

March 12, 2015

The Honorable Ron Wyden  
United States Senator  
221 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Orrin G. Hatch  
United States Senator  
104 Hart Senate Office Building  
Washington, DC 20510

The Honorable Edward J. Markey  
United States Senator  
218 Russell Senate Office Building  
Washington, DC 20510

The Honorable Sherrod Brown  
United States Senator  
713 Hart Senate Office Building  
Washington, DC 20510

Dear Senators Wyden, Hatch, Markey and Brown,

The undersigned organizations, representing millions of Americans with rare and genetic diseases, advocates, industry, and academic institutions, write to express strong support for S.139, the Ensuring Access to Clinical Trials Act of 2015. This legislation will permanently remove a barrier to clinical research and allow Supplemental Security Income (SSI) and Medicaid recipients to participate in and benefit from clinical trials without fear of losing vital benefits.

The Ensuring Access to Clinical Trials Act of 2015 eliminates the sunset clause from the Improving Access to Clinical Trials Act of 2009 (IACT), legislation signed into law in 2010, making the IACT a permanent law. This will allow patients with rare diseases to continue to receive up to \$2,000 in compensation for participating in clinical trials without that compensation counting towards their income eligibility limits for SSI and Medicaid.

Removing barriers to drug trial participation is particularly important as recent advances in medical research and technology allow for the development of new and promising medications. Securing an adequate number of clinical trial participants is vital for therapies that treat rare conditions, but rare disease researchers in particular often have difficulty recruiting drug trial participants, simply because they have a smaller pool of patients.

Further, with the advent of precision medicine, therapies are being customized to treat a patient's specific genetic makeup. These types of trials often require clinical trial participants bearing specific genetic mutations, which necessarily creates an even more complex and exclusive clinical trial recruitment process. Ensuring that all patients with rare diseases are able to participate in clinical trials can help open the door for the advancement of new targeted therapies in many important areas of medicine, including cancer and rare diseases like cystic fibrosis.

Now is the time to ensure that all patients have access to clinical trials for potentially life-saving treatments. We look forward to working with you to secure passage of this bill to enable Social Security beneficiaries to participate in clinical trials so that research into life-saving treatments may continue to advance.

Sincerely,

Actavis

Adult CF Program - Northwestern University

Adult Polyglucosan Body Research Foundation APBDRF

Alpha-1 Foundation

ALS Association

American Association for Respiratory Care (AARC)

American Autoimmune Related Diseases Association (AARDA)

Amyloidosis Support Groups Inc.

Ann & Robert H. Lurie Children's Hospital of Chicago

Antonio J. and Janet Palumbo Cystic Fibrosis Center, Pediatric and Adult Program, Children's Hospital of Pittsburgh UPMC

Association of Clinical Research Organizations (ACRO)

Association of Gastrointestinal Motility Disorders, Inc. (AGMD)

Batten Disease Support and Research Association

Biotechnology Industry Organization (BIO)

CADASIL Association Inc.

Cardio-Facio-Cutaneous International

CARES Foundation, Inc. (Congenital Adrenal hyperplasia Research, Education and Support Foundation)

CF Care Center at Dayton Children's Hospital

Congenital Hyperinsulinism International (CHI)

COPD Foundation

Cure CMD

Cure SMA

Cystic Fibrosis Foundation

Cystinosis Foundation

Debra of America

FasterCures

First Focus

Foundation Fighting Blindness

Foundation for Prader-Willi Research

Foundation to Eradicate Duchenne

Friedreich's Ataxia Research Alliance (FARA)

Genetic Alliance

Hide & Seek Foundation for Lysosomal Disease Research

Huntington's Disease Society of America

International Fibrodysplasia Ossificans Progressiva Association (IFOPA)

Indiana University School of Medicine, CF Care Center

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International Society of Nurses in Genetics (ISONG)  
Lymphangiomatosis & Gorham's Disease Alliance  
Lymphedema Advocacy Group  
Maine Medical Center CF Program  
M-CM Network  
MEBO Research, Inc.  
Medical College of Wisconsin, Milwaukee Cystic Fibrosis Care Center  
MitoAction  
MLD Foundation  
Moebius Syndrome Foundation  
Muscular Dystrophy Association  
Myotonic Dystrophy Foundation  
National Gaucher Foundation, Inc.  
National MPS Society  
National Organization for Albinism and Hypopigmentation (NOAH)  
National Organization for Rare Disorders (NORD)  
National PKU Alliance  
National Spasmodic Torticollis Association  
Parent Project Muscular Dystrophy (PPMD)  
Parents and Researchers Interested in Smith-Magenis Syndrome (PRISMS)  
Progeria Research Foundation  
ProMedica Toledo Children's Hospital  
PXE International  
Research! America  
Rett Syndrome Research Trust  
Stanley Manne Children's Research Institute  
Tarlov Cyst Disease Foundation  
The Children's Hospital of Philadelphia  
The Detroit Medical Reserve Corps  
The Massachusetts Medical Society  
The National Alopecia Areata Foundation (NAAF)  
The State University of New York School of Medicine and Biomedical Sciences  
Trimethylaminuria Foundation  
Tuberous Sclerosis Alliance  
University of Michigan Health System, Cystic Fibrosis Center  
University of Pennsylvania Health System, Cystic Fibrosis Center  
University of Washington, Cystic Fibrosis Care Center  
Vertex Pharmaceuticals  
Virginia Commonwealth University Health System, Adult Cystic Fibrosis Program  
Wilson Disease Association