An Open Letter to the Honorable Kathleen Sebelius, U.S. Secretary of Health and Human Services

Original Letter – September 23, 2013
Update with additional signatures – October 25, 2013

Dear Secretary Sebelius,

We are writing as biomedical researchers and clinicians with expertise in the disease of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) to inform you that we have reached a consensus on adopting the 2003 Canadian Consensus Criteria (CCC) as the case definition for this disease.

The 1994 International Case Definition (Fukuda et al., 1994), commonly known as the Fukuda definition, was the primary case definition for ME/CFS for almost two decades. However, in recent years expert researchers and clinicians have increasingly used the CCC, as they have recognized that the CCC is a more scientifically accurate description of the disease.

The CCC was developed by an international group of researchers and clinicians with significant expertise in ME research and treatment, and was published in a peer-reviewed journal in 2003 (Carruthers et al., Journal of Chronic Fatigue Syndrome, 2003). Unlike the Fukuda definition, the more up-to-date CCC incorporates the extensive scientific knowledge gained from decades of research. For example, the CCC requires the symptom of post-exertional malaise (PEM), which researchers, clinicians, and patients consider a hallmark of the disease, and which is not a mandatory symptom under the Fukuda definition. The CCC was endorsed in the Primer for Clinical Practitioners published by the International Association of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (IACFSME). This organization is the major international professional organization concerned with research and patient care in ME/CFS.

The expert biomedical community will continue to refine and update the case definition as scientific knowledge advances; for example, this may include consideration of the 2011 ME International Consensus Criteria (Carruthers et al., Journal of Internal Medicine, 2011). As leading researchers and clinicians in the field, however, we are in agreement that there is sufficient evidence and experience to adopt the CCC now for research and clinical purposes, and that failure to do so will significantly impede research and harm patient care. This step will facilitate our efforts to define the biomarkers, which will be used to further refine the case definition in the future.

We strongly urge the Department of Health and Human Services (HHS) to follow our lead by using the CCC as the sole case definition for ME/CFS in all of the Department’s activities related to this disease.

In addition, we strongly urge you to abandon efforts to reach out to groups such as the Institute of Medicine (IOM) that lack the needed expertise to develop “clinical diagnostic criteria” for ME/CFS. Since the expert ME/CFS scientific and medical community has developed and adopted a case definition for research and clinical purposes, this effort is unnecessary and would waste scarce taxpayer funds that would be much better directed toward funding research on this disease. Worse, this effort threatens to move ME/CFS science backward by engaging non-experts in the development of a case definition for a complex disease about which they are not knowledgeable.
ME/CFS patients who have been disabled for decades by this devastating disease need to see the field move forward and there is no time to waste. We believe that our consensus decision on a case definition for this disease will jump start progress and lead to much more rapid advancement in research and care for ME/CFS patients. We look forward to this accelerated progress and stand ready to work with you to increase scientific understanding of the pathophysiology of this disease, educate medical professionals, develop more effective treatments, and eventually find a cure.

Sincerely,

United States Signatories

Dharam V. Ablashi, DVN, MS, Dip Bact.
Scientific Director of HHV-6 Foundation
Co-founder of IACFS/ME
Santa Barbara, California

David S. Bell, MD, FAAP
Researcher and Clinician
Associate Professor of Pediatrics
State University of New York at Buffalo
Lyndonville, New York

Gordon Broderick, PhD
Professor, Center for Psychological Studies
Director, Clinical Systems Biology Lab
Institute for Neuro Immune Medicine,
Nova Southeastern University
Fort Lauderdale, Florida

Paul R. Cheney, MD, PhD
Director, The Cheney Clinic, PA
Asheville, North Carolina

John K.S. Chia, MD
Researcher and Clinician
President, EV Med Research
Lomita, California

Lily Chu, MD, MSHS  (Added 10/25/2013)
Independent Researcher
Burlingame, California

Todd E. Davenport, PT, DPT, OCS  (Added 10/25/2013)
Associate Professor, Physical Therapy
University of the Pacific
Stockton, California
Kenny L. De Meirleir, MD, PhD
Professor Emeritus Physiology and Medicine (Vrije Universiteit Brussel)
Medical Director, Whittemore-Peterson Institute
University of Nevada
Reno, Nevada

