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Julie M. Scofield

December 7, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fisher Lane  
Room 1061  
Rockville, MD 20852

RE: *Recommendations for Clinical Laboratory Improvement Amendments (1988) Waiver Applications* (Docket Number 2001D-0044)

To whom it may concern:

I am writing on behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD) regarding the Food and Drug Administration's draft guidance *Recommendations for Clinical Laboratory Improvement Amendments (1988) Waiver Applications* (Docket Number 2001D-0044). NASTAD represents state health department HIV prevention and care programs. Currently, our members are one of the largest implementers of HIV rapid testing programs using both OraQuick Advance, manufactured by OraSure Technologies, and Uni-Gold, manufactured by Trinity Biotech. As you know, both of these tests have a CLIA waiver for certain uses. We are concerned that neither of these tests would have received a CLIA waiver under the draft recommendations, and that improved tests will be kept off the market.

There are several troubling sections to the guidance:

- On page eight, the third bullet under the heading "We believe that a test that is simple to use should not have the following characteristics:" indicates that any test where the disease is reportable to the health department should not be eligible for a waiver. This will effectively block any HIV and STD test from being eligible for a CLIA waiver.
- On page eight, the ninth bullet under the heading "...FDA considers that a simple test should have characteristics such as the following:" indicates that a waived test should provide the ability for obtaining and shipping specimens for confirmation testing. This represents a highly burdensome and complex requirement for HIV and STD testing.
- The study design requirements are excessive, requiring a minimum of 120 positive and 120 negative patient samples using no more than 10% archival samples. This would require the testing of thousands of individuals. The requirements for waiver would be in excess of what is even needed for device approval. Such a burden removes any incentives for companies to come forward with new products.

This is just a sample of our concerns. These requirements are not based in the reality of what we know is occurring with HIV rapid tests. Health department AIDS programs, in cooperation with their public health laboratories, have clearly demonstrated their ability to manage this new technology and provide quality results. That HIV is reportable has not impacted the ability of HIV surveillance programs to identify new infections. Health departments have clearly demonstrated their ability to link individuals with confirmation testing. Finally, health departments need a strong market with multiple devices available to meet program needs which would not occur under these recommendations.

Health departments have come to depend on HIV rapid testing technology. The use of both OraQuick and Uni-Gold has allowed individuals who have previously avoided testing to learn their serostatus. This is powerful information that has ensured positive persons are effectively linked to care, support, and prevention services and have the opportunity to live a healthy life. To publish these recommendations would put in place needless barriers in allowing new technologies to be used at the point-of-care where they can meet the most critical public health need. Publication of these guidelines by FDA would be unconscionable.

We urge FDA to reconsider and rewrite these guidelines. We recognize and support the need for FDA to provide guidance to companies seeking a CLIA waiver, but these recommendations would only serve to limit or prevent companies doing so. FDA should consider seeking further guidance and hearing from the communities that could be most impacted by these potential tests.

Please contact me if you have any questions regarding this letter.

Sincerely,

A handwritten signature in black ink that reads "Julie M. Scofield". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Julie M. Scofield  
Executive Director