

Moves to Vaccinate Girls For Cervical Cancer Draw Fire

As Merck Lobbies States To Require Shots, Some Fret Over Side Effects, Morals

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By JOHN CARREYROU

Bills being drafted in some 20 U.S. states that would make a cervical-cancer vaccine mandatory for preteen girls are sparking a backlash among parents and consumer advocates. The bills coincide with an aggressive lobbying campaign by Merck & Co., the maker of the only such vaccine on the market. Called Gardasil, the three-shot regimen provides protection against the human papillomavirus, a sexually transmitted virus that is responsible for the majority of cases of cervical cancer. If the state bills become law, they would guarantee the Whitehouse Station, N.J., drug maker billions of dollars in annual revenue from the vaccine. Proposed legislation varies from state to state, but the bills generally would require girls to show proof that they have received the inoculation in order to enter school. A number of immunizations — including those for measles, chicken pox and polio — are mandatory for U.S. schoolchildren because they block highly contagious diseases that can be spread easily in a group setting. But HPV is different because it is transmitted sexually. At \$360 for the three shots, Gardasil is also costlier than many vaccines (a measles-mumps-rubella shot costs about \$42.85 per dose, for instance), though it is generally covered by insurance. Conservative Christian groups have long voiced opposition to the vaccine, saying it would conflict with their message of abstinence because it would, in effect, condone premarital sex. However, concern has spread beyond the religious right as momentum has grown for making inoculation mandatory. A growing number of parents are worried about exposing their children to the unforeseen side effects of a new vaccine to protect them from a disease that is no longer very common in the U.S. and often doesn't develop until much later in life. Tina Walker, the mother of an 11-year-old girl in Flower Mound, Texas, says she would prefer to wait until the vaccine has been on the market for several years before subjecting her child to it. "We are the guinea pigs here," she says. Last week, Texas Gov. Rick Perry issued an executive order mandating that the vaccine be administered to all girls entering the 6th grade in the state as of September 2008. The Texas executive order, which includes an opt-out clause for religious or other "reasons of conscience," enabled the governor to bypass what would have likely been a heated debate in the Texas Legislature. Many of the state bills contain opt-out clauses, but a few don't. The bill pending in Florida would bar students ages 11 or 12 from being admitted to public or private school in the state unless they can provide proof that they have been vaccinated or that their parents opted them out after

receiving information about cervical cancer and the vaccine. Merck says cervical cancer is the second-leading cancer among women around the world, but the disease's prevalence is actually low in the U.S. The American Cancer Society estimates that 11,150 women will be diagnosed with cervical cancer and 3,670 will die from it in the U.S. this year. That's equivalent to 0.77% of cancers diagnosed in the U.S. and 0.65% of U.S. cancer deaths each year. By comparison, the society estimates that 178,480 American women will get diagnosed with breast cancer in 2007 and 40,460 will die from it. Adding to some parents' concern, 82 adverse events among both teens and adult women have been reported since Gardasil became available last June. Many involve common immune-system responses to vaccines, such as nausea, fever or rashes. But a number of patients suffered syncopes, or fainting spells. Richard Haupt, Merck's executive director of medical affairs, says the syncopes are caused by patients' anxiety at having a needle stuck in their arm and not due to any neuro-immune reaction to the vaccine. Mr. Haupt adds that the number of adverse events is small compared with the hundreds of thousands of doses of the vaccine administered so far in the U.S. However, with any newly approved drug or vaccine, side effects often don't become apparent until a regimen has been on the market for a while, leading some patient and consumer advocates to urge states to hold off on requiring vaccination until Gardasil's safety is more clearly established. Of the more than 25,000 patients who participated in clinical trials of Gardasil, only 1,184 were preteen girls. "That's a thin base of testing upon which to make a vaccine mandatory," says Barbara Loe Fisher, co-founder of the National Vaccine Information Center, an advocacy group that lobbies for safer vaccines. Gardasil is approved for females ages 9 to 26, and the three-dose regimen is the same for all age groups. The vaccine protects against four strains of HPV that cause 70% of cervical cancer cases. So it would not eliminate the need for vaccinated women to have regular Pap smears to detect cancerous cells caused by other HPV strains. HPV is also the virus that causes genital warts. Merck acknowledges that it doesn't know yet whether an initial vaccination will offer lifetime protection or whether patients will need booster shots. So far, the company has shown only that the vaccine lasts five years. Merck started lobbying state legislatures to pass laws requiring vaccination last year after the Centers for Disease Control and Prevention's Committee on Immunization Practices recommended that all girls get the vaccine when they turn 11 or 12. Another HPV vaccine, called Cervarix, is in development from GlaxoSmithKline PLC, but so far Gardasil is the only regimen on the market. As part of its lobbying campaign, Merck has been funding Women in Government, a Washington, D.C.- based advocacy group made up of female state lawmakers. An executive from Merck's vaccine division, Deborah Alfano, sat on Women in Government's business council last year, and many of the bills across the country have been introduced by members of the group. Merck declined to say how much money it has funneled into its lobbying campaign, or contributed to Women in Government. A spokeswoman for Women in Government, Tracy Morris, declined to say how much it had received from Merck. In Texas, one of Merck's lobbyists is Gov. Perry's former chief of staff,

and Merck's political action committee contributed \$6,000 to the governor's re-election campaign. "Parents should be concerned that the only company that makes this vaccine is pushing behind the scenes for mandatory laws," says Maryann Napoli, associate director for the Center for Medical Consumers, a consumer group based in New York. At a Merrill Lynch conference yesterday, Margaret McGlynn, the president of Merck's vaccine division, acknowledged the company's aggressive lobbying campaign but said, "States decide what works for them." She added that she had her own daughter vaccinated with Gardasil and "immunizing females against cervical cancer is absolutely the right thing to do." Mandatory vaccination across the U.S. would make Gardasil an automatic blockbuster for Merck at a time when the patents on some of its bestselling drugs are expiring and it's desperate to replace their revenue streams. Gardasil's sales in 2006 were \$235 million. Cervical cancer is a much bigger problem in the developing world, which accounts for more than 80% of cases of the disease. Merck says it's committed to bringing the vaccine to developing countries, but for now its availability is limited there to a few studies and demonstration programs.

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POINTS OF CONTENTIONConcerns over mandating shots: • Some parents say a vaccine for HPV, the sexually transmitted disease that can cause cervical cancer, effectively condones premarital sex. • Long-term efficacy and risk of side effects are unclear. There have been 82 reports of adverse events associated with the vaccine. • Gardasil is typically covered by insurance, but is costlier than many other common vaccines.

National Vaccine Information Center

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