Andrew Maniotis, Ph.D.
Program Director in the Cell and Developmental Biology of Cancer
Department of Pathology, and Bioengineering,
University of Illinois at Chicago
Chicago, IL 60607

GARDASIL, THE SACRIFICE OF THE VIRGINS, AND ANOTHER FIRST CANCER VACCINE.

HPV and cervical cancer became AIDS-defining illnesses in the early 1990's. HPV and its imagined link to cervical cancer has, in addition, become the new molecular signature used to terrorize millions of women with the threat that they will develop deadly cervical cancer if they harbor the HPV 16 or 18 DNA sequences. Again, as a putative cancer virus that causes cervical cancer years after infection, HPV DNA sequences 16 and 18 have been shown to transform susceptible cells in vitro, such as MCF-10 breast epithelial cells that were derived supposedly from a breast hyperplastic lesion (not a normal cell type because it exhibits immortal growth In Vitro). This is an important point because the ideal situation would be to obtain normal cervical cells, and transform them using purified “HPV virions, and prove that this virus could cause cancer in Petri dishes at least.

However, it is not established if secretions taken from either esophageal growths, or cervical cancers can induce transformation of cells in vitro, or in Humans.
In this segment I will review the evidence that HPV causes cancer, that it can be immunized against, and review its similarities to "HIV" and “HBV,” which I hope will help to cast light on these signatures and the syndromes they are associated with.

In the 1930’s, Shope, the pioneer who discovered a filterable extract of wart-like growths can cause cancer in animals such as rabbits was the first to suggest that a filterable extract might be a cancer-causing virus in these animals. The case of Human HPV, however, remains unproven that it causes the cancers it's molecular signature is associated with.

These loose ends have not prevented the development of rampant HPV testing among young women, or a vaccine, which is said to prevent cervical cancer in the vaccinated (unless they already have had a positive HPV 16, 18 test result).

In a front page Chicago Tribune story printed September 18, 2005, by T. M. Phung, and in a front page May 18, 2006, by J. Graham Chicago Tribune Story, we see how The Media has become big pharma's biggest ad spinners, as Merck is given a free and unchallenged platform to tout the wonders of "GARDASIL," (cleverly named I think), where they claim that this new vaccine against human papillomavirus, or "HPV,"was **100 percent effective in preventing precancerous cervical disease, but only when given to women and girls who had never engaged in sex at the time of the shots.**"

How good is the science behind such claims that vaccines against viruses can prevent pre-cancerous cervical disease in the case of "HPV"? Unfortunately, instead of science or evidence, moralistic debates, fear, and authoritative opinions, simplifications, and distortions are routinely presented as fact through media campaigns regarding the safety and efficacy of vaccines.

In the September 18th, T. Phung Chicago Tribune article about the "HPV" vaccination trial, instead of being provided any substantiated data, there are numerous distortions, inaccuracies, unqualified and unreferenced statements from Public Health Officials, a clinical pediatrician/ psychologist, moralistic and conservative Christian religious groups who oppose sex such as the Abstinence Clearinghouse, pharmaceutical drug-makers such as Merck and GlaxoSmithKline, a mom and her 3 children, the CDC, The American Cancer Society, The Illinois Department of Public Health, and NIAIDS. It is even advanced in the article that young children should at some point be asked about what they believe (regarding "HPV" and cervical cancer) in the context of their future sexual behavior:

*"Julietta Bolivar of Little Village, a mother of three adolescents--ages 10, 12, and 15--said she does not know how she feels about the vaccines. I would have to think about it," Bolivar said. "I want to learn about it before I make a decision. I guess I would have to talk to my doctor about it first**, then talk to my kids too and hear what they think**."*

Aside from the possible future opinions of Mrs. Bolivar's children about Merck's new vaccine (which would probably be negative ones-what 10-year old do you know wants to go to the doctor to get a shot?), or the imagined association between "HPV" and cervical cancer, not a single reference is provided to validate the wild claim advanced by Merck that "a wave of experimental vaccines against sexually-transmitted diseases could revolutionize the prevention of such infections in the next few years." Instead, what is advanced is a threat: "but there is a catch: the shots will likely work best when administered to (***our***) children" (*my emphasis*).

