



### **Testimony for the October 24, 2007 Senate Democratic Conference Hearing on HPV Vaccination Requirement**

Presented by Suzanne Topping, Executive Director, Women's Health Collaborative

#### ***Introduction***

My name is Suzanne Topping and I am the Director of the Women's Health Collaborative (WHC) headquartered here in Rochester, NY.

The WHC was founded about a year ago out of frustration. Because reproductive health issues are so politicized, women seldom hear frank discussions about the risks and side effects of various medical choices. The same old pro-life vs. pro-choice arguments come up for every reproductive health issue, and these arguments prevent women from getting the information they need in order to make informed decisions.

And so the WHC was born.

Our participants and advisors include physicians, nursing professors, midwives, nurses, substance abuse counselors, social workers, EMTs, mental health practitioners, healthcare workers, lawyers, and others.

I administer the organization and am its spokesperson. I am not however a medical professional myself, and therefore may need to refer specific medical questions to someone else within the WHC.

#### ***Objections to the Bills***

We have been tracking the HPV vaccine Gardasil with interest over the past months, and are encouraged by what it promises. However, we are adamantly opposed to any bill which creates law requiring children to receive the vaccination in order to attend school.

Senate bill S04394 and Assembly bill A05810 amends existing NYS Public Health Law by adding Human Papillomavirus (HPV) to the list of immunizations currently required for attendance in school at the sixth grade level. This list includes diseases such as polio, measles, diphtheria, etc. which an infected child could easily spread to others, or a well child could easily catch from others while interacting socially within the environment of the classroom.

HPV however does not fit into this general category of communicability. It is caught through sexual activity, not by being nearby when someone sneezes. Existing vaccination requirements protect children from biological hazards that exist simply by being in a building full of other children. They make sense because they protect children who are required by law to be there, and they protect society as a whole by preventing schools from turning into compact disease incubators. A child entering sixth grade will not catch HPV simply by being in a classroom or lunch with another child who has it.

The American College of Pediatricians effectively summarizes the issue:

*“The American College of Pediatricians is opposed to any legislation which would require HPV vaccination for school attendance. Excluding children from school for refusal to be vaccinated for a disease spread only by penetrating vaginal intercourse is a serious, precedent-setting action that trespasses on the right of parents to make medical decisions for their children as well as on the rights of the children to attend school.”<sup>1</sup>*

The other major problem with the current bills is that the requirement for HPV vaccination is designated for –all children-, girls and boys, despite the fact that Merck (Gardasil’s manufacturer) will not complete studies on boys until next year.<sup>2</sup> It is ridiculous to put law in place requiring parents to have children vaccinated with a drug that has not yet been approved for use with them!

This is a major flaw in the legislation as proposed.

### **Efficacy Concerns**

In addition to the problems we see with the bills themselves, we have significant concerns about the efficacy of the vaccine, both in regards to HPV and cervical cancer.

The vaccine protects against only 4 types of HPV (out of about 40 which are sexually transmitted).

The vaccine does not protect against HPV types which cause approximately 30% of cervical cancers.

Merck’s product safety information webpage states “The duration of protection of Gardasil is unknown at present.”<sup>3</sup>

Merck’s product efficacy webpage states: “Vaccination with Gardasil may not result in protection in all vaccine recipients.”<sup>4</sup>

During a meeting of the FDA advisory panel that reviewed Gardasil in May 2006, one of the attendees (Dr. Emerson) questioned the lack of proof that the vaccine actually prevents cancer, stating:

*“I do believe that Gardasil protects against HPV 16 and 18, but the effect it will have on cervical-cancer rates in this country is another question entirely. There is a leap of faith involved.”<sup>5</sup>*

Dr. Elizabeth Unger of the Centers for Disease Control stated:

*“So it is believed that infection alone is insufficient to cause cancer, and additional factors are required for neoplasia. There are certainly lots of questions about HPV infection...”<sup>6</sup>*

An additional concern about efficacy relates to the vaccine being administered in a series of three shots. Cervical cancer is primarily a problem for women who are socioeconomically disadvantaged<sup>7</sup>, and this subpopulation is less likely to receive all three inoculations at the prescribed schedule.

### **Safety Concerns**

The vaccine has only been tested in conjunction with Hepatitis B vaccinations, and reactions and responses to Gardasil when given in conjunction with other required vaccinations are not yet known. A summary of study data on the Merck website admits: “Co-administration with other vaccines has not been studied.”<sup>8</sup>

Only a few hundred 11-12 year olds have been studied so far, and a large scale study of that age group ordered by the FDA will not be completed until 2009.<sup>9</sup>

The federal Vaccine Adverse Event Reporting System (VAERS) database has collected hundreds of reports of vaccination reactions, including thrombosis, seizures, Guillain-Barre syndrome, kidney failure, severe allergic reaction, anaphylactic shock, and death.<sup>10</sup>

A Background Document for the FDA Vaccines and Related Biological Products Advisory Committee in May 2006<sup>11</sup> stated that there may be:

