

TOP STORY IIII

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Quick cancer mandate raises health concerns

By Daniel C. Vock, Stateline.org Staff Writer

(Updated 12:30 p.m. EST, Monday, April 9)
None of the dozen or so inoculations widely required for children — from polio to chickenpox — has stirred as large an outcry as has the new cervical cancer vaccine, Gardasil.

Most of the turmoil is over questions involving teen sex and lobbying. Should parents or the state choose whether to vaccinate adolescent girls against a sexually transmitted disease? Did [Merck & Co.](#) overstep in pushing states to mandate the vaccine it produces?

But among a number of vaccine experts, there's a different concern. Many worry there's too big a rush to require girls to be inoculated against human papillomaviruses, or HPV, the culprit in cervical cancer, which kills 3,700 American women a year. Among their concerns: the chance of adverse side effects, difficulties in getting pre-teens inoculated, a question of supply shortages, the vaccine's high cost and damage to the public's views toward vaccines.

“For many of us in public health who have been involved in immunization and state laws, it's been too quick,” said Dr. Neal Halsey, the director of the Institute for Vaccine Safety at the Johns Hopkins Bloomberg School of Public Health.

“You want the demand to come from the public who realize the potential benefits from the vaccine, not to be imposed upon them,” he said.

Just seven months after the [U.S. Food and Drug Administration](#) approved the cervical cancer vaccine, Texas Gov. Rick Perry (R) in February decreed that sixth-grade girls must get the three-shot regimen — though his edict was ruled unenforceable by the attorney general and now might be overturned by the Legislature.

Meanwhile, the Virginia Legislature approved Gov. Tim Kaine's (D) revisions to an HPV mandate proposal it passed earlier this spring. The revisions require parents to receive

| Common HPV vaccine questions | |
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| What is HPV's link to cervical cancer? | With the Food and Drug Administration's approval of Gardasil, both the vaccine and HPV, the disease it protects against, have become issues in the debate over whether to mandate vaccinations. Click on any of the common questions to the left to learn more about HPV and Gardasil. |
| How does the vaccine work? | |
| How effective is Gardasil? | |
| Does HPV infect men? | |
| Can boys and men get Gardasil? | |
| Why is Gardasil so expensive? | |
| Is Gardasil the only HPV vaccine? | |

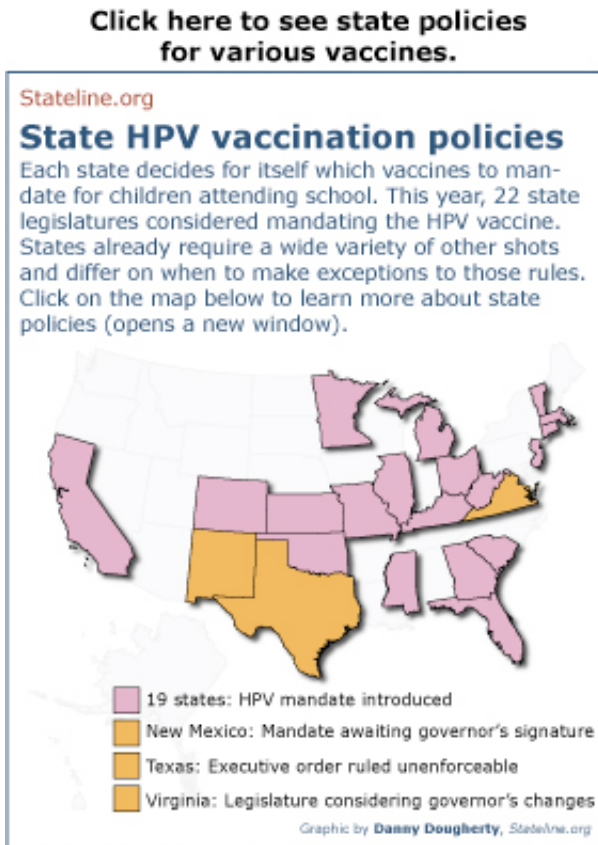
Sources: The American Cancer Society, the Centers for Disease Control and Prevention, the National Network for Immunization Information and Stateline.org reporting

Graphic by **Danny Dougherty**, Stateline.org

information about the vaccine and cervical cancer, but parents can choose not to have their kids inoculated for any reason.

