September 17, 2020

Stephen M. Hahn, M.D.                                               Peter Marks, M.D, Ph.D.
Commissioner                                                        Director
United States Food and Drug Administration                          Center for Biologics Evaluation and Research
10903 New Hampshire Avenue                                           10903 New Hampshire Avenue
Silver Spring, MD 20993                                              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
America 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