

October 6, 2020

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

Dear Dr. Hahn:

As medical academics, scientists, and leaders, we believe the safety of a COVID-19 vaccine is paramount. As you know, a vaccine is given to healthy individuals and must adhere to the principle “first, do no harm.” The Food and Drug Administration has a duty to protect those who are vaccinated from harm.

But the FDA’s duty extends further. If the public does not have the utmost trust in the safety of the vaccine, the vaccination rate may not be sufficient to achieve herd immunity. In other words, the FDA’s decision could alter the course of the pandemic.

This is why a rigorous safety standard is so essential—and why the FDA’s reported standard is of grave concern. Dr. Peter Marks has indicated that the FDA will require only a **median** of at least two months of safety observation of trial participants. He explained that this standard is “not such a high bar” because it would allow for fewer than two months of observation of some trial participants.

We respectfully urge you to require a high bar for safety. The FDA should require a minimum of two months of safety observation for all trial participants. Trial participants are already a sample of the population; to diminish the weight of some trial participants does not make sense. Under the FDA’s proposed lower bar, a vaccine could be authorized before many trial participants have been observed through the period when most adverse vaccine events occur.

There is too much at stake. Authorization of a vaccine before a high safety bar is met would severely erode public trust and set back efforts to achieve widespread vaccination. In short, premature authorization would prolong the pandemic, with disastrous consequences. The integrity of the Food and Drug Administration would be severely compromised, with long-term repercussions.

We stand ready to publicly verify the safety and efficacy of a vaccine if the science and scientific process support such a determination. In that case, we look forward to working with you to promote vaccination that will help bring this pandemic to an end.

Respectfully,

Paul S. Appelbaum, MD
Elizabeth K. Dollard Professor of Psychiatry, Medicine & Law
Director, Center for Law, Ethics, and Psychiatry
Director, Center for Research on Ethical, Legal & Social Implications of Psychiatric, Neurologic & Behavioral Genetics
Columbia University Vagelos College of Physicians & Surgeons

Richard J. Baron, MD, MACP
President and CEO
American Board of Internal Medicine and the ABIM Foundation

Barbara E. Bierer, MD
Faculty Director, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
Professor of Medicine, Harvard Medical School

Uché Blackstock, MD
Founder & CEO
Advancing Health Equity

Jeffrey R. Botkin, MD, MPH
Professor of Pediatrics and Medical Ethics
University of Utah

Helen Burstin, MD, MPH, MACP
Clinical Professor of Medicine
George Washington University School of Medicine

Christine K. Cassel, MD
Adjunct Professor of Medicine
University of California, San Francisco

Esther Choo, MD, MPH
Professor, Emergency Medicine
Oregon Health & Science University

Ellen Wright Clayton, MD, JD
Craig-Weaver Professor of Pediatrics
Professor of Health Policy
Center for Biomedical Ethics and Society
Vanderbilt University Medical Center
Professor of Law
Vanderbilt University

Molly Joel Coye, MD, MPH
Former Commissioner of Health, New Jersey
Former Director of Health Services, California

Sue Curry, PhD
Dean Emerita and Distinguished Professor of Health Management and Policy
College of Public Health
University of Iowa

Gail D'Onofrio, MD
Professor and Chair
Department of Emergency Medicine
Yale University School of Medicine

Ezekiel J. Emanuel, MD, PhD
Vice Provost for Global Initiatives
Chair, Department of Medical Ethics and Health Policy
University of Pennsylvania

Jonathan Epstein
Executive Vice Dean and Chief Scientific Officer
Perelman School of Medicine
University of Pennsylvania

Jeremy Samuel Faust, MD, MS, MA, FACEP
Brigham & Women's Hospital Department of Emergency Medicine
Division of Health Policy and Public Health

David A. Fiellin, MD
Professor of Medicine, Emergency Medicine and Public Health
Yale School of Medicine

Lynn E. Fiellin, M.D.
Professor of Medicine and the Yale Child Study Center

Elliott S. Fisher, MD, MPH
Professor of Medicine and Health Policy
The Dartmouth Institute

Vivian Fonseca, MD
Assistant Dean for Clinical Research
Tullis Tulane Alumni Chair in Diabetes
Chief, Section of Endocrinology
Tulane University Health Sciences Center

Howard P. Forman, MD, MBA
Professor of Radiology, Public Health, Management, and Economics
Yale University

Wilfred Y. Fujimoto, MD
Professor Emeritus of Medicine
University of Washington

James R. Gavin III, MD, PhD
Clinical Professor of Medicine &
Trustee Emeritus
Emory University

Lynn R. Goldman, MD, MS, MPH
Michael and Lori Milken Dean
Professor of Environmental and Occupational Health
George Washington University
Milken Institute School of Public Health

Celine Gounder, MD, ScM, FIDSA
Clinical Assistant Professor of Medicine & Infectious Diseases
NYU School of Medicine & Bellevue Hospital

Jeremy Greene, MD, PhD
William H. Welch Professor and Chair
Department of the History of Medicine
Director, Center for Medical Humanities and Social Medicine
The Johns Hopkins University School of Medicine

