

HPV vaccine in question
More professionals question rush to mandate

BY CINDY BEVINGTON
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One less.

One less death from cancer.

It's been over a year since the American public began hearing on TV and radio an advertisement that was part of a marketing campaign to promote a new vaccine that protects against two viruses that sometimes lead to cervical cancer and two that can lead to genital warts.

The viruses are called human papilloma, HPV for short. Scientists have identified more than 100 different HPVs, about 40 of which can cause genital cancers or genital warts. Of that number, 15 types of HPV can cause cancer, and 12 can cause genital warts. Most often, HPV is spread by sexual contact. However, unlike other sexually transmitted diseases, HPV is only passed on by skin-to-skin contact, meaning it can live anywhere on the skin and, in some cases, can be spread in nonsexual ways.

The vaccine's name is Gardasil. And, ever since the U.S. Food and Drug Administration OK'd its use, and the Advisory Committee on Immunization Practices recommended it for females age 9 to 26, it has been a political hot potato as state legislatures attempted to make the vaccine mandatory.

In Indiana, after a vaccine mandate failed, the General Assembly decided instead to mandate that schools send information on HPV and the availability of a vaccine for it to parents of all Hoosier sixth-grade girls, beginning this school year.

That information was compiled by the Indiana State Department of Health (ISDH) and distributed to the Department of Education for dissemination to local schools. In the coming days and weeks, schools will either send the three-page letter – which includes a form that parents must sign and return – home with the girls or, like DeKalb Central Schools, deliver to parents through the mail.

The ISDH has the letter posted on its Web site. It is short and succinct, purposely written in simple language so it can be easily understood, according to Dr. Charlene Graves, a pediatrician who serves as the medical director for the ISDH immunization program.

Acknowledging that it was difficult to streamline facts about HPV and the vaccine, Graves said, "What we were doing was translating sophisticated medical information as best we could to give information

to the general public. We had to convert it to an eighth-grade level. That is the balance we were trying to achieve, and I think we did achieve it.”

Researcher disagrees

While the letter does give important information, it also omits or gives incorrect information, according to Dr. Diane Harper, a professor, gynecologist and researcher at Dartmouth University. She has studied HPV for 20 years, and helped develop Gardasil.

For example, the letter says HPV is spread during sex – but fails to mention that it can be transmitted in other ways. It also should have said explicitly that the vaccine is not effective if, at the time she is vaccinated, a girl is positive for the four types of HPVs Gardasil targets, Harper said.

(A graphic accompanying this story shows Harper’s suggested changes or additions to the state’s actual letter.)

Graves admitted that the letter could have been longer or more detailed. And she said that the “already positive concern” is a legitimate issue.

But, she countered, it was difficult to decide what to include or exclude because the letter needed to be short – too long or too full of medical terminology, and parents may not read it at all. The important thing is, the essentials are there, she said.

“I’m not surprised that some issues are being made (over the letter),” Graves said. “Sophisticated medical people may quibble about the wording. But it did go to a wide variety of nurses and doctors for review. We tried to do the best we could.”

No longer alone

In March, Harper shared with this newspaper her frustrations about how this vaccine was being mis-marketed by its maker, Merck. (GlaxoSmithKline is coming out with its own HPV vaccine, Cervarix, soon. Harper also was involved in developing Cervarix.)

Her concern then was that the “one-less” campaign was selling the idea that this vaccine is a cancer vaccine, when it is not. “It is a vaccine against two viruses that in some instances can lead to cancer in some women,” Harper said.

Accusing Merck of trying to boost sales by misleading the public about what the vaccine can do, Harper said that mandating the vaccine was “a great big public health experiment” because nobody knows for sure just how long the vaccine lasts. Also, at this point, because it can take 10 to 20 years to actually develop cervical cancer, nobody knows whether it will even prevent cancer, she said.

(The incidence of cervical cancer in the U.S. is one of the lowest in the world because Pap tests, which detect cell abnormalities that could lead to cancer, are so prevalent. The majority of cervical cancer cases in the U.S., in fact, are in women who have not had a Pap test in at least five years.)

For months, Harper stood alone in her criticisms, with the mainstream media mostly ignoring her. But now, as major medical journals have come out with similar concerns, and as other doctors have spoken up, major print and broadcast media have begun to publicize what Harper said all along.

In what is considered the bible of the medical world, the Journal of the American Medical Association (JAMA) in May echoed her concerns about the rush to mandate this vaccine. With no holding back, JAMA accused Merck of “putting wealth ahead of public health.”

Next, the New England Journal of Medicine (NEJM) also stepped up to the plate in May, when its editors questioned the vaccine’s effectiveness.

The month before, in April, the Wall Street Journal had reported that some scientists writing for the NEJM were raising doubts about whether the vaccine would really reduce cervical cancer.

In May, the Journal pointed out that other researchers, George F. Sawaya and Karen Smith-McCune at the University of California, San Francisco, were advising a slowdown on the rush to mandate the vaccine, because there were “too many unanswered questions” about its “effectiveness, duration of protection and adverse effects.”

CMAJ article too

Then, this past week in a commentary in the Canadian Medical Association Journal, an epidemiologist at McGill University in Quebec took a no-holds-barred approach against a universal immunization program for Gardasil.

Using Merck’s own data to prove her point, Abby Lippman said that “methodologic weaknesses in the trial reports, combined with the limits in currently available data, continue to leave many information gaps.”

Those gaps include the effectiveness of the vaccine when administered with other immunizations.

But, more important, she said, is the idea that misunderstandings about what the vaccine can and cannot do possibly could lead to reductions in safer sex practices and Pap screening rates.

Calling attention to the fact that the youngest girls in the Gardasil trials were followed for only 18 months, Lippman said,

“Clearly, this is a thin information base on which to construct a policy of mass vaccination.”

Almost immediately, Lippman, like Harper, saw a swift backlash to her comments. Wednesday the Society of Obstetricians and Gynecologists of Canada published a statement lambasting Lippman for her position.

This week Lippman told this newspaper that she and three co-authors of the piece had been watching the vaccine’s development closely.

Noting that the CAMJ on Monday plans to devote a whole issue to HPV and a review of the vaccine, Lippman questioned the Canadian Minister of Finance’s motives for announcing, without warning, that the government would earmark \$300 million specifically for Gardasil to be given to Canadian girls.

“That is unheard of,” Lippman said.

“What happens in six months if another vaccine comes along? Will they need a booster? There are things that haven’t been pulled out tightly enough. I’m not anti-vaccine across the board.

“But, there are things to consider, such as adverse effects.

“For example, the placebo group in the Merck study had aluminum as its adjuvant, just like the vaccine. That may mean nothing, but we don’t know.”

Don’t give up

The state’s Web site at www.in.gov/isdh, as well as the Centers for Disease Control’s site on HPV at www.cdc.gov/vaccines, gives a plethora of information about HPV and the vaccine’s effectiveness.

Like Indiana’s letter to parents, the information is presented in simple language. However, clicking on buttons directed at clinicians and physicians will give the most precise and detailed information, including guidelines on HPV testing, diagnosis and cervical cancer.

In some instances the clinician information compared to the general public’s is far superior in making clear what the vaccine can and cannot do. Similar differences – and discrepancies – are evident in almost every comparable publication on the topic in print, broadcast or Internet niche news.

So what is a parent to do? Should you have your daughter vaccinated or not?

The important thing is to first become informed from the most reliable sources possible, Harper said.

That means go to research sites where the actual researchers for the

vaccine often post their findings, including online free access to JAMA, the NEJM and CAJM, click on the clinician and physician information buttons on government sites, scrutinize who is giving the information – some doctors who speak as “authorities” on a pharmaceutical topic actually are paid spokespersons – and then decide what is best for your daughter.

Don't give up, Harper said. “It is a good vaccine, and we know that it does work at least five years, although there are indications at this point that a booster may be needed.”

Look for more information on this topic, including details on what this vaccine can and cannot do, on this newspaper's Web site at www.fwdailynews.com.

NVIC reports 87 adverse reactions to Gardasil in Indiana

By Cindy Bevington
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The reports are out: According to the national Vaccine Adverse Event Reporting database, 8,864 adverse events have been recorded since Gardasil, a vaccine that protects against four types of human papilloma viruses (HPVs) was approved in June 2006. The vaccine has been approved for females ages 9 to 26.

The latest reports were made public June 25 after Judicial Watch, a non-lobbyist group that advocates complete transparency in government, obtained them through a Freedom of Information Act request.

While Judicial Watch doesn't break down the reports by state, another vaccine-watching group, the National Vaccine Information Center, does, and that group shows 87 adverse reactions to Gardasil reported in Indiana.

The reactions among Hoosier girls and women range from fainting to one case of Guillain-Barre Syndrome.

Other reactions include dizziness, swelling at the injection site and in lymph nodes in the neck and groin, low grade fevers, vasculitis, hives, rashes, itching at the injection site, a miscarriage of a pregnancy, shortness of breath, nausea and flu-like symptoms.

More serious were the appearance of blisters on a 20-year-old's upper arms and back and ano-genital warts on a 12-year-old. A 15-year-old reported blisters that started in the vaginal area within two days of

receiving the vaccine. The blisters then spread to her trunk and behind her ears and knees. It was noted that the blisters lasted five to seven days and then developed scabs.

Other vaccine recipients complained of musculo-skeletal pain, chest pain, neuralgia and vasculitis of the legs, buttocks and belly. One patient with a history of convulsions suffered a seizure within 15 minutes of receiving Gardasil. Another, 15 years old, had to be treated by a pediatrician, a rheumatologist and an orthopedist for her symptoms of arthralgia, erythema and fatigue. These symptoms, the report said, "correspond to timing of first and second doses of Gardasil vaccine."

What was described as a "life-threatening" illness after Gardasil was reported in December when a 15-year-old was sent to Riley Children's Hospital in Indianapolis with Guillian-Barre Syndrome, a neuro-muscular disease, about 86 days after receiving Gardasil.

'Not responsible'

Activists who are skeptical about the vaccine's safety and efficacy (effectiveness) believe that most, if not all, the reactions could be related to Gardasil. However, the Centers for Disease Control, the FDA and Merck Inc., the vaccine's manufacturer, have issued press releases in the past few days, saying the VAERS reports do not necessarily mean the reactions were caused by the vaccine.

According to the FDA, safety data reviewed in approving Gardasil showed only mild side effects, such as pain at the injection site or fainting.

Also, according to the CDC, the FDA and Merck, most of the reactions being reported after Gardasil are not unusual for the age group, or unexpected in the large number of girls who have been vaccinated. For example, fainting is quite common when young girls get vaccines, both agencies say. The other reports, such as hives and anaphylactic reactions, are common too, they say.

