AIDSACTIONBALTIMORE, INC.

14 EAST EAGER STREET. BALTIMORE, MARYLAND 21202 (410) 837-2437 FAX (410) 837-2438
BaltoAIDS@aol.com www.aidsactionbaltimore.org

August 5, 2020

William C. Gruber, MD, FAAP, FIDSA
Senior Vice President, Vaccine Clinical Research and Development
Pfizer, Inc.

Dear Dr. Gruber:

We write to urge you to amend your Phase 3 BNT162b2 COVID-19 vaccine trial to include stable treated people living with HIV (PLWHIV) and people with successfully treated or stable hepatitis B (HBV) and C (HCV). It is critical to generate data in these populations to ensure a broad FDA indication and associated payer reimbursement for the vaccine if it is approved.

There is no clinical justification for excluding PLWHIV from COVID-19 vaccine trials. Since the advent of triple combination antiretroviral therapy (ART) in the mid-1990s, HIV infection has not been synonymous with immunodeficiency. For this reason, routine immunizations are recommended for PLWHIV, with the only caveat being withholding of certain live vaccines if the CD4 T cell count is below 200, according to the CDC.

At most, CD4 T cell threshold criteria might be employed if there are concerns about people with very low counts being able to mount insufficient vaccine responses. If there are concerns about differing immune responses in PLWHIV, this can be studied through a subset analysis. This approach should be considered for participants with other controlled co-morbidities, and is especially important with respect to communities of color who are disproportionately affected by, and who experience disparate outcomes from HIV, HBV, HCV and SARs-CoV-2.

Our position is supported by the June 2020 FDA's Development and Licensure of Vaccines to Prevent COVID-19 Guidance for Industry which provides in pertinent part on page 11:

> "Evaluation and vaccine safety and efficacy in late phase clinical development in adults should include adequate representation of elderly individuals and individuals with medical comorbidities."

Further, enrollment in COVID-19 clinical trials, including vaccine trials—especially Phase 3 trials—must reflect the populations who have been most impacted by COVID-19, especially communities of color. Polling indicates that just 50% of Americans plan to get a COVID-19 vaccine when one becomes available, with just 25% of Black/African Americans and 37% of Latinx reporting that they plan to get a vaccine when available. To build trust and avoid policies that can compromise trials, such as the exclusion of PLWHIV or other populations, community representatives must be involved in COVID-19 clinical trials design and development from the onset, not only engaged to further study recruitment.

The HIV community is ready willing and able to work with Pfizer with respect to protocol development as well as recruitment and retention issues. Please consider discussing these matters with us, including sharing your plan to ensure communities of color and people with HIV, HBV and HCV are enrolled in Phase 3 US clinical trials and involved in community engagement regarding not only recruitment efforts, but also in trust-promoting clinical trial design issues and protocol development. Your time and efforts are greatly appreciated. We look forward to your prompt response.

Yours truly,

Lynda Dee
Executive Director

Richard Jefferys
Treatment Action Group