

Good Afternoon Senator Handley, Representative Sayers, and Members of the Public Health Committee,

My name is Theresa McGrath, Executive Director of the Family Alliance for Children in Education. We are a true grassroots group of parent advocates who baby-sit legislation which effect children in their education.

I am here today to adamantly oppose Raised H.B. No. 6977, an Act Concerning Prevention Strategies for Diseases caused by Human Papilloma Virus, and any bills which correlate with it which may be produced this upcoming session.

I have been in touch with thousands of people throughout the state of Connecticut and all over the US, who have grave concerns for many legitimate reasons. I have been on Talk of CT with Dan Lovallo twice within the past two weeks with regard to this bill and expect to report back to Dan to provide his listeners with the outcome of this hearing and this bill.

With organizations such as The American College of Pediatricians and The National Vaccine Information Center reporting on adverse side effects caused by this vaccine, one must truly consider the detrimental effects of such a mandate on all CT females between the ages of 11 and 26 years of age.

Just late yesterday, Merck announced that they are stopping their entire lobbying efforts nationwide, do to the outcry from the public and the concerns with which they have. I ask you, if this is truly a cervical cancer wonder drug, then why would such a company pull their lobbying efforts to mandate on our little girls?

I must say, I am a bit perplexed with the contradicting legislation this year. We have bills written by legislators concerned with our children at school being exposed to chemicals in the grass, yet, similar legislators are sponsoring legislation to mandate little girls to be directly injected with a chemical that has potentially fatal or long term side effects. Does this make sense?

I ask that you refer to my compiled report of the scientific evidence taken directly from the Merck report approved by the FDA, links to various Medical reports from renowned National and Professional Medical organizations, and articles which refer to parental rights being trampled by mandating such a vaccine on our daughters.

I thank you for your time and commitment to hear my testimony. I truly hope that you will do the right thing. Kill this bill in this committee. When there is evidence that this drug will not hurt my daughter and all women, I will support it 100%. Meanwhile, I will take my chances as an informed mother to teach my daughter to be a responsible young lady. I would like to inform you that it most certainly my responsibility, not yours, to rare my child. I do know what's best for her.

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Report on Human Papilloma Virus Vaccine
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Medical Perspective:

- ☑ This is a medical issue in many ways including potential harm to a fetus and fertility issues in women. Merk, the makers of this vaccine, conclude and report a 5:0 (5 - Gardasil : 0 - Placebo) rate of pregnant woman who had congenital anomalies as a result of taking this vaccine. (see Merk Report and/or summary below)
- ☑ The American College of Pediatricians has taken a position against this immunization. <http://acpeds.org/?CONTEXT=art&cat=12&art=95&BISKIT=3971992680>
 - According to the American College of Pediatricians, the dangers in taking this immunization outweigh the purpose of taking it. They state that we cannot know the real effects of this immunization for another 20 years...meaning...we'll see what will happen to the captive audience that has already been injected with it.
 - Will this be another form of genocide?
 - **Thalidomide** given to pregnant women in the 60's comes to mind. http://www.intentblog.com/archives/2007/02/say_al_runs.html
- ☑ There are no studies to look at the long term effects of Gardasil.

☑ **FDA Report from Merk in relation to Studies and Outcomes on Animals and Women:** (see attached for full report..) Here's the Summary:

- **Adverse effects on Women between the ages of 9-26:**

The vaccine-related adverse experiences that were observed among female recipients of GARDASIL at a frequency of at least 1.0% and also at a greater frequency than that observed among placebo recipients are shown in Table 6.

 - **Injection Site:** Pain, Swelling, Erythema, Pruritus
 - **Systemic:** Fever (101-102+ F), Nausea, Dizziness, Headache, Gastroenteritis, Appendicitis, Pelvic Inflammatory Disease
 - **One case of Bronchospasm**
 - **2 cases of asthma and serious adverse experiences occurred during Day 1-15 of any vaccination visit.**
 - **Deaths: 17 deaths were reported in 21,464 male and female subjects**
 - **Potential Autoimmune Disorders (Summary of Subjects Who Reported an Incident Condition Potentially Indicative of Systemic Autoimmune Disorder After Enrollment in Clinical Trials of GARDASIL) such as:**
 - Juvenile arthritis
 - Rheumatoid arthritis
 - Systemic lupus erythematosus
 - Arthritis
 - Reactive Arthritis

Adverse effects on Pregnant women:

"...Further sub-analyses were conducted to evaluate pregnancies with estimated onset within 30 days or more than 30 days from administration of a dose of GARDASIL or placebo. For pregnancies with estimated onset within 30 days of vaccination, **5 cases of congenital anomaly** were observed in the group that received GARDASIL compared to 0 cases of congenital anomaly in the group that received placebo. The congenital anomalies seen in pregnancies with estimated onset within 30 days of vaccination included pyloric stenosis, congenital megacolon, congenital hydronephrosis, hip dysplasia and club foot..."

