

## Who's Afraid of Gardasil?

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The HPV vaccine story has gotten all tangled up.

As recently as June 8, 2006, public health advocates, progressives and many parents were celebrating a huge victory: The Food and Drug Administration had approved Merck's new vaccine Gardasil, a shot series that would help protect girls from cervical cancer and genital warts. To their continuing delight, the Centers for Disease Control's immunization committee recommended less than a month later that the shots immediately be given to all females between the ages of 9 and 26. The committee acted on persuasive data indicating that the vaccine, which prevents the sexually transmitted human papillomavirus (HPV), works best before girls are sexually active.

Human papillomavirus is the most common sexually transmitted infection in the world, and most women have had it-- 80 percent of US women, by the CDC's estimates. Often it goes away on its own, without its carrier's awareness. But each year hundreds of thousands of women and girls in the United States develop persistent infections from it, more than 10,000 get cervical cancer and 3,700 die from the cancer.

Gardasil, given in a series of three shots, protects against four strains of HPV. Two of those strains cause 70 percent of the nation's cervical cancer cases, and two of them cause 90 percent of genital warts. This new vaccine, widely given, has the potential to make cervical cancer almost obsolete here.

All good news, right?

Apparently not.

Today, as thirty-one state legislatures consider mandating the vaccine for middle school girls, skepticism about the wisdom of embarking on this swift and widespread inoculation program has bubbled up from critics who span the political spectrum. These strange bedfellows include Christian conservatives and their abstinence-only ilk, who have long argued that safe sex encourages profligate sex; a slew of Big Pharma critics, who see how Merck (which stands to make \$4 billion a year on the vaccine by most estimates) is angling to corner this huge new vaccine market; the growing antivaccine movement, which objects to all such school-entry requirements; the parental-rights folks with a libertarian strain, who bridle at any mandates regarding their children's health; and a smattering of women's health advocates, who worry that the pace of the vaccine's introduction is jeopardizing its ultimate success.

What's all the noise about?

Some of it is predictable and comes from the usual quarters. Cultural conservatives and abstinence-only hardliners have been trotting out familiar arguments: Safe sex leads to more sex, they insist. Conservative California State Senator George Runner told the *Los Angeles Times* recently that he objected to this immunization because the disease was a result of lifestyle decisions, as opposed to contagion. He wondered: "Is there a more productive way for us to spend the money that may help someone who's in a health situation that has nothing to do with their personal choices? Where do you want to focus your resources?" Conveniently avoiding any logical extension of his argument to lifestyle decisions like, say, smoking, Runner and his allies insist Americans have to distinguish between the deserving and the undeserving ill.

The face of the undeserving ill, according to the moral conservatives, belongs to Illinois State Senator Debbie Halvorson, who, as co-sponsor of a bill to require the vaccine in her state, admitted that she herself had HPV and underwent a hysterectomy because of precancerous cells. Pro-abstinence bloggers and columnists see this as permission to grill her regarding her sexual history: "You would think she'd focus on her behavior that caused her to contract that sexually transmitted disease," Jill Stanek wrote in the online *Illinois Review*. "Halvorson could discuss the number of sex partners she has had in her lifetime and how each one increased the likelihood of contracting HPV...whether it was her husband who passed HPV on to her after sleeping with other women...[or] if Halvorson contracted HPV through rape, she could discuss ways to avoid rape."

Enter, stage left, anticorporate muckrakers and consumer rights activists. These players fret about the role Merck has played in peddling this drug and are wisely skeptical of a pharmaceutical industry with a track record for putting profits before safety.

A couple of things set off alarm bells. First, what was the pro-abstinence Republican Governor of Texas, Rick Perry, doing fast-tracking this vaccine by issuing an executive order that would make the shots compulsory for all sixth grade girls? This made everyone sit up and say, hmmm. (His conservative constituents expressed their befuddlement by screaming bloody murder. Perry did his best to mollify them in a linguistic high-wire act that laced the language of abortion foes with reproductive rights rhetoric: "While I understand the concerns expressed by some, I stand firmly on the side of protecting life. The HPV vaccine does not promote sex, it protects women's health.")

But that was only the beginning of Perry's problems--and by extension the problems many state politicians were having as they tried to get the vaccine mandated. The press discovered Perry's ties to Merck: Not only did his former chief of staff now work as a lobbyist for Merck but the Governor had accepted \$6,000 in campaign contributions from Merck's political action committee. It didn't look good.

And it got worse.

A nonprofit called Women in Government, comprising female state legislators, has been behind

the push to make the vaccine compulsory, educating members about its value and urging them to introduce bills in their respective states requiring the shots--even going so far as to offer sample wording for the legislation on its website. It turns out Merck--whoops!--was a big WIG donor.