Derek Enlander, MD, MRCS, LRCP
Attending Physician
Mount Sinai Medical Center, New York
ME CFS Center, Mount Sinai School of Medicine
New York, New York

Mary Ann Fletcher, PhD
Schemel Professor of NeuroImmune Medicine
Institute for Neuro Immune Medicine
Nova Southeastern University
Fort Lauderdale, Florida

Kenneth J. Friedman, PhD  (Added 10/25/2013)
Associate Professor of Pharmacology and Physiology, New Jersey Medical School (retired)
Research Associate, Green Mountain College
Adjunct Instructor, Castleton State College
Pawlet, Vermont

Ronald Glaser, PhD, FABMR
Director, Institute for Behavioral Medicine Research
Kathryn & Gilbert Mitchell Chair in Medicine
College of Medicine - Distinguished Professor
Professor, Molecular Virology, Immunology and Medical Genetics
Professor, Internal Medicine
Professor, Division of Environment Health Sciences, College of Public Health
Institute for Behavioral Medicine Research
Columbus, Ohio

Maureen Hanson, PhD
Liberty Hyde Bailey Professor
Department of Molecular Biology and Genetics
Cornell University
Ithaca, New York

Leonard A. Jason, PhD
Professor of Psychology
DePaul University
Chicago, Illinois

Betsy Keller, PhD, FACSM  (Added 10/25/2013)
Professor, Department of Exercise & Sport Sciences, Ithaca College
Ithaca, New York
Nancy Klimas, MD
Director, Institute for Neuro Immune Medicine
Professor, Nova Southeastern University
Fort Lauderdale, Florida

Konstance Knox, PhD  *(Added 10/25/2013)*
Director of Research, Coppe Healthcare Solutions
Wisconsin Viral Research Group
Waukesha, Wisconsin

Gudrun Lange, PhD
Clinical Neuropsychologist
Professor, Rutgers New Jersey Medical School
Newark, New Jersey

A. Martin Lerner, MD, MACP
Professor, Infectious Diseases
Oakland University William Beaumont School of Medicine
Emeritus Director, Infectious Diseases, Wayne State University School of Medicine
Master, American College of Physicians
Reviewer, Viral Diseases, Medical Letter
Beverly Hills, Michigan

Susan Levine, MD
Researcher and Clinician, Private Practice
New York, New York
Visiting Fellow, Cornell University
Ithaca, New York

Alan R. Light, PhD
Professor, Department of Anesthesiology and Department of Neurobiology and Anatomy
University of Utah
Salt Lake City, Utah

Kathleen C. Light, PhD
Researcher
Professor, Department of Anesthesiology
University of Utah School of Medicine
Salt Lake City, Utah

Peter G. Medveczky, MD
Professor, Department of Molecular Medicine
College of Medicine
University of South Florida
Tampa, Florida

Judy A. Mikovits, PhD
Researcher, MAR Consulting, LLC
Carlsbad, California
Jose G. Montoya, MD, FACP, FIDSA
Professor of Medicine
Division of Infectious Diseases and Geographic Medicine
Stanford University School of Medicine
Stanford, California

James M. Oleske, MD, MPH
François-Xavier Bagnoud Professor of Pediatrics
Director, Division of Pediatrics Allergy, Immunology & Infectious Diseases
Department of Pediatrics, Rutgers New Jersey Medical School
Newark, New Jersey

Martin L. Pall, PhD
Professor Emeritus of Biochemistry and Basic Medical Sciences
Washington State University
Portland, Oregon

Daniel Peterson, MD
Founder and President of Sierra Internal Medicine
Incline Village, Nevada

Richard Podell, MD, MPH
Clinical Professor, Department of Family Medicine
UMDNJ Robert Wood Johnson Medical School
New Brunswick, New Jersey

Irma Rey, MD
Clinician
Institute for Neuro Immune Medicine
Nova Southeastern University
Fort Lauderdale, Florida

