CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

February 26, 2015

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

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

The Honorable Orrin G. Hatch
United States Senator
104 Hart 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,

On behalf of the Cystic Fibrosis Foundation, representing 30,000 people with cystic fibrosis (CF) in the United States, I 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.

Cystic fibrosis is a rare, genetic disease that primarily affects the lungs. It causes the body to produce thick, sticky mucus that clogs the lungs and leads to life-threatening infections and serious digestive complications. In the 1950s, few children with CF lived to attend elementary school. Since then, tremendous progress in understanding and treating CF has led to dramatic improvements in the length and quality of life for those with CF. Many people with the disease can now expect to live into their 30s, 40s and beyond.

The Ensuring Access to Clinical Trials Act of 2015 eliminates subsection (e) from the Improving Access to Clinical Trials Act of 2009 (IACT), making the IACT a permanent law. This will allow patients with cystic fibrosis and other 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.

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The Cystic Fibrosis Foundation actively supported the Improving Access to Clinical Trials Act when it was introduced and advanced in 2009, and we commend you for your work to make this law permanent. Through the Cystic Fibrosis Therapeutics Development Network (TDN), a clinical trials network funded in large part by Cystic Fibrosis Foundation, we have observed patients participating in clinical trials who otherwise would not be able to for fear of losing vital public benefits. We are deeply grateful for your work to ensure that this progress continues.

With the advent of precision medicine, therapies are being customized to treat a patient's specific genetic makeup. As this new concept in drug development quickly becomes a reality, it opens the door for the advancement of new targeted therapies in many important areas of medicine, including cancer and rare diseases like CF. One such therapy, ivacaftor, has been approved to treat the basic defect of CF in 6% of patients with the disease.

Further, the drug pipeline for cystic fibrosis treatments is becoming increasingly robust with similar treatments that operate using the same basic principle. A new therapy is currently under review by the FDA to similarly treat an estimated 50% of those with cystic fibrosis. As research develops in this area, finding clinical trial participants bearing specific genetic mutations will become increasingly necessary.

The necessity of securing adequate clinical trial participants holds true not just for genetically targeted medications, but also for therapies that treat the symptoms and effects of cystic fibrosis, including antibiotics and pancreatic enzymes.

With more ongoing drug trials for people with cystic fibrosis than ever before, now is the time to ensure that all patients have access to clinical trials for potentially life-saving treatments. We greatly appreciate your support in breaking down barriers to clinical trial participation so that the number of trials can continue to grow.

I look forward to working with you to secure passage of this bill to enable Social Security beneficiaries to participate in clinical trials for the advancement of cystic fibrosis research. Thank you for supporting the CF community in achieving our mission to find a cure for cystic fibrosis and improve the quality of life for people living with this disease.

Sincerely,

Robert J. Beall, Ph.D.
President and Chief Executive Officer