In the May 18th, 2006 J. Graham article, there are also numerous claims advanced that are not supported by any evidence (I am not being inclusive here regarding all the flaws that appear in this story but only presenting the most egregious) that addresses the claims that:

1) HPV vaccine prevents cervical cancer---no evidence.

2) HPV causes cervical cancer----no evidence.

3) HPV is the first cancer vaccine--what about hepatitis B and hepatocellular carcinoma? Merck told us 20 years ago that that the hepatitis B vaccine was the first cancer-preventative vaccine, and the Taiwan, and Korean studies are often provided to support that the vaccine reduced cancer in these countries. Can't these folks remember the history of vaccinology for 20 years prior to the present?

4) "The unanimous recommendation inspired cheers from the medical community, which said the vaccine could help save the lives of tens of thousands of women worldwide."

You don't hear the parents of vaccine damaged children cheering (as many as 1% are severely damaged by the hepatitis B vaccine according to Merck's own package insert-

which in many cases is being co-administered along with GARDASIL-see VAERS reports toward the end of this article). Many of our colleagues who have worked directly with “HPV” diagnosis and treatment also aren’t cheering, because they diagnose and treat cervical cancers and they know that the molecular HPV tests have not been validated, nor have the cell based smears been elucidated (why would the ASCUS test mean Atypical Squamous Cell Carcinoma of UNDETERMINED SIGNIFICANCE if this were not the case)?

Certainly, the US’s chief and most respected workers in HPV research aren't cheering because they state in a recent CAP Today (College of American Pathologists Today) article that they have grave medical concerns even regarding the validity of HPV test kits.

Moreover, we work with HPV in my laboratory, and we are horrified at such a dangerous suggestion-the implementation of this vaccine will place the lives of millions of our daughters at risk. Where are the long-term safety data? Will they be conveniently lost like the hepatitis B data which we asked the CDC to show us several years ago?

5) "…this is a watershed event ... that we hope will help usher in a new era of cancer prevention,"

It is a "watershed event" designed to reap untold profits at almost $900 dollars for the series at the expense of our daughter's (and possibly son's health).

6) "Haupt doesn't expect women to be tested routinely for HPV before being inoculated, in part because commercial tests can't pinpoint which HPV strain a woman has."

How can any scientific study on vaccine efficacy be conducted without an accurate test to detect the presence of a suspected pathogen?

7) ***"Documents prepared by the FDA suggest some women with persistent HPV infections could be at higher risk of cervical cancer after taking the vaccine."***

How could this be science based upon the immunology that we learned in school, or anything resembling science? Why should some women be at greater risk if they receive the vaccine? Is the HPV vaccine, GARDASIL, like the SV40-contaminated polio vaccines that increased the polio rate 3 fold in California, and 15 fold in Idaho, and hundreds of folds in certain outbreaks over normal summer background incidences of polio in the US weeks after the first vaccine wave was given? Does it increase disease like MMR and pertussis vaccines have, or is it due to the possibility that the HPV vaccine contains poisons, toxins, other viruses, or non-disclosed immune-disease-stimulating adjuvants (such as squalene) that cause autoimmune disease such as lupus, demyelinating syndromes, arthritis, or even cancer in animals?

What leading pathologists are saying about the molecular HPV kits and their validation as cancer diagnostics:

Both of these Chicago Tribune articles differ considerably from a front-page statement and 5 page article published in the September 2005 issue of Pathology/Laboratory Medicine/ and Laboratory Management article released monthly by The Collage of American Pathologists (CAP). Instead of asking Merck, The Public Health Service, or

Moms and their children what they think about the merits of the new Gardasil "HPV" vaccine, a highly pointed and critical 5-page article was advanced regarding the uncertainties of "HPV" testing. A few examples from the article make the point:

"Dr. Schiffman heads the HPV Troup in the Division of Cancer, Epidemiology, and Genetics at NCI and is a tenured senior investigator. In mid March, Dr. Mark Schiffman, MD, MPH, called CAP TODAY's editor to voice a troubling concern: that laboratories are failing to clinically validate their HPV tests."

