



United States Senate

April 30, 2021

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Director Collins:

As the National Institutes of Health (NIH) works to improve our understanding of COVID-19, I urge you to require NIH-funded research to appropriately assess whether clinically important sex/gender and race/ethnicity differences play a role in study outcomes regarding the disease.

While NIH has strengthened its efforts to include women and minorities in clinical research, it is equally critical for studies to evaluate data to determine whether differences across sex and race categories may have affected study outcomes. Studies have shown that despite no difference in likelihood of infection, men are associated with a higher risk of severe COVID-19 outcomes compared to women, suggesting fundamental sex/gender differences in immune response to infection.

Ensuring that NIH-funded research includes these clinically-relevant assessments not only benefits our understanding of risk factors associated with short and long-term COVID-19 health outcomes, but may also have significant consequences on potential treatments. In a study published in *Biology of Sex Differences*, researchers found that standardized doses for several FDA-approved drugs resulted in higher blood drug concentrations in women and took longer to be eliminated from their bodies. Women also experienced worse side effects and greater occurrence of adverse drug reactions compared to men, overall.

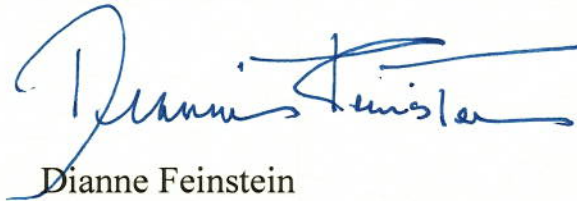
Furthermore, it is evident that the disease's disproportionate burden on racial and ethnic minorities must also be considered when evaluating sex/gender effects on COVID-19 outcomes. Research has shown that while there is higher risk of severe COVID-19 outcomes for men compared with women, this only existed within separate race categories. Even more, further analysis has found that Black

women are actually up to four times more likely to die of COVID-19 than white men, demonstrating that examining racial/ethnicity variables in COVID-19 sex/gender disparities is crucial to fully understanding the impact of the disease.

I appreciate the work NIH is doing to prioritize the inclusion of women and communities of color in the recently announced studies on self-administered COVID-19 treatment options and vaccination for individuals who are highly allergic. The subsequent analyses of how sex/gender and racial/ethnicity variables impact their outcomes will be critical to improving our understanding of COVID-19 and how to fight it.

I thank you for your attention to this important issue and look forward to your response.

Sincerely,



Dianne Feinstein
United States Senator

DF/af