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 to 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