Legislative Analysis



HPV INFORMATION IN SCHOOLS

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House Bill 5171 (Substitute H-1) Sponsor: Rep. Mark Meadows

House Bill 5322 (Substitute H-1) Sponsor: Rep. Brenda Clack Senate Bill 415 (Motion to Discharge from House Committee) Sponsor: Sen. Deborah Cherry

Senate Bill 416 (Motion to Discharge from House Committee)

Sponsor: Sen. Tony Stamas

House Committee: Health Policy Senate Committee: Health Policy

First Analysis (2-6-07)

BRIEF SUMMARY: The bills would require the Department of Community Health to identify, and school districts to distribute, information about HPV and HPV vaccines to parents and guardians of pupils in grades 6, 9, and 12.

FISCAL IMPACT: The bills may have a fiscal impact on the Department of Community Health and school districts. See Fiscal Information for details.

THE APPARENT PROBLEM:

There are over one hundred strains of human papillomavirus (HPV), the most common sexually transmitted infection in the United States. According to the Centers for Disease Control and Prevention, more than six million people in the U.S. become infected each year and the CDC estimates that more than half of all sexually active men and women will become infected in their lifetimes. The human immune system clears HPV from most people's systems; however, for some women, an HPV infection can result in changes to the cells of the cervix that can develop into cancer years later.

After decades of research, scientists learned that two strains, 16 and 18, were responsible for 70 percent of the cases of cervical cancer. Armed with that knowledge, scientists have developed a vaccine that, if given before a person becomes infected, can protect against HPV Types 16 and 18, as well as two strains that cause about 90 percent of the cases of genital warts (a benign but painful condition). The first vaccine, Gardasil, manufactured by Merck, was approved by the Food and Drug Administration on June 8, 2006. A second vaccine, Cervarix, manufactured by Glaxo-Smith-Kline, is currently undergoing clinical trials but is expected to gain FDA approval in the near future. The vaccines are most effective when given before a woman becomes exposed to the virus, and also produce a stronger immune protection when given to girls in early adolescence. For those reasons, the CDC and the federal Advisory Committee on Immunization

Practices (ACIP) recommend routine HPV vaccination for girls aged 11 and 12, with the ACIP recommending the vaccine for girls as young as nine years old, as well as for all other FDA-approved age groups (i.e., Gardasil is recommended for women ages 9 to 26, as it does not provide the same level of protection if given to women aged 30 and older).

As news of this medical breakthrough—the first cancer that could be largely prevented by a vaccine—was disseminated by the media, initiatives in many states were launched to require that all young girls of middle school age be inoculated with the Gardasil vaccine. Michigan was at the forefront of this effort and in the fall of 2006, Senate Bills 1416 and 1417 were introduced to, among other things, require all students entering the sixth grade (with some exceptions) to be immunized with the HPV vaccine.

Though many hailed the proposed legislation as a measure that would spare many women from a painful and potentially fatal disease, critics raised concerns about the long-term safety of a vaccine that was fast-tracked though the FDA approval process, the use of a legislative mandate to override parental decisions, and that widespread use of the vaccine could give sexually active women a false sense of security about their health status and even encourage others to become more sexually active than if they had not had the vaccine. Though the bills were amended in response to some of the concerns raised, and were passed by the Senate and reported by the House Health Policy Committee, they were not able to get through the legislative process before the end of the two-year legislative session.

However, many believe that the chance to prevent many cases of cervical cancer should not be abandoned. Supporters of widespread vaccination against HPV cite statistics that remain daunting. In the U.S., over 11,000 new cases of cervical cancer are diagnosed each year. About one-third of these women will die of the disease, even with treatment. In fact, after breast cancer, cervical cancer is the second leading cause of cancer deaths among women in their 20s and 30s. Symptoms may not appear until the disease is advanced, and not all women have access to the exams that may catch the disease at an earlier and more treatable stage. And, because most cervical cancers are caused by a persistent HPV infection, which may only be discovered if a DNA test is done on a sample of cervical cells, women in their later years, who have been in long-term monogamous relationships or not been sexually active for decades, can also develop cervical cancer from an infection that started in their youths. Treatment requires surgery, from minor procedures to major pelvic and abdominal surgeries, including removal of the bladder, uterus, and portions of the colon. Radiation and chemotherapy are often required. Treatment of cervical cancers costs several billions of dollars a year. Early vaccination could prevent up to 70 percent of these cases.

Legislation has once again been offered to address these concerns.

THE CONTENT OF THE BILLS:

Together, the bills would require the Department of Community Health to identify materials for schools informational materials on the risks associated with the human

papillomavirus (HPV) and information regarding immunization for HPV, and require schools, under certain circumstances, to further disseminate the information to parents.

