HPV Vaccine Mandates: Parents Trump Politics

Governor Rick Perry stunned the nation when he signed an executive order requiring girls in Texas get the HPV vaccine before entering the sixth grade. State legislators around the country, including Texas, had introduced bills to mandate the newly-approved vaccine to prevent this sexually-transmitted disease that can lead to cervical cancer. But Gov. Perry's action came without warning and launched an unprecedented backlash, from federal legislation to penalize states that would mandate the HPV vaccine, to parents filing a lawsuit against the order. Within two months the Texas legislature overwhelmingly passed a bill overturning the order. The numerous state bills had raised eyebrows, but the governor's mandate unleashed scrutiny and skepticism over the link between politics and healthcare. And it heightened sensitivity for the right of parents to determine their child’s medical care.

The Best Prevention
HPV (humanpapilloma virus) is the most common sexually transmitted disease in the United States, with about 30 sub-types. It is primarily transmitted by skin-to-skin contact involving genital touching (including oral sex).

In most cases there are no symptoms; others can develop genital warts and pre-cancerous cells. In 70 percent of those infected the body's immune system effectively eradicates HPV within 18 months and 90 percent within two years. The younger the body, the quicker the immune system responds.

However, the virus can lead to cancer. HPV is the primary cause of cervical cancer, the 14th most frequent cancer in U.S. women.¹ In the past 40 years, since the introduction of the Pap test, deaths from cervical cancer have declined 74 percent.² Pap exams detect pre-cancerous cells caused by HPV which can be successfully treated with the survival rate at more than 90 percent.

The paramount prevention for males and females from contracting HPV is avoiding sexual contact with an infected person. This is best achieved by being abstinent outside of marriage and faithful within marriage. Many parents prefer this method and message for their children, knowing the multiple benefits of sexually responsible behavior. Abstinence and fidelity provide greater emotional security, freedom from fear of an unwed pregnancy and of ever-increasing disease risks.

But even those who make best choices can face contracting HPV through a spouse who brings the disease into a marriage, or from sexual assault. An additional option now

¹ Cancer Advances in Focus (National Cancer Insitute); http://www.cancer.gov/aboutnci/cancer-advances-in-focus/cervical

available is the HPV vaccine. As Gov. Perry found out, when it comes to minor girls many people want that decision to be left up to parents. They prefer that the vaccine be taken by choice not mandate, at an appropriate age, or prior to marriage if a fiancée brings a risk.

In 2006 the FDA and CDC approved Gardasil, Merck's HPV vaccine, as safe and effective in preventing four strains of HPV (subtypes 6, 11, 16 and 18), two that cause genital warts and two responsible for 70 percent of cervical cancers. Glaxo-Smith-Kline's version of the HPV vaccine, Cervarix, expected to be approved by the end of 2007, addresses two strains (16 and 18).

The HPV vaccine has been breathlessly touted as a cancer vaccine that will eliminate cervical cancer, and 100 percent safe and effective. While it is the first vaccine for a virus that causes cancer, it will not eliminate all cervical cancer if for no other reason than it does not address all cancer producing subtypes of HPV. Physicians currently screen for 15 “high risk” HPV subtypes.

Doubts have been raised about early assurances of its absolute effectiveness and safety, especially for young girls. The trials, with carefully selected participants, only followed women for four years. Dr. Diane Harper, director of the Gynecologic Cancer Prevention Research Group at the Norris Cotton Cancer Center at Dartmouth Medical School a lead researcher in development of the HPV vaccine, calls the mandates “a great big public health experiment.”

“It is an experiment because we do not know how long the vaccine will last; we do know that a small number of young girls will already be exposed to a cancer-causing HPV type at the time of their first HPV vaccine, a condition the vaccine will not cure; and we do not know whether these young girls will continue to pursue Pap testing at regular intervals throughout their adult life.”

"Given that we don't know how long the vaccine will last until Gardasil needs a booster, it makes no sense to mandate it," Dr. Harper said.

In trials, the shot was given alone or in combination with the Hepatitis B vaccine. Since it has been on the market, more than 40 cases of Guillain-Barre syndrome (an immune disorder that causes tingling, numbness and paralysis) have been reported in girls who

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3 Human Papillomavirus Vaccines: Question and Answers (National Cancer Institute); www.cancer.gov/cancertopics/factsheet/risk/hpv-vaccine

4 Research Adds to Vaccine Comments (KPCNews.com); http://www.kpcnews.com/articles/2007/04/14/online_features/hpv_vaccine/hpv01.txt
were given the HPV vaccine along with the meningitis vaccine.\(^5\) Other reported complications include loss of consciousness, seizures, and joint pain.\(^6\)

**Parents Know Best**

Medical decisions weigh risks versus benefits. Usually the patient or her guardian makes those decisions. Government officials can step in if a disease carries a public health risk. A student with tuberculosis will be barred from classes to protect other students. This rationale drives mandates for vaccines that prevent diseases that can be easily spread, through air or simple touch. One child can put a whole class in jeopardy. Vaccinating most people protects even those not vaccinated because there are fewer people carrying the disease.