The FDA has not responded to requests for an interview.

At the Indiana State Department of Health, Dr. Joan Duwve, medical director for the department, cautioned that people need to look at the whole picture that VAERS presents, before attributing all of the events to Gardasil.

"With the VAERS reports, the name implies that it actually is an adverse event," Duwve said. "But in reality, anything that happens after a vaccine is reported in there."

Since there is always a risk for something to happen with a vaccine, from allergic reactions to fainting to something more serious, doctors and clinicians ask patients to wait in the office for a time after receiving a vaccine.

Guillain-Barre Syndrome (GBS) can happen after a viral or bacterial infection and after lots of different vaccines, she added, and the ones reported in the Gardasil VAERS have yet to be definitively linked to the vaccine.

"These adverse reports are misnamed because people assume that whatever has happened is directly attributable to the vaccine, when the VAERS is just a monitoring system," Duwve said.

'Illogical and unscientific'

For Barbara Loe Fisher, who heads NVIC, this explanation isn't good enough to make her believe that Gardasil isn't causing some very bad reactions in young girls.

"I don't believe Merck was honest in its trials with the GBS, muscle weakness and asthenia (fatigue, lack of energy)," Fisher said. "I believe they didn't report it all. And the argument that it's just a coincidence that the girls now are getting some of these neurological reactions is the most illogical and unscientific I've ever seen.

"Things like GBS is almost unheard of at that age."

Another reaction, that of the appearance of genital warts after the vaccine which is supposed to protect against genital warts is one that both Merck and the FDA noted in Merck's trials, but glossed over when approving the vaccine, Fisher said.

"At least one study says that if you are HPV-positive for the viruses against which Gardasil protects at the time you are immunized, the vaccine could enhance the possibility of your getting genital warts or lesions on your cervix," Fisher said.

"And if that's true, they should be testing for HPV infections before the girls get vaccinated."

Dr. Diane Harper is a scientist and professor from New Hampshire who spent 20 years studying HPV and working on a vaccine for it for both Merck and GlaxoSmithKline, which is expected to come out with its own HPV vaccine soon.

Since the vaccine doesn't contain any "live" viruses, it's not possible that it causes genital warts or cervical dysplasia abnormal cell changes in the cervix, Harper said.

"But it is possible that the ones (who reacted in that way) were already on their way to getting the infection anyway," Harper said. "The injection has nothing to do with it."

For Fisher, though, the adverse reports simply point to another reason for moving more slowly on promoting this vaccine. Parents need to be wary of embracing a vaccine for a disease that isn't even in the top 10

for deaths in the U.S., she said. They also need to remember that the vaccine is so new that no one knows how long it lasts, and whether it will still be effective when the girls reach their 20s. For example, it is widely known that measles and mumps vaccines are wearing off, and young people in their 20s and 30s may not be protected from those shots, she said.

"Merck made \$1.5 billion in the last year on this vaccine," Fisher said. "It was in the news. And I believe that one reason the FDA didn't approve it for the older women (ages 27 to 45) last week is because of the possibility of getting cervical changes after the vaccine, if you're positive for the relevant HPVs.

"Besides that, we don't even know if the girls who do get the vaccine will still be protected when they really need it no vaccines give permanent immunity."

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FDA rejects HPV vaccine for women 27-45

BY CINDY BEVINGTON
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Yes to girls. No to women. A few days ago the U.S. Food and Drug Administration refused to approve a vaccine for women ages 27 to 45 that the agency says is OK for girls ages 9 to 26.

The announcement came from the maker of the vaccine, Merck & Co., which issued a short press release carried by some news wires and major newspapers.

The vaccine, Gardasil, has been a center of controversy since June 2006, when the FDA approved it for the younger group of U.S. females.

Gardasil protects against four human papilloma viruses (HPVs) that sometimes can lead to cervical cancer or genital warts.

The four viruses are spread by skin-to-skin contact.

There are over 100 HPVs. Two of the HPVs against which Gardasil protects are believed to cause about 70 percent of cervical cancer when they become persistent and are left untreated.

The other two are believed to cause about 90 percent of genital warts.

According to Merck clinical studies the vaccine is almost 100 percent effective.

However, it does not protect against the viruses if a woman is positive for them at the time she is vaccinated.

The same day it made its decision not to allow the vaccine for the older group of females, the FDA also turned down Merck's request to market the vaccine as a preventative against HPVs beyond the four already approved.

Not talking

The FDA's decision left both critics and proponents of the vaccine speculating as to the reason behind the decision, because Merck and the FDA are not talking about it.

The FDA did not respond to requests for an interview for this story. Merck said in its press release that the FDA had "issues" the company needs to address before the FDA can recommend the vaccine for women over age 26.

As far as extending it to be sold as protection against HPVs other than the original four, Merck said, "According to the FDA, the data submitted do not support extending the indication for Gardasil (for this use)."

An extensive Internet search yielded no clues, either, as to what was behind the FDA's decision, leaving critics left to offer reasons of their own.

Pointing to the May 18, 2006 committee meeting where the FDA grilled Merck about the vaccine before approving it, some people are wondering whether possible side effects discussed in that meeting might be showing up since the vaccine was approved - and that the FDA wants to address those issues before it approves the vaccine for any further uses.

Unknown side effects?

Dr. Sin Hang Lee is a Connecticut pathologist who contacted this newspaper about an HPV DNA test that can tell a woman not only whether she is positive for HPV at any given time, but also which HPV it is. The test gives no false positives and is economical - about \$50 to \$60, which most insurances will pay, Lee said.

This is important information for women and mothers of girls being vaccinated with Gardasil to know, Lee said, since the vaccine doesn't work for any vaccine-relevant HPV that you are positive for at the time you get the shot.

Not only that, according to transcripts and minutes from the May 18, 2006 meeting, there is a possibility of an “enhanced” chance in getting precancerous lesions or genital warts if a woman is positive for the HPVs at the time she gets the shot, Lee said, which makes it even more important to know whether you are positive for a vaccine-relevant HPV before you get the vaccine, Lee said.

“The HPV DNA test is very important because if a woman is positive for just one of the (cervical cancer-causing) HPVs, that means she only has 50 percent protection from the vaccine for cervical cancer,” Lee said. “And, Merck’s slides show that there is a 44.6 percent increased chance of getting precancerous lesions if she is positive for one of those two.”

Know your HPVs

At his lab in Milford Hospital, Lee’s job is to develop HPV-accurate tests that can help women and their doctors decide what course of action to follow when they are found to be HPV-positive.

“The fact is a lot of women have HPV, but many never develop cervical cancer,” Lee said. “What you want to do is follow the women through a persistent HPV infection which can lead to cancer. It’s important to realize, too, that HPV itself doesn’t cause cancer. It’s the persistence of the infection that causes it. And, not all HPVs can lead to cancer, so you wouldn’t want to treat them all the same. Most of them just go away on their own.”

While some doctors don’t believe it’s important to know which HPV a woman is positive for, others are very interested in finding that out, Lee said. “And I am one of them. I am a surgical pathologist, and I want 100 percent accuracy in this test, so women and their doctors can know how to properly treat the infection.”

The Associated Press reported on the enhanced possibility of precancerous lesions when the FDA approved the vaccine, but until now no one has elaborated on it.

Minutes from the Gardasil review meeting – found by this newspaper through Internet research on the FDA Web site – talks about “potential concerns by the review team” of “apparent increased incidents” in precancerous lesions on the clinical trial subjects if they were positive for the vaccine’s HPVs when they were vaccinated. The concern was dropped, however, when Merck responded that the tests may have been biased, since a higher number of test subjects had abnormal Pap smears at the beginning of the trial, than did those in the placebo group.

Efficacy challenged

At Judicial Watch, a non-lobbying, national organization that advocates transparency in everything the government does, Chris Farrell,

the agency's investigative director, questions whether efficacy (effectiveness) tests with Gardasil were good enough for women ages 27 to 45.

Farrell also points to what he calls alarming evidence of serious adverse reactions that girls who have had the vaccine are reporting (see accompanying story: HPV VAERS are out).

He also questions why the FDA and Merck aren't talking about the FDA's recent turn-downs on the vaccine.

"We've filed a Freedom of Information Act (FOIA) request on this," Farrell said. "But the manner in which the FDA replied was very vague. They said if we filed an FOIA we might get the answer."

But that doesn't necessarily mean they will, Farrell said. "And even then they may redact (keep out) a certain portion of it."

'Not possible'

According to Dr. Diane Harper, a former lead researcher for the vaccine, it isn't possible for girls to get cancer or genital warts from the vaccine. Because HPV can be spread in other ways besides intercourse, it is possible that a young girl might already be infected with one of the HPVs when she is vaccinated, even if she's never had sexual intercourse, Harper said.

For example, if she is positive for genital warts and doesn't know it because she has no lesions yet, they could show up later, but not because of the vaccine.

"The vaccine will not cause genital warts," Harper said. "Likewise, Gardasil will not cause genital warts to grow faster."

In the meantime, at least two local physicians are advocating the vaccine. Dr. William Smith, a gynecologist in Angola, doesn't see many younger girls, since they generally are seen by pediatricians and family practitioners.

However, he does talk to mothers of younger girls, and he does see a few girls who are brought in either by their mothers, who are concerned that the girls have become sexually active, or who have come in with the girls to discuss specific sexual health questions or problems.

Time for 'the talk'

"It's not all it's cranked up to be, because it doesn't protect against all the HPVs. But I am in favor of this vaccine because girls today are so sexually active," Smith said. "And if we're going to make a dent in (the HPVs against which the vaccine does protect) we're going to have to have it available to everyone, not just high-risk kids."

In fact, Smith said, every woman and girl should be thinking about getting the vaccine, rather than talking about who should and who shouldn't.

"I just saw a 14-year-old the other day, whose had four sex partners, and a 19-year-old who's had 20. These young kids today are having much more sex than you can imagine, and I although I would like to prevent pregnancies more than HPV, which you can deal with, it's important to protect these kids as much as possible with a vaccine like this."

Besides HPV, young people are getting more and more sexually transmitted diseases, such as herpes and Chlamydia, which can cause infertility, Smith said. Kids today need to learn how to protect themselves from these diseases, he said.

That's why he also advocates sex education for younger children. In other words, it's time to talk "the talk" with your kids, he said: "It's a conversation that needs to take place with parents that's not happening."

A survey conducted by the Centers for Disease Control in 2007 of Indiana teenagers supports Smith's statements: 32.5 percent of Indiana ninth graders reported already having had sexual intercourse. By 12th grade, 65 percent said they'd had intercourse.

Even more startling were the number who had had sex before age 13: of ninth graders, 6.4 percent had had sex before they were 13.

