

My name is Dr. Thomas J. Coates and I serve as a Professor of Infectious Diseases at the David Geffen School of Medicine at the University of California, Los Angeles. I am also the Director of the UCLA Program in Global Health, and have ongoing research among gay men in the US, and among a variety of populations in Central and Southern Africa, Latin America, and China. I have been working in HIV prevention research since 1983, and one of my focus areas has been HIV counseling and testing. I published some of the earliest studies on this topic from San Francisco and Africa, and have continued to conduct research on this topic.

The following thoughts are offered in response to the FDA announcement seeking public commentary in relation to the over-the-counter availability of rapid HIV testing. For the purposes of reaching a broader audience whom we hope will engage in this discussion, it will be useful to review the most recent data on HIV in order to make an informed decision on whether to permit HIV rapid testing over the counter.

Twenty-four years after the first diagnosis, gay men are still infected the most, but it's rising fastest in African-Americans and other minorities. African-Americans are about 12 percent of the population, but about 50 percent of the AIDS cases. Hispanics are about -- 14 percent of the population, about 20 percent of the AIDS cases. It is also important to note that HIV has become more feminine, about 27 percent of cases are now women.

Data suggests that new hopes in AIDS treatments have overshadowed the fact that the virus continues to spread, and AIDS is increasingly an epidemic of teenagers and young adults in America. For perspective, every hour, two Americans under the age of 25 become infected with HIV; and every minute, 50 young Americans contract a sexually transmitted disease. We should be encouraged by the fact that people are living longer now, and when the new treatment was first introduced, we weren't sure how long it was going to last and how long it was going to be beneficial. That said, while

research has delivered exceptional HIV treatments, continued enhancements in therapies is also critical.

There are nearly 40,000 new infections each year in United States, bringing the total number of persons living with HIV to more than one million. Perhaps most troubling is the fact that an estimated quarter of these individuals don't even know they are infected, and could be passing on the virus. This is why proven prevention strategies, including regular and routine HIV screening across all public health settings, including emergency rooms, labor and delivery, and broader use of new rapid testing technologies remains critical.

With respect to the question at hand, studies clearly demonstrate that once a person is aware of their status, if positive, they are up to 70% less likely to engage in behaviors that will place themselves and others in jeopardy. We also know, from numerous studies, that choice helps people engage in prevention. More choice translates into a greater likelihood that people will find a strategy acceptable to them.

With regard to HIV testing, this means making testing available in a variety of ways and in a variety of formats. Right now, in the US, most HIV testing occurs in doctor's offices. Some occurs in anonymous or confidential testing sites, or in STD clinics or drug treatment programs. Testing also occurs in pre-natal clinics and hospitals with high prevalence of HIV. These offer many ways for people to get tested— with or without counseling, anonymous or confidentially, in an opt-in or opt-out framework, when they are needing it the most (with symptoms of an STD or needing drug treatment).

Offering over the counter testing is another excellent way to make testing available to people. Concerns have been raised that people need counseling. Most people now accessing testing do not get counseling. Concerns are also raised that people cannot handle the information. That concern has been raised from the beginning of HIV testing, and the casualties are few and far between. While the news of an HIV diagnosis is not great, it's also not the end of the world and most people know that and

can handle the information. In fact, with advances in treatment, HIV can be a chronic manageable disease. Further, we need to normalize HIV, and it is time to realize that people can handle the news of an HIV diagnosis just like they can handle the news of pregnancy and other issues like that.

Therefore, I support making the new FDA approved rapid saliva test available over the counter. It offers the possibility of expanding the reach of HIV screening in ways previously unavailable.

Thank you for fostering this dialogue and I ask that a copy of my remarks be placed in the record. Also, for the record, I receive no support from any pharmaceutical or diagnostic manufacturer. My work is totally supported by private donations, NIH funding, and foundations.