

May 29, 2008

Anthony S. Fauci  
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Dear Dr. Fauci,

Thank you for the opportunity to comment on the proposed PAVE 100A trial.

Simply put, as prevention advocates representing a network of 13,000 people, we strongly urge that NIH commit to a process of strategic, comprehensive consultation of stakeholders and constituents in, but also beyond, communities located where there are potential trial sites *before* making any definitive decision about this trial.

As you know, the agent to be evaluated in this proposed study is neither being considered as a preventive vaccine nor a true therapeutic vaccine, and thus is *not* a vaccine as that term is understood by laypeople and the media. The investigation is not a clinical trial evaluating a product for commercial development and broader distribution, but instead is an experiment seeking to achieve an incremental gain in knowledge for the next vaccine. To be ethical, the trial would have to stress these factors in both general publicity and in individual consent discussions, which may well militate against adequate enrollment and thus feasibility. At both the community and the individual levels, the trial thus faces potentially serious obstacle to acceptability and achievability.

Furthermore, to some knowledgeable community observers who have followed and generally support the vaccine development enterprise, the scientific merit of PAVE 100, in the light of the MRK-Ad5 experience, has not yet been sufficiently demonstrated. While plausible arguments have been advanced, so have plausible objections and strategic disagreement with this approach. This high degree of public scrutiny around this research requires a high level of consultation and endorsement from a wide range of stakeholders.

The enrollment criteria are extremely limited, and focus on a subset of just one population group – currently, gay men and other men who have sex with men in the United States, and perhaps more broadly in the Americas – for whom there are few studies with incidence endpoints despite their extremely high rates of infection. The general epidemic in gay men in this country, in fact, pales *only* in comparison to the even more severe particular epidemic in Black gay men. In particular, LGBT organizations that may not have ongoing capacity to track HIV/AIDS research must be consulted in regards to this trial, due to the specific population involved and the issues that make this proposal different than other parts of the HIV/AIDS research enterprise.

Further, we continue to urge NIAID to not only document and distribute an assessment of prevention research in gay men and other men who have sex with men in the United States, but to collaborate on a community-

informed agenda which leverages resources of large trials, research networks and researcher-initiated investigations to answer a range of pressing questions in these populations.

The PAVE 100 proposal holds very real questions of acceptability to the community, and its potential scientific value must be measured against, and scrutinized for potential damage to, future acceptability of more promising vaccine trials. These concerns must be carefully assessed against its potential as a discovery trial that will aid the scientific understanding of vaccine development, specifically T cell-based approaches, and its acceptability to at least a minimal number of altruistic volunteers.

To engage in productive discussion on these issues, community members, constituents and stakeholders must be versed in immunologic concepts, recent developments in research, and proposed pathways for future vaccine research. Thus, we believe that serious community/constituency engagement around these complex issues has only just begun. While our organization has been cited by some as a leader of community involvement in this proposal, we must point out that we are happy to both distribute information and facilitate dialogue, but are in no way able to accept front line responsibility for what must be a strategic, transparent and comprehensive process of information-sharing, debate and dialogue with a wide range of stakeholders.

Best wishes,

A handwritten signature in cursive script, appearing to read "Julie Davids".

Julie Davids  
Executive Director