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February 21, 2006

Julie Davids
Executive Director
CHAMP
Email: Jdavids@champnetwork.org
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Dear Julie,

We are writing in response to “A Statement of Support for HIV Prevention Research on Pre-Exposure Prophylaxis” dated February 7th, 2006. The conduct of HIV prevention trials, especially those involving TDF as chemoprophylaxis, has been associated with scientific, social and operational challenges. Rather than deter progress, those challenges have ultimately fostered important innovations in research design, capacity building, and partnerships among stakeholders. We cannot let recent challenges stop the vital research on TDF as an HIV prevention intervention. We cannot turn our backs on anything that holds promise for stemming the tide of 14,000 new infections every day. And, as you state, *we must swiftly and ethically answer the question: Does PrEP work and is it safe?*”

The final results of Family Health International’s West Africa trial will be available 2nd quarter 2006. This study will provide valuable product safety information in this population of women at risk for HIV as well as social and behavioral data on HIV risk that is of value for HIV prevention efforts among both men and women in diverse African settings. The trial was designed to have more than 90% power (i.e., “chance”) to conclude that tenofovir is highly effective, if the true effectiveness of TDF is 85% (i.e., if TDF prevents 85% of infections that would otherwise have occurred in the study population). Unfortunately premature study closers in Nigeria and Cameroon, as well as lower than expected HIV incidence at all three study sites, meant that the number of infections observed during the trial - and hence the amount of information available to make reliable conclusions - was less than that required to unequivocally demonstrate effectiveness of TDF.



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To fully study and confirm the safety and effectiveness of oral TDF additional, larger Phase III studies, particularly among women and heterosexual men, will need to be undertaken. The most difficult challenge ahead is building support within countries that is durable in the face of controversy and competing interests. This challenge will be met only if governments see strong, global leadership for HIV prevention research on a par with what has emerged for HIV treatment.

Sincerely yours,

A handwritten signature in blue ink that reads 'Willard Cates'.

Willard Cates, Jr., MD, MPH
President/Chief Executive Officer
Institute for Family Health
Family Health International