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Vaccine center delivers warning Cervical cancer shots at issue

By Gregory Lopes
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The National Vaccine Information Center yesterday warned state officials to investigate the safety of a breakthrough cancer vaccine as Texas became the first state to make the vaccine mandatory for school-age girls.

Negative side effects of Gardasil, a new Merck vaccine to prevent the sexually transmitted virus that causes cervical cancer, are being reported in the District of Columbia and 20 states, including Virginia. The reactions range from loss of consciousness to seizures.

"Young girls are experiencing severe headaches, dizziness, temporary loss of vision and some girls have lost consciousness during what appear to be seizures," said Vicky Debold, health policy analyst for the National Vaccine Information Center, a nonprofit watchdog organization that was created in the early 1980s to prevent vaccine injuries.

Following federal approval of the vaccine in July 2006, a storm of legislation was introduced across the nation that would make the vaccine mandatory in schools. The District and Virginia are part of a group of at least 17 states considering such legislation. A measure had been introduced in Maryland, but it was shelved last week over concerns about the mandatory language in the bill.

Yesterday, Texas Gov. Rick Perry signed an order making

see VACCINE, page A4

FROM PAGE ONE

VACCINE

From page A1

Texas the first state to require the vaccine. Girls ages 11 and 12 would receive the human papillomavirus (HPV) vaccine before entering the sixth grade starting in September 2008.

The American Cancer Society estimates there were 9,710 new cases of cervical cancer in the United States in 2006. The District's cancer control center estimates a total of cervical cancer cases in the city last year, and the American Cancer Society estimates that last year Maryland and Virginia each had 210 cases of cervical cancer.

Merck began marketing Gardasil last year after the Food and Drug Administration approved it for females ages 9 to 26. The vaccine is the first of its kind to build immunity against two strains of HPV, which lead to 70 percent of cervical cancer cases in the United States.

The vaccine is not effective in men, who can get cancer from other strains of HPV.

Its side effects were reported to the Vaccine Adverse Event Reporting System, a federal reporting system for consumers to notify federal regulators of bad reactions to medications. The adverse

events began being reported in July 2006, when an advisory panel to the Centers for Disease Control and Prevention recommended girls ages 11 and 12 receive the series of shots.

The types of side effects reported are not cause for alarm, according to the American Cancer Society.

"We have not been informed of an instance that would call into question the overall safety of the vaccine," said Debbie Saslow, director of breast and cervical cancer control at the American Cancer Society, adding that about 70 similar events had been known in October 2006.

Likewise, the CDC will not alter its approval of the vaccine despite the number of adverse events revealed through the reporting system.

"A report to the Vaccine Adverse Event Reporting System does not necessarily mean the adverse event was serious or that it was caused by the vaccine," said CDC spokesman Curtis Allen. "This vaccine has been tested around the world and has been found to be safe and effective."

Merck is heavily promoting the vaccine through its salespeople imploring doctors to provide it and running TV ads urging young women to get vaccinated so there will be "One Less" cancer patient.

But physicians disagree with public health officials over whether Gardasil is the panacea for cancer. Clayton Young, an obstetrician/gynecologist in Texas, objects to Merck's claim that Gardasil will prevent cervical cancer.

"There is no proof Gardasil will stop cervical cancer," he said. "They haven't been studying it long enough to make that claim."

Merck spokesman Chris Loder said the vaccine is effective for five years and the Whitehouse Station, N.J., drug maker is not sure how long afterward the vaccine will work. Critics point out that an additional booster shot may be necessary.

Advocates for a mandatory vaccine say that although the vaccine does not prevent all causes of cervical cancer, Gardasil is an effective vaccine against the most prevalent cause and therefore is a correct public health measure.

Gardasil is delivered in three separate injections that cost \$120 to \$150 per injection. Blue Cross Blue Shield, an omnipresent health insurer in the Mid-Atlantic region, covers the vaccine for girls in the federally recommended age groups.

Merck revenue from Gardasil reached \$155 million for the fourth quarter of 2006 and \$255 million for the entire year.