

Congress of the United States
House of Representatives
Washington, DC 20515—1306

June 16, 2020

Commissioner Stephen Hahn, M.D.
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD, 20993

Secretary Alex M. Azar II
U.S. Department of Human Health Services
200 Independence Avenue SW
Washington, DC, 20201

Dear Commissioner Hahn and Secretary Azar:

We write to urge the U.S. Food and Drug Administration (FDA) to collect and report the aggregate sex, race, and ethnicity data of all participants in COVID-19 vaccine trials. Collecting and reporting demographic data on vaccine trial participants would ensure that the eventual COVID-19 vaccine is safe and effective for the entire U.S. population without slowing the pace of the vaccine development process. Comprehensive data collection is not only sound science; it is also necessary to protect all of communities from a virus that has killed more than 106,000 Americans.

The coronavirus is not constrained by the sex, race, or ethnicity of its human host, demonstrating the importance of diverse clinical trial participation. However, women and people of color have historically been left out of or underrepresented in clinical trials.¹ This lack of representation has led to the mistreatment or even misdiagnoses of patients in the United States and across the globe. For example, between 1998 and 2000, “Women represented 22 percent of initial small-scale safety trials for new drug applications submitted to the F.D.A.,” according to the U.S. Government Accountability Office (GAO). In this same report, the GAO also found that 8 of the 10 FDA-approved drugs that were withdrawn from the market between 1997 and 2001 “posed greater health risks for women than men,” including causing valvular heart disease and liver failure.² More than a decade later, this problem has still not been solved: according to a 2015 report by GAO, “It is still unclear whether women and minorities are sufficiently represented in all research areas.”³

Sex, race, and ethnicity can potentially explain variation in risk levels for and response to infectious disease: there are already data showing male and female COVID-19 patients present symptoms of the virus differently. These differences must be acknowledged during the development of a COVID-19 vaccine. If women and people of color are consistently missing or

¹ Liu, Katherine A, and Natalie A. Dipietro Mager. 2016 March 5. U.S. National Library of Medicine National Institutes of Health. “[Women’s involvement in clinical trials: historical perspective and future implications.](#)” Pharmacy practice vol. 14,1 (2016): 708. doi:10.18549/PharmPract.2016.01.708

² Government Accountability Office. 2001. “[Report to Congressional Requesters: Women’s Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement.](#)”

³ Government Accountability Office. 2015. “[Report to Congressional Requesters: National Institutes of Health: Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research.](#)”

underrepresented in COVID-19 trials, we will be unable to assess how these populations react to the eventual vaccine. With the lives of Americans on the line, we need to take proactive steps to ensure that no demographic group is left behind.

Efforts to ensure diversity in study populations are already underway. FDA and the Department of Health and Human Services (HHS) are working with federal agencies and private companies, including the National Institutes of Health (NIH), Inovio Pharmaceuticals, and Moderna, to conduct trials with adult volunteers of all ages. Johnson and Johnson, a private partner working with NIH on the development of a COVID-19 vaccine, announced they would analyze data by sex and age as they begin clinical trials.⁴ However, more actions are needed: FDA must require all public and private organizations developing or testing a COVID-19 vaccine to report and collect sex, race, and ethnicity data to ensure that there is a diverse, representative population sample.

We also request a written response that describes specific steps HHS and FDA are taking to ensure that ongoing and upcoming COVID-19 vaccine trials have diverse and representative participation of historically underrepresented subgroups, such as sex, race, ethnicity, and women who are pregnant and lactating.

We acknowledge that this is a challenging time and we do not intend to add undue burdens to your agencies. However, in order to ensure that there will be a safe and effective COVID-19 vaccine for all Americans, we request your timely attention to these matters.

Sincerely,



SEAN CASTEN
Member of Congress

Abigail D. Spanberger
Alcee L. Hastings
André Carson
Ayanna Pressley
Barbara Lee
Bennie G. Thompson
Jesus “Chuy” García
Daniel T. Kildee
Darren Soto
David E. Price



LAUREN UNDERWOOD
Member of Congress

David N. Cicilline
David Scott
David Trone
Debbie Wasserman Schultz
Denny Heck
Donald M. Payne, Jr.
Donna E. Shalala
Earl Blumenauer
Eddie Bernice Johnson
Elaine G. Luria

⁴ Johnson and Johnson. 30 March 2020. “[*Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19: Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use.*](#)”

Eleanor H. Norton
Frederica S. Wilson
Gilbert R. Cisneros, Jr.
Grace Meng
Jackie Speier
Jahana Hayes
James P. McGovern
Jason Crow
Jim Cooper
Jimmy Panetta
Joaquin Castro
John B. Larson
John Yarmuth
Juan Vargas
Judy Chu
Lucille Roybal-Allard
Lucy McBath

Madeleine Cunnane Dean
Mary Gay Scanlon
Peter DeFazio
Bill Foster
Brian Higgins
Robin L. Kelly
Rosa L. DeLauro
Sean Patrick Maloney
Steve Cohen
Sylvia R. Garcia
Ted Deutch
Terri A. Sewell
Tom O'Halleran
Tony Cárdenas
Val B. Demings
Xochitl Torres Small

CC:

Dr. Robert Kadlec
Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Francis S. Collins, M.D., Ph.D
Director
National Institutes of Health
U.S. Department of Health and Human Services