

NETWORK ORGANIZATION for VACCINE AWARENESS and CHOICE

Sharing resources to raise awareness about vaccine injuries and deaths, while working to promote individual
choice without force, fear or threats.

NOVAC

Long Valley, New Jersey, 07853

ATTORNEY GENERAL ANNE MILGRAM
OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
P.O. BOX 080
TRENTON, NEW JERSEY 08625

April 17, 2008

Dear Attorney General Milgram:

When a State takes upon itself, a statutory requirement to disseminate public health information (Exhibit 1), the State then has an obligation to its citizens, to fully disclose the factual and pertinent information. The Network Organization for Vaccine Awareness and Choice takes particular issue with the *HPV Vaccine: Questions and Answers for Parents* sheet recently distributed in our public schools. (Exhibit 2) Our statewide organization, acting on behalf of its members, requests your immediate investigation into the arbitrary and fraudulent claims made by the New Jersey Department of Health and Senior Services in this "question and answer sheet." We also request that a retraction and a clarification of the misinformation be disseminated in a timely manner.

Countless calls and e-mails have come in from our members about the HPV sheet I bring to your attention. Each inaccuracy has been delineated and the details are as follows:

Exhibit 1: *State of New Jersey, Department of Education letter*, March 24, 2008, states in paragraph one:

"In accordance with N.J.S.A. 18A:40-42, the New Jersey Department of Health and Senior Services has developed the attached *educational fact sheet* about the Human papillomavirus (HPV)." "...public school districts are statutorily required to distribute *the fact sheets...*" (emphasis mine)

The reference to a "fact sheet" appears four times in a single paragraph. Naturally, one expects the attached information to be factual. Upon close examination, however, the information provided by NJDHSS is incongruent with the enclosed documentation. Paragraph ten of Exhibit 2 deserves priority consideration.

Exhibit 2: NJDHSS, HPV Vaccine: Questions and Answers for Parents (Paragraph Ten) “Is the HPV vaccine safe?”

“These studies have shown no serious side effects.”

Even prior to its licensure, the clinical trials for GARDASIL told a grim tale. “Across the clinical trials, 17 deaths were reported in 21,464 male and female subjects. A total of 102 subjects out of 21,464 total subjects who received GARDASIL reported a serious adverse reaction experience on day 1-15 following any vaccination visit during the clinical trials.” Merck also lists reports of potential autoimmune disorders including various types of arthritis and systemic lupus. Other adverse reactions include disorders of the lymphatic, nervous, gastrointestinal, musculoskeletal and immune systems. (Exhibit 3)

In my thirty-three minute conversation with DHSS, I directed their attention to the Vaccine Adverse Events Reporting System (VAERS). This federal register currently lists 7,379 adverse reactions to HPV vaccines. These include 89 reactions considered to be life threatening; 204 vaccine recipients required hospitalization; 913 had not recovered at the time of the report; 124 are disabled at the time of the report; 13 have died in addition to those who died in the clinical trials. NOVAC recognizes all of those side effects to be “serious side effects.”

Exhibit 2: (Paragraph One) “What is human papillomavirus (HPV)?

“HPV is a common virus that is passed from person to person through oral sex, anal sex or penile-vaginal sex.”

It is important to mention that many of the complaints and concerns NOVAC has fielded about this “fact sheet” pertain to the opening paragraph which states, “HPV is ... passed from person to person through oral sex, anal sex or penile-vaginal sex.” (Exhibit 2) These sheets went home with students who are 11 and 12 years old. Parents who do not believe discussions about such sexual activity is appropriate for that age group of children have just been stripped of their right to reserve that discussion for a time when they do deem it appropriate.

While sexual contact is a common form of transmission, Diane Harper, M.D, Ph.D., states the importance of informing people that HPV infection is also passed on by skin to skin contact, it can live anywhere on the skin and can also be spread by non-sexual transmission.

Exhibit 2: (Paragraph One) “HPV is the major cause of cervical cancer in woman.”

Since there is no reference to site for this claim, NOVAC has taken the onus to investigate many studies, which inconclusively draw correlatives between some types of human papillomavirus and the development of cervical cancer. No study demonstrates, conclusively that, “HPV is the leading cause of cervical cancer in women.” An inquiry by telephone to the DHSS revealed that they had no such study on file proving that claim. No such study can be accessed through the Centers for Disease Control website, either.