"In two subsequent interviews with CAP TODAY, Dr. Schiffman says labs are stumbling badly. His case is straightforward. Laboratories that use HPV tests need to make sure those tests are clinically validated." "It's amazing to me that someone would sell a product that's influencing a patient's life in terms of treatment for cervical cancer without being sure, based on data, that they can do it again and again and again with reliability."

"Mark Stoler, M.D., professor of pathology and clinical gynecology and associate director of surgical pathology and cytopathology, University of Virginia Health System, Charlottesville, says the problem is a major concern, not 'some' concern. It's beyond anecdotal." "I certainly see-in the chat areas of the different organizations, at conferences, on the Internet-advertisements and statements that are troubling, because they're indicating an excessive faith in poorly validated assays, he says."

In the CAP TODAY article, Dr. Stoler also pointedly asks,

"The essential question for ASCUS triage (atypical squamous cells of **undetermined** significance), is what is the sensitivity of the HPV test, and therefore its negative predictive value, in patients who have equivocal cytology for high-grade lesions? Many physicians, however, focus instead on the positive predictive value of the test, that is, the likelihood of finding high-grade lesions with colposcopy." The problem," he says, "is colposcopy is a terrible gold standard, missing anywhere from one-third to one-half of high-grade disease." "Lots and lots of labs say, 'We think the PCR test is more sensitive because we can pick up fewer DNA copies.' That has nothing to do with what we're talking about," says Dr. Stoler. "If you're going to bring forward a test, you've got to do a clinical validation trial that establishes its performance relative to these other benchmarks," he continues. "And the standard is not analytical molecules of DNA. It's not the analytic validation that matters, it's the clinical validation-how does the test perform in the real world? How sensitive are you with finding high-grade disease in a population of minimally abnormal cytology patients?"

These are all very good questions and warnings. However, when the reference labs throughout the world, and the doctors who run them are asking what the tests mean "in the real world," it should cause some pause, and certainly caution with respect to the certainty with which HPV and cervical cancer and a potential vaccine against HPV and cervical cancer may have been worked out by Merck, and broadcast in the Chicago Tribune and L.A. Times with statements like:

"…this new vaccine against human papillomavirus, or HPV, was 100 percent effective in preventing precancerous cervical disease, but only when given to women and girls who had never engaged in sex at the time of the shots."

Even Attila Lorincz, PhD, chief scientific officer and senior VP of research development at Digene (one of the principal HPV test-kit makers) says that:

"much of the confusion simply boils down to analytical and clinical accuracy is not well enough understood or described by people who write or talk about it," and that "the problem surfaces in the HPV literature with distressing regularity."

Toward the end of the CAP TODAY article, Dr. Shiffman again is quoted as saying that:

"What surprises me is that this {the certainty with which these tests for HPV and cervical cancer} could in any way be controversial, he says. "The issue is not so much controversial, of course, as it is loaded-with money and competitive claims, scientific complexity, and grave medical concerns."

If what Dr. Shiffman, a world expert on "HPV," is describing the state of the art in "HPV" testing, then how could anyone suggest that:

"…this new vaccine against human papillomavirus, or HPV, was 100 percent effective in preventing precancerous cervical disease, but only when given to women and girls who had never engaged in sex at the time of the shots,"

unless madness about making money, rather than sound public health policy, were behind it?

The Illinois Department of Public Health versus the Parent Teachers Association of Illinois

A few years ago, small group of physicians and scientists gained the support of the Illinois PTA in a unanimous decision to support a current halt to the current mandated hepatitis B vaccine. Another way of saying this is that every school representative present at the convention, when shown the data we had obtained, had agreed with our concerns, and immediately held a brief session to advance a motion to direct PTA funding to disseminate literature so that parents would be informed.

This group of perhaps a thousand parents (mostly women), appeared to have only one concern: the total welfare, protection, and education of the school children of Illinois.

