March 3, 2013

PATIENT ALLIANCE FOR NEUROENDOCRINEIMMUNE DISORDERS
P-A-N-D-O-R-A
ORGANIZATION FOR RESEARCH AND ADVOCACY .org
3209 Charlesgate S.W., Wyoming, MI 49509
Phone: 231-360-3680
Email LoriKroger@PANDORAorg.net

10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

Dear Dr. Janet Woodcock, Dr. Sandra Kweder, Dr. Theresa Michele, Dr. Margaret Hamburg:

Patient Alliance for Neuro-endocrine-immune Disorders Organization for Research and Advocacy, Inc. (PANDORA) would like to suggest the following expert clinicians to sit on the panels or be invited to the FDA Workshop on Drug Development for Chronic Fatigue Syndrome and Myalgic Encephalomyelitis:

- Dr. Derek Enlander, contact 212-794-2000 at Mount Sinai Medical Center – Clinician and researcher in New York focusing on ME/CFS. Noted for years of experience and thinking "outside of the box" in searching for effective treatments, including Gc protein-derived macrophage activating factor (GcMAF).
- Dr. John Chia, contact 310-784-5880 in private practice and associate professor of UCLA School of Medicine – Clinician and researcher who discovered the role of enteroviruses in ME/CFS and developed Equilibrant as an antiviral therapy.
- Dr. Andreas Kogelnik, contact 650-691-8633 at the Open Medicine Institute – Clinician and researcher who organized a 2012 "Merit Meeting" to develop a research priority list for ME/CFS.
- Dr. Charles Lapp, contact 704-543-9692 at the Hunter-Hopkins Center – Clinician and researcher who see's severe cases and is a trained pediatrician.
- Dr. Nancy Klimas, contact 954-262-2850 at the NSU College of Osteopathic Medicine's Institute for Neuro-immune Medicine – Clinician and researcher in AIDS, Gulf War illness and ME/CFS, discovering many of the immune system abnormalities of ME/CFS.
- Dr. Dan Peterson, contact 775-832-0989 at Sierra Internal medicine Associates – Clinician and researcher at the center of an ME/CFS outbreak.
- Dr. Jose Montoya, contact 650-76-5200 at Stanford University – Clinician and researcher who works with antivirals.
- Dr. Italo Biaggioni, contact 615-32-2318 at Vanderbilt Heart and Vascular Institute – Clinician and researcher focusing on autonomic interactions in cardiovascular regulation.
- Dr. Brian Crucian, contact 281-483-0968 at NASA Johnson Space Center – A PhD studying human immune system changes in outer space. His research has shown similar findings in astronauts as is found in ME/CFS patients.
- Dr. Harvey Alter, contact 301-496-8393 at National Institutes of Health – Researcher who was in the 2011 NIH ME/CFS Workshop and serves on the NIH Trans-NIH ME/CFS Research Working Group.
- Ian Lipkin, contact 212-342-9033 at Center for Infection and Immunity at Columbia University – Researcher focusing on pathogens and a lead researcher in the Chronic Fatigue Initiative looking at pathogens in ME/CFS patients.

- Leonard Jason, Ph.D., contact 773-325-2018 at DePaul University – Psychology professor studying outcomes from differing ME/CFS diagnostic criteria.

Secondly, we ask you to make sure that all who attend have a clear understanding of what disease the workshop is about. The variety of definitions of the disease, many of which have been shown inadequate to distinguish ME/CFS patients from those with other causes of chronic fatigue, has hindered progress in this field, including in treatment trials. Thus, as the FDA is attempting to aid in making progress in outcome measures and other features of ME/CFS, all participating in the discussions must be clear on what disease is the focus of the workshop.

Two disease definitions are not appropriate and have failed to properly identify those who have ME/CFS to the exclusion of other diseases: the Oxford criteria and Empirical criteria. These focus primarily or solely on the symptom of fatigue, one of the most common symptoms reported to clinicians as a result of many different illnesses. Thus, these do not distinguish ME/CFS patients from those with other causes for their fatigue.

The FDA can set the stakeholder workshop on the right track by including a statement at the beginning of the meeting and in any pre-meeting written material given to the attendees that says something like the following two paragraphs:

> Myalgic encephalomyelitis / chronic fatigue syndrome has multiple definitions with varying symptom criteria. Yet, progress will be made when patients with other fatigue-causing illnesses are not included in the cohort of clinical trials that purport to look for a treatment for ME/CFS. Other illnesses that should be excluded from ME/CFS cohorts include untreated thyroid disorders, untreated Addison's disease, multiple sclerosis, fibromyalgia, lupus, cancer, psychiatric disorders, psychological disorders, depression, deconditioning, medication side effects, anemia, sleep disorders, renal disease, diabetes and other causes of chronic fatigue.
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> As research has progressed, some biological abnormalities are now known to be in those with ME/CFS and some are distinctive to this disease. Also, post-exertional neuro-immune exhaustion (a.k.a post-exertional malaise or post-exertion relapse) is now recognized as the "hallmark symptom," distinguishing it from other causes of chronic fatigue. Gene expression studies, anaerobic threshold studies and others have shown ME/CFS post-exertional neuro-immune exhaustion has a biological basis and holds promise as a biomarker. Similar to the way the tender-point test helped to identify fibromyalgia patients from other pain patients, measurable post-exertional neuro-immune exhaustion along with other symptoms or biological abnormalities can be effective in identifying ME/CFS patients.

If you have any further questions on how to ensure the April ME/CFS Stakeholders Workshop is successful, please contact us.

Sincerely,

Lori Chapo Kroger

Lori Chapo-Kroger, RN
PANDORA President