HPV Vaccine Researcher Blasts Mandatory Marketing

Tuesday, 13 March 2007

Dr. Diane M. Harper, a lead researcher in the development of the humanpapilloma virus vaccine, who says giving the drug to 11-year-old girls "is a great big public health experiment."

AHRP's stated rationale for objecting to a policy mandating Merck's HPV vaccine in 11 year old girls http://ahrp.blogspot.com/2007/03/nyt-vital-discussion-clouded-mandatory.html is validated by an internationally recognized expert in the field who tested the vaccine in clinical trials.

Dr. Harper, a scientist, physician, professor and the director of the Gynecologic Cancer Prevention Research Group at the Norris Cotton Cancer Center at Dartmouth Medical School in New Hampshire, said: "It is silly to mandate vaccination of 11- to 12-year-old girls There also is not enough evidence gathered on side effects to know that safety is not an issue."

All of her trials have been with subjects ages 15 to 25.
"This vaccine has not been tested in little girls for efficacy. At 11, these girls don't get cervical cancer - they won't know for 25 years if they will get cervical cancer."

Dr. Harper said, Merck was required to put together a database on the efficacy in children before Gardasil was approved. But instead, the company put together four study sites that "are not necessarily representative, and may not even have enough numbers to determine what they need to know."

She believes the ideal way of administering the new vaccine is to offer it to women ages 18 and up. At the time of their first inoculation, they should be tested for the presence of HPV in their system. If the test comes back negative, then schedule the follow-up series of the three-part shots.

But if it comes back positive?
"Then we don't know squat, because medically we don't know how to respond to that," Harper said.

She said that vaccinating little girls now is not going to protect them later. Since it can take a decade or more to even manifest itself as dysplasia, the HPVs against which this vaccine works may infect a little girl at the age she needs the vaccine most - meaning she will have to have a booster at the right point in time or she will not be protected. And, remember, it won't work at all if she was positive for the virus when she was inoculated in the first place.

Merck knows this, Harper said. "To mandate now is simply to Merck's benefit, and only to Merck's benefit," she said.

Dr. Harper said, she's been trying for months to convince major television and print media to listen to her and tell the facts about the usefulness and effectiveness of this vaccine. "But no one will print it," she said.

Something is very wrong with this commerically driven frenzied marketing which all those who shape public policy and public opinion were caught shilling for Merck.

Independent advocates need to take to the streets to protect our children from irresponsible pharmaceutical companies whose financial largesse buys public officials, government agencies that are supposed to protect us from potentially harmful drugs and vaccines, and the uncritical transcribers of hype in the press!

What role did the FDA play in this Gardisal promotion debacle?
Today the FDA orderd manufactures of 13 sleeping pills to add warning labels that sleeping do indeed cause sleep driving!! Imagine 13 different sleeping pills and all of them put pedestrians and drivers at risk of a sleeping driver behind th wheel!!
With the current regime in command, the FDA is lending the governmen seal of approval to the creation of chemically induced disasters.

Contact: Vera Hassner Sharav
212-595-8974
veracare@ahrp.org <mailto:veracare@ahrp.org>

http://www.kpcnews.com/articles/2007/03/14/online_features/hpv_vaccine/hpv01.txt

Researcher blasts HPV marketing
BY CINDY BEVINGTON cindyb@kpcnews.net

Wednesday, March 14, 2007

Diane M. Harper, a lead researcher in the development of the humanpapilloma virus vaccine, says giving the drug to 11-year-old girls "is a great big public health experiment." (Photo contributed)

LEBANON, N.H. — A lead researcher who spent 20 years developing the vaccine for humanpapilloma virus says the HPV vaccine is not for younger girls, and that it is "silly" for states to be mandating it for them.

Not only that, she says it's not been tested for effectiveness in younger girls, and administering the vaccine to girls as young as 9 may not even protect them at all. And, in the worst-case scenario, instead of serving to reduce the numbers of cervical cancers within 25 years, such a vaccination crusade actually could cause the numbers to go up.

"Giving it to 11-year-olds is a great big public health experiment," said Diane M. Harper, who is a scientist, physician, professor and the director of the Gynecologic Cancer Prevention Research Group at the Norris Cotton Cancer Center at Dartmouth Medical School in New Hampshire.

"It is silly to mandate vaccination of 11- to 12-year-old girls There also is not enough evidence gathered on side effects to know that safety is not an issue."

