

Tuesday, September 23, 2008

Anthony Fauci, NIAID
Kevin Fenton, CDC
Renee Ridzon, Gates Foundation
Henrietta Holsman Fore, USAID

cc. Sandra Lehrman, Merck
Lynn Marks, GSK
Jim Rooney, GILEAD
Randy Tressler, Pfizer

Dear Drs. Fauci, Fenton and Rizdon and Ms. Fore,

The undersigned organizations and individuals are writing to voice our strong and continued support for research into Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV infection and to urge you to take necessary steps to ensure this research has the best chance of success. The need for effective biomedical interventions to prevent acquisition of HIV remains desperate, and PrEP is widely considered the best near-term hope given the stern scientific challenges being faced by the vaccine and microbicide fields.

In light of PrEP's potential we urge you, as research sponsors, to:

- Ensure that appropriate resources are invested in PrEP trials so that definitive answers regarding efficacy in diverse populations can be obtained as rapidly and reliably as possible. Sample size decisions should be made based on maximizing confidence in the trial outcome and minimizing the confidence intervals associated with the results. We are particularly concerned that trials experiencing difficulty with recruitment not be abandoned, but that the challenges be proactively analyzed and addressed, with additional resources committed if necessary to ensure completion. There are several PrEP trials ongoing, each addressing different populations and the data produced will be complementary rather than duplicative. These data will be vital for planning future PrEP trials and/or implementation.
- Ensure priority questions are addressed in PrEP research without placing undue burden on clinical trials. Studies evaluating adherence and acceptability of PrEP are a critical part of the overall portfolio, as are immunological studies to evaluate the impact of the intervention on HIV-specific immune responses (in both trial participants who remain uninfected and those who seroconvert despite PrEP). PrEP research also offers an opportunity to advance behavioral research on HIV transmission.
- Ensure that resources are allocated to collect longer-term safety data and conduct careful studies of the behavioral impacts of PrEP should efficacy be shown. One efficient means to this end is to sponsor open label roll over studies for participants of trials that are completed if PrEP is shown to be safe and effective in that trial. Such studies may not be feasible for every trial. However, if investigators propose roll over observational cohorts these proposals should be given careful consideration for funding. The time for planning those studies and identifying funding is now.
- Move rapidly to begin the next generation of PrEP trials. While current research is focused on continuous use of PrEP, there is also a need to investigate the efficacy of intermittent use of the intervention. As current clinical trials begin to report data in the coming years it may become

much more difficult to do intermittent trials. These trials should be planned now and launched without delay. Studies on different dosing levels may also be required. In addition, to build strength through diversity, antiretroviral agents not currently in PrEP trials should undergo rigorous preclinical and clinical evaluation for prevention indications.

- Plan now for PrEP trial outcomes. We echo the points made last year in *The Lancet* by Lynn Paxton, Tony Hope and Harold Jaffe (Lancet, 2007; 370:89-93). As these authors wrote, “the severity of the HIV epidemic and the potential benefits of pre-exposure prophylaxis should lead us to begin planning for implementation as soon as possible.”
- Be responsive to community stakeholders. Community engagement in the design of PrEP research and planning for PrEP delivery must be continued and expanded.

We appreciate and salute your support for PrEP research and look forward to working with you on the issues raised in this letter. We hope to meet with each of you in the coming months to talk about the state of PrEP clinical studies and planning for PrEP delivery, and how we can work collaboratively with you to support this extremely important area of HIV prevention research.

Sincerely,

A handwritten signature in black ink, appearing to read 'Vanessa Brocato', with a stylized, flowing script.

Vanessa Brocato
Executive Director, Community HIV/AIDS Mobilization Project (CHAMP)

On behalf of members of the PrEP Committee of the CHAMP Prevention Research Advocacy Working Group (PRAWG). *List in formation:*

Organizations

AIDS Vaccine Advocacy Coalition (AVAC)
Center for Health Justice
Community HIV/AIDS Mobilization Project (CHAMP)
The Fenway Institute, Fenway Community Health, Boston
Gay Men's Health Crisis (GMHC)
L.A. Gay & Lesbian Center
National Alliance of State and Territorial AIDS Directors (NASTAD)
Global Campaign for Microbicides
Project Inform
SisterLove, Inc
Treatment Action Group (TAG)

Individuals

Susan Buchbinder, San Francisco
Chris Collins, AVAC
Julie Davids, CHAMP

Robert Grant, Gladstone Institute of Virology and Immunology, University of California, San Francisco
Albert Liu, San Francisco
J. Jeff McConnell, Gladstone Institute of Virology and Immunology, University of California, San Francisco
Kaijson Noilmar, Seattle
Rachel Pacheco, Native American community advocate
Robert H. Remien, Ph.D., HIV Center for Clinical and Behavioral Studies, Columbia University
Sharif Sawires, David Geffen School of Medicine, University of California, Los Angeles
Melanie Thompson MD, AIDS Research Consortium of Atlanta
Steven Wakefield, Seattle.