Of those who reported having had multiple partners, 7.3 percent of ninth graders and 19.4 percent of 12th graders said they'd had sex with four or more partners.

Even more startling in the survey was the revelation that, the more teenagers used birth control pills, the less they used condoms.

The numbers don't surprise Dr. John Egli, a general practitioner in Shipshewana and Topeka. Even though he treats what he calls a "cloistered community," he says he hears about the numbers from his colleagues.

"I've talked with two physicians recently who said they're seeing more and more kids with venereal warts and other sexually transmitted diseases," Egli said. "For example, I heard about the increase in herpes infections, and I couldn't believe it, but they said they did."

HPV vaccine adverse events reports are out

BY CINDY BEVINGTON
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The adverse reaction reports on Gardasil, a vaccine that protects against four human papilloma viruses, are out. According to the VAERS reports – the national Vaccine Adverse Event Reporting database – 8,864 adverse events have been reported since the vaccine was approved by the U.S. Food and Drug Administration in June 2006.

Of that number, 18 deaths have occurred, and possibly 20, as well as 140 “serious” reports, 27 of which were life-threatening. Also, 10 miscarriages and 38 cases of Guillian-Barre Syndrome, a neurological disease that strikes muscles and the nervous system, have been reported.

The reports were obtained through a Freedom of Information Act request by Judicial Watch, a non-lobbyist group that advocates complete transparency in all forms of government, from law-making to record-keeping.

The FDA released the reports on June 10. On June 12, it quietly approved a change to the warnings in Gardasil’s package insert to include arthralgia, myalgia, asthenia, fatigue and malaise in the adverse reactions list.

The change was not announced when the FDA and Merck made public the FDA’s decision a few days ago not to approve Gardasil for young adult and middle-aged women ages 27 to 45. The vaccine has been approved for females in the U.S. ages 9 to 26.

In an examination of the VAERS report, Judicial Watch noted that Gardasil is still in its testing stages, and that it has been tested only with one other childhood vaccine for hepatitis.

Among some of the adverse reactions in the report, several include outbreaks of both genital warts and facial or body warts. Other reactions include fainting, dizziness, weakness and nausea.

The more severe reactions are muscle and joint pain, and Guillian-Barre-like symptoms, such as loss of motor skills and neurological problems.

While the FDA has gone on the record as saying most of the more serious adverse reactions cannot be pinpointed to Gardasil, Judicial Watch alleges that they are connected to the shot.

The FDA did not respond to requests for an interview about the reports or the change in Merck’s Gardasil package insert with this newspaper.

However, according to the FDA's "product approval information" form on its Web site, the changes were made "to reflect reports received during post-marketing surveillance." The FDA's approval for the package insert is available at the FDA's Web site at fda.gov/cber/products/gardasil.htm.

A full report on the VAERS reports is available at judicialwatch.org.

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HPV letter going home

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INDIANAPOLIS – After several months of work on a document that is to go home to the parents of sixth-grade girls this school year, the medical director for the immunization program at the Indiana State Department of Health has sent it on to the Department of Education for distribution.

Public Law 80 of 2007 requires schools to provide information to parents or guardians of all Hoosier sixth-grade females on the human papilloma virus (HPV) and the availability of a vaccine for it. This fall, that information will go home in the form of a three-page letter. Once they've read it, the parents or guardians must check one of three statements on one of the pages, sign it and return it to the school. The parents' responses will inform state officials of parents' decisions regarding HPV immunization.

Dr. Charlene Graves said Tuesday that she had sent the letter out four different times over the summer for review and revision by a wide group of people. One factor that made the task so arduous was that she knew the letter had to be written to at least an eighth-grade level to make it easy to understand.

Meeting that criteria was a challenge, Graves said. But she believes she did the best she could, and that parents are receiving good information in the letter.

However, a lead researcher who has studied HPV for 20 years, and who helped develop the HPV vaccine, thinks Indiana can do a better job.

Specifically, Dr. Diane Harper, a gynecologist and professor at

Dartmouth University, said the letter incorrectly states how the infection is spread. While HPV is the most common sexually transmitted infection, it also can be acquired in other ways that don't involve sexual activity.

For example, the fact that researchers have found the virus under the fingernails of young men was published Aug. 6 in the Seattle (Washington) Post-Intelligencer. Harper and other HPV scientists also have known for some time that HPV has been found present in babies and celibate women, such as nuns who have never had sex.

Harper also is concerned that the letter fails to inform parents that if a girl or woman is positive for the virus at the time she receives the vaccine, the vaccine will not be effective. This newspaper reported that fact in an interview with Harper in March. Two days ago, national news media also began reporting it.

In 2006 Harper was named New Hampshire's Family Physician of the Year.

Sunday: More on Indiana's HPV letter, Harper's comments and a graphic showing the whole letter with Harper's suggested changes or additions. To read other articles previously printed on this vaccine, go to fwdailynews.com/online_features/hpv_vaccine on the Web.

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Canadian epidemiologist criticizes HPV hype

BY CINDY BEVINGTON
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MONTREAL, Quebec – A Canadian professor of epidemiology and biostatistics at McGill University in Montreal is questioning the motives behind the rush to mandate and fund a new vaccine that protects against two viruses that sometimes lead to cervical cancer.

Professor Abby Lippman, who also is active in the Canadian Women's Health Network, is publishing her comments on the HPV vaccine in the Aug. 28 issue of the Canadian Medical Association Journal (CMAJ).

Lippman co-authored the article with three women's health advocates after analyzing numerous data about the vaccine and its merits. Currently, Merck Inc. is the sole distributor of an HPV vaccine – Gardasil – but GlaxoSmithKline is expected to begin marketing its version, Cervarix, soon.

Using data from Merck's own trial reports, Lippman's article asserts that there are too many unanswered questions as to what the vaccine can and cannot do, and as to the safety of it when administered with other vaccines, to rush into mandating and funding it. Warning that universal immunization for girls and women could have negative effects, Lippman says that governments are making decisions on the vaccine based on "a handful of randomized controlled trials."

She also points out that all of the HPV vaccine trials were funded in whole or part by the manufacturer. Questioning why no data on boys and men are available yet, Lippman asks that "unbiased research programs free of conflict of interest" be conducted to obtain evidence-based information on which to base mass immunization decisions.

She also stresses that governments need to begin education programs, now, to teach consumers not only how HPV can be spread, but also lessons in healthy living.

In the U.S., the HPV vaccine was recommended for girls and women ages 9 to 26 by the U.S. Food and Drug Administration (FDA) a year ago. The vaccine caused a storm of controversy around the U.S. this spring when several states, including Indiana, tried to mandate it.

In the midst of the uproar in March, a scientist and physician, Dr. Diane Harper, who was a lead researcher in developing the vaccine at Dartmouth University, spoke out against the mandates in an interview with this newspaper. Consequently, this newspaper was the first media outlet to publish Harper's allegations that a rush to mandate the vaccine is "a great big public health experiment."

Harper stood alone in her comments for several weeks until the Journal of the American Medical Association in May concurred with her.

Sunday: An interview with Dr. Lippman and more on her CMAJ article. To read past articles on the HPV vaccine published by this newspaper, go to fwdailynews.com/online_features/hpv_vaccine on the Web.

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Medical journal sides with HPV scientist

BY CINDY BEVINGTON
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CHICAGO – An editorial May 2 in what is considered the Bible of the medical profession vindicates a researcher who told this newspaper months ago that mandating the human papillomavirus (HPV) vaccine for young girls is “a great big public health experiment.”

The vaccine, Gardasil, offers protection against four of the more than 100 known HPVs, two of which scientists believe cause about 70 percent of cervical cancers.

Last week, The Journal of the American Medical Association (JAMA) took a public stand against legislation to mandate this vaccine. The article, “Mandatory HPV Vaccination: Public Health vs. Private Wealth,” was co-authored by Chicago-based JAMA editor Dr. Catherine D. DeAngelis and Washington, D.C.’s Georgetown University professor Lawrence O. Gostin. Gostin specializes in public health law.

Declaring it unethical to rush into mandates, the authors accuse Gardasil’s manufacturer, Merck & Co., of putting profits ahead of the safety of the 2 million girls and women in the U.S. who, if it were mandated, would receive the vaccine before the long-term effectiveness and safety of it had been determined.

Pointing out that the Federal Drug Administration’s approval of the vaccine was conditional upon Merck agreeing to further test the safety and effectiveness of it, the JAMA article says, “Making the HPV vaccine mandatory contributes to long-standing parental concerns about the safety of school-based vaccinations.”

In fact, legislating the vaccine now “could have the unintended consequence of heightening parental and public apprehensions about (all) childhood vaccinations,” the article adds.

The article also questions how vaccine recipients would be compensated in the event of their suffering adverse effects from it, since some courts may determine that the manufacturer would not be liable if the states mandated it.

The article also admonishes Merck, which could rake in billions of dollars from a mandated vaccine, for financing efforts to persuade states and public officials to mandate it. “Private wealth should never trump public health,” the article says.

Vindicated

Until the JAMA article came out, Diane Harper, a physician, scientist and professor at Dartmouth University Medical School in New Hampshire, who spent 20 years studying the virus and helping to develop a vaccine for it, had stood virtually alone among her peers in denouncing efforts to mandate the vaccine. When she first interviewed with this newspaper, she said she’d tried to convince major print and broadcast media to “tell the whole story” about the vaccine and why she, as a lead researcher on it, believes it is premature to mandate it.

“But no one would listen,” she said. She said she was speaking out with this newspaper because “it was the only one willing to listen to the whole story.”

Answering questions by e-mail, Gostin said he was aware of Harper’s concerns. (DeAngelis sent word through an aide that she was unavailable for an interview.) He and DeAngelis were motivated to write the editorial, Gostin said, because of the states’ rush to mandate the vaccine before all of the safety and effectiveness data were collected and analyzed.

In place of mandates, Gostin’s and DeAngelis’ JAMA article encourages public education about HPV and routine, voluntary vaccination as part of a comprehensive package aimed at preventing the infection. It also suggests that a young girl’s assent to being vaccinated is as essential as her parents’ consent.

“As for work with the states, it is important to stress that the vaccine is an important public health innovation, but it is necessary to move carefully and deliberately, taking a science-based approach,” Gostin said in his e-mail. “I think that mandatory vaccination has its place, but should be a last resort only if it is clear that it would be safe, effective and in the public’s interest. That standard has not yet been met with HPV vaccination.”

Relieved

Tuesday, Harper was at a national conference of gynecologists in San Diego when she learned of the JAMA article. Acknowledging that she’d experienced some backlash because of her views – but declining to go into specifics – Harper said she felt relieved and excited that a publication as prestigious as JAMA was basically vindicating her and validating her views.

