

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.

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 & Auto-inflammatory 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