



May 8, 2012

Food and Drug Administration
Blood Products Advisory Committee
1401 Rockville Pike, HFM-71
Rockville, MD 20852

Dear Committee Members:

On behalf of the HIV Health and Human Services Planning Council of New York (Planning Council), I write to encourage your support of proposed studies to validate an over-the-counter (OTC) home-use HIV test kit with regard to accuracy, test interpretation, and follow-up including phone and Internet support.

I write from the front lines of the HIV epidemic in this country. With over 99,000 New Yorkers lost to HIV and AIDS, 110,736 New Yorkers living with HIV and AIDS, and 3,481 New Yorkers diagnosed in 2010, my colleagues on the Planning Council and I join the multitude of voices calling for expanded HIV testing options.

Comprised of HIV service providers, public health officials and people living with HIV and AIDS, the Planning Council collectively represents three decades of knowledge about how to survive an epidemic. Since the early '90's, the Planning Council has set priorities and allocated resources for the treatment and care of New Yorkers living with HIV and AIDS. In 2010 alone the Planning Council allocated \$120 million dollars for medical and support services to 19,000 New Yorkers living with HIV and AIDS. Among the treatment and care services funded by the Planning Council is HIV testing.

The current estimate from the Centers for Disease and Control and Prevention is that fully one-fifth of HIV-positive individuals do not know that they are infected. Despite a well-developed system to conduct outreach to communities at risk, testing, linkage to, and maintenance in care, tens of thousands of New Yorkers do not know that they are living with HIV and cannot take steps to ensure their own and their partners' health.

My colleagues on the Planning Council and I believe that an OTC in-home HIV test holds promise for reaching people who will not test in conventional settings such as a doctor's office, hospital, clinic or community-based organization. OTC home-use test kits are not new – blood glucose, cholesterol, and pregnancy test kits have been successfully used by consumers for a number of years. We believe that the time has come to consider an OTC home-use HIV test.

Currently one FDA approved home-use "collection kit" is on the market for HIV testing. With a collection kit, an individual takes his or her own blood sample, mails it to a

laboratory, and receives the results over the phone or in the mail. Under consideration today is a self-administered OraSure Technologies OraQuick Advance Rapid HIV-1/2 test -- an oral swab HIV test that delivers results in 20 minutes. The labeled sensitivity of the test is 99.3% (95% CI = 98.4%-99.7%) and the specificity is 99.8% (95% CI= 99.6%-99.9%), -- i.e., within the acceptable performance set by the FDA. One advantage of the test currently under discussion is that an individual, especially one who shuns direct contact with others regarding so sensitive an issue, could receive the test result almost immediately at home, rather than waiting for a phone call or a mail delivery.

Members of the Planning Council recognize the important role face-to-face contact has in conventional HIV testing. A trained HIV counselor can provide information and guidance to the recipient of the HIV test on behavioral choices and encourage healthy decision-making and, for HIV-positive individuals, link them to care. My colleagues and I also believe, however, that OTC home-use HIV testing, coupled with available 24/7 phone and Internet support provided by a trained HIV counselor, can play a critical role in reaching New Yorkers who, for a variety of reasons, are not accessing HIV testing through our conventional programs.

In an interview with POZ Magazine in September 2009, Dr. Yvette Calderon of Jacobi Medical Center in the Bronx observed that "It's important to allow individuals to have control over what's going on with their bodies," noting that having the option to use an OTC home-use HIV test "is just as important as taking an HIV test in a medical setting."

In testimony submitted to the FDA Blood Products Advisory Committee in November 2005, clinicians and researchers made the following observations about OTC home-use HIV testing:

- Dr. Freya Spielberg, MD, an assistant professor of Family Medicine at the University of Washington and a researcher in the Center for AIDS Prevention Research, who has spent 15 years studying rapid testing and alternative HIV counseling and testing strategies, observed that "people who have never tested are more likely to prefer an over-the-counter test" because of its "privacy" and "convenience."
- Dr. Patrick Keenan, MD, of the University of Minnesota, Department of Family Practice, when discussing the technical simplicity of the OTC home-use HIV test, noted that "with a minimum of training, basically the time it takes to demonstrate one run through of the test, people from diverse backgrounds, such as being a painter, a bus driver, chef or bartender, were able to do the test well. How people would do with no previous training certainly needs to be studied, but it is a fact that you don't have to be a laboratorian to perform this test."
- Elliott Millenson, founder and chief executive officer of Direct Access Diagnostics, a company that developed Confide, the first home HIV test, observed: "In our sexually active society, testing must be accessible in many places, especially the home. The majority of people don't want to go to a doctor's office or clinic for an HIV test."

Food and Drug Administration, Blood Products Advisory Committee, HIV Planning Council, Public Comment, May 8, 2012

Planning Council members join our colleagues at the National Association of People With AIDS, the National Minority AIDS Council, the San Francisco AIDS Foundation, the National Black Gay Men's Advocacy Group, the AIDS Healthcare Foundation, the Latino Commission on AIDS, and youth advocates at Who's Positive in believing that OTC in-home HIV testing provides an important option for individuals who would like to learn their own and/or their partner's HIV status outside of the conventional clinic situation. We strongly encourage you to support proposed studies to validate an over-the-counter (OTC) home-use HIV test kit with regard to accuracy, test interpretation, and follow-up including phone and Internet support.

The views expressed in this letter do not necessarily reflect the views of the Mayor or the Commissioner of Health of the City of New York.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dorella Walters". The signature is fluid and cursive, with a long horizontal stroke at the end.

Dorella Walters, MPA
Community Co-Chair

cc: Michael R. Bloomberg, Mayor
Thomas Farley, MD, MPH, Commissioner of Health
Jan Carl Park, Governmental Co-Chair