It should be stated emphatically, that the current hepatitis B mandate threatens not only our children's health, but also serves to threaten our children's education and admission to all kinds of institutions (day care and school admission), with the bluff that “if you don't get your kid vaccinated against this STD, that is detected only in subpopulations of injection drug users and perhaps highly promiscuous persons, as well as in healthy black Australian aboriginal men, Micronesians, Vietnamese, Taiwanese, Native Americans, patients with Down syndrome, leukemia and transfusion recipients, he or she cannot enter school to learn how to read and write.” This is not overstating it. Children cannot gain admission into day-care, Kindergarten, elementary schools, junior highs, high schools, and now even colleges, without showing evidence of a mandated (federally-recommended), and dangerous vaccine (hepatitis B).

Pursuing these issues, we presented the current head of the IDPH (Illinois Department of Public Health) Director Whitaker and his staff, with the same publicly available data from Medline, the vaccine manufacturer's package insert warnings, data from the Vaccine Adverse Events reporting System, the CDC, Vaccine-link, and other databases, that we had presented to the Illinois PTA convention. After visits with numerous

Senators, and public officials during the past several years, over a year later, in June of 2005, we finally were granted a brief meeting with the IDPH, after they could put us off no longer.

As a response to our pleas to institute informed consent regarding the dangers of the hepatitis B vaccine's side effects and safety record as it appears on the Federal governments VAERS database, and after many weeks of deliberation, Dr. Whitaker and his staff emailed us a one paragraph letter stating:

"Parents are currently given enough informed consent."

Well, one may ask Dr. Whitaker, "how do threats that our children won't be admitted to school unless they are jabbed with the hepatitis B vaccine (a rare syndrome) and whose safety data we have yet to see, constitute, informed consent?"

Shouldn't parents at least be given a list of the adverse syndromes induced by the vaccines that are presented on the manufacturer's package inserts, as shown above on Merck's insert? Should parents be shown the VAERS data? Should a list of the hundred or so articles on Medline regarding adverse syndromes induced immediately after vaccination, by mostly private physicians? Shouldn't parents be informed that the data supposedly supporting the safety of the hepatitis B vaccine in neonates doesn't exist (Lewis E, Shinefield HR, Woodruff BA, Black SB, Destefano F, Chen RT, Ensor R; Vaccine Safety Datalink Workgroup. Safety of neonatal hepatitis B vaccine administration. Pediatr Infect Dis J. Nov;20(11):1049-54, 2001; Also, Testimony of Dr. Marc Geier at IOM hearing, Aug. 2004).

Somebody should tell the public, as we have tried to warn for the past several years, that parents have the right to refuse all vaccines or medical treatments on their children's behalf, with the aid of a publicly-available form on which either religious or philosophical objection to these experimental medical interventions can be declared. The school nurse and Public Health Department, or school admittance policies should not be used to threaten you that you cannot enroll your kid, based on the madness surrounding the possibility that your 5-year-old will transmit a sexual, or needle-borne, or blood-product-transmitted "syndrome" that has a 95% or greater spontaneous resolution rate, to someone else's 5 year old, (when they have sex or shoot heroin in the gym locker-room, or if they share razor blades-are the reasons typically given to support mandatory hepatitis B vaccination) as the pharmaceutical company and Public Health Service logic goes. These same kinds of threats, mandates, and fear-mongering are already beginning to occur within the arena of GARDASIL and the undemonstrated link between the HPV molecular sequence and cervical cancer.

We beg the Public Health Service in the case of both hepatitis B and "HPV" to regard your own children as potentially at risk for becoming sexually promiscuous so they won't contract a rare disease that poses almost 0 risk, that will resolve without treatment in most cases, that simply presents as an ill-defined molecular sequence, or presents as harmless molecular signatures, or that may represent immunological stress or a simple genetic polymorphism. Please leave our infants and children alone.

Why in the face of all this damning evidence against the vaccine, does the hepatitis B vaccine mandate still stand with no end in sight? It is because new legislation has

insured that there is no incentive, compensation laws, or mechanisms in place anymore to guard against dangerous universally mandated experiments.

