

September 28, 2009

The Honorable Edward Markey
United States House of Representatives
2108 Rayburn House Office Building
Washington, DC 20515

The Honorable Cliff Stearns
United States House of Representatives
2370 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Markey and Stearns:

The undersigned organizations, representing millions of Americans with rare and genetic conditions, strongly support H.R. 2866, the Improving Access to Clinical Trials Act of 2009. We appreciate your efforts to remove the regulatory barrier that prevents Social Security beneficiaries from participating in clinical trials that provide compensation. The fear of losing Medicaid coverage is a strong disincentive for Social Security beneficiaries to participate in these clinical trials.

This problem is a barrier for people who wish to participate in clinical trials. For example, a high percentage of people with cystic fibrosis (CF) are needed to enroll in the large number of CF clinical trials in the pipeline, but many CF patients who are on Social Security cannot participate because of this regulation. With the efforts to develop new therapies to treat more diseases, it also could impact 30 million Americans affected by one of the nearly 7,000 known rare and genetic conditions.

This legislation advances Congress' commitment to stimulate research on drugs for rare and orphan diseases. Twenty-five years ago, there were only 10 drugs to treat rare diseases. Today, thanks to the Orphan Drug Act, and support of new treatments by patient organizations, academic medical centers, and industry, there are 339 orphan drugs, biologics and humanitarian devices that treat 12 million men, women and children.

We look forward to working with you to secure passage of this bill to enable Social Security beneficiaries with serious diseases to participate in clinical trials so that one day they may have a life-saving therapy for their conditions.

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
ALS Association
Alström Syndrome International
American Sleep Apnea Association
Amyloidosis Support Groups
ARPKD/CHF Alliance (Autosomal Recessive Polycystic Kidney Disease and Congenital Hepatic Fibrosis Alliance)
Association of Clinical Research Organizations

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Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
Axcan Pharma US, Inc.
Batten Disease Support and Research Association
Benign Essential Blepharospasm Research Foundation
Beyond Batten Disease Foundation
Biotechnology Industry Organization
BVVL International (Brown-Vialetto-Van Laere disease)
Cadasil Foundation
Children's Hospital Denver, Cystic Fibrosis Care Center
Children's Hospital of Pittsburgh of UPMC, CF Center (Adult and Pediatric Care)
Children's Hospital-University of Birmingham, Cystic Fibrosis Center
Children's Memorial Research Center, affiliated with Northwestern University Feinberg School of Medicine
Children's Rare Disease Network
Coalition of Heritable Disorders of Connective Tissue
Congenital Adrenal hyperplasia Research Education and Support (CARES) Foundation, Inc.
Connecticut Children's Medical Center
Cushing Support and Research Foundation
Cutaneous Lymphoma Foundation
Cystic Fibrosis Foundation
Detroit Medical Reserve Corps
Dystonia Medical Research Foundation
DebRA (Dystrophic Epidermis Bullosa Research Association)
Ehlers Danlos National Foundation
Eurand Pharmaceuticals, Inc.
FasterCures
First Focus
FORCE: Facing Our Risk of Cancer Empowered
Foundation Fighting Blindness, Inc.
Foundation for Prader-Willi Research
Freeman-Sheldon Parent Support Group
Friedreich's Ataxia Research Alliance (FARA)
Genentech, Inc.
Genetic Alliance
Hannah's Hope for Giant Axonal Neuropathy
Hermansky-Pudlak Syndrome Network, Inc.
HHT Foundation International
Hollis Eden Pharmaceuticals
Human Genetic Disorders.com
Huntington's Disease Society of America
Hydrocephalus Association
International Dravet syndrome Epilepsy Action (IDEA) League
International Foundation for Functional Gastrointestinal Disorders
International Myeloma Foundation
Interstitial Cystitis Association

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Johns Hopkins Hospital, Cystic Fibrosis Program
Joubert Syndrome Foundation & Related Cerebellar Disorders
Kaiser Permanente Northwest Region, Cystic Fibrosis Care Center (Portland, OR)
Kakkis Everylife Foundation
Kaleida Health
Kennedy's Disease Association
LAM Treatment Alliance
Lymphatic Research Foundation
MHE Research Foundation
MLD Foundation
Mpex Pharmaceuticals
Muscular Dystrophy Association
Myotonic Dystrophy Foundation
Narcolepsy Network
National Adrenal Diseases Foundation (NADF)
National Alopecia Areata Foundation
National Association of Social Workers
National Gaucher Foundation
National Health Council
National Jewish Health (Denver, CO)
National Marfan Foundation
National Niemann-Pick Disease Foundation
National PKU Alliance
National Organization of Rare Disorders
National Spasmodic Dysphonia Association
National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD)
Nationwide Children's Hospital (Columbus, OH)
NBIA Disorders Association
The Olive Branch Fund
Oregon Health Sciences University, Cystic Fibrosis Center
PCD Foundation (Primary Ciliary Dyskinesia)
Pediatric Adolescent Gastroesophageal Reflux Association (PAGER)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Progeria Research Foundation, Inc.
PTC Therapeutics
Pull-thru Network, Inc.
Pulmonary Hypertension Association
PXE International
Rainbow Babies and Children's Hospital
Research!America
Rett Syndrome Research Trust
SADS Foundation (Sudden Arrhythmia Death Syndromes)
Seattle Children's Hospital
Shire
Solvay Pharmaceuticals, Inc.

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ST/Dystonia, Inc.
Stanford University Medical Center, Cystic Fibrosis Center
State University of New York at Buffalo
State University of New York at Buffalo, School of Medicine and Biomedical Sciences
Trimethylaminuria Foundation
Tuberous Sclerosis Alliance
UNICConnect, L.C.
University of Colorado Health Sciences Center, Adult Cystic Fibrosis Center
University of North Carolina at Chapel Hill, Cystic Fibrosis Care Center
University of Oklahoma Health Sciences Center, Cystic Fibrosis Center (Oklahoma City and
Tulsa)
University of Washington Medical Center, Adult Cystic Fibrosis Center
Wilson Disease Association
Women and Children's Hospital of Buffalo
XLH Network, Inc.
Yale University School of Medicine, Adult Cystic Fibrosis Program