



## Health Alert!

Issued: February 13, 2007

# The Capsule...

*A Dose of Good Health*

## HPV Vaccine Update

On February 2, 2007, Texas Governor Rick Perry issued Executive Order RP65 which made Texas the first state to require girls entering the sixth grade (beginning in September 2008) to receive the human papillomavirus vaccine (HPV). By issuing an executive order, Governor Perry bypassed the legislative process for requiring the HPV vaccine.

More than a dozen states including California have considered introducing legislation to mandate the vaccine for middle school-aged girls. The Michigan legislature let a mandatory HPV immunization bill die over questions about why the government should be involved with the delivery of the vaccine.

Under the executive order, Texas health insurers will consider covering, and probably amend their contracts to provide coverage for, the HPV vaccine for their fully-insured Texas employees. The executive order does not directly impact self-insured employers governed by ERISA. Nevertheless, those employers providing preventive benefits for Texas employees will no doubt have questions about the HPV vaccine and the provision of coverage.

For individuals not covered by health insurance, Governor Perry's order directs the Health and Human Services Commission (HHSC) and the Department of State Health Services (DSHS) to make the vaccine immediately available to eligible young females ages 9 to 18 through the Texas Vaccines for Children program and through Medicaid for women ages 19 to 21.

A Parents' Rights clause is included in the order which allows parents to opt-out of the mandatory vaccination for reasons of conscience, including religious beliefs. DSHS has the responsibility of easing the opt-out process by providing a conscientious objection affidavit form via the internet.

A Lockton publication *The Capsule Health Alert!*, originally issued on October 4, 2006, discussing the vaccine is attached for those who desire additional information.



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## Health Alert!

Issued: October 4, 2006

# The Capsule...

*A Dose of Good Health*

## HPV Vaccine

*by Lawrence H. Levy, MD, Medical Director*

Many of our clients have asked questions concerning the new human papillomavirus (HPV) vaccine. This information will hopefully help answer your questions and provide useful information for your employees.

Over the past several months, there have been numerous news stories and articles concerning the HPV vaccine. One such news story comes from Michigan. If legislation recently introduced into the Michigan Senate passes into law, Michigan would become the first state to require girls entering sixth grade to receive a vaccine that can prevent cervical cancer.

The Advisory Committee on Immunization Practices (ACIP) – who advises the U.S. Centers for Disease Control and Prevention (CDC) – agreed to recommend the human papillomavirus (HPV) for three age groups:

- \* All girls between ages 11 and 12
- \* Girls and women ages 13 to 26 who have not yet received the vaccine
- \* Women who have had abnormal PAP smears or genital warts

At a physician's discretion, girls as young as nine could receive the vaccination.

The U.S. Food and Drug Administration (FDA) has licensed Merck's **Gardasil**, presently the only HPV vaccine for use in females 9 to 26 years of age. Glaxo is in late-stage trials on their HPV vaccine, Cervirix. Gardasil helps protect against four of the 100 HPV types. These four types – Types 6, 11, 16 and 18 – cause approximately 70 percent of cervical cancers (cancer of the lower end of the uterus or womb) and 90 percent of genital warts. Clinical trials have shown that three doses, administered at intervals of two and six months after the first dose, can prevent more than 90 percent of lesions that cause genital warts and cervical cancer.

The anticipated cost for the Gardasil vaccine is \$125 per dose or \$375 for the standard series of three doses. A number of national carriers have already included this immunization series (for women and girls ages 9 to 26) in their preventive care immunization guidelines for their insured business.



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Since this is significant expense and is the first vaccine developed which prevents cervical cancer, notification is given to clients who may want to modify their preventive care maximums if they decide to cover the vaccination.

## Q & A

Question	Answer
<i>Why is the new Human Papillomavirus (HPV) vaccination, Gardasil, useful?</i>	The vaccine helps protect against diseases which include cervical cancer; abnormal and precancerous cervical, vaginal and vulvar lesions; and genital warts caused by four types of HPV. This vaccine is not a treatment, but is useful as a prevention of these diseases.
<i>Should I continue to have routine cervical cancer screenings after the vaccine?</i>	Yes. Females who receive the vaccine should continue cervical cancer screenings.
<i>Who should receive the vaccine?</i>	For preventive measures the vaccine is for females ages 9 through 26. The primary immunization time is girls between the ages of 11 and 12, but may include 9 and 10 year-old girls at their physicians' direction. Girls and women ages 13 to 26 who have not previously received the vaccine will also be immunized to provide initial protection since they missed their primary immunization time.
<i>Why is the vaccine recommended for girls so young?</i>	The vaccine works best when given before any contact with the four specific types of HPV. HPV is one of the most common sexually transmitted infections. In 2005, the CDC estimated that at least 50 percent of sexually active people catch HPV during their lifetime.
<i>Who should not receive the vaccine?</i>	Anyone allergic to the ingredients in the vaccine or who has had an allergic reaction after getting the first dose. The vaccine is not recommended for pregnant women. Your physician should determine anyone else who should not receive the vaccine.
<i>Is the vaccine safe?</i>	As with all vaccines, there may be some side effects. Generally, the reported side effects have been mild. Ask your physician for more information about the potential side effects.
<i>Why is it important to receive the vaccination?</i>	This is the first vaccination which has shown to be effective in the prevention of cervical cancer and other conditions with a high degree of effectiveness. It is estimated that approximately 20 million American men and women are infected with HPV. In most people, HPV appears to go away on its own. In the United States, approximately 10,370 new cases of cervical cancer were diagnosed in 2005, and approximately 3,710 deaths resulted from cervical cancer. Genital warts are common – 500,000 to 1,000,000 cases in the U.S. alone – and treatment options may be painful. Cervical cancer is the second most common cause of cancer in women globally and one of the major causes of cancer deaths. Around the world, about 300,000 women between the ages of 14 and 44 die from it annually.



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