The future is here: Medical Terrorism into law

From the “Biodefense and Pandemic and Vaccine and Drug Development Act of 2005—a bill to amend the Public Health Service Act to enhance biodefense and pandemic preparedness activities, and for other purposes, **SEC. 319F-3**:

"(a) Authority- As provided in subsection (b), and subject to subsection (b)(1)(C), a manufacturer, distributor [sic; distributor]*, or administrator of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A) or a health care provider shall be immune from suit or liability caused by or arising out of the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure, or a qualified pandemic and epidemic product, described in subsection (b)(1)(A).*”

Further, subsection (b)(1)(A)(i) reads:
“(i) IN GENERAL- No cause of action shall exist against a person described in subsection (a) for claims for loss of property, personal injury, or death arising out of, reasonably relating to, or resulting from the design, development, clinical testing and investigation, manufacture, labeling, distribution, sale, purchase, donation, dispensing, prescribing, administration, or use of a security countermeasure or qualified pandemic or epidemic product distributed, sold, purchased, donated, dispensed, prescribed, administered, or used in anticipation of and preparation for, in defense against, or in response to, or recovery from an actual or potential public health emergency that is a designated security countermeasure or a qualified pandemic or epidemic product by the Secretary in a declaration described in paragraph (2).”

What is being described here is almost carte-blanche freedom to use untested vaccines, drugs, medical products, or "security countermeasures". And there is nothing you, or we, can do about it because it is in the interest of "National Security."

The costs of these giant Nuremberg-violating programs to insurers and to our society are catastrophic. We have met "slightly damaged" vaccine-damaged kids whose parents have spent more than 1.2 million dollars for several years of care.

In 2007, the Human Papilloma Virus Vaccine Safety information were as follows:
(March) http://www.909shot.com/Diseases/HPV/HPVrpt.htm

This information is divided into three sections. The first section describes reaction reports for a number of reported adverse events: neurological symptoms including syncopal episodes and seizures, arthralgia and joint pain, Guillian-Barre Syndrome, and other immunological reactions. The second section addresses concerns related to vaccinating individuals already infected with HPV. The last section discusses issues that need to be addressed by government regulators and the manufacturer and considerations for clinicians and consumers.

Analysis of Vaccine Adverse Events Reporting System Reports:
Adverse Reactions, Concerns and Implications

On June 8th 2006, the Food and Drug Administration (FDA) announced the approval of GARDASIL, and on June 29th the Advisory Committee on Immunizations Practices (ACIP) voted to recommend adding GARDASIL human papilloma virus vaccine to the Centers for Disease Control's national childhood recommended immunization schedule.

On July 14th the first report of a serious reaction to the vaccine was filed with the federal Vaccine Adverse Event Reporting System (VAERS). A 16-year-old Illinois girl was vaccinated July 7th and 13 days later developed symptoms eventually diagnosed as Guillian-Barre Syndrome. A 14-year-old girl in the District of Columbia was vaccinated on July 11th and complained of severe pain immediately following the injection, fell off the examining table and experienced a 10 to 15 second fainting spell ending up in the emergency room with a headache and speech problems. The report of this reaction, the first in the nation, was filed on July 14th, 15 days after the ACIP vote.

Six months later, 82 reports of GARDASIL reactions have been submitted to VAERS on behalf of at least 84 young girls and 2 boys.[1] Reaction reports have come in from 21 states and the District of Columbia.[2] Reactions were reported for children and young adults ranging in age from 11 to 27. Of the reports indicating what day the vaccine was given and the reaction occurred, 63 percent stated that the reaction occurred the same day the vaccine was given. All but three of the reports were for reactions that occurred within one week of vaccination.

Reported Adverse Events

Presumably, the reactions described below occurred after the first dose of GARDASIL. GARDASIL is given in a three-dose series. None of the reports stated that the children and adults experiencing problems had previously been vaccinated with GARDASIL.

Syncopal Episodes and Seizures. One-quarter of all reports filed after GARDASIL vaccination were for neurologic adverse events including loss of consciousness, syncope, syncopal events and seizures. An additional five reports included symptoms of dizziness and feeling faint.

