

February 7, 2021

President Joe Biden
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

The Honorable Xavier Becerra
Secretary-designate
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear President Biden and Secretary-designate Becerra:

We, the undersigned organizations, are writing to express strong support for Dr. Janet Woodcock in her current role as Acting Commissioner and as she is considered for potential nomination as Commissioner of the U.S. Food and Drug Administration (FDA). Dr. Woodcock is a passionate advocate for American patients and consumers, an ally to patient advocacy groups, and a fearless leader at the FDA. Dr. Woodcock's outstanding record of civil service at the FDA has helped transform the agency into one that strives to put patients at the center of its decision-making. We are honored to commend her leadership and highlight the difference she has made in advancing the American public's health.

We currently face a daunting challenge to health and returning to "normal life" due to the Coronavirus 2019 (COVID-19) pandemic. FDA staff have facilitated the development, review, and approval of safe and efficacious vaccines and treatments over the last year. Unfortunately, the fight is far from over. New variants have emerged that may impact the efficacy of current vaccines and therapeutics. At the same time, public confidence in our nations' public health infrastructure has waned.

Dr. Woodcock's distinguished history as a career leader at the FDA will help the agency meet this challenge. Her candor and integrity have permeated her career at the agency, including through her public testifying to Congress more than 50 times under six different Administrations. Her history as an impartial civil servant will be critical in rebuilding the public's confidence in the agency. For example, in response to concerns about contamination of the active ingredient in heparin, Dr. Woodcock called on Congress to provide funding to ensure needed oversight and inspections of overseas drug-manufacturing, earning plaudits from Congress. Former Representative John Dingell (D-Mich.), whose committee had jurisdiction over the FDA, said of Dr. Woodcock in 2008, "Again, I want it known that I appreciate Dr. Woodcock's candor. To her credit, she has stepped forth in the midst of a public health crisis to deal honestly with Congress. How I wish others in the Administration showed the same vigor, responsiveness, and leadership."

Dr. Woodcock's 37 years of senior-level experience at the FDA serves as both a touchstone for how to get things done and a master class in understanding the intricacies of the agency's work. This earned experience, and the respect that accompanies it, allow her to speak authoritatively on the processes that can be streamlined to ensure a rapid response to public health emergencies while ensuring that the structures that are vital to ensure the FDA's mission and standards of independence and rigor are upheld. Her efforts on the "Pharmaceutical Quality for the 21st Century Initiative," started in 2002, have helped modernize pharmaceutical manufacturing—critical regulatory issues that will be at the forefront of ensuring the production of FDA-approved vaccines and therapeutics can meet global demand. Further, her relationships and history as a civil servant will promote morale within the agency—an essential asset at a time when so much is asked of the FDA's staff.

More broadly, Dr. Woodcock has continuously brought steadfast leadership and helped guide the agency to a patient-centered focus. Under Dr. Woodcock's leadership from 1994-2004 and 2007-2019, the Center for Drug Evaluation and Research (CDER) regulatory decision-making processes have become more open and transparent to the public. Changes included publishing CDER's regulatory procedures and policies; developing more than 100 technical guidance documents that describe regulatory standards; providing an unprecedented degree of participation of consumer and patient representatives in FDA processes; and creating an extensive Center web site which includes drug reviews and consumer information. Dr. Woodcock has advanced medical discoveries from the laboratory to patients more efficiently under the Critical Path Initiative; and launched the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively.

Senior career civil servants are required to make thousands of decisions over their careers and carefully guard their independence in a political environment. These unbiased decisions are often thankless, guided by the best available knowledge and the focus of living up to the agency's mission. Dr. Woodcock's principles have remained steadfast: to protect and promote the health and well-being of the American public and to base decisions on sound science in support of FDA's public health mission. At the most fundamental level, Dr. Woodcock has demonstrated over nearly four decades that she cares deeply about the agency, its mission, and its people.v

Our organizations enthusiastically support Dr. Woodcock's continued service to the FDA in her role as Acting Commissioner and support her candidacy to lead the agency permanently at this critical time. We thank you for your consideration of her nomination.

Sincerely,

5p- Society
AliveAndKickn
Allergy & Asthma Network
Alliance for Aging Research
Alstrom Syndrome International
Alzheimer's and Dementia Alliance of Wisconsin
Alzheimer's Drug Discovery Foundation
Alzheimer's Foundation of America
Alzheimer's Los Angeles
Alzheimer's Orange County
Alzheimer's San Diego
American Association for Cancer Research
Arthritis Foundation
Association of Jewish Aging Services
Caregiver Action Network
CaringKind, the Heart of Alzheimer's Caregiving
Congenital Adrenal Hyperplasia Research, Education & Support Foundation
Congenital Hyperinsulinism International
Cure HHT
Cutaneous Lymphoma Foundation
LuMind IDSC Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
M-CM Network
Men's Health Network
MitoAction
MLD Foundation
Mucopolidosis Type IV Foundation
National Alliance for Caregiving
National Caucus and Center on Black Aging, Inc.
National Consumers League
National Fabry Disease Foundation
National Hispanic Council on Aging
National Infusion Center Association (NICA)
National Minority Quality Forum
National Task Group on Intellectual Disabilities and Dementia Practices
NBIA Disorders Association
Nicholas Volker One In A Billion Foundation
NTM Info & Research
Ohio Council for Cognitive Health
One Rare
Organic Acidemia Association
Parkinson & Movement Disorder Alliance
Patients Rising
Phelan-McDermid Syndrome Foundation
Powerful Patient, Inc.

Dementia Alliance International
Depression and Bipolar Support Alliance
Dup15q Alliance
EveryLife Foundation for Rare Diseases
Fabry Support & Information Group
Friends of Cancer Research
Foundation for Prader-Willi Research
Genetic Alliance
Global Coalition on Aging
HealthyWomen
Hermansky-Pudlak Syndrome Network
HFC
Infusion Access Foundation (IAF)
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Pemphigus and Pemphigoid Foundation
K-T Support Group
Kids with Heart National Association for Children's Heart Disorders, Inc.
Latino Alzheimer's and Memory Disorders Alliance
PSC Partners Seeking a Cure
PXE International
Quantum Leap Healthcare Collaborative
RARE-X
Retiresafe
Spina Bifida Association
StopAfib.org
The American Society of Consultant Pharmacists
The Association for Frontotemporal Degeneration
The diaTribe Foundation
The Global CEO Initiative on Alzheimer's Disease
The I-SPY Consortium
The Mended Hearts, Inc.
The Sudden Arrhythmia Death Syndromes (SADS) Foundation
Tuberous Sclerosis Alliance
U.S. Pain Foundation
United Leukodystrophy Foundation
UsAgainstAlzheimer's
Usher 1F Collaborative
Usher Syndrome Coalition
VHL Alliance
Volunteers of America
WomenAgainstAlzheimer's