New Mexico Gov. Bill Richardson (D) on April 6 vetoed an HPV vaccine mandate passed by his Legislature. “While everyone recognizes the benefits of this vaccine, there is insufficient time to educate parents, schools and health care providers. ... This vaccine will still be available to every young woman in New Mexico and covered by their health insurance,” Richardson said in a statement.

Legislators in [19 other states](#) also have considered similar mandates.



A look at the history of vaccines in the United States sheds light on why there's unease over the quick march toward requiring the new vaccine.

No other vaccine has been pushed so quickly to be mandatory. No other vaccine has been required for just one sex. No commonly administered vaccine is more expensive. And none has been so aggressively marketed, lobbied for and promoted by its manufacturer as Gardasil was by Merck.

The track record of other vaccines also deflates certain arguments raised against Gardasil.

Because HPV is spread exclusively through sexual contact, the debate over the vaccine often shifts to frank talk about teen sex. Yet Gardasil isn't the first widely required vaccine that fights a sexually transmitted disease. Forty-eight states require schoolchildren to get shots against hepatitis B, a disease that attacks the liver and also causes cancer. That disease can be transmitted by sexual contact, dirty needles or

blood transfusions.

Some question whether Gardasil was thoroughly tested before it won federal approval. In fact, Gardasil's trials were typical in size and duration for vaccines.

A historical standout

Perhaps the most important way Gardasil stands out from the dozen or so other vaccinations routinely required for U.S. children is in effectiveness.

Dr. Walter A. Orenstein, a 26-year veteran of the [Centers for Disease Control and Prevention](#)

who's now at Emory University, said Gardasil had "the highest efficacy I've ever seen with any vaccine."

There are more than 120 types of HPV, including a dozen that cause cervical cancer. Gardasil proved 100 percent effective against its target of two strains blamed for 70 percent of cervical cancers, plus another two that cause 90 percent of genital warts. By comparison, the chickenpox vaccine is effective in preventing outbreaks in 85 percent to 90 percent of patients, and the series of hepatitis B shots is 95 percent effective, according to the [National Network of Immunization Information](#).

Compared to other vaccines, Gardasil has moved at breakneck speed from FDA approval in July to a potential state-required inoculation.

It took three years for the first state to require the chickenpox vaccine for schoolchildren after the FDA approved it in 1995. For Hepatitis B, it was eight years between FDA approval in 1986 and the first state mandates for schoolchildren. First, only some groups were told to get it, then, five years later, everyone.

The [Association of Immunization Managers](#) (AIM), a group of state and local officials who handle immunization policy, promotes a take-it-slow [policy](#) toward vaccine mandates that is often cited by public-health officials as a model approach.

One benefit of a slow roll-out is that it helps scientists discover adverse side effects, said Halsey of Johns Hopkins. Gardasil is still so new there's been no time to see whether any problems not discovered during test trials might crop up as more patients get the injections.

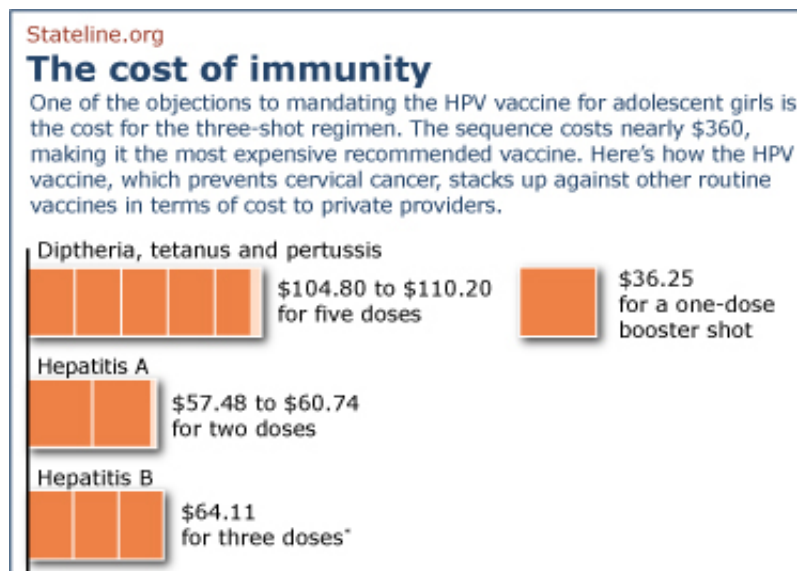
Although rare, problems have surfaced with FDA-approved vaccines. A manufacturer withdrew its year-old [rotavirus](#) vaccine in 1999, after a million children received it, because it led to higher risk of a bowel disease. (The FDA approved a new rotavirus vaccine last year.)