Malcolm S. Schwartz, DO, FAOCP  (Added 10/25/2013)
Clinical Associate Professor of Pediatrics, Drexel University College of Medicine
Philadelphia, Pennsylvania
Pediatric Endocrine LLC.
Long Branch, New Jersey

Christopher R. Snell, PhD
Professor, Health, Exercise and Sport Sciences
University of the Pacific
Stockton, California

Connie Sol, MS, PhDc
Clinical Exercise Physiologist, Institute for Neuro Immune Medicine
Nova Southeastern University
Fort Lauderdale, Florida
Staci Stevens, MA
Exercise Physiologist
Founder, Workwell Foundation
Ripon, California

Julian M. Stewart, MD, PhD  (Added 10/25/2013)
Director, Center for Hypotension, Associate Chairman of Pediatrics, Professor of Pediatrics, Physiology and Medicine
New York Medical College
Vahalla, New York

Rosemary A. Underhill, MB BS, MRCPG, FRCSE
Independent Researcher
Palm Coast, Florida

J. Mark VanNess, PhD  (Added 10/25/2013)
Associate Professor, Department Health, Exercise and Sport Sciences – College of Pacific
Adjunct Professor, Department of Bioengineering – College of Computer Sciences and Engineering
University of the Pacific
Stockton, California

Marshall V. Williams, PhD
Professor, Departments of Molecular Virology, Immunology and Medical Genetics; Microbiology
The Ohio State University
Columbus, Ohio

International Signatories

Alison C. Busted, MD, FRCPC  (Added 10/25/2013)
Medical Director, Complex Chronic Diseases Program
British Columbia Women’s Hospital and Health Centre
Clinical Associate Professor, Faculty of Medicine, University of British Columbia
Vancouver, British Columbia, Canada

Nicoletta Carlo-Stella, MD, PhD  (Added 10/25/2013)
Clinician
Nazzani Studio
Pavia, Italy

Birgitta Evengard, MD, PhD
Professor, Division Infectious Diseases
Umea University
Umea, Sweden

Øystein Fluge, MD, PhD  (Added 10/25/2013)
Consultant in Oncology, Department of Oncology
Haukeland University Hospital
Bergen, Norway
Malcolm Hooper, PhD, BPharm, MRIC, CChem  *(Added 10/25/2013)*
Emeritus Professor of Medicinal Chemistry, University of Sunderland
Sunderland, Tyne and Wear, United Kingdom

Sonya Marshall-Gradisnik, PhD
Director, National Centre for Neuroimmunology and Emerging Diseases
Griffith Health Institute
Professor, Griffith University Parklands Gold Coast
Queensland, Australia

Olav Mella, MD, PhD  *(Added 10/25/2013)*
Professor, Director, Department of Oncology
Haukeland University Hospital
Bergen, Norway

Kunihisa Miwa, MD, PhD  *(Added 10/25/2013)*
Director, Miwa Naika Clinic
Toyama City, Toyama Prefecture, Japan

Charles Shepherd, MB BS
Honorary Medical Adviser to the ME Association
London, United Kingdom

Nigel Speight, MA, MB, BChir, FRCP, FRCPCH, DCH  *(Added 10/25/2013)*
Pediatrician
County Durham, United Kingdom

Eleanor Stein, MD, FRCP(C)  *(Added 10/25/2013)*
Psychiatrist
Assistant Clinical Professor, University of Calgary
Calgary, Alberta, Canada

Rosamund Vallings, MNZM, MB BS
IACFS/ME Secretary
Clinician, Howick Health and Medical Clinic
Auckland, New Zealand

Cc:

Dr. Howard Koh, Assistant Secretary for Health
Dr. Richard Kronick, Director, Agency for Healthcare Research and Quality
Dr. Thomas Frieden, Director, Centers for Disease Control and Prevention
Ms. Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services
Dr. Margaret Hamburg, Commissioner, U.S. Food and Drug Administration
Dr. Mary Wakefield, Administrator, Health Resources and Services Administration
Dr. Francis Collins, Director, National Institutes of Health
Ms. Carolyn W. Colvin, Commissioner, Social Security Administration