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March 10, 2006

Oral Testimony to the U.S. Food and Drug Administration Blood Products Advisory Committee

Good morning, thank you for allowing me time today to speak on this important topic. My name is Laird Petersen, and I serve as the Chief of Staff for Illinois State Representative Larry McKeon. Prior to my commentary on an OTC rapid HIV test, I would like to give you some background on Representative McKeon and myself. Larry is currently serving his 5th term as a Representative to the Illinois General Assembly. He has been HIV positive for 20 years, and is the only openly HIV positive gay member of the Illinois Legislature. Larry serves as the chair of the Labor Committee and vice chair of the Housing and Urban Development Committee and is a commissioner on the newly formed Legislative Ethics Commission and the Commission on Discrimination and Hate Crimes. Several of Larry's top priorities include education, health care and human rights. I have been HIV positive for over 27 seven years, and have been actively working in the field of HIV/AIDS for the last 14 years. Prior to joining Larry's staff, I served as Director of Prevention Services for the AIDS Foundation of Chicago. HIV testing and the provision of more options when seeking testing is an extremely important topic and it is good we are having this dialogue today.

In the 80s and early 90s a positive HIV diagnosis was a crippling, life altering event and face-to-face counseling was a critical component of HIV testing. A positive HIV diagnosis left little hope for those infected. Since then, more effective treatments have become available that allow people to live longer and healthier lives. Due to these more effective therapies, a positive HIV diagnosis is not the death sentence it once was. Now, the greater danger is not in becoming infected, but rather ignorance of one's own positive serostatus.

Each year 40,000 Americans become infected with HIV, that's approximately 110 persons a day. 55% of new transmissions occur because of unsafe sex practices by HIV positive individuals who are unaware they are infected. In 2003, the Centers for Disease Control and Prevention estimated that between 850,000 and 950,000 Americans were infected at the end of the year 2000. Approximately, 240,000 of those infected

were unaware of their positive serostatus. In 2005, those numbers increased 24%. According to the CDC at the end of 2003, between 1.039 million and 1.185 million Americans were infected with HIV, with the numbers of those unaware of their infection increasing to between 250,000 and 320,000.

In 2003, the CDC announced its new strategy, AHP or Advancing HIV Prevention. The AHP focus on increased HIV testing, identification of newly diagnosed positives and linking them into care has been a step in the right direction. Rapid testing has proven to be a great asset in this endeavor. With rapid testing, more people are being tested than ever before, more people are receiving their test results and most importantly, more HIV cases are being newly diagnosed. Oral fluid rapid testing has had even a more profound impact, providing more options to individuals seeking testing in traditional public health settings.

Even with the increased amount of testing that has occurred since the implementation of AHP and the use of rapid testing technology, there are still a large number of individuals who are unaware of their HIV status. These persons are reluctant to seek HIV testing through traditional channels. There is still a need in this country for easier access to HIV testing. Although officials in both the public health and the private sectors have increased their HIV testing efforts, many Americans are still unaware of their HIV status.

Many people still don't seek testing because they don't want to wait in a public health clinic. Many don't seek testing because they don't want to disclose risk behaviors to their family physician. Many do not want a blood draw nor the waiting time required for traditional HIV tests. The technology is finally here in a simple to use oral fluid test that can accurately be performed by individuals with little or no clinical experience. This has been demonstrated time and time again as over the past year and a half, traditional HIV counselors across the country have taken on the role of clinicians and accurately performed rapid HIV testing in non-traditional settings.

As I mentioned earlier, counseling was a critical component of HIV testing in the 80s and early 90s due to the ramifications of a positive test result. As testing technologies and therapies have advanced, the role of HIV counseling has evolved. Persons living with this disease such as myself and Larry are living longer because we are better educated about the disease, take better care of our bodies and we utilize newer therapies. In many ways, an HIV diagnosis can be viewed as a chronic infection that must be managed instead of a fatal diagnosis. Counseling with an OTC product must contain three critical components. The first is easy to read, easy to use instructions on how to perform the test and interpret test results. The second is a comprehensive counseling message that is provided in simplistic terms, in several languages. This would include pre-test counseling messages, an individualized risk assessment, appropriate post-testing counseling messaging including the need to seek additional testing if in the event of a reactive test result, and finally the importance of seeking therapy. The third component is assistance in linking a client to

appropriate services for confirmatory testing and linkage into care. These three components must include a method for personal contact with a counselor who can link them to local health departments or community-based organizations during a difficult time for the consumer of this product. It is unrealistic to expect a company to ensure clients with reactive tests seek confirmatory testing, however it is realistic and should be expected that an OTC product provide clients with as much information and assistance to linkages as possible.

An over the counter oral fluid, rapid HIV test will provide more people with options when seeking HIV testing. It is critical that the FDA understand this. Clinical trials and the approval process should not be designed to hinder this advancement, but rather ensure that test performance is acceptable, users are informed and comprehend the proper usage of the test, users receive appropriate counseling messages, they understand the meaning of their results and have easy access to resources that can aid them in linking to a clinic for confirmatory testing and care.

Ultimately, an OTC test will allow more people easier access to HIV testing and ultimately provide more individuals knowledge of their HIV serostatus.

The impact of more people knowing their HIV serostatus of course will lead to more people seeking Ryan White CARE Act services, which, while not in your purview, will impact future funding of this Act, and I would hope that this committee and the FDA will support increased funding requests.

Thank you for your time.

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