



January 21, 2021

President Joseph Biden
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Biden,

We, the undersigned patient organizations, are writing to applaud your appointment of Dr. Janet Woodcock for the position of Acting Commissioner of the Food and Drug Administration. The FDA needs a strong leader with vision, passion, and experience. Dr. Woodcock is, and has been, that leader for decades.

As you know, Dr. Woodcock joined the FDA in 1986 and most recently served as Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). In 2015, Dr. Woodcock also held the role of Acting Director of CDER's Office of Pharmaceutical Quality (OPQ). From 2005 until 2008, she served in the FDA's Commissioner's office, holding several positions, as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities encompassed oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research.

The current public health emergency makes it imperative that the Commissioner have extensive background in public health and regulatory science in order to provide leadership through the challenges and opportunities before the agency at this time. Dr. Woodcock is uniquely qualified for such a role.

For the past 10 months, Dr. Woodcock has shifted her focus from regulatory approvals to the ongoing COVID-19 crisis. In May 2020, she temporarily stepped away from her CDER duties to assist Operation Warp Speed and the federal government's efforts to rapidly develop vaccines against the novel coronavirus. She also has pushed to modernize pharmaceutical manufacturing to increase safety and encourage production in U.S. factories rather than overseas.

In addition to mastery of regulatory science, drug development, and oversight, the Commissioner must have a deep knowledge of how the FDA functions and to have the respect and trust of the staff. In her tenure, Dr. Woodcock has innovated a paradigm shift in

therapeutic development, infrastructure, and stakeholder engagement within the ecosystem that has yielded robust development pipelines in disease areas with significant unmet need. Most recently, Dr. Woodcock led a full reorganization of CDER, improving the specialization of the drug review divisions. This type of change was critically needed and could have only been done by leadership within the organization. More of this type of change is needed to ensure the scientific rigor of the FDA keeps up with the new innovations in science, therapeutics and medical technology.

As commissioners have transitioned in and out of this role over the years, Dr. Woodcock has remained a steadfast leader for the agency and the public.

Most important to us, the undersigned, is that the FDA must continue to expand upon the patient focused drug development momentum, including patient communities and clinical experts as key stakeholders within development and regulatory review. Patients are key partners in all aspects of health, and in all phases of the continuum in therapy and intervention development. While Dr. Woodcock's focus remains evidence-based, she understands the critical role of patient representation in evidence collection and product development.

Dr. Woodcock's leadership within the FDA will continue to greatly benefit the 10 of millions of patients in need of lifesaving treatments and cures. In all her work, Dr. Woodcock leads with clarity and vigor, and a value for diverse stakeholder perspectives. She is very practical, pragmatic, and patient centered. She is the pressure tested leader we need to bring the country out of the Public Health Emergency and lead the agency into the future to improve the health of all Americans.

Sincerely,

A Cure for Ellie
A Day in our Shoes, LLC
Acromegaly Community Inc.
ADNP Kids Research Foundation
Alpha-1 Foundation
American Behcet's Disease Association (ABDA)
Amyloidosis Foundation
Amyloidosis Research Consortium
Angelman Syndrome Foundation
Answer Cancer Foundation (AnCan)
Association for Creatine Deficiencies (ACD)
Avery's Hope
AXYS
Barth Syndrome Foundation
Batten Disease Support and Research Association
Best Day Ever Foundation
Boomer Esiason Foundation

Bridge the Gap - SYNGAP Education and Research Foundation
CFC International
CFRI - Cystic Fibrosis Research, Inc.
Children's PKU Network/ NPKUA
Choroideremia Research Foundation
Congenital Hyperinsulinism International
Cure Sanfilippo Foundation
Cure VCP Disease, Inc.
Cyclic Vomiting Syndrome Association
Daphne's Lamp
EB Research Partnership
EveryLife Foundation for Rare Diseases
Fibromuscular Dysplasia Society of America
Foundation for Sarcoidosis Research
Friedreich's Ataxia Research Alliance (FARA)
Gene Giraffe Project
Global Liver Institute
Hermansky-Pudlak Syndrome Network
Histiocytosis Association
Hunter Syndrome Foundation
International Cystinuria Foundation
International Pemphigus Pemphigoid Foundation
Jack McGovern Coats' Disease Foundation
Jonah's Just Begun
Little Hercules Foundation
Let's Breathe Sarcoidosis Support Group
Lowe Syndrome Association
MEPAN Foundation
Mission: Cure
MitoAction
MLD Foundation
MPS Society
MTM-CNM Family Connection
Myasthenia Gravis Foundation of America
Myositis Support and Understanding
Myositis Support Foundation
National Fragile X Foundation
National Tay-Sachs & Allied Diseases Association (NTSAD)
NKH Crusaders
NTM Info & Research
One Rare
Organic Acidemia Association
Oxalosis & Hyperoxaluria Foundation
Parent Project Muscular Dystrophy (PPMD)

People With Empathy
Pompe Alliance
Project Alive
PTEN Hamartoma Tumor Syndrome Foundation
Rare New England
RASopathies Network
Remember The Girls
Rett Syndrome Research Trust
SCAD Alliance
Sick Cells
Spastic Paraplegia Foundation
Spina Bifida Association
Stronger Than Sarcoidosis
Super T's Mast Cell Foundation
SynGAP Research Fund, 501(c)(3)
Team Joseph
The E.WE Foundation
The Global Foundation for Peroxisomal Disorders
The Jack McGovern Coats Disease Foundation
The Sickle Cell Foundation of Tennessee
Williams Syndrome Association