Eve J. Higginbotham, SM, MD, ML
Vice Dean for Penn Medicine Office of Inclusion and Diversity
Senior Fellow, Leonard Davis Institute for Health Economics
Perelman School of Medicine
University of Pennsylvania

Irl B. Hirsch, MD
Professor of Medicine
UW Medicine Diabetes Institute
University of Washington

Peter Hotez, MD, PhD, FASTMH, FAAP

Co-Director, Texas Children's Hospital Center for Vaccine Development
Dean, National Tropical School of Medicine
Co-Head, Section of Pediatric Tropical Medicine
Baylor College of Medicine

Tom Inglesby, MD
Director, Johns Hopkins Center for Health Security
Professor, Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health

Steven E. Kahn, MB, ChB
Professor of Medicine
Leonard L. Wright and Marjorie C. Wright Chair
Director, Diabetes Research Center
University of Washington

Dara Kass, MD, FACEP
Associate Professor of Emergency Medicine
Columbia University Medical Center

Harlan M. Krumholz, MD, SM
Harold H. Hines, Jr. Professor of Medicine
Yale School of Medicine

John M. Lachin, Sc.D.
Research Professor of Biostatistics
The George Washington University

Mark S. Litwin, MD, MPH
Professor of Urology, Public Health, and Nursing
University of California, Los Angeles

Raghu G. Mirmira, MD, PhD
Professor of Medicine and the College
Director, Translational Research Center
The University of Chicago

K.M. Venkat Narayan
Professor, Emory University
Member, National Academy of Medicine

David Nash, MD, MBA
Founding Dean Emeritus
Jefferson College Population Health

Stephen Oesterle, MD
Former Associate Professor of Medicine
Harvard Medical School

Trevor J. Orchard, MD, FAHA, FACE
Distinguished Professor of Epidemiology Emeritus
Professor of Medicine Emeritus
Department of Epidemiology
Graduate School of Public Health
University of Pittsburgh

Stuart H. Orkin, MD
David G. Nathan Distinguished Professor of Pediatrics
Investigator, HHMI
Harvard Medical School

Kavita K. Patel, MD, MS
Fellow, Brookings Institution

Monica Peek, MD, MPH
Associate Professor of Medicine
Associate Director
Chicago Center for Diabetes Translational Research

Megan Ranney, MD, MPH
Associate Professor of Emergency Medicine
Alpert Medical School, Brown University
Director, Brown-Lifespan Center for Digital Health

Matthew C. Riddle, MD
Professor of Medicine
Oregon Health & Science University

Deb Schrag, MD, MPH
Chief, Division of Population Sciences, Dana Farber Cancer Institute
Professor of Medicine, Harvard Medical School

Michael W. Schwartz, MD
Robert H. Williams Endowed Chair
Professor of Medicine
University of Washington

Joshua M. Sharfstein, MD

Vice Dean for Public Health Practice and Community Engagement
Professor of the Practice
Johns Hopkins Bloomberg School of Public Health

Jay S. Skyler, MD, MACP
Professor of Medicine
University of Miami

Marcella Nunez Smith
Associate Dean of Health Equity
Yale University

Craig Spencer, MD, MPH
Director of Global Health in Emergency Medicine
New York-Presbyterian/Columbia University Irving Medical Center
Assistant Professor of Emergency Medicine and Population and Family Health
Columbia University Irving Medical Center

Glenn Steele
Former Chief Executive Officer
Geisinger Health System

Eric Topol, MD
EVP and Professor, Molecular Medicine, Scripps Research
Founder and Director, Scripps Research Translational Institute

Robert D. Truog, MD
Frances Glessner Lee Professor of Medical Ethics, Anaesthesia, & Pediatrics
Director, Center for Bioethics
Harvard Medical School

Paul Volberding, MD
Emeritus Professor and Director, AIDS Research Institute
University of California, San Francisco

Kevin Volpp, MD, PhD
Founders Presidential Distinguished Professor
Perelman School of Medicine and Wharton School
Division Chief, Health Policy, MEHP

Robert M. Wachter, MD
Professor and Chair, Department of Medicine
University of California, San Francisco

David S. Weinberg, MD, MSc
Chief, Department of Medicine
Fox Chase Cancer Center

Rachel M. Werner, MD, PhD
Executive Director, Leonard Davis Institute of Health Economics
Professor, Medicine, Perelman School of Medicine
University of Pennsylvania

Douglas B. White, MD, MAS
Vice Chair and Professor of Critical Care Medicine
UPMC Endowed Chair for Ethics in Critical Care Medicine
Director, Program on Ethics and Decision Making in Critical Illness
University of Pittsburgh School of Medicine

Benjamin Wilfond, MD
Treuman Katz Center for Pediatric Bioethics
Seattle Children's Hospital and Research Institute

David S. Wilkes, MD
Dean
University of Virginia School of Medicine

Carol Wysham, MD
Clinical Associate Professor of Medicine
University of Washington School of Medicine

Affiliations listed for identification purposes only.