

Statement to the Blood Products Advisory Committee

Open Public Hearing on OTC, Home-use, Rapid HIV Tests

November 3, 2005

Good afternoon. My name is William Parra and I am Senior Vice President and Chief Operating Officer of the American Social Health Association (ASHA). I would like to advise the committee that ASHA has no financial relationship to OraSure Technologies, although we have met with them to discuss possible algorithms to telephone-based test results counseling.

ASHA has been informing the public about, and advocating for, the prevention of sexually transmitted diseases since 1914. Since our inception we have encouraged early diagnosis and treatment as a way to reduce further transmission in the community.

The Centers for Disease Control and Prevention (CDC) currently estimates that about 250,000 people in the United States are infected yet unaware of their human immunodeficiency virus (HIV) status. Since HIV infection often takes a decade to develop into acquired immunodeficiency syndrome (AIDS), people living with HIV who remain undiagnosed risk spreading HIV without their knowledge for many years.

For decades, ASHA has been an advocate of broader availability and use of HIV tests to facilitate more rapid diagnosis and treatment for those infected and to prevent further transmission. Unfortunately, many people avoid or are unable to get tested in clinics or a physician's office for a variety of reasons, including lack of access to health care services, distrust of the healthcare system, and the stigma of discovery.

We support CDC's goals to implement new models for diagnosing HIV infection outside medical settings and to prevent new infections by working with persons diagnosed with HIV and their partners. A greater set of options, including over-the-counter, home-use, rapid HIV tests, may increase the number of people willing to be tested.

Clearly, it would be preferable for all individuals seeking HIV testing to receive pre- and post-test counseling in a supportive environment. However, the availability of these home-use tests could be a very powerful strategy to reduce barriers to testing and increase early detection of HIV infection.

It is imperative that those who test negative fully understand the implications of their test results, and those who test positive to have immediate access to counseling services and referral to quality medical care.

In closing, we ask that the Blood Products Advisory Committee recommend the approval of the over-the-counter, home-use, rapid HIV test.