However, in the March 31, 2003 issue of *FDA NEWS*, “**FDA Approves Expanded use of HPV Tests**,” it is stated, “Most HPV infections are short-lived and are not associated with cervical cancer.” The article continues, stating, “HPV oncogenesis (tumor growth) is a

rare event with a long interval between infection and cancer.” It also states that infection alone is insufficient to cause cancer; additional factors are required. NOVAC asks, “On what basis does DHSS support their claim?”

Exhibit 2: (Paragraph Two) **“How common is HPV?”**

“At least half of sexually active people will get HPV at some time in their lives.”

Again, there is no reference to site demonstrating the accuracy of this statement. I asked for a copy of this study from DHSS and I was informed that there is no study on file. An inquiry to the CDC was fruitless. Without a published, peer-reviewed reference to support the claim that, “At least half of sexually active people will get HPV at some time in their lives,” this statement is arbitrary and untruthful. In contrast, the National Cancer Institute proclaims, “Most HPV infections occur without any symptoms and go away without any treatment over the course of a few years.”

Exhibit 2: (Paragraph Four) **“What is the HPV vaccine?”**

“The HPV vaccine is the first vaccine developed and licensed to prevent cervical cancer, genital warts...”

While GARDASIL may have been “developed and licensed to prevent cervical cancer,” this statement falsely implies that it unconditionally does. Merck’s product information for GARDASIL states, “Cervical cancer prevention focuses on routine screening and early intervention. This strategy has reduced cervical cancer rates by 75% in compliant individuals...” The vaccine maker also states, “The overall efficacy of GARDASIL ... will depend on the baseline prevalence of HPV infection related to vaccine types in the population vaccinated, and the incidence of HPV infection due to types not included in the vaccine.” (Exhibit 3).

In translation, scientists have identified more than 100 types of HPV, of which 40 have been associated with cervical cancer or genital warts. The vaccine’s effectiveness is dependent upon the individual’s exposure to ONLY the four strains prepared in the vaccine—HPV 6,11,16 and 18. Merck also states, “As for any vaccine, vaccination with GARDASIL may not result in protection in all vaccine recipients.” According to Diane Harper, M.D., Ph.D. and twenty year developer of the vaccine, “It [GARDASIL] is not a cancer vaccine or cure. It is a preventive vaccine for a virus that can cause cancer.”

A distinction must be clarified between a vaccine against cancer and a vaccine against certain strains of viruses with the potential to cause cancer. DHSS not only has a professional obligation to understand that distinction, they have an ethical obligation to clarify that distinction and to represent this product in alignment with the product limitations as specified by the manufacturer.

Exhibit 2: (Paragraph Five) **“How is the HPV vaccine given?”**

“HPV vaccine can be given at the same time as other vaccines.”

While it is true that HPV vaccine may be given with other vaccines, this statement implies that it is SAFE to give HPV with other vaccines. According to Merck’s product information on GARDASIL, this vaccine has been tested, ONLY in conjunction with Hepatitis B vaccine. “Results from clinical studies indicate that GARDASIL may be

administered concomitantly with Hepatitis B vaccination.... Co-administration of GARDASIL with other vaccines has not been studied.” (Exhibit 3) In an article published March 14, 2007, “**Researcher Blasts HPV Marketing**” by Cindy Bevington, KPC News, Indiana, Diane Harper, M.D., Ph.D. and twenty-year developer of the HPV vaccine, cited more than 40 cases of Guillian-Barre Syndrome and extremity paralysis in women who received HPV vaccine in conjunction with the meningitis vaccine. It is unacceptable and irresponsible of NJDHSS to suggest the “safe” use of a product, which surpasses the product’s testing limitations. In contrast to falsely claiming the safety of administering HPV with other vaccines, DHSS more aptly should have informed the public that the vaccine has **safety limitations** and should not be administered with any other vaccine except Hepatitis B vaccine.

Exhibit 2: (Paragraph Nine) “**How effective is the HPV vaccine?**”

“This vaccine is effective at preventing four types of HPV...”