“I’m glad we are starting to get clarification in our communications, and in understanding the details of points that need to be considered for this vaccination,” Harper said. “The Associated Press has consistently miswritten, and consistently reported information that was not accurate about HPV. I have gone to them in New Hampshire several times for corrections, and they did correct a couple of things, but the last time they were unresponsive.”

So many people had questioned her because of her non-politically-correct stance on the issue that there were times when it looked like even her research was being doubted, she said, which made her position even more troubling. However, she stood behind her convictions.

“There is a lot of collegial pressure to conform to the message, and be united in the message,” she said. “But I think we are too early in our knowledge of information to have just one message.”

She reiterated that this is “a wonderful vaccine,” and that this is an exciting time for medicine in this area. Today, the New England Journal of Medicine (NEJM) is publishing some HPV articles that she co-authored, and that should help explain what this vaccine can and cannot do, she said.

“But there are things we still don’t know about this vaccine,” she said. “For one thing, it takes 129 women to be vaccinated to prevent one case of CIN 2/3 (a type of cervical cell dysplasia), and that is important for people to know. It will be interesting now that the JAMA article is out, and the NEJM articles about Gardasil are published, what the public understanding will be.”

For more on this story and to read past stories in the HPV vaccine series, go to http://kpcnews.com/online_features/hpv_vaccine/ on the KPC Media Group Web site.

<http://images.townnews.com/fwdailynews1.com/art/boxtr.gif>-----

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State adds HPV to list – a year ago

BY CINDY BEVINGTON
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http://www.fwdailynews1.com/content/articles/2009/04/07/online_features/hpv_vaccine/doc46222048f21eb214183243.jpg

Monica Boyer, president of the Indiana Childcare Association, said that daycare providers began receiving vaccine lists a year ago that included the human papilloma virus (HPV) vaccine on them - even before the vaccine was approved by the Centers for Disease Control's Advisory Committee on Immunization Practices. According to state officials the vaccine is NOT mandated, although it appears on the Indiana State Department of Health's Web site in a list of recommended vaccines. (Photo by Cindy Bevington)

WARSAW – While the Indiana General Assembly haggled this winter over whether to mandate a controversial vaccine for young girls, some Hoosier home childcare providers already thought there was a mandate for it – in the form of a check-off list of vaccines children must have to enter daycare.

Under Indiana law, licensed daycare providers must maintain and annually update documents verifying that all children under their care have received all state-mandated childhood vaccines.

The Indiana State Department of Health (ISDH) posts a vaccine

administration record of all vaccines recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP) for children and teens on its Web site. Available at www.n.gov/isdh/form/imm_forms.htm, the list includes the human papilloma virus (HPV) vaccine, which the ACIP approved last June for girls ages 9 to 26.

A Word document indicating when the list was created is dated March 31, 2006 – three months before the vaccine was approved. Monica Boyer, president of the Indiana Childcare Association, said she received a copy of this document in May of last year. The association is an advocacy group for childcare providers, with 300 members. As president, Boyer acts as a voice for both members of the association as well as non-members who may contact her about various concerns.

Boyer said that when she received the list last year with some materials she received at a training meeting, she already knew that Indiana might consider making the HPV vaccine mandatory this year, because she'd been following similar legislation in other states. She even called an Indiana state legislator, Jackie Walorski, R-Lakeville, to tell her about the list at the time, Boyer said.

"A typical provider who isn't up on this would look at that list and presume that it's mandated," Boyer said. "That's because providers are consumed with making sure that they do everything the way the state wants, and that the list is complete, with no questions asked."

Not mandated

While the list is part of the ISDH Web site, ISDH assistant director Steve Sellers said he didn't know that the HPV vaccine was on it.

"The Family and Social Services Administration (FSSA) is actually the one that licenses daycares, so they must have done this," Sellers said. "I don't know how they did it, or who approved it. But I can tell you that we only add something to the list after the legislature mandates it. You can't just add something to that list."

Over at the FSSA, Dennis Rosebrough, director of communications and media for that agency, said emphatically, "We do NOT require the HPV vaccine. That's a fact."

After conferring with Michelle Thomas from the Bureau of Child Care, Rosebrough said that the list with HPV on it is only of "recommended vaccines," not mandated ones and, besides, it is not a list given to daycare providers. "That list comes from the American Academy of Pediatrics and the American Academy of Family Physicians," Rosebrough said. "The actual list with mandated vaccines on it for providers is five pages long, and it does not have HPV on it," he said.

Back at the ISDH, Sellers explained that the health department's list is just a form, not a mandate. But he still didn't know who had

added HPV to the form before it was even approved by ACIP.

“Somebody must have put that on there in anticipation of it being approved,” Sellers said. Questioning why daycare providers were receiving copies of it, he said, “It’s not for daycare use.”

However, some providers have received this form, and because many providers try to follow state rules to the “T” without asking questions, Boyer said she knows that some providers probably have thought for a year that this was a vaccine they had to make sure their clients were getting.

“Now I think we need to go on a massive education move for all 3,000 providers in the state, and let them know it is NOT mandated,” Boyer said.

Who pays

At the start of the current General Assembly, Indiana state Sen. Connie Lawson, R-Danville, did introduce a bill that would have mandated the vaccination for all Hoosier 11- and 12-year-old girls by 2008. However, in the face of a vocal opposition from fellow legislators and the public, the bill was reduced to an education-only document that, if passed and signed by the governor, will require schools to inform parents that the vaccine is available.

Schools also will be required to ask parents whether their young daughters have been vaccinated, and report the answers to the state.

If the vaccine were to be mandated, however, county health departments might have trouble administering it to everyone who might come in for them, Sellers said.

“We get funding for vaccinations from the Vaccines for Children program, a federal entitlement program for children on Medicaid, with no insurance, or who are American Indian or Native Alaskan. That program provides unlimited funding and goes to health departments and private physicians,” Sellers said.

All children eligible for these programs can receive all mandated vaccinations through the public health department at no cost, Sellers said.

“Then, we have Federal Public Health Service 317 funding (PHS 317) that is discretionary for kids who are not eligible under Vaccines for Children, and we (the state) decide how that gets spent.”

Under PHS 317, the county public health departments requisition vaccines from the state, and the state rations them out according to how much money the state has to work with, Sellers said. Since the state doesn’t impose restrictions on who can get the vaccines from this source, it’s possible that not all vaccines would be available through a

health department, he explained.

In fact, this source has become so limited that the ISDH has asked the legislature to appropriate \$11 million a year from the proposed cigarette tax to supplement the program, he said.

“If we get that, we should be able to provide all the required vaccines, except possibly the new HPV because it’s extremely expensive,” Sellers said. “For us, it’s unbelievable – \$96 a dose even with federal contract prices, which means about \$300 since it’s given in three doses. And, when we requested that \$11 million, HPV wasn’t figured into it.”

Just since the ACIP approved the vaccine, well over 15,000 doses have been ordered by county health departments throughout the state, Sellers said. That includes 200 for Noble County; 170 for DeKalb; and 80 for Steuben. LaGrange County hasn’t ordered any HPV vaccines, he said.

Women In Government

Women In Government (WIG) is a national 501(c)(3) group of female legislators that has come under fire for spearheading mandatory HPV legislation, as well as children’s mental health laws in their home states. Several Indiana state women legislators are members of the organization, including Connie Lawson, who also authored SEA 529 in 2005, a state law that mandates mental health testing in all Indiana children ages 0 to 22.

WIG also has been criticized for its coziness with its long list of sponsors and its select “business council” members that include major pharmaceutical companies with high stakes in the legislation the women sponsor, such as Merck & Co., which manufactures the HPV vaccine Gardasil, and GlaxoSmithKline, which is planning to introduce its version of the vaccine, Cervarix.

Sponsor money, which WIG newsletters indicate is “unrestricted” – meaning they can use it for whatever purpose they see fit – goes to support educational programs, seminars and summits that WIG presents in various locations around the nation, mostly five-star hotels such as Westin and Ritz-Carlton. The events last from one to three days.

Sponsor money also goes to pay “full scholarships” for “all travel, hotel and meal costs” for women legislators to attend these programs in cities such as Atlanta, Washington D.C. and Las Vegas, according to information obtained by this newspaper from cached WIG Web pages. (WIG has redesigned its Web site and has taken down many pages that were available only a few months ago.)

For months while the HPV vaccine issue raged in states where WIG legislators had introduced mandatory vaccine laws, WIG president Susan Crosby – a former Indiana state legislator – has steadfastly refused to say how much money the group receives from its sponsors.

However, also from cached Web pages no longer available on the group's live Web site, this newspaper has discovered actual registration forms for single events.

For example, for the 6th Annual Western Regional Conference at the Ritz-Carlton at Lake Las Vegas in 2003, sponsors were invited to sign up for one of six levels of sponsorship, including:

- \$50,000 for a President's Circle donation; \$25,000 for a Governor's Circle designation; \$15,000 for a Senator's Circle; \$10,000 as a Delegate's Circle; \$5,000 for a Friend's Circle; and undisclosed amount as a Corporate Host/Meal Sponsor.

- In addition to these sponsorships, non-sponsors were told, "Companies interested in attending this conference, who are not sponsors, must pay a registration fee of \$2,000 per day, per person."

- Delegates and Friend's Circle sponsors received one complimentary registration. President's, Governor's and Senator's Circle sponsors received two complimentary registrations. "Any additional registrants from sponsoring companies are required to pay a \$1,000 per day registration fee."

Emotions erupt in HPV vaccine hearing

BY CINDY BEVINGTON
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http://www.fwdailynews1.com/content/articles/2009/04/07/online_features/hpv_vaccine/hpv00.jpg

State Rep. Tim N. Brown, R-Crawfordsville, is a physician as well as a legislator who serves on the Indiana House Committee on Public Health. Wednesday during a hearing on the Senate's HPV vaccine bill, Brown had plenty of questions for supporters of the bill. Using articles from professional medical publications, Brown sought to clarify misconceptions and confusion about HPV statistics.

INDIANAPOLIS – Choked-back tears, innuendoes of "impugnment" and testimony that included a flurry of statistics that were questioned from the floor of the Indiana House of Representatives were all highlights of a hearing held Wednesday by the Indiana House Committee on Public Health.

A string of medical professionals and members of the public, including private school officials and family advocacy groups, testified at the hearing on SB 327. The bill, which was approved by the committee Wednesday and now goes to the full House, was authored by state Sen.

Connie Lawson, R-Danville. It requires that schools send home to parents of all 11- and 12-year-old Indiana girls information about the human papilloma virus (HPV) and the existence of a vaccine for it.

