

Breakthroughs that change patients' lives

Pfizer Inc.

401 North Middletown Road
Building 190, Room 3187
Pearl River, NY 10965

August 6, 2020

Dear Ms. Dee,

Thank you for your letter. We understand and appreciate your concern regarding the inclusion of people living with HIV (PLWHIV), and people successfully treated for hepatitis B (HBV) and hepatitis C (HCV) in our Phase 2/3 BNT162b2 COVID-19 vaccine trial. Pfizer has already been in the process of amending the protocol to clarify that people with stable HIV, HBV and HCV infections can enroll in the study. This will require discussions with regulators, who will ultimately make the decision whether this clarification can be included.

Our goal in this vaccine clinical trial, as with all our trials, is to guard the safety of our participants. Our protocol currently states: "Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included." This leaves the decision to clinical investigators in terms of inclusion or exclusion of potential participants, but should serve to exclude people with uncontrolled infections, not people with a manageable and stable disease. While the current protocol specifically excludes individuals with "Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)," we understand the importance of amending the protocol, with regulatory approval, to specifically state that volunteers living with stable HIV, HCV and HBV, and others living with stable disease, can be included.

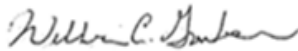
Diversity in clinical trials has long been a priority for Pfizer and is more critical than ever now. With COVID-19 disproportionately impacting communities of color in the United States, we share your concerns and understand the importance of developing vaccines and potential treatments that are safe, effective and easily accessible to people of color. To that end, ensuring that our COVID-19 clinical trials include diverse populations is of primary importance.

Our goal is to establish diversity in terms of race, ethnicity, age, gender and sexual orientation across our entire research portfolio as a key scientific variable, so that our study populations reflect the epidemiology of the diseases we target with our medicines.

The COVID-19 pandemic is a crisis unprecedented in recent history. We are working with utmost speed and urgency to develop a safe and effective potential vaccine, while keeping paramount the wellbeing of clinical trial volunteers and study staff.

We appreciate your leadership in advocating for people living with HIV, HBC, HCV and other diseases who are disproportionately impacted by COVID-19. Now and always, we are truly grateful to every person who participates in clinical trials.

Sincerely,



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