Fueling everybody's mistrust was Merck's own image problems. As maker of the arthritis drug Vioxx, which may have been responsible for 28,000 deaths before it was withdrawn from the market in September 2004, Merck was, well, suspect. Especially since it stands to make a bundle by charging \$360 for each shot series. And it has a motive to corner the market quickly: GlaxoSmithKline is hot on its heels with an HPV vaccine of its own that it hopes to introduce before the end of the year. What's more, if it's lucky Merck stands to double its money. When seeking approval for the vaccine, the company also submitted data on clinical trials for Gardasil and boys. Though the vaccine thus far appears safe for young men, it may be more complicated to prove it effective--and to sell to parents. (After all, the cancer-preventing imperative is more circuitous: Boys aren't the ones being protected from cancer; their future partners are.)

In an effort to defuse the controversy, Merck backed off a bit in late February, issuing a statement saying, "We are pleased that Gardasil has been so widely embraced and do not want any misperception about Merck's role to distract from the ultimate goal of fighting cervical cancer, so Merck has re-evaluated its approach at the state level and we will not lobby for school requirements for Gardasil."

Enter the antivaccine groups, which had been waiting in the wings for the big break that finally arrived with Merck's public whipping. These groups, an eclectic mix of alternative medicine proponents, conspiracy theorists and libertarians, form a growing contingent of parents who are refusing to vaccinate their children against any diseases. They have assailed the HPV shots and, because their network of skeptics was already in place, were able to serve up outspoken critics on the spot to eager reporters. "Our concern is that this vaccine has not been studied long enough, or in enough children, to start mandating its use," said Barbara Loe Fisher, who heads the National Vaccine Information Center, a self-described organization of "parents of vaccine-injured children." This group, which according to its website pretty much opposes every vaccine mandate for every reason it can muster, strongly objects to this one being a requirement of school entry for sixth graders. "This is particularly egregious because HPV is not a disease communicated in a school setting like other diseases with mandatory vaccines," Fisher says, insisting (nonsensically) that this negates the government's "compelling interest" in curtailing HPV.

Those who work in public health were not blindsided by these critiques from the antivaccine organizations--and in fact have been worriedly monitoring the swelling ranks of vaccine opponents for several years now. "Vaccines have raised concerns for similar reasons throughout history," says Greg Zimet, a professor of pediatrics and clinical psychology at Indiana University School of Medicine who served on the Society of Adolescent Medicine's HPV committee. (The society strongly endorses the vaccine and is confident of its efficacy and safety but has not yet formally weighed in on the mandating issue.) When you consider that only a century ago infant mortality in the United States was 20 percent and another 20 percent of kids died before the age of 5, according to a 2005 article in the journal *Health Affairs*, the critical role that compulsory

vaccination plays is clear; the infant mortality rate today is less than 1 percent. "But vaccines are their own worst enemy," Zimet says. "When they work, they reduce the element of risk to almost negligible. Who knows anyone who has ever had diphtheria or polio today? Take the deadly diseases so far out of the equation, and these parents will focus on what the vaccine's side effects may be."

Pointing out that as many as 3 percent of US children are no longer being vaccinated against any disease because their parents object (a number that jumps as high as 20 percent in some school communities), Zimet says public health officials and pediatricians worry that the positive effects of what they call "herd immunity" are already being compromised. Because there is a class of people for whom inoculation poses a health risk--those with AIDS or a host of other illnesses, for example--requiring that everyone else be vaccinated can help protect these populations as well. That's how the government justifies mandating immunization.

But, like many of the rifts that divide our civic conversations into opposing camps, the vaccine debate pits individual rights against group rights--and some parents are hopping mad. It's here that Fisher's antivaccine group marches in lockstep with antigovernment libertarians. Both insist that making the HPV vaccine compulsory violates their parental rights. "We are not against vaccine availability, just vaccine mandates," says Fisher. While she concedes that every state but two has some kind of opt-out clause for parents who object to the vaccine for health, religious, moral or ethical reasons, she says parents who refuse immunization are harassed. "Your name goes on a state list. You get harassing calls from the CDC for your views on vaccines. Some families get thrown off health insurance plans, thrown out of their pediatricians' offices, thrown out of public schools--or parents are put in a room and grilled by officials about the depth of their religious convictions on this."

Finally, the backdrop to all these conversations is one unfurled by women's health advocates, who insist that we set the current action in a historical context. Walking around with the DES-Thalidomide-Dalkon Shield pharmaceutical disasters in the back of their minds, some worry that Merck's profit-driven rush to mandate this drug may prove problematic. "There's merit to questioning industry's motives in this case," says Heather Boonstra, public policy analyst at the Alan Guttmacher Institute, a nonprofit organization focused on sexual health research and analysis. "Because Merck itself has pushed so hard to make the vaccine mandatory, there's a bit of skepticism about industry's motives."

