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PLACE: Press Conference to Announce the New Rapid HIV Test,  
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"Announcing the New Rapid HIV Test"

Good afternoon, everyone, and thank you so very much for coming today.

Let me welcome Dr. Murray Lumpkin, Principal Deputy Commissioner of the FDA ... Dr. Tony Fauci, Director of the National Institute on Allergy and Infectious Disease ... my long-time friend and advisor Scott Evertz ... and seated in the front row, Dr. Kathy Zoon, Director of the Center for Biologics Evaluation and Research at the FDA.

We're here to announce an important step in America's war against HIV/AIDS. It is a step that will help us accomplish the most fundamental mission of the Department of Health and Human Services: Save lives and improve health.

The FDA has approved a remarkable new rapid HIV test. The OraQuick Rapid HIV-1 Antibody Test, manufactured by OraSure Technologies, is simple, accurate and fast. It uses only one drop of blood, and in just 20 minutes it can detect HIV antibodies with 99.6 percent accuracy.

Instead of waiting up to two weeks to get HIV test results, the OraQuick test can provide test results in one visit and in less than half an hour. By virtue of its speed, simplicity, and portability countless more Americans will be able to find out their HIV status.

At the same time, more needs to be done to make this OraQuick test available to everyone who needs it. I strongly encourage OraSure to ask the FDA for a Clinical Laboratory Improvement Amendments, or CLIA, waiver so that the test can be reviewed on that basis.

If the FDA finds that the company's data proves that the OraQuick test is easy and safe to use, it can get a CLIA waiver.

Then the test could be given in many more health care settings, perhaps even administered by social workers in HIV counseling centers ... and it would make the OraQuick test more accessible to those who need to be tested.

But the process can't begin until OraSure applies for the waiver, so again I say to OraSure - please ask for the waiver.

The Centers for Disease Control and Prevention has estimated that one-fourth of the up to 950,000 HIV-infected people in the U.S. are not aware that they are infected. That means that more than 225,000 of our fellow Americans are don't know that they have this life-threatening viral infection, an infection that they may unwittingly pass on to others.

Each year, 8,000 HIV-infected people who take an HIV test do not return one or two weeks later get their test results. The OraQuick test will almost certainly reduce that number by giving a result in less than 30 minutes.

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This test will also be a great help in identifying HIV-positive women during labor who were not tested during pregnancy. It will mean that they and their newborns can quickly receive the drugs necessary to help prevent the newborns from becoming infected.

And, every day, health-care and emergency workers risk HIV infection while caring for accident victims and patients. When a needle-stick or other mishap puts them at risk, they need to know if their patient is HIV-positive. Time is of the essence in giving these workers necessary medications that may prevent an infection.

It is also important to know if treatment is not required, because anti-HIV medications may have side effects.

Extraordinary cooperation between HHS and the manufacturer helped expedite getting this OraQuick test to market. The FDA deserves high marks for the unprecedented speed and diligence with which they reviewed the OraQuick application.

And I know the FDA stands ready to work with other manufacturers to evaluate and, where appropriate, approve more rapid HIV tests that can help in the fight against the HIV epidemic.

This approval is also the product of departmental cooperation, including the FDA, CDC, and CMS. The Centers for Disease Control and Prevention is actively working with public health officials, and the Centers for Medicare & Medicaid Services is offering technical assistance and training to testing personnel and laboratories interested in providing this test.

My friends, President Bush and I are passionate about stopping the spread of HIV and AIDS. Overall HIV/AIDS spending by the U.S. government has increased from \$14.2 billion in fiscal year 2001 to well over \$16 billion for fiscal year 2003.

That includes a doubling in international HIV/AIDS funding over the same period. Let me repeat that: we have doubled international funding in just 18 months.

We have made an unprecedented commitment to prevention programs, both at home and abroad. And this Administration is devoted to finding a cure and an effective vaccine.

That's why it has allocated unprecedented resources to the National Institutes of Health, the unquestioned leader in biomedical research. The NIH budget request for fiscal year 2003 includes \$2.8 billion for HIV research - a more than \$500 million increase over 2001.

Simply put, no administration has ever made fighting HIV/AIDS as high a priority as the Bush administration. That's a point of pride with me, and I'm very pleased that today's announcement furthers this essential work. Now, I will ask my colleagues to offer their insights and then take questions from the media.