

Chair  
Michael Montgomery  
California  
(916) 449-5905

Officers

Vice-Chair  
Kevin Cranston  
Massachusetts  
(617) 624-5303

Chair-Elect  
Jack Jourden  
Washington  
(360) 236-3466

Secretary-Treasurer  
Patricia Young  
Iowa  
(515) 242-5838

Kip Beardsley  
Minnesota

Michael Butler  
Indiana

Humberto Cruz  
New York

Lisa Daniel  
Kentucky

Evelyn Foust  
North Carolina

Thomas Libert  
Florida

Paul Loberti  
Rhode Island

Sharon Renter  
Wyoming

Felipe Rocha  
Texas

Deb Szwedja  
Michigan

Don Torres  
New Mexico

Jim Vergeront  
Wisconsin

James Welch  
Delaware

Peter Whiticar  
Hawaii

Anne Williamson  
Idaho

Ex-officio  
Beth Scalco  
Louisiana

Executive Director  
Julie M. Scofield

Executive Committee

October 25, 2005

James R. Allen, MD, MPH  
Chairman  
Blood Products Advisory Committee  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike  
Rockville, MD 20852

Dear Dr. Allen and Committee Members:

On behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD), I am writing to provide comments regarding criteria considerations for an over-the-counter (OTC) HIV rapid screening test. NASTAD's membership consists of state health department AIDS directors who have primary responsibility for HIV prevention and care programs within each jurisdiction. Our membership has always been a strong supporter of HIV rapid testing, and state AIDS programs are currently the largest implementers of rapid testing in the country.

At this time, there is insufficient data for NASTAD to support or oppose the concept of an OTC HIV rapid screening test or any specific test that may eventually seek OTC status. Currently, there is no comparable device on the market that would suggest the impact of such a test. The closest available is the Home Access home collection kit, but there are many key differences between a home collection device and a proposed home rapid test kit. The discussions of the Blood Products Advisory Committee will be extremely important as the required studies will provide information essential to helping NASTAD and other organizations determine their positions. The following questions outline some of the information NASTAD would need to fully understand the impact an OTC test will have on the HIV epidemic and on HIV programs:

- **What are the demographics and risk levels of those most likely to purchase OTC HIV rapid test kits and how many individuals are estimated to be tested this way?** Recent studies suggest a public health benefit even if the only individuals who use an OTC kit would not be considered at high risk. However, understanding the response of high risk populations and whether the use of such a test will be widespread in specific communities will be important to tailoring public health programs.

- **What documentation will be needed to ensure home users perform the test correctly and understand the results?** Untrained user studies have shown that OraQuick Advance can be performed correctly with the current package insert. Instructions with a home test should ensure that the home user can perform the test as easily. Accompanying information should also ensure that users understand the meaning of their results including that this test is only for screening purposes and individuals could be in a window period where they would not test positive.
- **How effectively will individuals be linked to counseling, medical, and support services?** Any OTC test will likely include extensive information on how to access counseling and services, but it will be up to the individual to take the needed steps. Issues that must be considered include:
  - While adverse psychological reactions may be rare, in the instances where they do occur individuals will need to be quickly linked to counseling and mental health services.
  - Accessing care services in a timely manner will be important to ensure individuals receive confirmation of results and needed medical monitoring and treatment. Quick access to care will also be important to ensure that cases are reported to surveillance systems, essential to both disease monitoring and funding.
- **What will the impact be on individuals' risk behaviors?** As noted above, understanding the meaning of results will be critical. Individuals should understand that a test will not determine if they have been infected while they are in the window period and that adopting safer behaviors remains necessary.
- **What is the impact on state laboratory regulations of OTC status?** Several jurisdictions do not recognize the waivers for any currently available HIV rapid tests. Will this prevent the sale of an OTC test in those jurisdictions? In addition, it is not clear whether the OraQuick Advance test used by health departments will receive OTC status or if the test will be labeled differently. OTC approval of any test used by health departments in their testing sites will impact the use of controls, required training, etc. Any cost savings would make it possible for health departments to expand rapid testing in a resource constrained environment.
- **Will there be measures in place to prevent bulk sales of an OTC test to entities attempting to establish themselves as a counseling and testing site?** States carefully regulate sites that are allowed to do counseling and testing, generally requiring extensive training before anyone is allowed to become a test counselor. To preserve the quality of testing, health departments would want to ensure that their role in overseeing agencies and other entities that offer testing is maintained.

NASTAD appreciates the potential of an OTC HIV rapid test to increase the number of individuals that know their status. In addition to its use by individuals who purchase it, the availability of such a test creates new opportunities for AIDS programs to potentially get testing to individuals without access to traditional or outreach testing sites or that chose not to test at those sites. At the same time, NASTAD recognizes concerns associated with an OTC HIV rapid test and hopes additional information will be available soon to address these concerns. While some questions will be answered through required studies, others represent policy challenges. These policy questions will need to be considered by FDA, CDC, and other federal agencies in cooperation with state AIDS programs and other stakeholders.

Thank you for your time and consideration of these comments. If you have questions, please contact Chris Aldridge at (202) 434-8067 or by e-mail at [caldrige@nastad.org](mailto:caldrige@nastad.org).

Sincerely,

A handwritten signature in black ink that reads "Julie M. Scofield". The signature is fluid and cursive, with a long horizontal stroke at the end.

Julie M. Scofield  
Executive Director