Even those who would be expected to be chomping at the bit to promote this vaccine are holding back. "We haven't taken an official position on mandating the vaccine," says Amy Allina, program director for the National Women's Health Network. Though she acknowledges that "the data look excellent so far," she wavers, arguing with herself even as she speaks: "If you mandate the vaccine, this is how you get access for those with barriers to care--and if it's not mandated it's going to be much harder for many girls to get the vaccine. On the other hand, it's early to require this for such a huge population."

Almost all the major health organizations (American Academy of Pediatrics, the Society for Adolescent Medicine, the American College of Obstetricians and Gynecologists, the Institute for

Vaccine Safety, the CDC, etc.), whatever they think about the aggressive push to require the vaccine immediately, are strongly recommending that girls be inoculated and are confident the vaccine poses no dangers. "This is a remarkably safe vaccine," says Dr. Neal Halsey, a professor in the department of International Health and Pediatrics at Johns Hopkins's Bloomberg School of Public Health, director of the Institute of Vaccine Safety and chair of the vaccine group at the Infectious Diseases Society of America. "There is no evidence of any increased risk of serious adverse events."

What worries him are logistics. "I think it's premature to require this for school entry, because we don't have good systems in place to make sure we can deliver this to all girls," he says. "We need to make sure the supply can be maintained, and we need to make sure we have good mechanisms in place to get this shot to all those who need it." According to Halsey, we do a great job of getting babies and little kids immunized in this country because well-baby visits insure regular contact with doctors and because the government has a system in place to make sure all young children--even those without insurance--can get the required shots free. "But we are doing a terrible job delivering vaccines to adolescents, due to a lack of infrastructure at the CDC and state health departments," he says. He worries that rushing school immunization requirements for the HPV vaccine will just overwhelm an already stretched system. "We're pushing too early, too fast." This troubles him: "It is a very valuable, very useful vaccine--our first for cancer--so let's do it right."

One of the biggest obstacles to the vaccine, even strong advocates acknowledge, is the swiftness with which it is being mandated. There hasn't been enough time to educate parents properly, and that has led Americans to react with all the nuttiness that any whiff of teen sexuality evokes--despite the assiduous effort of promoters to frame it as a "cancer vaccine," downplaying the issue of sexual transmission and never, ever emphasizing the vaccine's role in reducing genital warts. "When you educate parents, research shows, the numbers who say they are likely to give the vaccine to their kids shoot up," says Deborah Arrindell, vice president of health policy at the American Social Health Association. She cites a 2004 study published in the *Journal of Lower Genital Tract Disease*: Among 575 parents, only 55 percent thought the vaccine was a good idea before they read a one-page educational fact sheet about HPV. Seventy-three percent of them favored the vaccine after learning more about it. "If we had just a little more time, we would have a lot less controversy."

Even so, Arrindell still thinks it is vital to mandate the shots. That's because leaving the shots voluntary means some girls will get them, but a lot won't. And those who won't get the shots are those who can't afford them. Mandating the vaccine makes it much more likely that insurers will cover the costs, that Medicaid will pay and that federally funded vaccine programs will quickly offer free vaccines for uninsured children. All the experts agree on one thing: Any serious effort to address cervical cancer and genital warts has to target these populations. After all, these are the communities hardest hit. According to the Guttmacher Institute, African-American and Latina women are 1.5 times more likely to develop the cancer and are more likely to die of the disease as well. The explanation for this discrepancy is easy: More than half of those who develop cervical cancer in this country haven't had a pap smear in the previous three years, and these are

disproportionately low-income and women of color who lack access to healthcare, Guttmacher reports.

"Unfortunately, there is a lot of distrust of the health community and their history of clinical trials among African-Americans," says Arrindell. For example, the *Washington Afro-American*, a local paper in DC and Baltimore, came out firmly against the vaccine in an editorial invoking the Tuskegee experiment and other efforts to restrict the reproductive rights of blacks, proclaiming that the government should "stop trying to shove it down our throats." Running with the piece was a cartoon featuring a young girl cowering from a huge syringe wielded by Uncle Sam in a Merck lab coat. "I'm really concerned that this controversy over the vaccine is causing the African-American community to shy away from a vaccine that can save women's lives," says Arrindell.

She says there are valuable lessons here. "Middle school may be the last public health gate we all walk through together, before kids begin dropping out of schools or get a crummy job without health insurance, or enter the workforce in general with its fragmented healthcare system."

"We should not get lost in the controversy over this," insists Arrindell, who would rather see a debate over the best ways of making this vaccine affordable and accessible--both to American girls and to those in developing countries who may never get the regular pap smears they need for early detection of cervical cancer. "This is the best public health news we've had for women in fifty years. It's huge. It's exciting. It's wonderful." She delivers a succinct epilogue: "It's a good thing."

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#### **About Karen Houppert**

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