doi:10.1371/journal.pone.0008519

Lombardi VC, Ruscetti FW, Gupta JD, Pfof MA, Hagen KS, Peterson DL, Ruscetti SK, Bagni RK, Petrow-Sadowski C, Gold B, Dean M, Silverman RH, Mikovits JA. *Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome. Science* 8 October 2009. 1179052.

Suzanne D. Vernon, PhD, earned her doctorate in virology at the University of Wisconsin at Madison and worked in public health research on infectious diseases at the U.S. Centers for Disease Control and Prevention for 17 years before joining the CFIDS Association of America's staff as scientific director in 2007. She has more than 70 peer-reviewed scientific publications on topics including human immunodeficiency virus, human papillomavirus, cervical cancer and chronic fatigue syndrome. Dr. Vernon has initiated and participated in numerous international and multidisciplinary research collaborations and she now leads the CFIDS Association's research program. The CFIDS Association of America is the nation's largest philanthropic supporters of CFS research.

Coming Events!



New Jersey Chronic Fatigue Syndrome Association, Inc.

Hi. My name is Marissa Newell. I am 17 years old and I have Chronic Fatigue Syndrome (CFS). I have had this disease for 10 years and it has really changed my life in both good and bad ways. Five years ago, I had to do a community service project. The project I chose was a fundraiser for the NJ Chronic Fatigue Association (NJCFSA). I ran a gift auction and it was a huge success. Over the last five years, I have run it again and I have chosen to continue to do this and make it an annual event. With the help of generous businesses like yours, I have raised over \$20,000 for the NJCFSA Research and Medical School Scholarship Funds.

I am asking for donations of items, gift certificates, and/or services for both adults and children. Monetary donations will be used to purchase items for the auction or simply added to the money donated to the NJCFSA, whichever you wish. **I have planned the auction for May 8, 2010** since May 12 is CFIDS Awareness Day. All of the money raised from this auction will go to the NJCFSA.

The New Jersey CFS Association, Inc. is a not-for-profit, tax exempt organization whose purpose is to support patients, disseminate reliable information, and promote research. It sponsors a wide range of activities, including: support groups, newsletter, phone list, statewide conferences, hotline, and interfacing with the CFS community. "Chronic Fatigue Syndrome (CFS) attacks people of all ages and walks of life, leaving many indefinitely disabled. According to the Centers for Disease Control (CDC), the number of sufferers is growing. CFS can strike anyone. It causes a wide array of symptoms including overwhelming weakness, extreme fatigue, chronic sore throat and tender lymph nodes, fever, muscle and joint pain, cognitive and neurological problems, irritable bowel syndrome, nausea, and vertigo. The course of CFS is uncertain. Some patients improve and recover, while others remain ill for long periods." More than one million people in the US suffer from CFS. **The NJCFSA mainly serves people in the tri-state area but is open to anyone who wishes to join.**

For this auction to be a success, I need you to **please** donate items, gift certificates or services that either adults or children will enjoy. Please help me to make a difference.

If you are able to donate item(s) please e-mail me at Teddies96@aol.com , mail the item(s) to Marissa Newell 84 Bennett Ave. Neptune City, NJ 07753 , or call me at 732-775-9326 and I will arrange for pickup.

I appreciate your help and support.

Sincerely,

Marissa Newell

NJCFSA Youth Trustee

For More Information about NJCFSA write to:

PO Box 477,

Florham Park, NJ 07932

Or visit www.njcfsa.org - (click on "youth" to read an essay I wrote.)

fighting for a cure

More Coming Events!

Watch for details!

- The NJCFSA Conference is set for Sunday October 17, 2010. The program line-up will be announced in the near future. Mark your calendar. It will be a great day.
- Watch for the announcement of an additional special NJCFSA event this spring. Information will be sent as soon as the details are completed.

Next Meeting

The next meeting will be held on Sunday February 21st. Agenda – We expect to show a video presentation by Patricia Fennell, MSW, LSCW-R. Ms. Fennel is a Social Worker and this is her presentation is from the NJCFSA Fall 2008 conference, “**CFS, Quality of Life, and the Chronic Illness Era.**”

For those who cannot attend the meeting, DVDs of this and other conferences are available for purchase from the NJCFSA. Members of the NJCFSA may also opt to borrow the DVDs from the NJCFSA Library for the cost of postage & handling. See www.NJCFSA.org for details.

This newsletter is intended for CFS & FM patients in the area of this support group. The purpose is to share information and support. If you have questions about meetings please contact: Pat LaRosa at pcl.njcfsa@gmail.net, Nancy Visocki at ngv.njcfsa@verizon.net, Judy Machacek at judymachacek@msn.com or leave a voice message at the NJCFSA HelpLine 888-835-3677 during business hours.

WEATHER or Emergency – *In the event of bad weather, or other emergency, we encourage you to check your email before leaving for Englewood. If it has been decide that a meeting will be canceled, an email will be sent via the yahoogroups list. The Hospital will also be notified of the cancellation. The email posting also applies to a cancellation of the First Wednesday of the Month luncheon which is an informal gathering, an opportunity for people to meet and chat with*