Syncope is defined as a temporary suspension of consciousness due to generalized cerebral ischemia (inadequate blood flow and lack of oxygen). The reports of syncopal episodes and their descriptions are remarkable. A physician from Washington State reported that in one morning, three patients experienced syncopal episodes. On August 8th another physician's office reported that two patients experienced syncopal episodes on the same day.

Although these reports did not detail what happened to the individuals experiencing these syncopal episodes, other reports did. The 14-year-old DC girl mentioned earlier experienced a syncopal episode combined with amblyopia (poor vision in one eye), abnormal speech, vomiting, and headache. Also experiencing vision problems, a 17-year-old New York girl reported feeling dizzy and her vision went "black for a few seconds" and she turned pale and lips turned purple and she also had fever and chills. Similar to the DC girl, on July 18th immediately after being vaccinated, a 22-year-old Kentucky woman experienced slurred speech accompanied by pallor and shock. On August 29th, two hours after being vaccinated, a 15-year-old New York girl who had a history of asthma and was on four asthma medications experienced difficulty swallowing prompting a visit to the emergency room. On August 17th, 15 minutes after being vaccinated, a 14-year-old Pennsylvania girl passed out in the car on the way home.

Most of the reports do not describe what happened as a result of the syncopal episode but a few do. One 11-year-old Florida girl fell from the examining table and two Washington girls fell - a 16-year-old girl fell and hit her head on a carpeted concrete surface and a 14-year-old girl fell down and broke her nose.

Whether the 22 girls who experienced syncopal episodes actually experienced atonic seizures cannot be determined from these reports. Four girls, however, displayed observable seizure activity. The 11-year-old Florida girl who fell from the table also displayed "tonic posturing." Tonic posturing is a type of seizure where sustained contraction of muscles in the legs and arms occurs and consciousness is impaired. The 16-year-old Washington girl who fell and hit her head on the floor lost consciousness for one minute and displayed tonic posturing of her right hand. Additionally, a 15-year-old girl from Virginia was described as having "a mild seizure." In California, a 13-year-old girl was walking down the hall after her vaccination, fell and had a 15-second tonic/clonic seizure. Tonic/clonic seizures are also known as "grand mal" seizures.

Additionally, there were reports of dyskinesia (difficulty or distortion in performing voluntary movements) and hypokinesia (slow or diminished movement of the body musculature) both of which have neurological implications.

Arthralgia, Joint Pain and Fever. Arthralgia is defined as pain in the joints. Concerns about arthritis were raised during the GARDASIL clinical trials. Reports of arthralgia in one or more joints accompanied by fever were noted in five instances from four young girls and women in Wisconsin, Texas and New York, and one 18-year-old New York male.

Guillain-Barre Syndrome. Reports state that two recently vaccinated 16-year-old girls - one from Illinois and the other from Mississippi - were diagnosed with Guillian-Barre Syndrome (GBS) following vaccination with GARDASIL. In both cases, the onset of symptoms occurred 13 days after vaccination. According to the National Institute for Neurological Disorders and Stroke:

GBS is a serious disorder in which the body's immune system attacks part of the peripheral nervous system. The first symptoms of this disorder include varying degrees of weakness or tingling sensations in the legs. In many instances, the weakness and abnormal sensations spread to the arms and upper body. These symptoms can increase in intensity until certain muscles cannot be used at all and, when severe, the patient is almost totally paralyzed. … Vaccinations can trigger onset of GBS.

The Illinois girl described earlier was vaccinated on July 7th and symptoms were evident by July 20th. The girl also experienced gait abnormalities (trouble walking properly), asthenia (weakness without loss of strength), paresthesia (burning, prickling, tingling or numbness sensation usually felt in the hands, arms, feet and legs), and hyperkinesia (abnormal increase in muscle movement). The Mississippi girl was vaccinated on July 31st and by August 13th she had increasing numbness and tingling in her feet and hands and was subsequently evaluated by a neurologist and diagnosed with GBS. The current health status of these girls is not known.

