



## The AIDS Institute

*Promotes action for social change through public policy research, advocacy and education*

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In our March 10, 2006 public comments before the Blood Products Advisory Committee of the Food and Drug Administration (FDA), The AIDS Institute raised the following issues that we believe must be addressed prior to the implementation of this approach:

1. The absence of direct counseling in the OTC home-use HIV test kit setting will require the provision of clear information with the kit including appropriate use of the kit, HIV prevention, and a statement that HIV infection is a treatable disease
2. Likewise, the absence of direct counseling with this method will need to be addressed by provision of a toll-free twenty-four hour, seven-day a week telephone number staffed by qualified counselors. The counselors will need to be prepared to answer questions about the test kit and its use; HIV prevention; and local referral options for medical and psychosocial evaluation and assistance
3. The CDC will need to address how this approach may impact HIV case reporting and HIV surveillance data.

The AIDS Institute is encouraged by the fact Dr. Elliot Cowan, Chief, Product Review Branch, FDA, reported to this body in the September 2006 Summary Report, that the Blood Products Advisory Committee (BPAC) recommendations call for informational material content and that the next steps for OTC home-use approval include identification of groups for clinical trials, evaluation of study proposals, and strategies of post-market surveillance.

Respectfully submitted,

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