



The Washington Post

A Vaccine Debate Once Focused on Sex Shifts as Boys Join the Target Market

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Thursday, March 26, 2009

When a vaccine designed to protect girls against a sexually transmitted virus arrived three years ago, the debate centered on one question: Would the shots make young girls more likely to have sex?

Now the vaccine's maker is trying to get approval to sell the vaccine for boys, and the debate is focusing on something else entirely: Is it worth the money, and is it safe and effective enough?

"We are still more worried about the promiscuity of girls than the promiscuity of boys," said Susan M. Reverby, a professor of women's studies and medical history at Wellesley College. "There's still that double standard."

The shift in the discussion about Gardasil illustrates the complex interplay of political, economic, scientific, regulatory and social factors that increasingly influence decisions about new types of medical care. For the vaccine, the new dynamic reflects a strategic tack by Gardasil's critics, growing concern about health-care costs, fears about whether medical treatments are being vetted adequately and stubborn biases about gender, experts say.

"There is the cost, the safety, the boys versus girls," said Susan F. Wood, a professor of public health at George Washington University. "These are some of the complexities that are going to have to be addressed one way or the other with this vaccine."

Gardasil protects against the human papillomavirus, the most common sexually transmitted infection. HPV causes genital warts and, in women, can lead to cervical cancer -- a disease that strikes about 10,000 American women a year and kills about 3,700.

For males, the vaccine is aimed at protecting against genital warts and less common malignancies that HPV can cause, such as penile and anal cancer, as well as cancer of the mouth and throat. The virus causes at least 250,000 new cases of genital warts and an estimated 7,500 cancers in males each year, causing perhaps about 1,000 deaths. Vaccinating boys and men would also help prevent the spread of the virus to their sexual partners.

"By vaccinating men as well as women, you reduce the amount of virus that is out there that can be transmitted back and forth," said Richard M. Haupt, who leads the HPV vaccine program at Merck & Co., which makes Gardasil. "Hopefully there will be a benefit not only to men themselves, but to their partners and future partners."

After the Food and Drug Administration approved the vaccine in 2006 for girls as young as 9, medical authorities recommended that they receive it at age 11 or 12 to protect them before they start having sex. Critics worried that vaccinating children would send a subtle signal that their parents assumed they would become sexually active and that it would give youngsters a false sense of security.

Merck also began an ambitious marketing campaign and lobbying push to persuade states to add the vaccine to the list of those required for children to attend school. But the company eventually abandoned the strategy in the face of an intense backlash from critics who argued that the decision should be left to parents. Although many states considered such mandates, so far only Virginia and the District have imposed one, and Haupt said the company has no plans to pursue that strategy again.

But in December, Merck asked the FDA to approve the vaccine for males ages 9 to 26, and in February it presented the results of a large study that tested the vaccine in men to the federal Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, in the hopes of winning the panel's endorsement. The committee's recommendations influence which vaccines schools require and whether private insurance companies and state programs will pay.

"There would be a tremendous public health benefit to vaccine 11- and 12-year-olds, both boys and girls," Haupt said.

The Merck study, involving more than 4,000 boys and men ages 16 to 23, showed that the vaccine is about 90 percent effective in preventing infection with four HPV types, as well as genital warts and precancerous lesions, Haupt said.

In preparation for a vote as soon as October, the CDC committee will meet again in June to consider cost-benefit analyses underway at the CDC and elsewhere. The relatively pricey vaccine costs about \$500 for three shots and the associated office visits.

"The cost-effectiveness data will be looked at very carefully," said Lauri Markowitz, who leads the HPV vaccine work group for the CDC. "There is increased interest in taking cost-effectiveness into consideration when considering prevention efforts."

The American Academy of Pediatrics will also consider cost-effectiveness in deciding whether to endorse Gardasil for boys.

Some question that focus.

"The cost-effectiveness studies are really important, but I don't think they should be the sole driver of public health policy," said Gregory D. Zimet, a professor of pediatrics and psychology at Indiana University. "This is a vaccine that principally benefits women's health. I wonder if it was the reverse, and there was a vaccine for women that helped prevent prostate cancer in men, this would be as much of an issue."

Groups that initially were critical when Gardasil was introduced for girls say they now want to make

sure the decision is left up to parents.

"We do not oppose the development or distribution of the vaccine," said Peter S. Sprigg of the Family Research Council. "The only concern we have is about proposals to make vaccination mandatory for school attendance. It's a parental rights issue."

Little research has been done on parents' attitudes about vaccinating their sons, but several experts said it would probably be a harder sell.

"For girls, you can go right to protection against cervical cancer. That's a powerful argument," said Zimet, who is studying the issue as part of his own research and in studies sponsored by Merck. "For boys, you have to make several arguments. Part of it is an altruistic argument. I think it's persuasive, but it's more complex."

Debbie Stein of Bethesda, whose 15-year-old daughter, Sara, was vaccinated, thinks she would agree to have her 11-year-old son, Ben, get the shots if his pediatrician recommended them.

"My feeling is it's a serious virus that causes cancer, and there's no reason not to vaccinate him," Stein said. "I think it will protect him and protect his wife in the future. I don't want to see him when he's 35 or 40 have a wife die of cancer."

But Agustin Zamora, who lives in the District, worries that Gardasil has not been studied enough to know that it is safe and effective for his 9-year-old son, Marco, and his twin 2-year-olds, Antonio and Joaquin.

"It's sort of like doing an experiment on people," Zamora said. "This is something you're giving to a lot of children. You need many years of study."

Federal health officials, Merck and others say they are confident that the vaccine is safe. But some experts said they are concerned that there is insufficient evidence about how long Gardasil's protection will last, whether serious side effects will emerge and whether the relatively modest benefits for boys are worth even the small risks associated with any vaccine.

"There are lots of things about this vaccine we do not know yet," said Karen K. Smith-McCune of the University of California at San Francisco. "I just want to be the voice in the room saying, 'What's the rush to vaccinate in the absence of the best available data?'"

Some also question whether the reduction in infections will mean fewer cancers in the future.

"There's probably enough data to say it probably is effective for the prevention of genital warts. They're not fun, but they're not at the same level as cancer or lethal infectious diseases," said Diane M. Harper, a professor of medicine at the University of Missouri at Kansas City who helped study the vaccine in women for Merck. "This may not be the best use of our resources at this time."

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