*“the potential for Gardasil to enhance cervical disease in subjects who had evidence of persistent infection with vaccine-relevant HPV types prior to vaccination.”*

The vaccine is not recommended for pregnant women or girls (though a pregnancy test is not listed as a requirement in the proposed bills), and there are concerns about a potential for negative impact on later fertility. A Gardasil patient information sheet states:

*“it is not known whether Gardasil can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity.” “For pregnancies with estimated onset within 30 days of vaccination, 5 cases of congenital anomaly were observed in the group that received Gardasil compare to 0 cases of congenital anomaly in the group that received placebo.”<sup>12</sup>*

The same document states:

*“The effect of Gardasil on male fertility has not been studied.”*

Diane M. Harper, Director of the Gynecologic Cancer Prevention Research Group at Dartmouth Medical School who has conducted longstanding work on the vaccine via funded by Merck and GlaxoSmithKline (maker of a competing vaccine) states”

*“It is silly to mandate vaccination of 11-12 year old girls. There is not enough evidence gathered on side effects to know that safety is not an issue.” “Giving it to 11-year olds is a great big public health experiment.” “The zealotry to inoculate all these younger girls may very well backfire at the very time they need protection most.”<sup>13</sup>*

An editorial in the May 2007 issue of the New England Journal of Medicine concludes with the statement:

*“a cautious approach may be warranted in light of important unanswered questions about overall vaccine effectiveness, duration of protection, and adverse effects that may emerge over time.”<sup>14</sup>*

The website for Rochester-based Center for Menstrual Disorders and Reproductive Choice provides a Gardasil advice sheet for parents which includes the following warnings:

*“Indeed what this vaccine may offer is possibly a very false sense of security. If you’re thinking about Gardasil for you self please understand that its effect on your overall health is probably minimal at best and unknown at worst.”*

The advice sheet continues:

*“We do not yet know the risks of this vaccine in a large study population over a period of 20 years. ... Many one-time ‘wonder drugs’ produced unintended consequences or simply didn’t live up to their marketing hype—hormone replacement therapy, Fen-phen, Celebrex, and Vioxx are just a few examples.”<sup>15</sup>*

## Conclusion

The Women's Health Collaborative concludes that while the vaccine shows great promise for preventing some of the HPV types which can lead to cervical cancer, it has not demonstrated sufficient efficacy and safety to be required for children attending school. It should remain as an option for parents too choose for their children rather than being mandated by state law.

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<sup>1</sup> American College of Pediatricians Human Papilloma Virus Vaccination Statement:  
<http://www.acped.org/?CONTEXT=art&cat=10006&art=140&BISKIT=3114289749>

<sup>2</sup> FDA Product Approval Information - Licensing Action: Gardasil Questions and Answers:  
<http://www.fda.gov/cber/products/hpvmer060806qa.htm>

<sup>3</sup> [https://www.merckvaccines.com/gardasilProductPage\\_frmst.html](https://www.merckvaccines.com/gardasilProductPage_frmst.html)

<sup>4</sup> <https://www.merckvaccines.com/vaccines/gardasil/efficacy.html>

<sup>5</sup> Questions of Efficacy Cloud a Cancer Vaccine, Wall Street Journal:  
[http://online.wsj.com/article/SB117668541991270825.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB117668541991270825.html?mod=googlenews_wsj)

<sup>6</sup> Minutes from: FDA Vaccines and Related Biological Products Advisory Committee, p. 21:  
<http://www.fda.gov/ohrms/dockets/ac/cber01.htm#Vaccines%20&%20Related%20Biological>

<sup>7</sup> Comparing Cervical Cancer by Race and Ethnicity, Centers for Disease Control and Prevention:  
<http://www.cdc.gov/cancer/cervical/statistics/race.htm>

<sup>8</sup> Merck product study summary: [http://www.merck.com/product/usa/pi\\_circulars/g/gardasil/gardasil\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf)

<sup>9</sup> Questions of Efficacy Cloud a Cancer Vaccine, Wall Street Journal:  
[http://online.wsj.com/article/SB117668541991270825.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB117668541991270825.html?mod=googlenews_wsj)

<sup>10</sup> <http://wonder.cdc.gov/vaers.html>

<sup>11</sup> Vaccine Safety Group Releases Gardasil Reaction Report, Medical News Today:  
<http://www.medicalnewstoday.com/articles/63586.php>

<sup>12</sup> USPPI Patient Information about Gardasil: [http://www.merck.com/product/usa/pi\\_circulars/g/gardasil/gardasil\\_ppi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_ppi.pdf)

<sup>13</sup> Researcher Blasts HPV Marketing, FWDailyNews.com: <http://wonder.cdc.gov/vaers.html>

<sup>14</sup> HPV Vaccination: More Answers, More Questions, New England Journal of Medicine:  
<http://content.nejm.org/cgi/content/full/356/19/1991>

<sup>15</sup> <http://www.cmdrc.com/YoungWomansHealthCare/#Gardasil>