

September 17, 2020

Stephen M. Hahn, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter Marks, M.D, Ph.D.
Director
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn and Director Marks:

We, the undersigned organizations representing physicians and other clinicians, public health experts, scientists, patients, and other advocates, write to urge you to ensure that a COVID-19 vaccine is only authorized or licensed when it meets the Food and Drug Administration's (FDA's) existing high standards of safety and efficacy. We greatly appreciate your leadership in Operation Warp Speed, and we share your goal of making available a safe and effective COVID-19 vaccine as a critical tool to help end this pandemic as soon as those standards are met.

We agree with your [statement](#) that the development of a COVID-19 vaccine, "must adhere to standards that will ensure any covid-19 vaccine's safety and effectiveness." However, approving a vaccine that has not been shown through clinical trials to be safe and effective could cause more harm by significantly undermining COVID-19 vaccination efforts and seriously eroding public confidence in all vaccines.

While we are encouraged by the rapid development of the COVID-19 vaccine, the process must be fully transparent and not circumvent regulatory standards. Sound safety and efficacy data that are reviewed by FDA and independent vaccine experts must support the authorization or licensure of a COVID-19 vaccine. COVID-19 vaccines should be studied in the populations for whom they are intended, including, but not limited to, Black, Indigenous, Hispanic, Latinx, Asian American, Native Hawaiian, Pacific Islanders, and other populations that face disparities in care and who have been disproportionately impacted by the pandemic, as well as older individuals, health care workers, and people with chronic conditions who are at greatest risk of serious illness and death due to COVID-19.

As you have noted, "All phases of vaccine clinical development should include the people most affected thus far by COVID-19, specifically racial and ethnic minorities, elderly individuals, and people with other medical conditions. Only by gathering data on these populations can we gain a full understanding of a vaccine candidate's safety and effectiveness." In addition, children, pregnant women, and other populations in whom vaccines may perform differently should be a priority.

Recent polls have found that less than 50% of Americans are committed to getting a COVID-19 vaccine, and some of the communities hit hardest by the pandemic may be particularly wary of

the vaccine. Thorough and transparent FDA review of data supporting a vaccine's approval is the essential foundation upon which we can strengthen public confidence in a COVID-19 vaccine.

We thank you for your leadership and attention to these issues. We also thank you for repeatedly pledging that "all FDA decisions have been, and will continue to be, based solely on good science and data. The public can count on that commitment." Now more than ever, Americans must maintain trust in the independent decision-making authority and scientific rigor of FDA.

Sincerely,

African American Health Alliance

AIDS Action Baltimore

AIDS Alliance for Women Infants Children Youth and Families

AIDS Foundation Chicago

AIDS Research Consortium of Atlanta

AIDS United

AIDS Vaccine Advocacy Coalition

American Society for Clinical Pathology

American Academy of Family Physicians

American Academy of HIV Medicine

American Academy of Pediatrics

American Association of Clinical Endocrinologists

American College of Clinical Pharmacy

American College of Obstetricians and Gynecologists

American College of Physicians

American College of Preventive Medicine

American College of Radiology

American Federation of State County and Municipal Employees

American Gastroenterological Association

American Geriatrics Society

American Heart Association

American Institute for Medical and Biological Engineering

American Lung Association

American Psychiatric Association

American Public Heart Association
American Society for Clinical Pathology
American Society for Microbiology
American Society of Hematology
American Society of Nephrology
American Society of Tropical Medicine and Hygiene
American Thoracic Society
American Urological Association
Asian and Pacific Islander American Health Forum
Association for Professionals in Infection Control and Epidemiology
Association of American Medical Colleges
Association of Nurses in AIDS Care
Association of Schools and Programs in Public Health
Big Cities Health Coalition
BJC Healthcare
Catholic Health Association of the United States
Council of Medical Specialty Societies
Duke University School of Medicine
Endocrine Society
Epilepsy Foundation
Evergreen Health
Foundation for AIDS Research
Fred Hutchinson Cancer Research Center
Gay Men's Health Crisis
Harvard Medical School
Health Resources in Action
HIV Dental Alliance
HIV Medicine Association
Infectious Diseases Society of America
International Association of Providers of AIDS Care

Johns Hopkins Medicine

March of Dimes

Mount Sinai Health System

National Alliance of State and Territorial AIDS Directors

National Black Nurses Association

National Coalition of STD Directors

National Health Care for the Homeless Council

National Minority Aids Council

National Network of Public Health Institutes

Penn Medicine

Prevention Access Campaign

Providence St. Joseph Health

Research!America

Right to Health Action

San Francisco AIDS Foundation

Society for Maternal-Fetal Medicine

Swedish Health Services

The AIDS Institute

The Rollins School of Public Health at Emory University

The Ryan White Medical Providers Coalition

The Steering Committee of the Massachusetts Consortium on Pathogen Readiness (MassCPR)

The Well Project

Treatment Action Group

Trust for America's Health

University of California Davis Health

University of California Health

University of California Irvine Health

University of California Los Angeles Health

University of California Riverside Health

University of California San Diego Health

University of California San Francisco Health

University of Chicago Medical Center

University of Washington Medical Center

Vaccinate Your Family

Warren Alpert Medical School of Brown University

Washington State Department of Health

Washington University in St. Louis