Practical questions

Another problem raised by public-health officials is that Gardasil requires three shots within six months for an adolescent population that seldom sees a doctor unless getting sports physicals.

For example, only about half of adolescents get a booster shot for tetanus and diphtheria, despite long-standing recommendations to do so, according to Halsey.

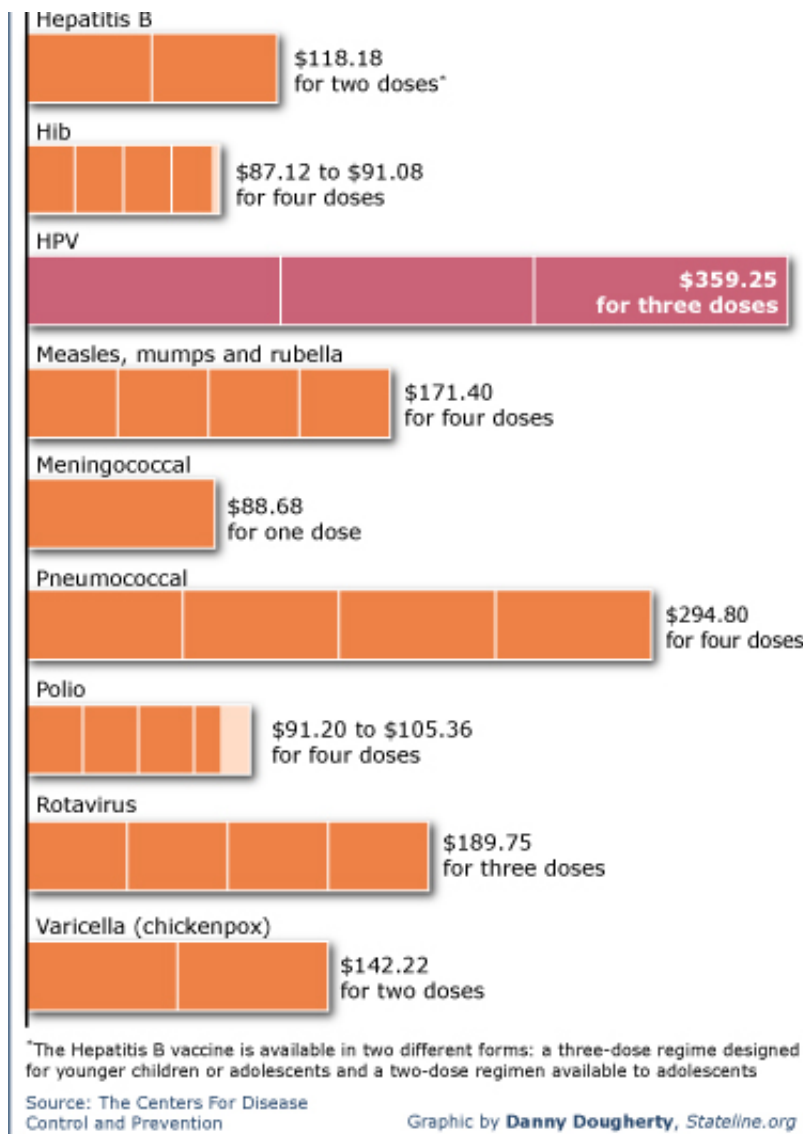
Maryland learned that lesson in



mid-January, when it barred 12,000 children from school because they couldn't prove they were vaccinated against chickenpox and hepatitis B. Nearly a month later, outreach teams went door-to-door in Baltimore to find more than 1,800 students who still hadn't returned to school.