The HPV vaccine deals with a disease that can only be caught through intimate sexual contact. Clearly, this is a realm left best to parents, who strive to teach their children to make the best choices in living healthy lifestyles and whose unease about the vaccine went beyond this sensitive issue.

Advocates point out that 3700 women die each year from cervical cancer. Yet the flu is responsible for 36,000 deaths annually, and the flu vaccine is not mandated. The decision is left up to individuals.

Medical trials only include people who fit a designated profile. The true test of any drug or vaccine comes when it’s used on a wider population. The chickenpox vaccine did not make it onto schoolchildren's immunization schedules until several years after its approval. Yet the HPV vaccine would jump straight from carefully controlled trials to the general population of girls, all unique with a variety of conditions.

Medical experts as well as parents oppose mandating the HPV vaccine, including Jon Abramson, chairman of the committee that advises the CDC on immunization practices. The Association of American Physicians and Surgeons and the American Academy of Pediatrics joined in, noting the lack of safety data on adolescent girls and decrease in the cervical cancer rates.

Many of the mandates allow for parents to opt-out. Parents in Texas pointed out that private schools follow the state vaccine mandate list but do not adopt the opt-out option. Children have been expelled from private schools and some physicians will drop patients for not receiving mandated vaccines. Opt-outs place the burden on the parent to follow complicated procedures and explain themselves to government officials who can exert pressure with questions such as "Do you want your daughter to get cancer?"

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\(^5\) Researcher Blasts HPV Marketing (KPCNews.com); [http://www.fwdailynews.com/articles/2007/05/07/online_features/hpv_vaccine/hpv04.txt](http://www.fwdailynews.com/articles/2007/05/07/online_features/hpv_vaccine/hpv04.txt)

Power Politics
When media first reported on the HPV vaccine, they relied on the usual storyline of religious groups imposing their morality on others by denying medical breakthroughs, forcing women to suffer, and besides, kids are going to have sex anyway. They didn't have a pre-set narrative to explain the widespread, immediate and unified outcry. Some investigated to figure out what prompted state officials to introduce mandates so quickly after the HPV vaccines' approval.

What they found, though, did fit an old narrative: financial ties between politicians and those who would benefit from government requirements.

The first bill mandating the HPV vaccine was introduced by Michigan State Senator Beverly Hammerstrom. She was the former chairman of Women in Government (WIG), a group comprised of female state and federal legislators. Many other bills were sponsored by WIG members. Merck gave an undisclosed amount of money to WIG and in 2006, Merck's Vaccine Division's executive director of health policy and external affairs sat on the board of WIG's Business Council.

Merck conducted an aggressive state-by-state lobbying and ad campaign. News stories noted legislators receiving campaign contributions from Merck and that Gov. Perry's former chief of staff is a lobbyist representing Merck. But this just opened the door. What was probably most persuasive was Merck's message: This vaccine prevents cervical cancer and mandates are necessary to ensure it will be covered by government and private insurance.

Gardasil is the most expensive vaccine in history at $360 for a series of three shots. The costs of doctor visits can bring the total to over $900.

Merck assured pro-family groups and doctors that it would market the vaccine through comprehensive efforts to educate stakeholders (physicians, parents, schools) with written materials and ads stressing the primary prevention - sexual responsibility - and respecting parental consent.

Its lobbying campaign for mandates undercut this effort. If the vaccine is mandated, stakeholders have reduced motivation to be educated on HPV. Many people will do what is necessary to get their daughter into school rather than learning that HPV is 100 percent preventable through abstinence and fidelity, that the vaccine cannot prevent all strains of HPV or all cervical cancer, that the immunity is only known to be effective up to four years, that a booster may be needed even before the patient is sexually active, and that the safety for all population groups is yet to be determined.

Mandates are as much about requiring insurance programs to pay for it as they are about vaccinating the most people. According to Wall Street analysts, mandates would boost sales from $1 billion to $4 billion per year. Pap tests, on the other hand, cost about $60 each. African American, Hispanic and Native American women have higher death rates
from cervical cancer than White women probably because they cannot afford Pap tests.\(^7\) Some note that healthcare dollars from insurance programs could be better spent on Pap exams than immunizing large swatches of the population who are not at risk.

Jon Abramson advised Merck not to lobby legislators. "Politics are not a good driver of health-care recommendations," he told the Washington Post.\(^8\)

Texas legislators agreed. They struck down the governor’s mandate. The rallying cry: Parents, not politicians, should make their child's medical decisions.

\(^7\) Cervical Cancer Fact Sheet; Cancer Research and Prevention Foundation; [http://www.preventcancer.org/healthyliving/cancerinfo/cervical.cfm.htm](http://www.preventcancer.org/healthyliving/cancerinfo/cervical.cfm.htm)

\(^8\) Parents Question HPV Vaccine (Washington Post); [http://www.washingtonpost.com/wp-dyn/content/article/2007/03/03/AR2007030301356.html?referrer=emailarticle](http://www.washingtonpost.com/wp-dyn/content/article/2007/03/03/AR2007030301356.html?referrer=emailarticle)