The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

cc:

The Honorable Dr. Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

The Honorable Dr. Anthony S. Fauci
Director
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane, MSC 9806
Bethesda, MD 20892

Stéphane Bancel
Chief Executive Officer
Moderna
200 Technology Square
Cambridge, MA 02139

Albert Bourla
Chairman and Chief Executive Officer
Pfizer
235 East 42nd Street
New York, NY 10017

Stanley C. Erck
President and Chief Executive Officer
Novavax
21 Firstfield Road
Gaithersburg, MD 20878

Kenneth C. Frazier
Chairman and Chief Executive Officer
Merck & Co.
2000 Galloping Hill Road
Kenilworth, NJ 07033

Alex Gorsky
Chairman and Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Pascal Soriot
Executive Director and Chief Executive Officer
AstraZeneca
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge CB2 0AA
United Kingdom

October 20, 2020

Dear Secretary Azar:

We, the undersigned, are researchers, scholars, professionals, and activists in the fields of medicine, public health, and health policy. Some of us have served in the executive branch and developed and implemented scientific and health policy.

We write at a critical moment. Public and private sector scientists have been working with unprecedented speed to develop a safe and effective vaccine to curb the COVID-19 pandemic. We all hope we will soon have such a vaccine. But many Americans are nervous about the possibility of a rushed or politicized decision.[1] **We write to urge you to provide researchers and the public with greater transparency regarding clinical trial design for all ongoing COVID-19 vaccine studies being conducted by any company that receives federal funding.** More openness will improve public confidence by allowing independent researchers to validate trial protocols and identify any modifications that could improve them. Indeed, transparency is one of the few tools at our disposal for increasing public trust in any vaccine proved safe and effective. It will also help protect the long-term reputation of our nation's public health agencies and enable researchers to better contribute at this moment of great public need.[2]

Though detailed trial design documents are not routinely shared in advance with researchers and the public, the stakes here are enormous and justify this step. Sharing is also particularly appropriate given the unprecedented public investment in a number of leading vaccine candidates via Operation Warp Speed,[3] as well as the government's agreements to purchase millions of doses of authorized vaccines from companies like Pfizer that are conducting trials outside of Operation Warp Speed.[4] We believe that the sharing of results data will be important, but we focus here on information on trial design as a first critical step to improve scientific understanding and public trust.

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[1] *See, e.g.*, Alec Tyson, Courtney Johnson, and Cary Funk, *U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine*, PEW RESEARCH CENTER (Sept. 17, 2020, https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/).

[2] Liam Bendickson, Joshua M. Sharfstein & Aaron S. Kesselheim, *Increase Transparency at the FDA: We Need Sunlight to Fight the Pandemic,* STAT (Sept. 29, 2020), https://www.statnews.com/2020/09/29/increase-transparency-at-the-fda-we-need-sunlight-to-fight-the-pandemic.

[3] As early as June, nearly $3 billion had been allocated, "no strings attached," for research, development, and manufacturing of Operation Warp Speed vaccines. Zain Rizvi, *The People's Vaccine,* PUBLIC CITIZEN (June 11, 2020), https://www.citizen.org/article/the-peoples-vaccine. Since then, the administration has ceased providing detailed breakdowns of how BARDA funding is allocated, but reports indicate that the budget for Operation Warp Speed has grown to "as large as $18 billion." John Tozzi, Riley Griffin & Shira Stein, *Trump Administration Dips into Protective Gear, CDC Funds to Fund Vaccine Push*, BLOOMBERG (Sept. 23, 2020, 6:00 AM EDT), https://www.bloomberg.com/news/articles/2020-09-23/how-much-is-the-trump-administration-spending-on-a-vaccine.

[4] *See, e.g., U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine,* U.S. DEPT. OF HEALTH AND HUMAN SERVICES (July 22, 2020), https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html.

We applaud Pfizer,[5] AstraZeneca,[6] Moderna,[7] and Janssen[8] for releasing significant new information in the last few weeks detailing vaccine trial protocols. This disclosure generated a wave of positive media coverage for the companies, sparked rapid review by independent scientists—who both critiqued and endorsed the trial design—and helped to rebuild public confidence in these companies' vaccine candidates.

However, more information can—and should—be made public to ensure both accountability in the development process and trust in any vaccine that is eventually approved. In particular, we believe that there is important scientific value to the release of the following documents for all ongoing trials, and that there are no risks to either commercial secrets or patient privacy:

(1) Not only current trial protocols, but all versions and amendments, for each phase of all clinical trials being supported by Operation Warp Speed;
(2) statistical analysis plans, including any amendments, for all ongoing and completed vaccine trials;
(3) stopping rules and the Data and Safety Monitoring Board (DSMB) Charters for all ongoing and completed vaccine trials;
(4) sample (blank) case report forms for all ongoing and completed vaccine trials;
(5) sample (blank) model consent forms for all ongoing and completed vaccine trials;
(6) minutes of Institutional Review Board (IRB) meetings of the lead institution for all ongoing and completed vaccine trials, if within HHS's power; and
(7) clinical trial agreements with the NIH and any other relevant government agencies.

