

**Comments of Susan Holleran, Coalition of Labor Union Women
to the FDA's Vaccines and Related Biological Products
Advisory Committee Meeting
May 18, 2006**

Good afternoon. My name is Susan Holleran. I am the D.C. alternate state vice president of the Coalition of Labor Union Women. CLUW is the only national organization of union women in the United States. Through the various communication channels available to us, CLUW reaches out to the 6.5 million union women across the country.

Founded in 1974, CLUW has long been committed to promoting women's health. The labor movement has always recognized the significance of preventive healthcare, and with the current healthcare financial crisis, we believe that prevention is more important than ever. In addition to our primary concern to alleviate human suffering, we know that catching illnesses early can provide huge savings in our nation's healthcare costs.

When we learned that the HPV virus causes cervical cancer – and that with the right tools used on the right women, we can eliminate this disease – CLUW made cervical cancer prevention a priority health issue.

In 2003, CLUW urged the FDA to approve the HPV/DNA test for women over 30. In 2004, CLUW was part of a Centers for Disease Control and Prevention-funded project: Working Women ROCC (Reaching Out against Cervical Cancer). This project's goal was to raise awareness of cervical cancer and its potential elimination with a primary focus on union women at highest risk – those in underserved populations.

In early 2004, CLUW created its own cervical cancer awareness program: Cervical Cancer Prevention Works, which is funded by an educational grant from Digene, the company that manufactures the HPV test. As a result of our efforts, we know that hundreds of thousands of union women have heard our message and taken action – and that even more have insurance coverage for the HPV test in addition to the Pap.

CLUW is pleased that girls and young women can help protect themselves with the new HPV vaccine. However, since the vaccine targets just two of more than a dozen types of HPV that can cause cervical cancer, protection will not be complete unless women are also screened regularly once they become sexually active.

For women who are already sexually active – and thus probably exposed to the targeted types of HPV – the data available today do not indicate any substantial benefit from the vaccine. Therefore, for the vast majority of women today, and for many in the future, regular screening is their primary weapon against this disease. CLUW believes that any communication about cervical cancer to women and to their healthcare providers needs to emphasize the importance of ongoing screening.

Today, the growing body of data is compelling in its demonstration that the most effective screening protocol is use of the Pap in women under the age of 30 and the combination of Pap and HPV test for those over 30.

CLUW joins in the excitement created by the significant potential benefit of this new vaccine. However, we call on you today to keep the big picture in mind. We ask the vaccine manufacturers and other interested parties to include education on the need for ongoing screening in all communication related to the proper use of vaccination, and to join us in educating women and healthcare providers on the most effective screening options available to them today.

Thank you.