House Bill 5171 and Senate Bill 415, which are identical, would add a new section to the Public Health Code (MCL 333.9205b) to require the Department of Community Health (DCH) to identify materials containing information regarding the risks associated with HPV and the availability, effectiveness, and potential risks of immunization for HPV. The DCH would have to notify each public school, public school academy (charter school), and nonpublic school in the state of the availability of these materials and must also post the materials on its website.

The DCH would also have to encourage each school to provide or make available to parents of students attending the school the materials described above. "Public school," "public school academy," and "nonpublic school" would mean those terms as defined in Section 5 of the Revised School Code (MCL 380.5).

House Bill 5322 and Senate Bill 416, which are nearly identical, would amend the Revised School Code (MCL 380.1177a) to require information about HPV and the HPV vaccine be provided to parents and guardians of pupils enrolled in certain grades. At a minimum, the information would have to include the risks associated with HPV; the availability, effectiveness, and potential risks of immunization for HPV, and potential risks of HPV immunization; and sources where parents and guardians may obtain additional information about HPV and vaccination of a child against HPV.

House Bill 5322 would specify that <u>if</u>, at the beginning of a school year, the board of a school district or the board of directors of a public school academy provided information on immunizations, infectious disease, medications, or other school health issues to parents and guardians of pupils in least Grades 6, 9, and 12, then information would also have to be included about HPV and the HPV vaccine.

Senate Bill 416 would require the information be provided to parents and guardians of pupils in or entering Grade 6 only.

BACKGROUND INFORMATION:

Information about HPV, HPV vaccines, and other sexually transmitted diseases can be found on many medical websites, including the Center for Disease and Prevention, www.cdc.gov/std.

The following information is reproduced from the Senate Fiscal Agency's analysis on Senate Bills 415 and 416:

According to the Centers for Disease Control and Prevention, "Genital HPV is a common virus that is passed on through genital contact, most often during vaginal and anal sex. About 40 types of HPV can infect the genital areas of men and women. While most HPV types cause no symptoms and go away on their own, some types can cause cervical

cancer in women. These types also have been linked to other less common genital cancers... Other types of HPV can cause warts in the genital areas of men and women...

At least 50% of sexually active people will get HPV at some time in their lives. Every year in the United States (U.S.), about 6.2 million people get HPV. HPV is most common in young women and men who are in their late teens and early 20s...."

The CDC also has reported that an estimated 11,100 new cases of cervical cancer will be diagnosed and approximately 3,700 women will die from the disease during 2007.

According to the FDA, "Four studies, one in the United States and three multinational, were conducted in 21,000 women to show how well Gardasil worked in women between the ages of 16 and 26 by giving them either the vaccine or placebo. The results showed that in women who had not already been infected, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed. While the study period was not long enough for cervical cancer to develop, the prevention of these cervical precancerous lesions is believed highly likely to result in the prevention of those cancers...

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

The safety of the vaccine was evaluated in approximately 11,000 individuals. Most adverse experiences in study participants who received Gardasil included mild or moderate local reactions, such as pain or tenderness at the site of injection."

A second vaccine, which is called Cervarix and targets the two strains of HPV that cause cervical cancer, has been developed by GlaxoSmithKline and is awaiting FDA approval.

FISCAL INFORMATION:

<u>House Bill 5171 and Senate Bill 415</u> may have modest fiscal implications for the Department of Community Health. The bills increase responsibilities of the department regarding information materials regarding HPV vaccination and notifications to schools. This may increase staffing needs if these functions cannot be performed with existing personnel and resources.

<u>House Bill 5322 and Senate Bill 416</u> would have minimal, if any, fiscal impact on school districts associated with adding information about the human papillomavirus and vaccine to information they distribute regarding immunizations and health issues.

ARGUMENTS:

For:

The bills represent a compromise. Instead of requiring all sixth-grade students – male and female – to be inoculated, as the original 2006 legislation would have done, the bills in their current forms focus on getting educational materials about HPV and the HPV vaccines to parents of middle and high school students. It is hoped that parents will use the materials (which also will be posted on the Department of Community Health's website) in their decision whether, or at what age, to have their school-age daughters inoculated against HPV.

Response:

The bills are a step in the right direction. In their current form, they preserve the right of a parent to decide what is in the best interest of his or her child. However, some still have concerns that young women and their partners may be misled into thinking that vaccination with the HPV vaccine means that sex is OK. Also, it would seem that interested parents could just ask their child's doctor for information.

Rebuttal:

If anything, sound scientific and medical information about HPV and the HPV vaccine is what is needed to dispel such misconceptions. For instance, the materials should educate parents and their children about how HPV is transmitted, that even use of condoms will not prevent all transmissions, that the vaccine does not prevent all cervical cancers (but stops the virus that causes most cases), and that it is not currently known how long the protection from the vaccine will be effective. As more research is conducted, the DCH will be able to update the information it identifies on its website and to schools, and schools can then update the materials in the packets they provide to their parents.