In an attachment, we list all of the information related to clinical trial design that, to the best of our knowledge, has not yet been released by the companies being supported by Operation Warp Speed or by the federal government. This information, we believe, can and should be released as soon as possible (see Attachment A). Our attached list is not comprehensive, and we encourage HHS to adopt a policy of trial design transparency that encompasses more than just the companies listed.

We ask that you issue a statement by Tuesday, October 27, identifying all such information that is in the possession of HHS agencies (including both NIH and FDA) and a timetable for its public release. We also urge you, for any information not in the possession of HHS agencies, to publicly call for cooperation from vaccine manufacturers to complete the disclosures needed to

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[5] *A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study To Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of Sars-Cov-2 RNA Vaccine Candidates Against Covid-19 in Healthy Individuals*, PFIZER (Sept. 2020), https://pfe-pfizercom-d8-prod.s3.amazonaws.com/2020-09/C4591001_Clinical_Protocol.pdf.
[6] *A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19*, ASTRAZENECA (Sept. 17, 2020), https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf.
[7] *A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older*, MODERNA (Aug. 20, 2020), https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf.
[8] *A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older*, JANSSEN VACCINES & PREVENTION B.V. (Sept. 15, 2020), https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol.

ensure confidence in the clinical trials and to allow high-quality scientific analysis of trial protocols.

Sincerely,

Peter Doshi, University of Maryland School of Pharmacy

Gregg Gonsalves, Yale School of Public Health

Amy Kapczynski, Yale Law School

Harlan Krumholz, Yale School of Medicine

Peter Lurie, Center for Science in the Public Interest

Christopher Morten, New York University School of Law

Joseph S. Ross, Yale School of Medicine

Caleb Alexander, Johns Hopkins Bloomberg School of Public Health

Sam Avrett, The Fremont Center

David Barr, The Fremont Center

Alison Bateman-House, New York University Grossman School of Medicine

Arthur L. Caplan, New York University Grossman School of Medicine

Holly Fernandez Lynch, University of Pennsylvania Perelman School of Medicine

Steven Joffe, University of Pennsylvania Perelman School of Medicine

Aaron S. Kesselheim, Harvard Medical School

James Krellenstein, PrEP4All

Jennifer Miller, Yale School of Medicine

David M. Oshinsky, New York University Grossman School of Medicine

Brendan Parent, New York University Grossman School of Medicine

Christopher Robertson, Boston University School of Law

Rachel Sachs, Washington University in St. Louis School of Law

Ameet Sarpatwari, Harvard Medical School

Jason M. Schultz, New York University School of Law

Peter Staley, independent activist

Deborah A. Zarin, Brigham and Women's Hospital

Attachment A: Unreleased Clinical Trial Documents for Six Major COVID-19 Vaccine Candidates

To the best of our knowledge, information still outstanding includes:

Pfizer has not released: (1) all versions of and amendments to its trial protocols for each phase of clinical trials in the United States, Argentina, Brazil, South Africa, and Turkey; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; and (7) clinical trial agreements with the NIH and any other relevant government agencies.

AstraZeneca has not released: (1) all versions of and amendments to its trial protocols for each phase of clinical trials in the United States, United Kingdom, Brazil, India, Japan, and South Africa; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) stopping rules and Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; and (7) clinical trial agreements with the NIH and any other relevant government agencies.

Moderna has not released: (1) all versions of and amendments to its trial protocols for each phase of clinical trials; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) stopping rules and Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; and (7) clinical trial agreements with the NIH and any other relevant government agencies.

Janssen has not released: (1) all versions of and amendments to its trial protocols for each phase of clinical trial in the United States and Belgium; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) stopping rules and Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; (7) clinical trial agreements with the NIH and any other relevant government agencies.

Merck & Co. has failed to publicly release any protocols that would aid in the independent review of vaccine development. We urge you to require Merck & Co. to release: (1) all versions of and amendments to its trial protocols for each phase of clinical trials; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) stopping rules

and Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; and (7) clinical trial agreements with the NIH and any other relevant government agencies.

Novavax has failed to publicly release any protocols that would aid in the independent review of vaccine development. We urge you to require Novavax to release: (1) all versions of and amendments to its trial protocols for each phase of clinical trials in the United States, Australia, South Africa, and the United Kingdom; (2) statistical analysis plans, including amendments, for its ongoing and completed vaccine trials; (3) stopping rules and Data and Safety Monitoring Board Charters for all ongoing and completed vaccine trials; (4) sample (blank) case report forms for all ongoing and completed vaccine trials; (5) sample (blank) consent forms for all ongoing and completed vaccine trials; (6) minutes of Institutional Review Board meetings of the lead institution for all ongoing and completed vaccine trials; and (7) clinical trial agreements with the NIH and any other relevant government agencies.