

Congress of the United States
Washington, DC 20515

May 13, 2020

The Honorable Alex M. Azar, II
Secretary, Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

The Honorable Francis Collins
Director, National Institutes of Health
U.S. Department of Health and Human Services
Bethesda, MD 20892

The Honorable Stephen M. Hahn, MD
Commissioner, Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Azar, Director Collins, and Commissioner Hahn

As you work to develop a vaccine in response to the novel coronavirus, we urge you to proactively take steps to ensure that all related clinical trials are diverse and inclusive, especially given COVID-19's disproportionate impact on communities of color. We must also ensure the vaccine or other COVID-19 treatments are affordable so that all communities can benefit. I urge you to work with all relevant federal agencies (such as the Food and Drug Administration) and other key stakeholders (researchers, medical professionals, pharmaceutical industry, minority health organizations, etc.) to achieve these goals.

Science's ability to develop new treatments and medical knowledge hinges on rigorous and generalizable clinical trials. In the spirit of the NIH Revitalization Act of 1993 and as noted by the Food and Drug Administration, "medical products are safer and more effective for everyone when clinical research includes diverse populations." Unfortunately, vulnerable populations have long been underrepresented in medical research despite being disproportionately affected by many of the studied diseases—this extends to the current COVID-19 crisis. Specifically, racial and ethnic minorities make up roughly 40% of the U.S. population (African Americans specifically represent about 13% of the population), yet these groups have never come close to that representation in crucial clinic trials. Studies that do not reflect the full diversity of the

United States may yield treatments that do not help, and may in fact harm, large segments of our population. These oversights are inexcusable, especially as COVID-19 ravages minority communities.

Reported barriers to minority group's participation include lack of awareness (including language barriers), access to healthcare, and distrust of the medical community. Patient travel and accommodations costs and logistics during trials represent another barrier. Yet these obstacles are not insurmountable with the right incentives and leadership. This pandemic offers us a fresh opportunity to work to correct the historic inequalities of past research efforts.

In the four coronavirus related funding bills enacted to date, U.S. taxpayers provided billions of dollars to support vaccine and treatment development. Consequently, we must ensure that all Americans benefit from the eventual treatments by ensuring a diverse study population. To meet this goal, we ask that HHS, NIH, and FDA undertake the following actions:

- **Incentives/Mandates for Minority Participation-** Ensure that the participants in COVID-19 clinical trials fully represent the populations being hit the hardest by this virus. This can be done by either creating incentives or mandates for clinical trial sponsors (researchers, drugmakers) to take all necessary steps, to ensure proportional inclusion of underrepresented groups, specifically participants from minority communities in a culturally appropriate and sensitive way. Within 30 days, please respond to this letter with the specific methods NIH and FDA currently use to achieve diversity in federally-funded trials, data on current diversity within COVID-19 trials, and proposals for how to improve.
- **Real-Time Data & Response Plan-** Implement systems for real-time tracking of diversity and inclusiveness in such trials. This data should be made publicly available and updated at least monthly. For any identified representation gaps, develop a strategic plan to enhance participation from underrepresented groups in a timely manner (30 days). Submit this plan to Congress and/or the Tri-Caucus (Congressional Black Caucus, Congressional Hispanic Caucus, and the Congressional Asian Pacific American Caucus) within 60 days.
- **Funding for Disparities Research and Diverse Grantees-** Augment funding for and fast track applications for research on the impact of COVID-19 on minority communities, both in terms of physiology and social determinants of health. These funds should also be granted to a diverse group of principal investigators and institutions (HCBUs, etc). As noted by one expert, "if you have trusted health care providers in your community who look like you, are culturally relevant, and understand the challenges associated with those communities, it helps to foster trust as well as promote the practice of medicine."¹ Within 30 days, please respond with the specific methods NIH and FDA currently use to achieve diversity among its grantees and data on the current diversity of awardees. Please also provide the raw number and percent of NIH COVID-19 grants that address disparities or minority health.

¹ R'kes Starling, Chief Executive Officer of Reveles Clinical Services; How to Address Racial Disparities in clinical trial data: November 21, 2019

- **Public Awareness-** Conduct a public awareness campaign, using the press, community-based organizations, and faith-based communities, to ensure affected communities understand the available research opportunities and the importance of participation. Funding for participants' transit and accommodations to participate in trials should also be provided on a needs-basis.
- **Affordability-** Work with the pharmaceutical industry and vaccine makers to ensure the affordability of all COVID-19 treatments. Publicly share all research and development costs for therapies that received public funding.

If we fail to enact the above efforts, minority communities run the risk of being sidelined in the race to find treatments for COVID-19, and our therapies and our nation will suffer for it. Therefore, as the scientific community rises to meet the virus, we must guarantee that our research efforts do not perpetuate societal inequalities, nor in our haste that we abandon our American values of health equity and diversity. Rather we must ensure that all communities, especially the communities of color disproportionately suffering from the virus, are fully represented in this vital work.

Sincerely,



Gwen Moore
Member of Congress



Karen Bass
Chair, Congressional Black Caucus



Robin L. Kelly
Chair, Congressional Black Caucus Health Braintrust