Though some doctors are very knowledgeable about the HPV vaccine, women testified before a House committee that their doctors and their children's pediatricians did not have up-to-date information on the vaccine, or even informational brochures to hand out. Also, the current capitated model of care can leave physicians with little time to examine and diagnosis a patient's current illness, let alone provide time to have an in-depth discussion of HPV and the available vaccine. Other children and parents, especially lower-income families without health insurance, may have limited access to doctors' offices. The information provided by the schools should not be seen as a replacement for a discussion with a physician, but could enable a parent and/or his or her child to maximize the time with their physician and more effectively and efficiently discuss any concerns.

For:

House Bill 5322 would require, at a minimum, that schools provide the information on HPV and the HPV vaccine to parents of 9th and 12th grade pupils as well as parents of 6th grade pupils. This change was made to keep the dissemination of HPV-related materials similar to material about meningitis and the vaccine to prevent meningitis. In so doing, schools would be able to package all the vaccination-related materials into one packet that could be distributed to parents of any student rather than having separate

packets for 6th grade students, a move that should decrease the burden on school personnel and district costs related to the bill's implementation.

For:

HPV is not just a concern for sexually active young women. A woman with a persistent HPV infection can develop cervical cancer years or decades after the initial exposure. Cancer can present at a time when she is trying to start a family or when she is a grandmother. HPV is the most sexually transmitted disease among men and women – infecting about half of sexually active people during their lifetime, men included. In addition, men can spread HPV to their partners. Recently, a study published in the *New England Journal of Medicine* in May of 2007 linked HPV infection to an increased risk for certain types of throat cancer. HPV, as well as other STDs such as herpes, syphilis, gonorrhea, and HIV can be spread through oral sex.

According to the study, as reported in an article appearing in the *Washington Post*, May 10, 2007, entitled "Virus Spread by Oral Sex is Linked to Throat Cancer", "those who tested positive for HPV were 32 times as likely to have oropharyngeal cancer" (cancer of the tonsils and surrounding tissue). In fact, the article reports that the type of oral cancer linked to HPV strikes about 11,000 Americans (both men and women) each year – about the same number of women diagnosed with cervical cancer annually. Rates of oral cancer have been increasing in recent years, even as the numbers of people who smoke or engage in heavy drinking, the usual risk factors for oral cancer, have been decreasing.

One factor could be the increase in the numbers of teens and young adults who engage in oral sex practices; teens often believe that it is a safer form of sex (and some don't believe it is sex at all). Moreover, though unclear at this time if kissing someone with HPV could pose a risk of developing oral cancer, the *Post* article quoted the lead researcher as saying "it is not out of the realm of possibility." If such a risk were also identified, and if the vaccines proved to be effective in protecting males from contracting and spreading strains of HPV associated with cervical cancer, genital warts, and oral cancer, vaccination protocols could expand in the future to include adolescent males.

This study makes it all the more important that parents be provided materials on HPV and the HPV vaccines. The materials that the DCH would have to post on its website and that schools would be required to provide could be used by parents as a springboard for discussions with their children – sons and daughters – about the health risks of HPV, the means of transmission, and the potential risks and benefits of the HPV vaccine.

For:

Cervical cancer carries a social, not just a personal, burden. Treatment of cervical cancer accounts for billions of dollars of the nation's overall annual health care costs. Whether the information required to be disseminated under the legislation leads to more young women being vaccinated against HPV, or discussions between parents and children as a result of the information leads to delay of sexual activity or more responsible sex on the part of teens, to the extent the legislation impacts the number of new cervical cancer cases (or oral cancer), the bill would have a corresponding impact on healthcare costs.

Assuming that a portion of treatment cases would involve people on public assistance, there could be a corresponding reduction in the need for Medicaid assistance and payments by Medicare.

POSITIONS:

The Department of Community Health supports the bills. (1-31-08)

The Michigan Women's Commission supports the bills. (1-31-08)

Michigan Family Forum supports the bills. (1-31-08)

M.O.M. (Michigan Opposing Mandatory Vaccines) supports the bills. (1-31-08)

A representative of the American College of Obstetricians and Gynecologists (ACOG) testified in support of the bills. (1-31-08)

The following indicated support for the bills on 1-31-08:

Michigan Association for Local Public Health American Academy of Pediatrics/Michigan Chapter Michigan NOW Planned Parenthood National Association of Social Workers/Michigan Chapter American Cancer Society Karmanos Cancer Institute

> Legislative Analyst: Susan Stutzky Fiscal Analyst: Susan Frey

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[■] This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.