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**STATEMENT BY LATINO COMMISSION ON AIDS TO BLOOD PRODUCTS
ADVISORY COMMITTEE MEETING TO DISCUSS APPROACHES TO OVER
THE COUNTER HOME USE HIV TEST**

Thank you for this opportunity to testify today as the Blood Products Advisory Committee hears a proposal from OraSure Technologies for its oral fluid OraQuick Advance Rapid HIV 1/2 Antibody Test. The Latino Commission on AIDS is a national and regional organization dedicated to addressing HIV/AIDS in the many Latino communities throughout the country. We have never testified before this or any other panel convened by the FDA. We are here because almost one-half of Latinos who are positive do not know their HIV status.

An OTC home test that provides rapid results that is available in any drug store or on-line would have direct and indirect benefits that would result in more Latinos knowing their status and getting connected to care. In addition, the mere fact that the test would be available just as glucose tolerance and pregnancy tests would help to destigmatize HIV testing. The stigma associated now with testing is that only “bad people” get HIV/AIDS. Men and women who use drugs, are homosexuals and/or who are seen as promiscuous are viewed by most Latinos as persons who become HIV infected. So just taking test is seen in many parts of the Latino community as admission of engagement in “bad behavior.” Making the test that produces rapid results OTC would help to routinize HIV testing.

We all share responsibility for fostering and even encouraging the stigma associated with HIV testing.

First, many state laboratories make it very difficult to obtain a limited waiver necessary for rapid testing. Some jurisdictions require that a nurse or medical technical technician administer the oral rapid test. Others charge exorbitant fees for those community based organizations that want to offer the rapid test. Still others make the application process needlessly complex. This contributes to the inaccessibility of the rapid test for those organizations that know the communities they serve best. This patchwork of regulatory requirements only serves to collect revenue for state governments and protect jobs. The requirements have little to do with public health, especially with the enormous investment that has been made in training community organizations to offer testing.

Second, many HIV/AIDS organizations and clinics have made a sizeable real estate and personnel investment in the testing process. The possibility of a home OTC quick test threatens the revenue and grants of these organizations. Many of them will try to block approval of the OTC rapid tests for reasons that may be public health oriented (proper counseling, coercive testing) but in reality turn on financial concerns.

Third, the FDA and CMS have contributed to this mythology that only certain people can perform the rapid test with the licensing requirements and the requirement of “control” tests. Hundreds of thousands of dollars have been spent on control kits that many in government and industry will tell you are completely unnecessary. All of these very powerful forces have combined to make testing as something other than routine. They have helped to perpetuate the hysteria that still surrounds an HIV positive test result and helps to reinforce the fear that many Latinos feel in an HIV positive diagnosis.

Still there are legitimate issues that must and can be addressed in any OTC rapid test. First the package inserts need to be written in very simple language that explains the necessity of a confirmatory test, follow-up medical care, the time lag between infection and the production of an HIV antibody. While our concern is that the inserts be in easy to understand Spanish, other languages are also important for the African and Asian communities.

Second, the telephone service that comes with the home test needs to be comprehensive and in several languages. We conducted an informal survey of the Home Access telephone service and found it to be excellent in providing needed referrals, access to medical and mental health care, the importance of partner notification and the need for a confirmatory testing. So we know it can work. We would only recommend that some way be found for the company offering the service to obtain a HIPAA waiver from the purchaser that would enable them to contact the person testing positive in some manner that respects privacy but ensures that there was follow-up. We need to think “outside the box” to make sure that persons testing positive are connected to care.

Third, state and local health departments need information on persons testing positive in their jurisdictions. This can be done through emphasizing that the OTC rapid test is only a screening device that requires a confirmatory test. Through the confirmatory testing or subsequent medical visits the government can collect the necessary information. The confirmatory test and follow-up medical visit is a challenge with the current system and will be a challenge with the rapid OTC test.

The Advancing HIV Prevention initiative of the CDC is an important step in reducing the number of HIV infections in the Latino community. Testing, condom use, monogamy and abstinence are all critical to lowering the number of new infections. But any testing, whether over the counter or in person, needs to be culturally and linguistically responsive.

- Responsive to the rigid gender roles that impact on women and gay men and contribute to accessing care and testing.
- Responsive to the Latino family realities that often fail the man or woman testing positive for HIV because of the stigma surrounding an HIV positive test.
- Responsive to the immigration realities confronting many Latinos making their accessing medical services, housing, employment and stabilizing their immigrant status more problematic.
- Responsive to the religious context of many Latinos that fosters the stigmatizing of so many behaviors associated with HIV infection.

- Responsive to the sexual silence imposed on so many Latinos, which make it so difficult for Latino parents to discuss HIV with their children or openly confront homophobia and sexism.

All of these challenges can and must be met by any counseling offered by the company offering home OTC rapid HIV testing in partnership with medical and community based social service providers.

Ultimately, only a relatively small number of Latinos will take advantage of the home OTC rapid test. But for those persons we need to respect their choices for home testing and the fact that HIV infection need no longer be a death sentence. By providing a rapid test over the counter we move one step closer to making it clear that HIV/AIDS just one more chronic disease – manageable with education and care and preventable with education.