

**Press Release
From the Office of
State Representative
Gale D. Candaras**

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**STATE'S CERVICAL CANCER COMMISSION CHAIR OPTIMISTIC AS
VACCINE AIMED AT ELIMATING THE DISEASE NEARS FDA DECISION**

BOSTON, MA—The Chair of the Massachusetts Special Commission on Cervical Cancer, Representative Gale D. Candaras (D-Wilbraham), expressed optimism today regarding news that the U.S. Food and Drug Administration (FDA) may soon approve for use a new vaccine that would add yet another weapon to the arsenal in the war against cervical cancer. Last week, the FDA's Vaccines and Related Biological Products Advisory Committee unanimously agreed that data from clinical trials support the efficacy and safety of a new vaccine developed to prevent cervical cancer.

“On average, eighty women die in Massachusetts from cervical cancer each year and approximately three thousand women nationwide lose their lives to this preventable and curable disease,” Candaras said. “An effective, FDA-approved vaccine that targets the human papillomavirus or, HPV, the virus that causes cervical cancer, could turn the possibility of eliminating this preventable disease into a probability,” she said.

Candaras sponsored legislation during a previous term that created the Commission and was appointed to serve as chair during her fourth and fifth terms in the legislature. Her interest in this issue stems from Women In Government's “Challenge to Eliminate Cervical Cancer Campaign,” which has two goals: first, to ensure that women are educated about cervical cancer, HPV and the need for prevention and second, to provide women with access to advanced and appropriate screening and preventive technologies regardless of their socioeconomic status.

“Given experts' knowledge that cervical cancer is caused by HPV and, with the availability of new preventive technologies, cervical cancer can be eliminated,” said Susan Crosby, president of Women In Government, a bi-partisan, non-profit group representing women state legislators. “If an HPV vaccine is approved by the FDA, it would provide a critical step towards achieving this goal.”

There are currently two HPV vaccines in development, and one—Merck & Co., Inc.'s “GARDASIL”—was submitted to the FDA for approval. The FDA advisory committee recommended on May 18 that the FDA approve it and an FDA decision is expected on June 8. Clinical research has shown the two vaccines to be both safe and 100 percent effective in preventing infection with the two types of HPV that account for 70 percent of all cervical cancers. The FDA is not bound by the committee's guidance,

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but takes its advice into consideration when reviewing investigational vaccines seeking approval.

“Merck is thrilled that the Advisory Committee has agreed that the extensive data from our decade-long, 27,000-patient clinical trial program support the use of GARDASIL to reduce the burden of cervical cancer and other diseases caused by HPV,” said Peter S. Kim, Ph.D., president, Merck Research Laboratories. “If approved, GARDASIL will be the first and only vaccine to prevent cervical cancer and other serious HPV-related diseases.”

Diseases caused by HPV represent a major burden in the United States. Approximately 10,000 women are diagnosed with cervical cancer each year, and an average of 10 women die each day from this cancer. HPV also causes approximately 40 to 50 percent of the more than 3,500 cases of vulvar and vaginal cancer that are diagnosed each year in the U.S.; about three women die each day from these two cancers. HPV-related diseases cost about \$5 billion per year in the United States.

Candaras said, “While more than 89 percent of Massachusetts women say they were screened for cervical cancer in the last three years, *all* women must be screened regularly and be educated about cervical cancer and the HPV virus that causes it. We must ensure that our screening programs use the most advanced and appropriate screening technologies available—such as HPV testing—which can enhance the traditional Pap test in identifying women needing early intervention. ‘Know your HPV status’ is our battle cry in Massachusetts,” she said. “Now, we can look forward to learning more about the HPV vaccine in order to advance the efforts of our Special Commission on Cervical Cancer and we are more optimistic than ever that we can eradicate this deadly disease so that no more Massachusetts women die of cervical cancer.”