

May 26, 2020

The Honorable Robert Menendez
United States Senate
528 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Menendez,

Thank you for your recent letter to Gilead, and your work to ensure that all Americans are represented and included in biomedical innovation. Gilead shares your conviction that diversity in clinical trials is essential to having a full understanding of how treatments work across all relevant patient populations. We also recognize the tremendous health disparities that are pervasive in this country and understand that we have a duty to ensure that our efforts – from clinical trials to treatment access—do not leave any group of Americans behind.

We have a long history working with diverse and minority populations, which are often the communities hit the hardest by the diseases we fight. Because of our long history of preventing and treating HIV and curing Hepatitis C, we know how disproportionate the impact of a virus can be. Unfortunately, we now see similar patterns appearing with COVID-19. I would like to share with you how our company is working to ensure our COVID-19 clinical trials are inclusive, and how we are committed to meeting the needs of minority and underserved populations in all our efforts to develop life-saving therapies.

Gilead is working to ensure diverse trial enrollment for COVID-19 trials

The remdesivir clinical trial program was designed to rapidly evaluate the potential for remdesivir to treat COVID-19, with various trials run by different entities to answer multiple scientific questions in parallel. Seven separate clinical trials of remdesivir were initiated across the world, involving thousands of patients with COVID-19. Active studies include trials sponsored by Gilead, the National Institute of Allergy and Infectious Disease, the World Health Organization and INSERM.

Across the two Gilead-sponsored studies, we expanded the original trial enrollment from 1,000 patients to enable the enrollment of 7,600 patients. We have been adaptive and flexible in the design and running of our clinical trials, to ensure they reflect the evolving epidemiology of the disease.

Given that these trials are ongoing, we are unable to disclose the specific patient population figures. However, based on the enrollment data, we believe the populations in the studies appropriately reflect the burden of disease in the communities where trial sites are located. The ethnic and racial make-up of study participants in the United States represents the demographics of the disease in these communities, with a substantial number of African Americans, Hispanic, and Asian patients enrolled in our trials. Data also indicates that men may be disproportionately affected by COVID-19 compared with women. As such, the study populations include a greater percentage of men.

Gilead acknowledges that diverse clinical trials begin with an inclusive approach to selecting trial sites

The selection of clinical trials sites for COVID-19 reflects our recognition that the burden of the COVID-19 pandemic is falling disproportionately on people from minority and underserved communities.

For the sites selected to participate in Gilead trials, as well as our Expanded Access Program, we worked to ensure locations reflected the epidemiology of the outbreak and regional need. We included sites across a broad U.S. geographic area, including many urban centers with a significant burden of COVID-19 cases in New York, New Jersey, Michigan, New Orleans and Chicago. Some sites were specifically included in the trials on the basis that they were able to expand enrollment to a more diverse population of people, such as the addition of a site in Boston that serves a high proportion of African American patients. By focusing on major metropolitan areas and working with clinical trial sites with broad patient coverage, we have seen robust enrollment of underrepresented groups.

We have also made efforts to support the physicians and hospital staff who are working at clinical trial sites. Clinical studies place extra burden on frontline workers and the facilities serving the most vulnerable populations are often the least equipped to absorb the additional demands. We have worked to streamline our processes to reduce administrative burden and to support trial sites in meeting the needs of diverse patient populations by, for example, providing translated documents to support the enrollment of non-English speakers.

Gilead has been committed to ensuring underrepresented populations are included in our clinical studies beyond COVID-19

In our HIV clinical studies, we have worked to recruit black men who have sex with men (MSM) to ensure that trial findings are inclusive, representative, and meaningful. These efforts include thoughtful site placement in areas with high incidence among black MSM, the selection of sites with diverse, culturally competent staff with expertise in recruiting and retaining members of this community, and training and support for community advocates to drive recruitment. We are actively working to further expand participation of marginalized and under-represented communities in our clinical studies, including trans- and cis-gender women. We will continue to seek and create partnerships to increase awareness, education and interest in clinical trials for these communities.

In our key therapeutic areas, research continues well beyond product approval. In fact, we have over 20 years of post-approval data for certain drugs, helping us to gather a comprehensive understanding of how treatment works in certain populations. We examine any unmet needs and data gaps that exist after the completion of pivotal trials, and work to address these areas in phase 3b/4 trials, collaborative research, and use of real-world data. One such example was our continued research in Hepatitis C and African Americans. Historically, African Americans had lower response rates to the prior standard of care, Interferon therapy. As such, we conducted multiple real-world analyses on African Americans to understand the effectiveness of Gilead's treatment in this population.

Beyond ensuring drug trial diversity, Gilead supports underserved communities to access treatment and broader health services

Gilead knows that it takes more than medicine to address the challenges patients and communities face in accessing the best possible care. Through our partnerships with community organizations, we work to help improve access to care, reduce disparities, improve education and support local communities. Gilead's corporate giving programs fund projects that support underserved communities, which systematically experience social or economic obstacles to health.

In 2019, Gilead provided \$380 million in cash donations to reduce health disparities, eliminate the barriers to healthcare encountered by underserved populations, advance education among healthcare professionals and support the local communities in which we operate.

Gilead works with a variety of governmental agencies and community partners to expand access to healthcare services, and to help address HIV-related societal disparities. Our efforts include medication donations and support of programs such as Gilead COMPASS (COMmitment to Partnership in Addressing HIV/AIDS in Southern States) Initiative® to develop solutions that meet the unique needs of the communities hardest hit by the epidemic.

In response to the intersecting US opioid and HCV epidemics, Gilead launched HepConnect, a five-year, multi-million-dollar initiative to help address the increase in HCV infections and support community partnerships in Indiana, Kentucky, North Carolina, Tennessee and West Virginia. HepConnect is focused on expanding HCV screening, linking people to care, improving healthcare professional education, and supporting evidence-based harm reduction through partnerships.

Most recently, Gilead announced a \$20 Million Philanthropic Fund called Gilead CARES (COVID-19 Acute Relief and Emergency Support) to support nonprofit organizations impacted by the COVID-19 Crisis. Organizations may be eligible to receive up to \$100,000 in emergency assistance.

Thank you again for reaching out and bringing attention to this critical topic. It is one that all of us at Gilead take extremely seriously and I'm grateful for the opportunity to share this information with you. Please do let me know if we can provide any additional detail on Gilead's activities to meet the needs of the increasingly diverse population in the United States.

Sincerely,



Daniel O'Day

Chairman and Chief Executive Officer, Gilead Sciences, Inc.