The information would go home through the schools, and parents would be required to return a form checking one of three boxes: Yes, my daughter has been vaccinated against HPV; no, she hasn't; or, "prefer not to answer."

Schools would keep the information in the child's medical records and report a total count of the answers to these questions to the Indiana State Department of Health. No names would be attached to the report.

The bill is a watered-down version from Lawson's original proposal, which would have required that all 11- and 12-year-old Indiana girls receive the HPV vaccine. The Senate approved the modified bill after a flurry of protesters voiced their concerns that the state was going too far in mandating a vaccine for a condition that is not generally spread by casual contact.

The vaccine, manufactured by Merck & Co., protects against two of 18 HPVs that can cause up to 70 percent of cervical cancers. Scientists have identified about 100 different HPVs. The vaccine does not protect against those that cause the other 30 percent of cervical cancers.

Wednesday, Lawson introduced the bill as one that "will empower parents" in helping them make decisions about their daughters' health care. As a member of the state's cervical cancer task force, Lawson said it is important for people to understand what having a vaccine like this means for the 80 percent of females who have HPV by the time they are age 15.

The vaccine is safe and approved with no thimerosal and no mercury in it, she said. Pointing out that it had been approved for 9- to 26-year-old females by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP) last summer, she stressed that the bill does not take away parents' rights to decide whether to vaccinate their daughters.

Lawson cited a litany of statistics and figures about the prevalence of cervical cancer and what it costs in lives and money. Annually, 3,700 women die in the U.S. from cervical cancer, she said.

Dodge raises questions

After Lawson's introduction of the bill, Rep. Dick Dodge, R-Pleasant Lake, said he was still trying to decide what the committee wanted to do with this bill. Asking for clarifications on the forms schools would send home to parents, he said, "Who's going to keep track of this over five years, 10 years? Where will the data come from?"

When Lawson replied that schools would be responsible for the data, Dodge said, "So how do we know if (all the record-keeping) is doing any good?"

"That's up to the State Department of Health," Lawson replied.

Concerns from the public included protests from private Christian schools that believe SB 327 violates their constitutional right to separation of church and state.

Family advocacy groups, such as Advance Indiana and the Indiana Eagle Forum, also spoke, reading from Merck's vaccine inserts and citing reports from the Vaccine Adverse Event Reporting System (VAERS).

VAERS tracks bad side effects of vaccines around the country.

Just since June – when the vaccine was approved – VAERS has received 385 reports on this vaccine, said Crystal Kristenluidhardt, of the Indiana Eagle Forum. A Christian-based advocacy group, the Forum has heard that two-thirds of that number required additional medical treatment, including some that had bad reactions to the vaccine when they received it in combination with other childhood vaccines.

Merck has publicly said the HPV vaccine was tested for safety with only one other of the 18 childhood immunizations – meningitis.

"Also, Merck's insert says the duration of immunity (of the HPV vaccine) is not known," Kristenluidhardt said. "And, the insert also says it hasn't been tested for its own ability to cause cancer. There are so many things that are unknown."

Pointing out that the American Association of Physicians and Surgeons has come out strongly against mandating this vaccine, Kristenluidhardt said that information about HPV and the vaccine should come through personal physicians, not schools.

Testimony went on for nearly three hours, with both proponents and opponents to mandating the vaccine and/or the bill as it was presented speaking. Several times throughout the meeting health committee members alluded to e-mails they'd received or other comments they'd heard from both the public and each other that "impugned" their integrity.

At other points, speakers questioned why the bill was being debated so hotly, as if the vaccine were being mandated, when it is now only an information mandate.

As the minutes and hours passed, speakers' emotions continued to build. Choking back tears, state Rep. Cleo Duncan, R-Greensburg, stood up near the end of the meeting and chastised people who questioned the bill or the vaccine.

"I support this bill with all my heart so one day we can eliminate

cervical cancer. I am so disappointed, so disappointed,” Duncan said. “This is the first vaccination we have ever had that will kill the virus that will cause a cancer.”

Clearing up the facts

While no one disputed Duncan’s belief that the vaccine kills the virus – numerous papers by various research groups around the world say that it can only prevent the virus, not kill it – one committee member, state Rep. Tim N. Brown, insisted on fighting numbers with facts.

A physician, Brown came armed with a laptop connected to the Internet and a sheaf of professional data on HPV and the vaccine.

Brown directed his first request for clarification of facts to Lawson, who had said earlier that cervical cancer “is second only to breast cancer as the leading cause of death in females.”

Actually, he pointed out, in the U.S. “it isn’t even in the top 10.” (It is in the top 10 in the world, because of Third World countries where women do not have access to Pap smears, which detect abnormal cells that can lead to cervical cancer.)

“Have you looked at the latest statistics?” Brown asked. “Lung cancer is No. 1 in women. Breast cancer is No. 2.”

Brown questioned whether the cervical cancer numbers in the U.S. validated the state spending so much money on this issue. With the flu vaccine, he said, “you only have to vaccinate three people” to make it cost-effective to save one person. With the HPV vaccine, he said, “you would have to treat 300 to make a difference for one.”

“Is that the public policy statement you’re trying to make?” Brown asked Lawson.

Lawson replied by repeating that 80 percent of females acquire HPV by the time they are 15. She added that Pap smears do help to prevent cervical cancer but, still, women die from the cancer.

“So what’s the natural history of HPV?” Brown shot back, adding that “90 percent of women clear the infection themselves, without any treatment.”

As the committee neared its time to vote on the bill, Brown also quizzed doctors from Indiana University, asking them to clarify statistics in their testimony. He also stressed that he is not anti-vaccine, and that he had offered the HPV vaccine to his four daughters, although they had declined to take it at this time.

Finally, committee chairman Rep. Charlie Brown, R-Gary, called for a roll call vote.

Before his vote, Tim Brown said, "(This vaccine) doesn't cure cancer. And, it's not going to do a damn thing about cost-shifting health disparity in this state," (referring to previous testimony about racial disparities in Indiana health care).

"I know there's a lot of emotion tied up in this. I am for vaccines. And in this present form, I can accept this bill."

The bill passed 9-2, and will move to the full House for consideration, possibly as early as this week.

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Researcher adds to vaccine comments

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http://www.fwdailynews1.com/content/articles/2009/04/07/online_features/hpv_vaccine/hpv01.jpg

Harper

A researcher who spent 20 years working on the vaccine for human papilloma virus, and who was interviewed by this newspaper for a story last week, has added to her comments, seeking to clarify her support of the vaccine while opposing states mandating it for young girls.

Diane Harper 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. She has gone on the record as saying that she believes it is "silly to mandate vaccination of 11- to 12-year-old girls" for HPV.

She also said that doing so "is a great big public health experiment."

This week she hopes to clarify those statements with added information that can help parents decide whether the vaccine is a choice for their young daughters.

Although she is adamant that it is wrong for states to mandate the vaccine for younger girls, she does believe that there is a difference between offering the vaccine to 11- and 12-year-olds as an available option and mandating it as a prerequisite to school enrollment.

"It is the mandate I am opposed to," Harper said. "For those parents and children who want the vaccine, it is safe - as we know from the bridging studies. We still don't know if it is effective for more than five

years, though."

Making the choice optional comes with some caveats, Harper added.

One is that girls who receive the vaccine need to remember that Pap testing must begin by age 21, or sooner, and that they must keep an ear out for whether the vaccine needs a booster when they turn 21. Otherwise, the money spent on the initial vaccine is wasted, Harper said.

According to Harper, the reasons why it is silly to mandate the vaccine are:

- Mandates mean that money is taken from other necessary programs to cover the vaccine's costs;
- That choice and free will of the persons getting the vaccine are withdrawn;
- That the priority of each person's health issues is no longer considered; and,
- "Given that we don't know how long the vaccine will last until Gardasil (the name of the HPV vaccine developed by Merck & Co.) needs a booster, it makes no sense to mandate it," Harper said.

"It is a public health experiment because we don't know what will happen to 11- and 12-year-old girls in 10 years or 15 years from now," Harper added. "That is why they have to be told to stay in Pap screening programs, and to listen for more news about when boosters may be needed.

"The experiment part of the public health experiment is the mandating of the vaccine for all girls. It is an experiment because we do not know how long the vaccine will last; we do know that a small number of young girls will already be exposed to a cancer-causing HPV type at the time of their first HPV vaccine, a condition the vaccine will not cure; and we do not know whether these young girls will continue to pursue Pap testing at regular intervals throughout their adult life."

Harper also said last week that, although major media are hyping HPV as a sexually-transmitted disease, HPV is contracted through skin-to-skin contact that most often is through sexual contact, but does not have to be, she said. That means even babies or toddlers have been shown to be positive for cancer-causing HPV types.

In fact, all through their lifetimes, 75 percent or more of girls and women may test positive for HPV at some points in their lives. But, in adolescents, in 75 to 90 percent of those cases, the virus clears up on its own within eight to 12 months, including those that may be cancer-causing. That is why long-term protection is important to achieving long-term benefits of cancer prevention, she explained.

Of the 10 to 25 percent of HPV infections that don't clear up on their own, the viruses can change to cervical cancer within five to 15 years, she said.

Then, if these viruses cause abnormal cell growth on a girl's/woman's cervix, having regular Pap tests will help a woman discover, and treat, the abnormality before it becomes cancer.

"Historically, Pap testing has been able to reduce the incidence of cervical cancer by 70 to 75 percent," Harper explained. But, with the HPV vaccination and appropriate boosters, along with regular Pap testing, that number can increase to more than 95 percent, she said.

An important thing to remember is that Gardasil - and GlaxoSmithKline's upcoming HPV vaccine, Cervarix - only protect against two cancer-causing HPV viruses.

They do not protect against the 13 other types of HPV that cause about 30 percent of cervical cancers, Harper explained.

"There is no one age at which all females are negative for all cancer-causing HPV types," Harper said. "Even with vaccinating 11- to 12-year-olds, there will be some girls who test positive for the vaccine-related types," she said. "For example, not all 3-year-old girls are negative for HPV 16 (one of the cancer-causing viruses against which Gardasil protects)."

The reason it is important to understand who HPV affects and how it is contracted is because, if a girl is positive for HPV when she receives the vaccination, the vaccine will not cure her HPV, nor will it protect her from that type in the future, according to clinical data, Harper said.

But the only way to know if a girl/woman is positive for HPV is through vaginal swab testing, and it is inappropriate to do the swab on a young girl, Harper said.

However, since the prevalence of cancer-causing HPV types starts to increase at around 15 years of age, vaccinating before 15 will be effective in most people," she said - assuming that the girl gets all her follow-up boosters.