Internationally recognized as a pioneer in the field, Harper has been studying HPV and a possible vaccine for several of the more than 100 strains of HPV for 20 years - most of her adult life.

All of her trials have been with subjects ages 15 to 25. In her own practice, Harper believes the ideal way of administering the new vaccine is to offer it to women ages 18 and up. At the time of their first inoculation, they should be tested for the presence of HPV in their system.

If the test comes back negative, then schedule the follow-up series of the three-part shots. But if it comes back positive? "Then we don't know squat, because medically we don't know how to respond to that," Harper said.

Harper is an independent researcher whose vaccine work is funded through Dartmouth in part by both Merck & Co. and GlaxoSmithKline, which means she is an employee of the university, not the drug companies. Merck's vaccine, Gardasil, protects against four strains of HPV, two of which cause genital warts, Nos. 6 and 11. The other two, HPV 16 and 18, are cancer-causing viruses.

Merck's vaccine was approved last year by the Food and Drug Administration, and recommended in June for females ages 9 to 26 by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP).

Glaxo has stated publicly that its vaccine, Cervarix, which protects against the two cancer-causing strains, should be on the market by 2008.

As the director of an international clinical trial for these vaccines, and as author of lead articles about the vaccines' effectiveness, Harper has been quoted widely as saying this vaccine could have enormous potential to eradicate the great majority of cervical cancers.

Not tested on young girls

Picking up on this, but before the trials were even completed, major news media and women's advocacy groups began trumpeting the vaccine as an answer to cancer of the cervix.

Once it was approved by the FDA and ACIP, Women In Government (WIG), a non-profit organization comprised of female state and federal legislators, began championing Merck's vaccine in their home states, with many of the ladies introducing legislation that would mandate the vaccine for 11- and 12-year-olds.

In Indiana, Sen. Connie Lawson, R-Danville, introduced such a bill in this year's General Assembly, but in the face of strong opposition, it was reduced to an education/information-only bill that requires data collection on any Hoosier girls who do get the vaccine. The bill is now awaiting a hearing in the Indiana House.

So far at least 26 states are reported to be considering some form of legislation requiring the new vaccine for younger girls. In February, Republican Texas Gov. Rick Perry bypassed his legislature and mandated it for all 11- and 12-year-old girls in his state. Monday, The Associated Press reported that New Mexico's governor, Democratic presidential contender Bill Richardson, is set to sign a bill requiring sixth grade girls in his state to get the vaccine.

The idea is to inoculate them before they become sexually active, since HPV can be spread through sexual intercourse. But that idea, no matter how good the intentions behind it, is not the right thinking, Harper said. The zealousness to inoculate all these younger girls may very well backfire at the very time they need protection most, she said.

"This vaccine should not be mandated for 11-year-old girls," she reiterated. "It's not been tested in little girls for efficacy. At 11, these girls don't get cervical cancer - they won't know for 25 years if they will get cervical cancer.

"Also, the public needs to know that with vaccinated women and women who still get Pap smears (which test for abnormal cells that can lead to cancer), some of them will still get cervical cancer."

The reason, she said, is because the vaccine does not protect against all HPV viruses that cause cancer - it's only effective against two that cause about 70 percent of cervical cancers.

For months, Harper said, she's been trying to convince major television and print media to listen to her and tell the facts about the usefulness and effectiveness of this vaccine. "But no one will print it," she said.

According to Harper, the facts about the HPV vaccine are:

• It is not a cancer vaccine or cure. It is a prophylactic - preventative - vaccine for a virus that can cause cancer. "Merck has proven it has zero percent effectiveness for curing cancer," Harper said. "But it is a very, very good vaccine that prevents types of HPV responsible for half of the high-grade cervical lesions that cause about 70 percent of cervical cancers. For the U.S. what that means is the vaccine will prevent about half of high-grade precursors of cancer but half will still occur, so hundreds of thousands of women who are vaccinated with Gardasil and get yearly Pap testing will still get a high-grade dysplasia (cell abnormality)."

• It is not 100 percent effective against all HPVs. It is 100 percent effective against two types that cause 70 percent of cervical cancers.

• The vaccine only works if the woman/girl does not have a current vaccine type related infection (in other words, the vaccine only works when the woman/girl does not have HPV 6, 11, 16 or 18 - the viruses that Gardasil targets when she receives her first vaccine shot).

