FDA In Focus: The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safe use of many products that we use every day - from drugs to microwaves, pacemakers to pet foods and infant formula to lipstick. The agency’s role in drug development is limited to making sure that compounds are tested according to prescribed standards and that safety and effectiveness are demonstrated in adequate trials before they are made available to consumers.

Until recently, CFS has not been an area of much concern or discussion by FDA, with few products being tested to treat CFS. A series of events this year has elevated discussion of CFS by agency officials, with affirmation that FDA considers CFS to be a “serious and life-threatening condition.” There are opportunities for patient advocates to get involved in the discussion and advance treatments for CFS.


- On December 20, the FDA’s Arthritis Advisory Committee will meet in open session to review the application from Hemisphère Biopharma to market its experimental immunomodulatory drug rintatolimod (Ampligen) as the first treatment for CFS. There will be time at the meeting for public testimony; details: [http://1.usa.gov/SVpfho](http://1.usa.gov/SVpfho). The meeting will be webcast live. The agency will render its decision by Feb. 2, 2013.

Under provisions of new legislation that guides FDA’s drug approval process, the agency is planning a series of 20 disease-focused meetings to explore ways to systematically include patient input in the review of new products. CFS was listed by FDA on its preliminary topic list and at a public meeting held Oct. 25, Association Board chairman Amy Squires gave testimony urging that it be retained in the final selection.
Abnormal Skin Response to Pain Stimulus: Dr. Marvin Medow and colleagues tested lower leg skin response to heat as a surrogate for vascular control in 9 CFS patients and 8 healthy controls. Microdialysis measures showed that the CFS patients had lower baseline readings and impaired response when heat was applied, particularly to the part of the pain response that is centrally controlled. (Journal of Applied Physiology, Nov. 8, 2012) Dr. Medow is one of the CFIDS Association’s Research Institute Without Walls grantees.

HHV-6 A/B Antibody Levels Don’t Distinguish: Researchers at the NIH and Georgetown University tested blood samples from 72 CFS patients and 59 healthy controls for HHV-6A and HHV-8 and found no differences in the antibody levels or frequency of these viruses between the groups. The authors suggest that these two viruses are unlikely to play a role in the pathogenesis of CFS. (American Journal of Translational Research, Oct. 30, 2012)

Responder Characteristics Elusive: A team led by Dr. Jose Montoya at Stanford University published results of a chart review of 61 CFS patients treated with Valcyte to identify differences between the 32 "responders" and 19 "nonresponders." No significant differences were found in the baseline antibody titres to HHV-6 or EBV or other variables analyzed. Longer treatment correlated with an improved response as judged by patient’s self-reported physical and cognitive functioning. (Journal of Medical Virology, Oct. 10, 2012)

LDX Treatment Improves Cognitive Function: A small double-blind placebo-controlled study of lisdexamfetamine dimesylate (LDX, marketed in the U.S. as Vyvanse) showed encouraging results treating cognition in CFS patients who reported impaired short-term memory and delayed reaction time. LDX is a long-acting psychostimulant approved by FDA for treatment of ADHD. CFS patients treated with the drug demonstrated improved cognition and less pain and fatigue compared to the subjects who received placebo. The author suggests that "LDX may reduce pain by improving individuals’ ability to filter out painful stimuli." Larger and longer studies are needed to assess the value of this therapy. (Psychiatry Research, Oct. 9, 2012)

NEWS & EVENTS

Nov. 15: The FDA will host a webinar, "Working Together for Change," to engage stakeholders in best practices for fostering treatment research. More details here.

Nov. 19: The Association will participate in two of the four finalist presentations for the Sanofi US Collaborate | Activate Challenge at an event to be hosted at the Newseum in Washington, D.C. (The event was rescheduled from Oct. 29 due to Hurricane Sandy.) Finalists compete for total prize money of $400,000 and access to non-monetary resources provided by one of the world's largest pharmaceutical companies. CEO Kim McCleary will lead the presentation for the Partnering to End Pain team. You’re invited to participate in person or by webcast.

Nov. 28-29: The Association will present its partnership with Biovista to re-purpose approved drugs for CFS at the Partnering for Cures conference hosted by FasterCures. Thirty organizations were selected by FasterCures for these sought-after "Innovator" presentations to feature collaborations that cut the time to get cures to people who need them.
Dec. 1: Members of our Board of Directors will host a Catalyst Café event in Chicago. Scientific director Dr. Suzanne Vernon will provide an update on the Association’s Research Institute Without Walls and our new director of development Mark Stone will be on hand as well. For more details, please send an email to Gloria Smith at gesmith@cfids.org.

Dec. 20: The Arthritis Advisory Committee will review the New Drug Application submitted by Hemispherx Biopharma to market its drug, Ampligen, to treat CFS. More details: http://1.usa.gov/SVpfho

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The CFIDS Association of America

Our Mission:
For CFS to be widely understood, diagnosable, curable and preventable.

Our Strategy:
To stimulate research aimed at the early detection, objective diagnosis and effective treatment of CFS through expanded public, private and commercial investment.

Our Core Values:
To lead with integrity, innovation and purpose.

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