

**United States Senate**  
WASHINGTON, DC 20510-3005

April 21, 2020

James C. Greenwood  
President and CEO  
Biotech Innovation Organization  
1201 Maryland Avenue SW  
Suite 900  
Washington, DC 20024

Dear Mr. Greenwood,

We write to request that you work with your member companies to ensure that any vaccine or therapeutic drug trials related to COVID-19 includes women, minorities, and LGBTQ+ persons. As the nation continues to respond to the COVID-19 pandemic, we know from history that we cannot afford to get this wrong—we must understand what treatments work for all communities in America.

In a matter of weeks, we have learned COVID-19 has a particularly devastating impact on racial minorities, like so many diseases that have come before it. According to a *Washington Post* analysis of early data, COVID-19 “appears to be infecting and killing black Americans at a disproportionately high rate.”<sup>[1]</sup> Specifically, the analysis shows “that counties that are majority-black have three times the rate of infections and almost six times the rate of deaths as counties where white residents are in the majority.”<sup>[2]</sup> In New Jersey, where demographic data is available, Hispanics and African Americans account for 25.8 percent and 25.7 percent of COVID-19 cases respectively.<sup>[3]</sup> This is despite the fact Hispanics make up only 20.6 percent of the State’s population, and African Americans only 15 percent.<sup>[4]</sup> In Milwaukee County, Wisconsin, “African Americans account for about 70 percent of the dead but just 26 percent of the population.”<sup>[5]</sup> In Chicago, African American residents have died at a rate six times that of whites.<sup>[6]</sup> The disparities likely persist in other groups as well. As Chicago Mayor Lori Lightfoot acknowledged, there is likely “‘significant underreporting’ among Hispanics, who account for roughly 14 percent of [Chicago’s] known [COVID]-19 cases and are 29 percent of the city’s overall population. Asians, representing about 7 percent of the population in Chicago, make up about 3.6 percent of known coronavirus cases.”<sup>[7]</sup> In Michigan, African Americans account for 13.4 percent of the population but make up a disproportionate 33 percent of COVID-19 cases and 40 percent of deaths.<sup>[8]</sup>

The disparities in the COVID-19 pandemic are exacerbated by higher rates of chronic disease among many minority populations, inequitable access to health care, and bias within the health care system itself.<sup>[9]</sup> As such, any clinical trials for vaccines and therapeutic treatments of COVID-19 must include participants that racially, socioeconomically, and otherwise demographically represent the United States. This virus is striking in its disproportionate impact

on minority populations, and it is more important than ever that these populations are represented in any clinical trials.

Alarming research shows that although “African Americans represent 12% of the United States population, they make up only 5% of all clinical trial participants. Only 1% of clinical trial participants were Hispanic, though they comprise 16% of the national population.”<sup>[10]</sup> As a result, “[i]nequitable research can lead to dangerous outcomes for those who are not represented in clinical trials. Drugs including chemotherapeutics, antiretrovirals, antidepressants, and cardiovascular medications have been withdrawn from market due to differences in drug metabolism and toxicity across race and sex.”<sup>[11]</sup>

As the Food and Drug Administration (FDA) notes, “[r]acial and ethnic minority populations continue to be underrepresented in clinical trials and remain disproportionately burdened by many chronic and debilitating diseases. This is due to factors including a lack of trust in the medical system—in part due to historical mistreatment—as well as a lack of transportation, time, or knowledge about clinical research opportunities.”<sup>[12]</sup> Recognizing these inequities, the FDA issued guidance on the collection of race and ethnicity data in clinical trials and created a Minorities in Clinical Trials Initiative.<sup>[13]</sup>

The FDA alone cannot fix the problem of underrepresentation. The private sector must also take proactive steps to ensure drug and vaccine trials include a diverse group of Americans. We urge you to examine new and creative ways to enroll a diverse set of participants in COVID-19-related trials such as reducing barriers to clinical trials, utilizing diverse clinical trial personnel, ensuring language accessibility, and investing in participant recruitment by partnering with minority health and community advocacy groups. We also request that you provide us with an update on the actions you have taken to address these barriers and prioritize diverse participation. Thank you for your continued work during this pandemic. We look forward to your response and thank you for your consideration of this important issue

Sincerely,

/s/ Robert Menendez

United States Senator

/s/ Chris Van Hollen

United States Senator

/s/ Thomas R. Carper

United States Senator

/s/ Elizabeth Warren

United States Senator

/s/ Richard Blumenthal  
United States Senator

/s/ Richard J. Durbin  
United States Senator

/s/ Maize K. Hirono  
United States Senator

/s/ Tammy Baldwin  
United States Senator

/s/ Bernard Sanders  
United States Senator

/s/ Amy Klobuchar  
United States Senator

/s/ Robert P. Casey  
United States Senator

/s/ Benjamin L. Cardin  
United States Senator

/s/ Edward J. Markey  
United States Senator

/s/ Cory A. Booker  
United States Senator

/s/ Sherrod Brown  
United States Senator

/s/ Mark R. Warner  
United States Senator