



**CG COPY**

October 6, 2008

Vanessa Brocato  
Executive Director  
Community HIV/AIDS Mobilization Project  
32 Broadway, Suite 1801  
New York, NY 10004

Dear Ms. Brocato,

I am writing in response to your letter to Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases regarding your interest in pre-exposure prophylaxis (PrEP) studies. The Division of AIDS (DAIDS) has the lead responsibility within NIAID for HIV/AIDS research and as such your letter was forwarded to my office for reply.

Let me begin by letting you know that we share your concerns and agree with many if not all of your points about the importance of continuing and expanding PrEP research and clinical trials. To respond to specific points made in your letter, I offer that we have invested the appropriate resources for this new prevention area, especially given the current budget restraints and competing priorities. In fact, we recently increased the sample size of our iPrex trial which included expanding to sites in the United States, Brazil, South Africa, and Thailand. This has been accomplished through a successful collaboration between the NIH and the Bill and Melinda Gates Foundation and we are happy to report that enrollment is going very well in the currently active sites. We also agree that the data from this trial will be complementary and not duplicative with other ongoing PrEP trials.

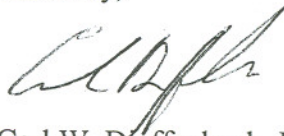
We are acutely aware that acceptance, adherence and behavioral research on issues surrounding HIV transmission are of supreme importance and to this end have supported their active evaluation within the currently ongoing iPrex trial. We also realize that further research will likely need to be done in this area and as such will continue to work with the researchers and our sister institutes, such as the National Institute of Mental Health and the National Institute of Drug Abuse, to ensure that the remaining priority questions are answered. We are also committed to conducting long term safety and behavioral follow-up of the current iPrex participants through expanded funding should the efficacy results prove favorable.

NIAID is planning for the next generation of PrEP trials and is currently discussing the prioritization of research questions and how those studies might be designed. We realize that the need to adequately address those questions will likely take a mixture of preclinical and clinical studies and as such are planning for those now.

As a result of the need for coordination of scientific efforts as well as efforts to plan implementation and communication with the larger community we have initiated a Federal PrEP Sponsors Working Group to attempt to address those important issues and are also participating in the PrEP Working Group being coordinated by the Forum for HIV Collaborative Research. We have begun discussions with CDC and UNAIDS to develop a plan for the issuance of recommendations or guidelines as well as planning now for dealing with implementation issues should results from the ongoing trials show efficacy.

Last, but by no means least, I would also like to note that the community has played and will continue to play an important part in all of our prevention trials. I would also like to express our appreciation of the support we have received from members of your organization on the development of the recent HIV Prevention Trials Network domestic studies and I certainly welcome the chance to meet with you at anytime. We appreciate and share your commitment to ending the AIDS epidemic. If you have additional questions or concerns, please feel free to contact me or Ms. Sheryl Zwierski, Acting Director of the Prevention Sciences Program in DAIDS. I can be reached at 301-496-0545 and Ms. Zwierski can be reached at 301-402-4032.

Sincerely,



Carl W. Dieffenbach, Ph.D.  
Director, DAIDS, NIAID