• The vaccine doesn't care if the girl/woman has been sexually active, Harper said. "HPV is a skin-to-skin infection. Although the only way to get cervical dysplasia is through an HPV infection, and HPV is most often associated with sexual activity, HPV is not just spread through sex. We have multiple papers where that's documented. We know that 3-year-olds, 5-year-olds, 10-year-olds, and women who have never had sex have been found to be positive for the cancer-causing HPV types."

• Therefore, for example, if a girl is positive for HPV 16 when she is inoculated with the vaccine at any age, she will not be protected against it later, Harper said. "That means it's a failure and those people are at risk for getting the HPV 16 and 18 cancers later."

• The only way to test for the presence of HPV is through a vaginal swab - which is inappropriate for young girls, she said.

• So what happens if the girls are vaccinated anyway, not knowing whether they were carrying the virus at the time of their inoculation? "They will not be protected if they were positive for the virus at the time they are vaccinated," Harper said.

• That is why it is important to note that the vaccine has not been tested for efficacy (effectiveness) in younger girls, she said. Instead, the effectiveness was "bridged" from the older girls to the younger ones - meaning that Merck assumed that because it proved effective in the older girls, it also would be effective in the younger ones. The actual tests on the younger girls, ages 9 to 15, were only for safety and immune response, Harper said, and then only as a shot by itself, or in combination with only one other vaccine, Hepatitis B. It has not been tested in conjunction with any other shots a girl receives at about age 11, Harper said.

• So far more than 40 cases of Guillian-Barre syndrome - a dangerous immune disorder that causes tingling, numbness and even paralysis of the muscles have been reported in girls who have received the HPV vaccine in combination with the meningitis vaccine. Scientists already know that sometimes a vaccine can trigger the syndrome in a subject. "With the HPV vaccine, it is a small number but higher than is expected, and we don't know if it's the combination of the two, or the meningitis alone," Harper said.

• In the end, inoculating young girls may backfire because it will give them a false sense of protection. And, for both young girls and women, because the vaccine's purpose has been so misinterpreted - and mis-marketed - Harper feels that too many girls and women who have had the vaccine will develop a false sense of security, believing they are immune to cancer when they are not, and failing to continue with their annual Pap exams, are crucial to diagnosing dysplasia before it can develop into cancer.

Keep getting pap smears

The message to consumers, Harper said, is don't stop getting Pap smears just because you've gotten the HPV vaccine. "This vaccine is good, and it will save a huge number of lives around the world," Harper said. "But an important point is that, if women get the vaccine and then not get their Pap smears, or decide to get them infrequently, what will happen in the U.S. is that we will have an increase in cervical cancer, because the Pap screening does a very good job.

"That's my main diatribe. We don't need mandatory vaccinations for little girls. What we do need to ask, though, is how long does it last, and when do you need a booster?"

Message for governors
For the governors of the states in this country, Harper has another message. One has to do with the fact that vaccinating little girls now is not going to protect them later. Since it can take a decade or more to even manifest itself as dysplasia, the HPVs against which this vaccine works may infect a little girl at the age she needs the vaccine most - meaning she will have to have a booster at the right point in time or she will not be protected. And, remember, it won't work at all if she was positive for the virus when she was inoculated in the first place.

Merck knows this, Harper said. "To mandate now is simply to Merck's benefit, and only to Merck's benefit," she said.

Merck was required to put together a database on the efficacy in children before Gardasil was approved, Harper said. But instead, the company put together four study sites that "are not necessarily representative, and may not even have enough numbers to determine what they need to know."

Since she doesn't personally have access to the money Merck and GlaxoSmithKline pay for her HPV vaccine research, Harper doesn't know exactly how much either has paid Dartmouth for her work.

The trials are expensive, between $4,000 and $5,000 for each patient, she said. With over 100 patients in her study, some big bucks could be in the balance, should Merck or Glaxo become upset with her for making these comments.

Why, then, would she risk speaking out like this - at a time when her words very well could influence legislation across the country, and prompt legislators to drop the mandates? Isn't she afraid of losing her funding?

"I want to be able to sleep with myself when I go to bed at night," Harper said. "My concern is still, let's get women's health better. It is still a good vaccine. But let's be honest. Don't over-promise."

For more stories on this topic, see the HPV Vaccine Series <http://www.kpcnews.com/online_features/hpv_vaccine/>