Trials from Cervarix show that the vaccine has an excellent immune response for girls and women from ages 9 to 55, she said.

The bottom line, then, is:

- Even with vaccinating all 11- to 12-year-olds who grow up to continue having routine cervical cancer screening tests, the U.S. will still have 3,300 new cervical cancer cases every year because they are caused by the other 13 cancer-causing HPV types;

- HPV vaccination without regular Pap testing afterward may serve to increase the incidence of cervical cancer because of the other 13 types not being caught through a Pap test early enough to catch them in their precancerous stages.

For the up to 10 percent of young girls - or any age woman - who are infected with HPV 16 or 18 at the time of their first vaccine, the vaccine will not clear their virus.

The most important thing for girls/women who are vaccinated to remember is to start and continue with their Pap tests as medically recommended because the testing detects abnormalities caused by any HPV type.

"So those who were positive for a cancer-causing HPV type at the time of vaccination have the Pap screening safety net, which is very effective at detecting early changes that are completely curable," Harper said.

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HPV vaccine stories have come full circle

By Cindy Bevington

The past few weeks have been a whirlwind of interviews with congressmen, legislators, researchers and local readers who have been affected by, or have an interest in, vaccines for children.

While a series I did on autism vaccines drew comments by phone, e-mail and online, it was the HPV vaccine stories that traveled around the world and back via the Internet, being posted on dozens of Web sites and ultimately resulting in Fox News coming to Kendallville to interview me about how I came to write the HPV vaccine stories.

To be honest, I am quite bewildered at the amount of attention the HPV stories have attracted. I've had stories go nationwide and worldwide. But I've never seen a reaction like this one - unless you count the children's mental health stories I did last fall, which garnered dozens of e-mails from all over the world.

The interesting thing about the HPV stories is that, were it not for the mental health stories, the HPV stories would not have been as in-depth as they were - which leads me around to the question everybody wants answered, and that is: How did I find the HPV vaccine researcher, who made my stories the scoop that they were?

The answer is simple, and the credit goes to two sources: first, to an area ob/gyn who tipped me off a year ago that the HPV vaccine was coming, and that it would be very controversial (in case I should want

to do a story on it); and second, because I was researching Women In Government (WIG) in connection with the stories I was doing last fall on mandatory mental health testing in children.

While working on the mental health stories, I spent a lot of time on Women In Government's Web site, studying what they do and who their sponsors are. I downloaded and printed out hundreds of pages from their site. The pages included agendas from seminars, as well as PowerPoint presentations by guests who spoke at the seminars. (The reason I was on the WIG Web site was because many WIG members, including some in Indiana, have been active in legislating children's mental health laws in their home states.)

As I studied WIG's activities, I noticed the HPV researcher's name, Diane Harper, popping up on pages detailing the seminars WIG has sponsored. I also found numerous documents about WIG's advocacy for eradicating cervical cancer, and their support for the HPV vaccine.

So, knowing that this topic was predicted to be a barn-burner, I kept all the WIG information about HPV and Harper. Then, a little over a week ago as I prepared to write another story on WIG's support for the HPV vaccine, I decided to give Harper a call and ask her personally why she advocated mandating the vaccine for younger girls.

Imagine my astonishment when she replied that she did NOT support the mandates!

From there, we had a nice, long conversation by phone, followed up by e-mails and a couple more phone calls. And there you have the rest of the story, and an explanation of how I came to have an interview that nobody else seems to have managed to acquire.

CINDY BEVINGTON is a special assignment editor for KPC Media Group.

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Researcher blasts HPV marketing

BY CINDY BEVINGTON
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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 zealotry 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.

The rest of the story

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."

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Legislators misguided about vaccine, researcher says

By Cindy Bevington

LEBANON, N.H. – Diane Harper, a scientist and physician who has been working on developing a vaccine for HPV for 20 years – both Merck & Co. and GlaxoSmithKline have helped fund her research – has been a guest speaker at three Women In Government events. Each was a symposium where the prevention and elimination of cervical cancer has been either the focus of the event or a topic at an event.

"All were more than a year ago, and they haven't invited me back, which is OK," Harper said.

Women In Government is a 501(c)(3) group comprised of women state and federal legislators. The group sponsors numerous events across the country, with the goal of educating legislators on hot topics that could have impact in their work.

WIG is a good group, Harper said. They have good intentions, she said. But, they are misguided in their mission to mandate this vaccine for little girls in their home states. She's tried to tell numerous

people that this is wrong, including major media, Harper said, but nobody wants to listen.

A fair question, then, would be what's the rush to mandate? And, if she's tried to tell them this isn't the thing to do, why are they so head-strong in going ahead with the mandates?

The answer, Harper believes, lies with drug company lobbyists who fill WIG's sponsor lists and sit on the organization's policy-making boards.

The HPV vaccine lobbyists are representatives and executives of Merck, Glaxo and Digene, the manufacturer of the test for HPV. All three companies at some point in the past few years have sat on WIG's Business Council, or are still there.

They all have been listed as sponsors for the organization for several years, too. Sponsors pay an undisclosed amount of money to support Women In Government and its goals.

The Business Council, according to a cached WIG 2006 Web page, is a "small, select group of industry leaders" who "play an integral role in planning for future growth... and (who identify) funding opportunities for Women In Government."

In 2006, Deborah Allen, Merck Vaccine Division's executive director of health policy and external affairs, had a seat on this board. Merck isn't listed as a 2007 Business Council member, but GlaxoSmithKline is.

"I think the coziness they have with the lobbyists (for this vaccine) has been what's affecting them to push for the mandates," Harper said.

"The Merck employee who is the lobbyist on this WIG panel is very, very good at her job. What these women are hearing is the excitement of, 'We have a vaccine, and it's effective.'

"And when you get people excited about something like that, the first thing they think is, 'Well, let's get rid of (cervical cancer).'

This lobbyist has been able to raise the excitement and initiatives of these legislators to do what they're doing.

"Now their motions are already filed, and if they back out now, they as legislators are going to look really silly if they say, 'This isn't what should be,' because there has to be some face-saving value for them. So they're just continuing on."

The women legislators who have been pushing HPV vaccine mandates for young girls across the country believe they are doing the right thing, Harper said. In their hearts they think their actions will have a positive impact on these girls' future cervical health. And, because their intentions are good and honest, they shouldn't be discredited

personally or individually for not realizing that their efforts were only helping Merck, she said.

“They have done what they believed was right,” Harper said. “They just didn’t realize the advantage was to Merck’s benefit, not little girls’.”

After spending two decades researching and developing this vaccine, Harper is not happy with the way Merck has marketed it.

“Both companies – Merck and GlaxoSmithKline – have very good vaccines,” she said. “But I’m disappointed in the marketing. Merck has not said anything incorrect, but the way they are marketing it makes it so people only hear, ‘This is a vaccine that protects me from all cervical cancer. ... And that’s wrong. That’s just wrong.’”

The mis-marketed message has spread through major media outlets, who insist on saying this vaccine prevents cancer, Harper said. “What they’re saying is true, but it’s not all true. I have said to them that vaccinated women and women who still get pap smears, some of them will still get cervical cancer.

“That’s the semantics. And then you have the lobbyists, and what the women hear is, ‘This vaccine will eliminate cancer – but it won’t. If I were to do the marketing I would say this is a vaccine that prevents the types of HPV responsible for half of high-grade lesions for about 70 percent of cancers – not 100 percent.

“It is effective against those 70 percent of those types. That’s the true message.”

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HPV vaccine mandate criticized

BY CINDY BEVINGTON OLMSTEAD
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Angola residents Chad and Wanda Emrick, parents of three girls between the ages of 1 and 13, are not hesitant to give their opinion of the state of Indiana's idea to mandate that all girls have the HPV vaccine by the time they turn 12.

"This isn't the state's business," Chad Emrick said. "Besides, it's not

even been out all that long. What do they know about it? How do they know it doesn't have side effects yet? No way will our girls have it."

Wanda Emrick is just as insistent. "They don't know enough about this," she said. "No way. Just no way."

State Sen. Connie Lawson, R-Danville, authored Indiana Senate Bill 327. She plans a public hearing on it Feb. 14 at the Statehouse. The proposed law requires all female students entering grade 6, beginning in the 2008-2009 school year, to be immunized against human papilloma virus (HPV).

HPV is a virus that occurs in about 100 forms, 17 of which have been directly linked to causing cervical cancer. Two pharmaceutical companies, Merck & Co. and GlaxoSmithKline, have been working on a vaccine that would prevent four of these viruses, two that cause cancer and two that cause genital warts.

Merck recently introduced its vaccine, which was approved by the Federal Drug Administration in June.

And, unlike the Emricks, Lawson is adamant that young girls in Indiana be given every chance to have this vaccine. "It is 100 percent effective against 70 percent of viruses causing cancer," Lawson said. "I do believe if this law is passed, it should be a partnership between parents and doctors. But one reason you pick girls in school for this law is because that's the one place where all girls are treated equally, and where you can give everybody a chance to make the decision whether to have the vaccine."

It could be that the state could offer encouragement or help in obtaining the vaccines without a law, a law would facilitate the ease with which that could happen, Lawson said.

The proposed law, if passed, also requires schools to keep records of who has complied with the law, and who has not. Its original form did not include a specific opt-out clause for parents who don't want to immunize their girls at this age for HPV, but Lawson indicated in a phone interview last week that she is looking at changing the wording to make the opt-out more clear.

The original bill has an opt-out already, Lawson explained, because it is current language in state law regarding childhood vaccinations. "So it's not necessary to be in the bills," she said. "It is optional for parents. But I've been listening to parents' concerns, and I am looking for a way to restate that opt-out for this bill."

Medical reviewers on the federal Advisory Committee on Immunization Practices, were reported in the New England Journal of Medicine as saying Merck's research data was "absolutely stunning" (Jan. 19) with "close to 100 percent efficacy."

But the Journal also quoted Jon Abramson, chairman of the review committee, as saying, "The problem is that we don't know how long the protection will last." Abramson also is chairman of the department of pediatrics at Wake Forest University. The ACIP in June endorsed the use of Merck's drug, Gardasil, in adolescent girls and young women, and voted to add it to the Centers for Disease Control's Vaccines for Children program, which uses federal funds to vaccinate children who are Medicaid-eligible, uninsured, underinsured or Native American.

Merck notes on its Web site that, "as with any vaccine," Gardasil may not result in protection in all recipients. Other medical sources have reported that Merck's research results are close to 100 percent effective – the American College of Pediatrics, for example, cites "95 percent efficacy."

In preliminary reports, GlaxoSmithKline touts its vaccine to be 100 percent effective, but it hasn't finished the review process, and therefore isn't available commercially. Also, according to information on Glaxo's Web site, its primary study didn't include girls younger than 15.