Conversely, in pregnancies with onset more than 30 days following vaccination, 10 cases of congenital anomaly were observed in the group that received GARDASIL compared with 16 cases of congenital anomaly in the group that received placebo. The types of anomalies observed were consistent (regardless of when pregnancy occurred in relation to vaccination) with those generally

observed in pregnancies in women aged 16 to 26 years. *Pregnancy Registry for GARDASIL Merck & Co., Inc.* maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL. Patients and health care providers are encouraged to report any exposure to GARDASIL during pregnancy by calling (800) 986-8999.

- ☑ 4:26 pm, Feb 13, 2007 called to ask what the Placebo that was used in this study: I was put on hold until 4:36 where I was told that my pediatrician needs to put in a request to the medical department for further questioning. He told me that he can only tell me what the term Placebo means. I requested that I be transferred to someone who can answer that question for me.
- ☑ 4:38 pm, I was again put on hold.

Adverse effects on Breast Feeding Infants:

Lactation It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk...In clinical studies, a higher number of breast-feeding infants (n = 6) whose mothers received GARDASIL had acute respiratory illnesses within 30 days post-vaccination of the mother as compared to infants (n = 2) whose mothers received placebo. In these studies, the rates of other adverse experiences in the mother and the nursing infant were comparable between vaccination groups."

☑ ***The National Vaccine Information Center Issues Warning to State Officials:***

- see, "Vaccine Center Issues Warning," Washington Times, Feb 3, 2007: " **The National Vaccine Information Center** yesterday warned state officials to investigate the safety of a breakthrough cancer vaccine as Texas became the first state to make the vaccine mandatory for school-age girls. Negative side effects of Gardasil, a new Merck vaccine to prevent the sexually transmitted virus that causes cervical cancer, are being reported in the District of Columbia and 20 states, including Virginia. The reactions range from loss of consciousness to seizures."]

Morality and Parental Rights Issues:

- ☑ **Testing Humans:** I would like to point out that FDA approval of Gardasil 2006. They've been testing humans for 4 years prior to their approval; without knowing long term effects.
- ☑ **Contraception Topic:** A Nurses/Midwife/Researcher's opinion

Here is what she had to say:

I have to say that I am for HPV vaccination. I see the expense and worry that women go through when they have HPV infections and abnormal paps-our current manner of screening, catching it early, and thus preventing evolution to overt cancer is inadequate in comparison to getting an injection.

I know that giving it to young girls seems pretty radical. And I think that only 1200 girls between 12 and 16 were in the trials, and I'm not sure that is enough. BUT, I have taken care of many 13 and 14 year olds who were pregnant, so obviously sexually active. HPV is very prevalent, I think at least 50% of people have it, and you can't tell by looking at them or their privates! Condoms only reduce the risk of transmission by a small amount. So all in all, I think the evidence is good for the use of this vaccine, and it is logical that it be used at the lower end of the age groups-before sexual activity- if it is to be used with its preventive intent.

Now I know that young girls aren't supposed to have sex, **and that's what I think the root of all the controversy is.** Our idea is that girls should be 'good' and if you give them this shot you are giving them permission to be 'bad' or symbolically deflowering them. I'm not so sure that people would be so up in arms about a vaccine for boys?

Legislation is one way to force insurers to pay for this vaccination, which they should if the actuarials were really looking at the long term instead of the next fiscal quarter!"

- Note: This Nurse/Midwife Researcher looks at this from a medical professional perspective, but does address her personal opinion, that the controversy seems to have more to do with the **contraceptive and parental rights issue.**

☑ **Contraception Argument inclusive of Parental Rights Argument:**

"There are a couple of other reasons for people to worry about this vaccine. Conservatives and right groups disprove any state mandate for inoculating young girls with this HPV vaccine because they believe such a requirement would encourage girls to have premarital sex and interfere with parents' right to making medical choices." <http://foodconsumer.org/7777/8888/Non-food Things 27/020307242007 HPV vaccine What you need to know.shtml>

