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A cancer vaccine with political will

Marketing conquers science, HPV Critics say

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It has been called "the medical breakthrough of the 21st century" and the most significant development in women's reproductive health since the Pill. Yet the same week that Ontario announced it was offering all Grade 8 girls a vaccine that could prevent cervical cancer, the country's medical journal carried an article from experts questioning the merits of the vaccine.

Such is the controversy around the HPV vaccine, which protects against the human papilloma virus associated with about 70% of cervical cancers: Hailed by some as a rare example of the government recognizing women's reproductive health care needs and derided by others as a case where powerful lobbying and marketing are winning out over science.

Vaccination programs are slated to begin in schools in Ontario, Nova Scotia, Prince Edward Island and Newfoundland and Labrador in September. It is already offered free to girls in Australia and in some U.S. states, including Texas and Virginia.

Some Canadian scientists and women's health groups say that because this rare cancer is well controlled in Canada, mass inoculation is not only redundant but could undermine existing, more comprehensive protections like Pap testing.

But cervical cancer can still be deadly, and so the vaccination has advocates. About 1,400 Canadian women will be diagnosed with cervical cancer this year, and 400 will die.

The vaccine has been backed by the Society of Obstetricians and Gynecologists of Canada and the Canadian Cancer Society, and in announcing her government's vaccination program, Sandra Pupatello, Ontario's Minister for Women's Issues, said: "There has never been an issue around women's health that has had this level of unanimity. It wasn't a difficult decision."

Gardasil, which is the only cervical cancer vaccine on the market, is the most expensive childhood vaccine developed for mass use. The federal government has allocated \$300-million to vaccinate girls ages nine to 13, but broad inoculation is estimated to cost much more, according to the Canadian Medical Association Journal, which prices a single round at about \$2-billion.

Gardasil protects against two strains of HPV associated with about 70% of cervical cancers. It does not protect against other HPV strains, the other 30% of cervical cancers or other sexually transmitted diseases.

It will not protect most women because they have already been exposed to HPV, the world's most common STD in women and men alike. (There may be as many as 200 HPV strains.)

The vaccination seeks to immunize girls before they become sexually active.

Merck Frosst, which produces Gardasil, says its clinical trials followed 20,000 females for an average of 3.5 years; only 241 subjects were followed for five years, and no one for longer. The youngest girls were followed for only 18 months; only 100 nine-year-olds were included. This group is assumed not to be sexually active or infected, when neither may be the case. Many types of HPV infection have been demonstrated in children, even in newborns.

Madeline Boscoe of the Canadian Women's Health Network said: "It's scary to think of vaccinating a whole generation of nine-year-old girls in this country based on a hundred ... The duty around evidence here should be so much higher."

But her biggest concern is the complacency that widespread vaccination might engender among girls and women about their sexual health.

Gardasil's best case is a 70% case for cervical cancer reduction, not prevention, whereas condoms and Pap tests are nearly 100% effective, not only against all cervical cancers but against all STDs. Because it has been studied for only five years, Gardasil is not yet able to demonstrate either long-term benefits or side effects and has not been shown to prevent cervical cancer. Its record in preventing pre-cancerous cervical lesions is at best only 46% better than a placebo.

When vaccination for girls was allotted \$300-million in the March federal budget, critics alleged pressure from drug manufacturer Merck and physicians' groups with which the company has commercial ties, as well as from Merck lobbyists who had once been advisors to Stephen Harper.

In the run-up to the budget, Merck's "Tell Someone" TV commercial ran night after night through January and February, featuring girls and women musing about "the cervical cancer virus." By means of what appeared to be a public service message, Canadians were suddenly aware about cervical cancer and HPV and its threat to women's health.

Ms. Boscoe, of the Canadian Women's Health Network, said the ads had a powerful impact: "It suggested there was a cervical cancer epidemic in Canada, and that a vaccine could cure it." She said that the roughly 400 women "who died of cervical cancer in this country last year didn't die because we don't know what to do, they died because we weren't caring for them. Either they didn't come in for care, or we didn't follow up on them."

The women most threatened by cervical cancer in the West as well as around the world are poor. In Canada, they are likely to be immigrants with language and cultural barriers, or aboriginal, or isolated, with disabilities or with their immunity compromised by stress and poor nutrition, and without access to Pap screening. Ms. Boscoe wonders whether a vaccine will serve these hard-to-reach populations any better.

Dr. Ryan Melnychuk, a virologist at the Canadian Centre for Vaccinology at Dalhousie University, said Gardasil might be redundant because there are already highly effective screening and treatment programs. Besides, he said, some experts think that HPV, like the chicken pox virus, is best left alone.

"We might alter the natural history of infection," Dr. Melnychuk said. "Who knows what will happen? With chicken pox -- typically a relatively mild childhood infection -- we've learned that vaccine protection [lasts] only 10 years or so. Thus, the infection typically experienced at [age] six now occurs later, with worse outcomes. There are similar concerns with Gardasil."

In their editorial in the latest issue of the Canadian Medical Association Journal, epidemiologist Dr. Abby Lippman and colleagues wrote this about the HPV vaccine: "It is time to take a breath and reflect on what we know and what we don't know? Individual girls and women, as well as policymakers, can make truly informed decisions about vaccinations only when they have all the evidence, and today, there are more questions than answers."