

**October 28, 2005**

**Mr. Donald Jehn**

**Center for Biologics Evaluation and Research**

**Food and Drug Administration**

**1401 Rockville Pike**

**Rockville, MD 20852**

**RE: Submitted written testimony to the BPAC Committee November 3, 2005 hearing.**

**See enclosure**

## **Testimony for Over-the-Counter (OTC) Home-Use HIV Test Kits**

**Comments submitted by: Rob Lunn, MPA, Director, HIV/AIDS Program, Vermont Department of Health.**

**October 28, 2005**

OraSure Technologies, Inc. has made public its imminent plans to seek OTC status for the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test for use with oral fluid specimens. FDA seeks advice regarding the conditions necessary to support approval of a home-use HIV test kit. The Committee is to consider what studies are needed to validate test accuracy, test interpretation, and medical follow-up based on the provision of informational material in place of a trained test operator and counselor.

### **Questions to be investigated by the BPAC:**

1. Are FDA's previously established criteria for sensitivity and specificity for rapid HIV tests also appropriate to support OTC use for home-use HIV test kits?
2. Please comment on the design of clinical studies necessary to validate the accuracy of an OTC home-use HIV test kit.
3. Please comment on proposed content of the informational materials and the steps that should be taken to validate the adequacy of the informational materials to communicate or provide pathways to adequately address issues including:
  - a. Accuracy of testing
  - b. Correct test interpretation
  - c. The importance of supplemental testing for confirmation of positive results
  - d. Management of psychological and social issues
  - e. Medical referral

### **Comments**

The State of Vermont Department of Health, HIV/AIDS Program, is dedicated to the mission of working with public and private partners to reduce the transmission of HIV and help Vermonters already infected live longer and healthier lives. This is accomplished by promoting and developing comprehensive compassionate and quality services for both prevention and care. The HIV/AIDS Program provides leadership, encourages input from infected and affected communities and uses scientific knowledge to guide the development of responsible, compassionate and effective policies and programs. Through the HIV/AIDS Program's Counseling, Testing and Referral (CTR) program, one of our goals is to identify as many persons as possible living with HIV so that they may learn their status and get into treatment. We are continually seeking to improve the ability of our program to meet this goal. One way is to target CTR and other services to persons who are high at risk, and to increase access to testing for those at risk.

Rapid testing is one more testing modality that can be used by HIV/AIDS programs to provide testing to persons of risk. Currently in Vermont, rapid testing is only utilized at one hospital medical clinic. Another program is under development by one Vermont ASO. The VDH HIV/AIDS Program is researching development of a state supported Rapid Testing program. Rapid testing in its current use, is utilized within very controlled environments and overseen by strict adherence to program policies and regulations including extensive quality assurance guidelines.

### **Benefits of an Over the Counter (OTC) Rapid Testing product:**

- The test is simple to use compared to other types of HIV tests and earlier versions of rapid HIV tests, suggesting that untrained persons will be able to perform the test properly.
- The test does not require special storage conditions.
- The test provides highly accurate results for the detection of antibody to HIV 1 /2 within 20 minutes.
- The use of a non-infectious oral fluid specimen eliminates concerns about biohazardous conditions, use of needles or venipuncture (no blood and no sharps).
- HIV home-use testing is anonymous and has the potential to encourage more people to learn their HIV status, to empower consumers in healthcare decisions, and to diagnosis HIV infection earlier and intervene sooner.

### **Concerns**

- How will quality assurance be addressed. Currently, control devices for OraQuick ADVANCE® are required to be used and results documented daily to ensure proper environment and operation of the device. Will an OTC device utilize such quality assurance requirements?
- HIV home-use test results could be misinterpreted or limitations of the test could be misunderstood, e.g., relying on the test to provide an accurate result after a very recent exposure.
- How will a person react to a positive test result without live counseling? How will a person reach individuals for follow-up and partner notification? (Perhaps by the self-tested individual?). Will there be coercive testing? What about Informed consent? What about use of the test by minors?
- How will supplemental tests be conducted to confirm diagnosis?
- What will be the cost and availability of an HIV home-use test kit?
- How will the test fit into or conflict with state and/or federal public health reporting requirements?

- How will individuals be linked to counseling and referrals to care and other services if they test positive? An OTC device does not provide an opportunity for prevention messages to individuals who test negative.
- Will individuals testing positive in isolation not seek care or supportive services in a timely fashion? Delays in seeking care will also mean delays in receiving surveillance data and may impact collection of incidence surveillance data.
- Plans to provide 24/7, 365 telephone access, or Internet connections to counseling or medical providers may provide adequate services to many individuals. What will help those who lack access to such technology, or the understanding to use such services.
- How will the introduction of an OTC device affect current state laboratory statutes and regulations that may not currently allow for HIV rapid testing? Several states still do not recognize the CLIA waiver for current test kits or otherwise prohibit rapid testing. What is the impact these statutes and regulations would have on an OTC kit?
- How would the sale of these kits to entities attempting to set-up HIV testing outside of current health department regulations and quality assurance measures be regulated? Can regulations be established to allow for individuals to purchase the kit, but that large numbers of kits could not be purchased or obtained by organizations (or individuals) for unregulated mass testing?
- Will an OTC HIV rapid test be utilized by persons who truly need it? Would demand for such a product be used by people who are not at risk, fall within the six week to six month window period, (e.g., “morning after” exposure) or otherwise will not benefit from having access to such technology. Experiences with the Home Access test kit suggest that demand may occur among the “worried well.”

An OTC device as proposed by OraSure has many challenges as will be addressed within this hearing. New technology such as this device requires careful consideration and the need to identify *all* areas of concern to ensure that such technology can be properly and correctly administered and used by the intended population, i.e., the general public. I am of the opinion, that if these obstacles can be addressed and accepted practices and solutions found, an OTC Rapid Test could be added to the arsenal of tools available to help fight the HIV/AIDS Epidemic.

Thank you for consideration of my comments.

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