The vaccine costs about \$120 and is administered in three sessions. In an informal telephone poll, this newspaper discovered that most area insurers already have decided to cover that cost. However, private insurers, such as Parkview Signature Care, would leave it up to employers in the group plan to decide whether the shots are covered, according to Lisa Schaumbacher, who spoke on behalf of Signature Care.

"With a PPO network, each employer defines their own plan," she explained. "That's why it's up to them. I can tell you that Parkview Health employees are covered, though."

Lawson's bill earmarks \$2.67 million to help girls who fall through the no-insurance or underinsured funding cracks. "I'm working with the fiscal people right now to figure it out," she said. "A lot of it depends on the (proposed increase of the) cigarette tax and the governor's proposed health plan."

In the meantime, Lawson is working feverishly to enlist support for the law in both houses.

"I do believe in this," she said. "Our country has spent billions and billions and billions of dollars on cancer research, and to me it benefits us on fiscal and public policy to prevent this type of cancer, if nothing else, to help prevent the treatment of, and the painful procedures that you go through to prevent the virus from turning into cervical cancer."

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HPV vaccine divides parents, legislators, medical community

BY CINDY BEVINGTON OLMSTEAD
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Until the Food and Drug Administration approved a groundbreaking vaccine for human papillomavirus (HPV) in June, the virus was not headline news.

But, now, TV commercials touting the necessity of vaccinating young women against HPV - as well as little girls as early as age 9 - frequent the airwaves. Talk radio and newspaper articles and commentary argue the vaccine's merits.

In some state legislatures, including Indiana's General Assembly, where bills are being introduced to mandate the vaccine in school girls, longtime colleagues are finding themselves on opposite sides.

And misconceptions about what HPV is and is not, and what the vaccine can and cannot do abound.

So what is true and what isn't? And what is HPV? This series of stories is meant to look at both sides of the issue and help readers understand these questions.

The virus

HPV is the acronym for human papillomavirus, a virus that both males and females can contract and, in turn, infect others. It has over 100 forms, 17 of which are known to sometimes cause cervical cancer in some women. It also can cause warts in many areas of the body on both men and women, including the genitals.

HPV is such a common virus that, according to the American Cancer Society, 6 million people in the U.S. contract it every year, almost half of that number between the ages of 15 and 25. And, the society says, about three-fourths of persons who have ever had sex will contract HPV at some point in their lives.

According to the National Cancer Institute, over 30 types of HPV can be passed through sexual contact. There is no cure for HPV. However, most HPV infections occur without any symptoms and go away without any treatment.

HPV infections can persist for years but, still, they don't always cause cell abnormalities that could lead to cancer.

When they do cause pre-cancerous cell changes in a woman's cervix, it often can take as long as 20 years - or more - to develop into cervical cancer. It also is known that just two types of HPV cause 70 percent of cervical cancer cases, and that two other types cause 90 percent of genital warts in both men and women.

In the United States, where a high number of women regularly have a Pap test (which screens for abnormal cell changes, or "dysplasia" of the cervix) the number of women diagnosed with cervical cancer has been dropping steadily since the Pap test was introduced 50 years ago.

One reason for this is because the Pap test can identify questionable cells on a woman's cervix, which then allows a woman and her doctor to decide on a course of treatment before the dysplasia develops into cancer.

Today in the U.S., the medical community agrees that about 10,000 to 11,000 women annually are diagnosed with cervical cancer. This year, it is estimated that 3,700 to 3,900 will die from it. More than half of these cases occur in women who have never, or rarely, had a Pap test, according to the New England Journal of Medicine (March 16, 2006).

In Indiana this year, the American Cancer Society estimates that 240 women will be diagnosed with uterine or cervical cancer. The numbers are lumped together because they are so low for both diseases.

In comparison, the society estimates that 3,500 Indiana women will be diagnosed with breast cancer this year.

Worldwide, however, cervical cancer numbers are staggering - 493,000 cases diagnosed in 2005 - with undeveloped countries contributing heavily to the figure, making it the world's second-leading cause of cancer in women. The Pap test in the U.S. is the single factor that experts attribute to this country's comparatively low cervical cancer numbers. Depending on which source is citing it, cervical cancer is between 11th and 15th as a cause of death in women in the U.S.

But, while the Pap test has been a critical tool in heading off cervical cancer, it is not foolproof, and it can report a false-negative. It also does not test for HPV, which has a test of its own, and which must be administered separately or in conjunction with the Pap test.

The vaccine

Two pharmaceutical companies - Merck and GlaxoSmithKline - have been developing and researching vaccines for several years for the types of HPV that are responsible for most cervical cancer cases. Merck is slightly ahead of the game, with its vaccine being approved by the FDA in an accelerated process in June. According to the FDA, this vaccine is 95 to 100 percent effective against four types of HPV, two of which cause cancer, and two that cause genital warts.

Since the FDA's approval, Merck has launched an aggressive marketing campaign for the vaccine, with legislators across the nation and other women's health advocates joining the vaccinate-now bandwagon.

According to information posted on various Merck Web sites (Merck did not return repeated calls for an interview) the company conducted research in four studies over a 3 1/2 year period on five continents in 33 countries.

The company also says that its clinical development program for its vaccine, Gardasil, included girls and women ages 9 to 26 and boys ages 9 to 15. According to the American College of Pediatricians, only 1,121 girls between 9 and 15 were included in this study; of that number, just 250 were 9-year-olds. The ACP reports that Merck included 20,541 women ages 16 to 26 in the study.

In reporting the vaccine's effectiveness, Merck says in its own report that some of the company's conclusions were "bridged" or "inferred" to the younger children from results in the older group when an evaluation was "not feasible" in the younger ones.

While Merck says it included boys in its trials, it is marketing the vaccine only to females, and the FDA has approved it only for females ages 9 to 26.

Gardasil is administered as three separate injections over a six-month period. The cost of each shot is \$120.

On its Gardasil Web site, Merck adds what it calls "important information" about Gardasil: "(It) may not fully protect everyone and does not prevent all types of cervical cancer, so it is important to continue regular cervical cancer screenings (Pap tests)."

Misconceptions

Imagine that there was a vaccine for a form of cancer that 10,000 women in the U.S. are diagnosed with each year, and which kills 4,000 annually. Now imagine that someone wouldn't want their daughter to get it. - Introduction to a blog on the new HPV vaccine at <http://blogs.chron.com/bluebayou>.

The message from Merck's paperwork is clear: While it's a remarkable drug with a 95 to 100 percent reported effectiveness, it still does not protect against all cancers, and even if a girl has been vaccinated for HPV, she still needs regular Pap and cervical cancer screenings all her life.

Yet, blogs like this one, as well as other community Web sites and even media reports and advertising, show that the public's understanding of Merck's new drug is often murky, and sometimes downright wrong. For example, an Australian news story posted on the Web announcing that Australia had refused to provide federal funding for the vaccine, calls

it a cancer vaccine - although in reality it is not a vaccine for cancer; it is a vaccine for a virus that can lead to cancer.

Later in the same story, the writer does say the vaccine is for HPV, "a precursor of cervical cancer," but does not clarify the difference.

Another Web story at www.birth.com includes reader comments that show they don't understand that being vaccinated does not release them from Pap tests - another misconception that seems to proliferate on the Web. On the other hand, the same posts show a hesitancy to administer the vaccine to young girls.

On the news, TV or radio, the statistics are inconsistent, with reporters and pundits using different numbers for effectiveness of the vaccine, for numbers of girls used in the studies - anywhere from a few thousand to a few hundred thousand - and for the cancer numbers themselves.

Even literature distributed at local Wal-Marts last weekend draws the eyes to the red-lettered words, "CERVICAL CANCER," "VACCINE" and "PREVENT IT," while the in-between words "could help" are printed in lighter letters that in some instances could cause an undiscerning eye to slide by them, and subsequently lead the reader to misinterpret what the vaccine does and does not do.

Controversy abounds

Last year a northeast Indiana gynecologist talked with this newspaper about an upcoming vaccine for girls that he said was going to be controversial. He invited this newspaper to come back for comments when the vaccine was introduced. However, last week when he was contacted, he refused to allow his name to be published, saying that the issue was so controversial - even among the medical community - that he didn't want to become part of the fray.

Although the American College of Obstetricians and Gynecologists has taken the official public position of supporting the vaccine's use with 11- and 12-year-old females, behind the scenes the doctors are not united in their opinion, this ob-gyn said. In fact, at a national meeting in Chicago he attended, the doctors were arguing over whether the vaccine has been out long enough to trust its effectiveness and safety on young girls, this doctor said.

"I am not prescribing this vaccine right now," the ob-gyn said. "The fact is, in all my practice I've only seen two of these cancers. Besides, this vaccine has only been out since June - some of us are wondering, will this be like the hormone therapy they told us to push, and then told us to pull?"

"What has happened with this vaccine," he said, "is that marketing,

advertising and technology are getting ahead of caution."

'I am giving it'

In Topeka, ob-gyn John Egli is enthusiastic about the vaccine's promise.

"Most of us feel if you can avoid HPV infection and alleviate the risk of cancer, we should use this vaccine," Egli said. "I am giving it already, and if I had a daughter at a young age, I'd encourage her to have it too."

Egli pointed out that precursors of cervical cancer are treatable in outpatient/in-office therapy. He also noted that statistics show that, from the initial contact with HPV, the actual cancer may not come along for 20 years.

"That's why we do the Pap," he said. "But it also means that, even if you've been monogamous and happily married for 15 or 20 years, it could show up at the age of 40 with something related to what you did as a teenager. Or, you could have been a virgin, and your husband was carrying HPV, and gives it to you. By giving this vaccine to girls now, we're trying to avoid that cancer."

He isn't pushing the vaccine, Egli said. "But I am talking to parents and girls about it. And, it's responsible on the part of the parents to talk to their girls at 12 or 13 about this. You can live in your dream world, and say you're going to make sure they don't have sex, but that's not the reality."

For 16-year-old Dani Lemke-Barrand, reality is the crux of this issue. Dani is the daughter of KPC Media Group reporter Jamie Lemke-Barrand and photographer Andy Barrand. She was chosen for the interview because of the sensitive nature of this topic.

Dani, a cheerleader, wants to study medicine when she graduates, possibly going into obstetrics and gynecology or neonatology.

"I've heard on the news that Indiana wants to give this to third-graders," Dani said. "And I know that it's mostly a sexually transmitted disease that's linked to cervical cancer. I also know that it's getting to be really common."

Dani said she thinks third grade is a little too young for mandatory vaccinations. But sixth or seventh grades do make sense, she said. (Indiana's proposed law specifies sixth grade.)