- Planned Parenthood supports this legislation. Why? For Women's Rights? What about my rights as a woman and mother? Does Planned Parenthood consider me when they formed their opinion? What about my daughter's rights? Or do they support this issue for the mere political fact that it really is an issue of contraception?** http://www.pprne.org/site/DocServer/HPV_Vaccine.pdf?docID=4401
- It's not a Parental Rights Issue?** We still don't know what causes Autism. There are no studies to say that current immunizations mandated on children don't cause Autism. 1 in 125 children are found to have Autism to date. It is a parental rights issue, a civil rights issue, a captive audience issue, need I go on?
- It's not a Parental Rights Issue inclusive of Contraception?** "AUSTIN, Texas — Bypassing the Legislature, Republican Gov. Rick Perry signed an order Friday making Texas the first state to require that schoolgirls get vaccinated against the sexually transmitted virus that causes cervical cancer. By issuing an executive order, Perry apparently sidesteps opposition in the Legislature from conservatives and parents' rights groups who fear such a requirement would condone premarital sex and interfere with the way parents raise their children." <http://www.startribune.com/484/story/977432.html>

The Cost:

The vaccine is \$120 per dose, so the series costs \$360.

Total Population of women between the ages of 9 – 26: Approximately 40,156,343

Total Cost: \$14,456,283,480

| Geographic Area Selected Age Groups | Projections |
|--|--------------|
| | July 1, 2005 |
| Female | 150,393,897 |
| Under 5 years | 10,024,243 |
| 5 to 13 years | 17,565,621 |
| 14 to 17 years | 8,366,101 |
| 18 to 24 years | 14,224,621 |

These numbers are estimated according to the 2005 census 2005 projections and do not reflect 2007 statistics. Because the age ranges are categorized, I took the numbers from these stats which add 4 years prior to the 9yr age group and less 2 years of the 26yr age group.

<http://www.census.gov/population/www/projections/projectionsagesex.html>

Even after approval by ACIP, school vaccination requirements are decided mostly by state legislatures. Some state legislatures have granted regulatory bodies such as the Health Department the power to require vaccines, but they still need the legislature to provide funding. If states make the vaccine mandatory, they must also address funding issues, including for Medicaid and SCHIP coverage and youth who are uninsured, and whether to require coverage by insurance plans. This has caused some to push for further discussion and debate about whether or not to require the vaccine.

<http://www.ncsl.org/programs/health/HPVvaccine.htm#hpvlegis>

Financing

<http://www.kff.org/womenshealth/upload/7602.pdf>

The 3-dose HPV vaccine is expensive, costing \$120 per injection (\$360 for entire series). Many, but not all, private and public sector payors will cover the vaccine, but policies about who will be covered and what amount will be paid are still being determined.

Private Insurance

- Most girls and women in the target age group for the HPV vaccine have private insurance. However, one in ten (12%) girls ages 9 to 18 and three in ten (29%) women 19 to 26 are uninsured (Figure 1).
- Private insurers typically follow ACIP guidelines and are likely to cover the vaccine. Several major insurers have already begun covering the vaccine in at least some of their plans.

HPV Vaccine: Implementation and Financing Policy

January 2007

Medicaid

23%

Medicaid

14%

Employer-sponsored

58%

Employer-sponsored

46%

Uninsured

12%

Uninsured

Individual 29%

Individual 10%

5%

Other

2%

Other

1%

Girls Ages 9 to 18 Women Ages 19 to 26

N = 20.5 million N = 15.8 million

Source: Kaiser Family Foundation analysis of Urban Institute estimates from March 2005 Current Population Survey, U.S. Census Bureau. Note: "Other" indicates other forms of public insurance, including Medicare, CHAMPUS, and TriCare. Percentages may not add to 100 due to rounding.

Figure 1

Health Insurance Coverage of Girls and Women Ages 9 to 26, 2004

Public Financing

- Vaccines for Children (VFC) – This federally financed program pays for vaccines approved by the ACIP for children ages 18 and under who are either Medicaid-eligible, uninsured, American Indian or Alaska Native, or underinsured; 41% of all children's vaccines are paid for by the VFC program.¹³
- Immunization Grant Program (Section 317) – Through this federal program, the CDC awards federal grants to state, local, and territorial public health agencies to aid with vaccine costs. Funds can help extend coverage to children who do not qualify for VFC program.¹⁴
- Medicaid – The VFC must pay for vaccinations for all children through age 18 with Medicaid. For adults on Medicaid, however, vaccine coverage is an optional benefit and is decided on a state-by-state basis.¹⁵
- State Children's Health Insurance Program (SCHIP) – States

Here are some other links and facts for your information:

[Gardasil Website](#)

[Source Watch Report on Women in Government - Linking them to the Pharmaceutical Industry](#)

[All States which Have HPV Legislation](#)

Public Hearing 02/14

Raised H.B. No. 6977

AN ACT CONCERNING PREVENTION STRATEGIES FOR DISEASES CAUSED BY HUMAN PAPILLOMA VIRUS.