Let it first be stated that according to the American Cancer Society’s website, the number of cervical cancer deaths in the United States has dropped by 74% between 1955 and 1992. A significant decline before the vaccine even comes to market.

The vaccine maker, Merck, claims in their television advertising campaign, *ONE LESS*, “GARDASIL MAY prevent some types of human papillomavirus which MAY cause cervical cancer. (Emphasis mine) The product information states, “On the basis of immunogenicity bridging the efficacy of Gardasil in 9-15 year old girls is INFERRED.” (Emphasis mine)

An article published in the *New England Journal of Medicine*, May 10, 2007, “**Quadrivalent Vaccine Against Human Papillomavirus to Prevent High Grade Cervical Lesions,**” (FUTURE II study group), the results read, “The estimated vaccine efficacy against the high grade cervical lesions, regardless of HPV type, in this intention-to-treat population was 17%.” (Exhibit 4)

Diane Harper, M.D., Ph.D., also stated in the above- mentioned article that giving HPV vaccine to eleven-year-old girls was a “great big public health experiment.” Dr. Harper expressed the importance of informing people that the vaccine will not protect against the vaccine-type strains if the recipient is already infected at the time of vaccination. “If a girl is positive for HPV 16 (6, 11 or 18) when she is inoculated at any age, she will not be protected against it later.” The *Journal of the American Medical Association*, published an article confirming this on August 15, 2007, “**Effect of Human Papillomavirus16/18 L1 Viruslike Particle Vaccine Among Young Women with Pre-existing Infection.**” (Exhibit Five) Quoted from the excerpt of the article, “Our results show that rates of viral clearance over a 12-month period are not influenced by vaccination.”

Canadian Professor of epidemiology and biostatistics at McGill University in Montreal, Abby Lippman, published her comments on the HPV vaccine in the August 28, 2007 issue of the Canadian Medical Association Journal. She 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. Citing Merck’s own data she observes, “... methodologic weaknesses in the trial reports, combined with the limits in current available data, continue to leave many information gaps.”

Exhibit 2: (Paragraph Eleven) “How long does the HPV vaccine protection last?”

“Studies show the vaccine provides protection for at least five years.”

According to Merck’s product information, “Four studies evaluated 20,541 women 16 to 26 years of age...with a maximum FOUR year follow up.” (Emphasis mine). “The duration of immunity following a complete schedule of immunization with GARDASIL has not been established.”(Exhibit 3) How is DHSS making the determination that the vaccine will “protect” for five years when the maker only conducted studies for four years? Does the department have permission from Merck to extend the information beyond the study limitations?

Who is at the helm of this shipwreck, Attorney General Milgram? Who is so grossly negligent and remiss in their responsibility to the people of New Jersey who blindly trust this information is true? Who will be held accountable for disseminating this fraudulent information? How many parents will rely upon this alleged “fact sheet” to have their daughters vaccinated? If the state cannot perform its obligations and responsibilities to the highest professional and ethical standards, then who can recall it from that task? In comparing and contrasting the factual vs. fraudulent information provided, NOVAC is inclined to believe that the NJDHSS is operating in the service of interests rather than in the service of its citizens. Who is the New Jersey Department of Health and Senior Services in service to?

A copy of this letter will be posted on our network, which reports to thousands of people in New Jersey and several hundred others in states across the nation. The members of NOVAC are anxious for you to correct this abomination of a “fact sheet,” and hold the DHSS and its Commissioner, Heather Howard, accountable for failing the people of New Jersey in their responsibility to EDUCATE on public health issues.

On behalf of the members of NOVAC and with deep consideration and regard for the people of New Jersey, I thank you for your attention to this.

Sincerely,

Maureen Drummond
Founder/Spokeswoman
Network Organization for Vaccine Awareness and Choice

ENCLOSURES

CC: Nancy Belonzi, Policy Advisor, Office of the Governor
Heather Howard, Health Commissioner, NJDHSS
Lucille Davy, Commissioner, State of New Jersey, DOE
Senator Richard J. Codey, Senate President, NJ State Legislature
Senator Joseph F. Vitale, Chairman, Senate Health Committee
Senator Loretta Weinberg, Vice-Chair, Senate Health Committee
Bruce Kahlik, Vice President of Public Affairs, Merck and Company