Claire Hannan, executive director of AIM, said lawmakers should check first whether there would be enough supply of the vaccine if several states jumped to require it, especially considering recent [shortages](#) of meningitis and pneumococcal vaccines.

For states, Gardasil's high cost also is a consideration. On the private market, Gardasil costs nearly \$360 for the three-shot regimen. States could end up footing the bill for inoculating kids with inadequate insurance, because federal funds for those state programs are stagnant, Hannan said.



Some also worry that a hastily imposed mandate could have long-lasting repercussions on public-health policy.

Lawrence Gostin, a public-health expert at Georgetown University Law Center, said the uproar over the cervical cancer vaccine could turn the public against mandatory vaccinations in general, noting that public suspicions about mandates date back [more than a century](#).

“What we find is that when concerns get heightened, people opt out of vaccinations and disease rates go up. So it's counterproductive to make it mandatory — both for HPV and also more generally,” he said.

A concern for Hannan is the special opt-out provision adopted by the Virginia General Assembly. For other vaccines, Virginia parents must have religious grounds for refusing to inoculate their children. The [new law](#) grants a broader-than-normal opt-out for HPV, after lawmakers adopted Gov. Tim Kaine's (D) [suggestion](#) to let parents refuse the vaccine for any reason, without written permission, after reading informational materials.

Hannan said different exemption policies could confuse parents and set a bad precedent that could lead to looser opt-out clauses later for other vaccines.

From a public-health perspective, a girls-only mandate is troublesome, too.

Limiting the vaccine to one sex undercuts one of the strongest arguments for vaccine mandates: herd immunity, said Gostin, the Georgetown University law professor, who opposes immediate mandates. With herd immunity, even people who don't get vaccinated are protected, because the disease peters out when it has so few hosts to infect.

HPV also infects [boys and young men](#) and can cause genital warts, penile cancer and anal cancer. So a girls-only mandate means the cancer-causing HPV strains could still infect at least half the population. Merck is still researching Gardasil's effectiveness in males and expects studies to wrap up next year.

Orenstein, a former director of the National Immunization Program, notes that rubella vaccine is universally required for both boys and girls, even though the main reason for the mandate is to prevent infections in pregnant women. The disease, sometimes called the German measles, can cause miscarriages and severe birth defects.

Roots of the controversy

So far, though, the public-health debate over whether to mandate the HPV vaccine largely has been overshadowed by arguments in state capitols over teen sex and Merck's aggressive lobbying.

"People have come to the fore and said, if you mandate this vaccine, you're giving a green light to my daughter's inappropriate sexual behavior," said Alexandra Stewart, a mandate proponent and an immunization policy expert at George Washington University.

Stewart contends that mindset doesn't acknowledge the sexual activity of most teenage girls or address the possibility a girl's eventual husband could have HPV.

Focus on the Family, a socially conservative group, in a recent [statement](#) said requiring the HPV vaccine "intrudes into private family and personal sexual health decision-making." It supports making the vaccine widely available but not mandatory.

Criticism of Merck's lobbying led the drug-maker on Feb. 21 to pull the plug on its efforts to push for state mandates of its HPV vaccine.

Merck's tactics particularly came under fire in Texas, where the governor's executive order to mandate the vaccine led to questions about the role of the governor's former chief of staff, now a Merck lobbyist. The company also launched a highly visible campaign for the vaccine, with [TV ads](#) and donations to [Women in Government](#), a bipartisan group of female public officials whose members actively fought for vaccine mandates.

“It felt like we were becoming a distraction. Because of that we decided we needed to re-evaluate our position and decided we would not lobby on behalf of middle-school requirements,” said Jennifer Allen, a company spokeswoman. She noted that Merck is still lobbying for funding to pay for the vaccine to cover poor children and providing information about Gardasil.

The company, whose reputation took a hit following the 2004 recall of the painkiller Vioxx, does have a financial interest in selling Gardasil quickly: A competing vaccine, Cervarix, made by GlaxoSmithKline, could be on the market within a year.

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