She and her mom and dad have frank talks about dating and sex, Dani said. "But a lot of my friends are scared to talk to their parents about things like this."

The down side of the whole issue is that, whether parents want to admit it or not, teenagers are having sex at young ages, she said.

"It's not necessarily what you might call being more sexually aware, but something that everybody does," she said. "The average age for a first date is junior high, about seventh or eighth grade.

"And sex, with some, it's just something everybody does on a date. Everybody says 'abstinence,' but the fact is teenagers do have sex, and you have to be prepared. Even if you're not sexually active, this vaccine is one way to protect yourself. My mom and I both feel this is safe to take."

Pediatricians speak

While the American College of Pediatricians (ACP) is not taking a stand against the vaccines, it has taken the position that HPV manufacturers establish registries of all girls who are inoculated, that long-term data be collected on those girls, and that future research address the vaccine in males.

The ACP position statement, posted on its Web site at www.acpeds.org, also says that all vaccine recipients should be fully informed as to "the current limits of knowledge regarding the vaccine's potency and duration of protection."

The college's statement also says, "Because the duration of protection offered by HPV vaccination is uncertain, these adolescents should be offered the option of deferring immunization until the age of initiation of sexual intercourse."

In a telephone interview, the president of ACP, Dr. Joseph R. Zanga, explained that the ACP does not oppose the use of the vaccine. "We are just asking people to be attentive to the details, and to be cautious," he said.

The reason for caution, he said, is because the studies on young girls have been done in such a short period of time with "very small numbers."

"They are numbers so small that the validity of those studies has to be called into question," Zanga said. "That's because you can't make scientific decisions if you don't have a critical mass of subjects. That means with numbers like these, the ones in this study, the results you see might be chance that is incidental to the vaccine - not something that happened by the use of it."

Zanga also stressed that the public needs to understand that the vaccine does not protect a woman from all cervical cancers, and that she still needs Pap smears. He fears that one fall-out from the vaccine will be a false sense of security that encourages women to believe they're now protected against all cancer, and that as a result fewer women will go for their annual screenings.

But, he added, an even more important caution for the public to be aware of is that the vaccine possibly could prove not to be effective long-term.

"Over the last 20 years or more, we have been promised vaccines that will provide lifetime protection, for example, measles," he said. "But we found that the measles vaccine provided protection for only 10 or 12 years, and then we had to start giving boosters. Now we're finding that even that isn't enough, and we're having to recommend further doses in late adolescence or adulthood.

"With the HPV vaccine, we don't know how long-lived it will be. That's one reason we're recommending a vaccine registry."

As far as legislatively mandating the vaccine, Zanga believes that choice should be left up to parents and teens who are old enough to make this decision for themselves, not government.

"Children are very often used as guinea pigs with social experiments like this, with leading health organizations behind it," Zanga said. "But all we are doing is putting our self-imposed mandates and adult wants over children's needs. These decisions should be made by individuals.

"Actually, this sets up an ideal scenario for frank discussion about sexuality between parents and their children, and that's what we would like to see happen, rather than these blanket government fiats."

Facts about Gardasil, the HPV vaccine

According to the developer of the new HPV vaccine, Merck & Co., the vaccine does not protect against all types of HPV. Other important information includes:

- The vaccine does help protect against two HPVs that cause 70 percent of cervical cancers and two that cause 90 percent of genital warts.
- As with all vaccines, it may not fully protect everyone who gets the vaccine.
- It also will not protect against HPV types to which you may already have been exposed.
- It also does not protect you against other diseases not caused by HPV.
- Vaccination does not substitute for routine cervical cancer screening that includes regular Pap tests.

These extra caveats are from a slide show, "Educate the Educators," that was produced by the American Society for Colposcopy and Cervical Pathology:

- The vaccines will not be able to protect everyone.
- To be fully effective, they must be administered before the onset of sexual activity.
- The protection offered by the vaccines is incomplete - they don't cover 30 percent of the other HPVs that also can cause cervical cancer.
- There are a lot of unknowns - for example, how long-lasting the vaccines are, and whether a booster will be needed.
- Males not only can contract HPV and transmit it, but also can get some types of cancer from it.
- Even with the vaccine, all women still need annual HPV and Pap tests.

Facts about HPV and cervical cancer

According to the Centers for Public Health Research and Evaluation:

- Infection with genital types of HPV is very common in sexually active populations. In the U.S. it is estimated that 20 million people have HPV at any given time, and that 6.2 million new cases of HPV infections are diagnosed annually, making it the most common sexually transmitted infection.
- HPV is spread through skin-to-skin contact.
- Most HPV infections clear without any medical intervention within two years of infection.
- Cervical cancer is an uncommon consequence of HPV infection in women, especially if they are screened regularly with Pap tests, and have appropriate follow-up for abnormalities.
- There is no cure for HPV.
- Abstaining from sexual activity is the most effective way to prevent transmission of HPV.

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Who is Women in Government?

By Cindy Bevington Olmstead
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Indiana Sen. Connie Lawson, R-Danville, has introduced a bill that would require all girls to be vaccinated against human papilloma virus by the sixth grade.

She also successfully authored another bill pertaining to children that became law (SEA 529) and which has since been the subject of controversy around the state and has drawn letters to the editor of this newspaper from across the nation. That section of the law that is most controversial is the Children's Social, Emotional and Behavioral Health Plan.

Lawson is the chair of the board of directors of Women in Government, a not-for-profit, by-partisan national organization of women legislators. On its Web site at womeningovernment.org, the group describes its purpose as a vehicle to provide to its members leadership opportunities, networking, expert forums, and educational resources to address and resolve complex public policy issues.

It has a membership roster of 136 listed. Nine Indiana women senators and representatives are on the roster.

WIG also lists a "business council" membership that includes the executive director of Merck's health policy and external affairs committee. The purpose of the business council, according to the WIG site, is to "be a highly visible leadership group ... and to (identify) funding opportunities for Women in Government."

In addition to the business council, WIG lists several pharmaceutical companies, including Merck, which makes the HPV vaccine.

In 2005, according to its Internal Revenue Service tax records of 2006, WIG received \$2.4 million in income from contributions and gifts and \$16,694 from membership fees. It listed the following as expenses in 2005:

- Salary for its president, Susan Crosby - \$117,417 a year
- Connie Lawson's salary as chair - \$5 per hour
- Total salaries and compensation for its officers, directors and others - \$600,000
- Professional fundraising fees to a Canadian firm - \$55,991
- Other fundraising - \$164,681

- Management - \$485,570
- Travel - \$224,815
- Conventions, conferences & meetings - \$739,667
- Grants & allocations - Zero
- Printing & publications - \$471,361

The 26-page tax return is currently not up-to-date on public document Web sites because it asked for an extension until November 2006 to complete the return. The reason given was "We still do not have sufficient information to complete an accurate return at this time."

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Vaccine opposition increases

BY CINDY BEVINGTON
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Across the country, at least 18 states have introduced legislation mandating that girls in those states be inoculated with the new HPV vaccine, Gardasil, by sixth grade. And, as adverse side effects from the new vaccine have been reported, the opposition to the vaccine has grown.

One reason opponents cite for their consternation is their belief that other childhood vaccines may be linked to the skyrocketing number of children diagnosed with autism and other neurological and behavioral disorders such as attention deficit hyperactivity disorder. The HPV vaccine is so new, these opponents claim, that they are afraid similar effects might occur with it.

Not only that, after Texas Gov. Rick Perry last month used executive privilege to bypass his legislature and mandate the vaccine in his state, vaccine opponents accused Perry of alleged conflicts of interest between the vaccine's maker, Merck & Co., and some of Perry's past and present staff, as well as between Women In Government, a group of women legislators who are promoting the vaccine in their home states.

Women In Government (WIG) has admitted that Merck is a sponsor of the organization. However, both WIG and Merck have declined to say how much money that sponsorship entails.

In a public statement Feb. 27, Perry, a conservative Republican, was reported by The Associated Press as saying that, although Merck had contributed to his campaign, it did not figure into his decision to help

cure cervical cancer by mandating the vaccine.

The AP had previously reported that Perry's chief of staff Deidre Delisi and aides discussed Gardasil on Oct. 16, 2006, the same day that Merck's political action committee donated \$5,000 to Perry's campaign and \$5,000 total to eight Texas lawmakers.

Delisi is a member of Women In Government. So is Indiana Sen. Connie Lawson, R-Indianapolis, who introduced a bill in this session's of the Indiana General Assembly that would have required Indiana girls to receive the vaccine. However, her bill received such a backlash of protest that by the time the bill reached the Senate floor, it was reduced to an information-only bill that just requires that parents be notified of the vaccine's availability.

Previously Lawson told this newspaper that Merck paid for "scholarships" for various WIG activities. Since then, this newspaper has discovered through WIG newsletters posted on cached pages of the group's Web site that scholarships from sponsors go to compensate legislators for transportation, lodging and their attendance at various educational seminars, such as regional and national meetings the group regularly holds.

Last week this newspaper learned, also from WIG's cached Web pages, that one of those meetings occurred over a three-day period in November 2005, and was attended by Delisi and Perry's wife, Anita Perry. The event was called the "HPV & Cervical Cancer Summit: New Opportunities for Partnerships and Prevention."

Anita Perry, who was billed on the event's agenda as dedicated to "improving childhood immunization rates serving as the state's immunization education spokesperson," was the keynote speaker at the seminar's opening "black tie optional gala dinner."

Another speaker during the three-day event was Laura Koutsky, chair of the steering committee for Merck Research Laboratories Phase III Prophylactic HPV vaccine trials. She was listed as on the agenda as a principle investigator in several HPV related studies and a member of the American Social Health Association National HPV Scientific Advisory Committee.

Another speaker was a researcher who serves as a consultant to Merck, and still another was one with connections to Digene, the manufacturer of the screening test for HPV.

List of reactions to Gardasil in Indiana, as reported to the National Vaccine Information Center

Neuralgia

Joint pain

Arthralgia rash

Swelling – face, lymph glands, stomach, lower extremities

Urticaria (welts, hives)

Missed menstrual periods 1,1

Hot flashes

Flu-like symptoms

Musculoskeletal pain

Fatigue

Dizziness

Blurred vision

MS-type symptoms

Genital warts

Acute allergic reaction

Chest pain

Shortness of breath

Subsequent abnormal Pap smear

Spotting

Herpes zoster (shingles) & zoster-like symptoms

Blisters in vaginal area, behind ears & knees – given Valtrex (which is for shingles)

Parasthesia, tingling in feet, tongue

Numbness in hand, foot, leg on one side

GBS