

October 27, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, & Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, & Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

On behalf of the 70 undersigned organizations, representing diverse stakeholders, dozens of diseases, and millions of Americans, we are writing to urge the swift confirmation of Robert Califf, M.D., as commissioner of the Food and Drug Administration (FDA).

We applaud Acting Commissioner Ostroff's stewardship of the agency but believe that the opportunities upon us necessitate strong, permanent leadership at FDA. The agency regulates 25 cents of every dollar spent by American consumers, and its work has a profound effect on our collective health and well-being. With user fee negotiations underway, landmark biomedical legislation moving through Congress, and precision medicine advancing at a rapid clip, FDA needs a confirmed, permanent leader who can skillfully harness these opportunities and ensure that the agency continues to effectively achieve its mission for the American people.

Dr. Califf is that leader. He is a world expert in the design of clinical trials that are driven by sound science and patient need. He is also a skilled manager, having founded the world's largest academic clinical research organization, which has completed nearly 1,000 clinical trials at over 37,000 sites in 65 countries.¹ Through that work, Dr. Califf has acquired decades of real-world experience running and evaluating clinical trials. He also maintains a deep understanding of the fast-moving science and the diverse stakeholders in government, academia, industry, and the patient community.

Becoming commissioner would be the culmination of a career dedicated to delivering the best care to patients. As a leader of the Clinical Trials Transformation

¹ Duke Clinical Research Institute at a Glance, <http://dcri.org> (accessed Oct. 12, 2015).

Initiative (CTTI), Dr. Califf consistently brought the voice of patients and their caregivers to the fore. He was an active participant in the planning and execution of the FDA's Mini-Sentinel project to develop an active safety surveillance system for medical products. He also served as a co-principal investigator of the coordinating center for PCORnet, the National Patient-Centered Clinical Research Network, an initiative to transform clinical research by engaging patients, care providers, and health systems to advance medical science and improve healthcare. These are but a few of the examples of Dr. Califf's commitment to the needs of patients.

We are at a transformative moment in science. Breathtaking opportunities to improve health and save lives are emerging from innovations in the science of patient input, precision medicine, immuno-therapies, whole-genome sequencing, gene editing, and mobile health technology, among others. FDA has begun to take advantage of these opportunities and, with a visionary leader like Dr. Califf who can adeptly navigate the transitions ahead, the agency can maintain and grow this momentum. We must seize the moment to move these innovations across the regulatory finish line to awaiting patients.

With 10,000 diseases and only 500 cures, there is much work to do, and Dr. Robert Califf is the leader FDA needs now. A swift confirmation process will enable him to help the agency continue its powerfully important work that patients are counting on.

Respectfully,

FasterCures, a center of the Milken
Institute

Accelerate Brain Cancer Cure

Accelerated Cure Project for Multiple
Sclerosis

Addario Lung Cancer Medical Institute

Adenoid Cystic Carcinoma Research
Foundation

Alliance for Aging Research

Alliance for Lupus Research

Alpha-1 Foundation

American Heart Association

Association of Clinical Research
Organizations

BCM Families Foundation

Bonnie J. Addario Lung Cancer
Foundation

Cancer Research Institute

Celiac Disease Foundation

Citizens United for Research in
Epilepsy

COPD Foundation

Cure AHC

Cure SMA

CureHHT

Cutaneous Lymphoma Foundation

Dysautonomia International

Dystonia Medical Research
Foundation

FH Foundation

Fight Colorectal Cancer
Foundation Fighting Blindness
Foundation for Mitochondrial
Medicine
Foundation for Prader-Willi Research
Friedreich's Ataxia Research Alliance
Friends of Cancer Research
Gastroparesis Patient Association for
Cures and Treatments
Genetic Alliance
Geoffrey Beene Foundation
Glaucoma Research Foundation
Hepatitis Foundation International
International Myeloma Foundation
Kids v. Cancer
Leukemia & Lymphoma Society
LUNgevity Foundation
Lupus Research Institute
LymeDisease.org
Lymphangiomas & Gorham's
Disease Alliance
Melanoma Research Alliance
MLD Foundation
MPN Research Foundation
Multiple Myeloma Research
Foundation
Muscular Dystrophy Association

Myotonic Dystrophy Foundation
National Alopecia Areata Foundation
National Brain Tumor Society
National Multiple Sclerosis Society
National PKU Alliance
New York Stem Cell Foundation
Parent Project Muscular Dystrophy
Pediatric Congenital Heart Association
PFO Research Foundation
Phelan-McDermid Syndrome
Foundation
Progeria Research Foundation
Prostate Cancer Foundation
Reflex Sympathetic Dystrophy
Syndrome Association
Research!America
Rett Syndrome Research Trust
Sjögren's Syndrome Foundation
Society of Women's Health Research
Solving Kids' Cancer
T1D Exchange
The diaTribe Foundation
The Hide and Seek Foundation
The Nicholas Connor Institute
USAgainstAlzheimer's
Wake Up Narcolepsy