In both of these cases, the girls were also vaccinated with Aventis Pasteur's Menactra, a vaccine for meningococcal infections. Menactra has previously been associated with Guillain-Barre Syndrome, and the FDA and others have issued alerts.

Other Adverse Reactions.

Additionally, a number of other reactions to GARDASIL are noted in VAERS reports and they include: urticaria (hives); pruritus (itching); macular and papular rashes; blisters and vesicles near the injection site; swollen arms; lymphadenopathy (swollen lymph nodes); red, hot swollen knots at injection site; burning, stabbing, severe and radiating pain at the injection site and in the affected limb during and after injection; nausea and vomiting; infections and skin ulcers, and other allergic reactions.

Other Considerations

GARDASIL is marketed as a "cervical cancer vaccine" and intended to prevent infection with specific HPVs - common viruses among sexually active women. It isn't clear what benefits or

potential harms could arise from vaccinating sexually active women who have already contracted HPV. Of the 86 reaction reports filed with VAERS so far, 12 reports were generated by young women 18 and older who were taking hormonal contraceptives and presumably sexually active.

With respect to concerns related to vaccinating women with known HPV infections, adverse reaction reports were filed on behalf of a 17-year-old Texas girl who was already diagnosed with HPV and genital warts. Similarly, the 22 year-old Kentucky woman who experienced slurred speech following vaccination already had an abnormal pap smear with evidence of cervical dysplasia.

Implications

The early reports of potential safety problems with GARDASIL raise concerns and questions that need to be addressed by government regulators, manufacturers and prescribing physicians. Specifically, the following concerns need to be addressed:

1. Syncope, seizures and Guillian-Barre Syndrome have now been reported with hours to a week after GARDASIL vaccination. GARDASIL manufacturer, Merck, should add these serious adverse events to the product manufacturer insert.

2. Considering that over 20 girls have experienced syncopal episodes sometimes combined with seizures and serious injuries, physicians should consider only giving GARDASIL when the patient is safely laying down on the examining table. Because there seems to be syncopal reactions up until 15 minutes after vaccination, patients should be asked to lie down for 15 minutes after receipt of GARDASIL.

3. The information provided by Merck indicates that it is safe to administer GARDASIL with Hepatitis B vaccine. The prescribing information states, "Results for clinical studies indicate that GARDASIL may be administered concomitantly (at a separate injection site) with hepatitis B vaccine (recombinant). Co-administration of GARDASIL with other vaccines has not been studied." Due to the small number of girls aged 9 to 15 who appear to have been evaluated for GARDASIL safety in Merck clinical trials
(fewer than 2,000) and lack of publicly available information about how many of these girls were given GARDASIL and hepatitis B vaccine simultaneously, the safety of administering GARDASIL and hepatitis B vaccine to all pre-adolescent girls is uncertain.

4. Aside from Hepatitis B, Merck does not state that it is safe to simultaneously administer GARDASIL with any other vaccine. Considering that there are ongoing evaluations of a reported association between Menactra (meningococcal vaccine) and Guillain-Barre Syndrome, and Merck does not explicitly indicate that it is safe to administer to administer GARDASIL and Menactra simultaneously, consumers and clinicians should question whether administering both GARDASIL and Menactra at the same time is safe.

5. Similarly, adverse reactions were reported when GARDASIL was administered with eight other vaccines: Hepatitis A, MNQ (?), MEN (Menactra), TD (Tetanus and Diptheria Toxoids), DPP (Diptheria/Pertussis/Polio), PNC Prevnar (Heptavalent pneumococca conjugate), DTaP (Diphtheria And Tetanus Toxoids and Acellular Pertussis Vaccine), and TDAP (Tetanus, Diptheria and Pertussis). Because Merck does not state that it is safe to administer simultaneously GARDASIL with any vaccine other than Hepatitis B, consumers and clinicians should question whether co-administration of GARDASIL and other vaccines is safe.

6. Most, if not all, of the reactions reported to VAERS were in response to the first of the three doses of GARDASIL. The Centers for Disease Control (CDC) Vaccine Information Sheet (VIS) developed for HPV vaccine states that severe reactions include "any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness."

The CDC also states that "anyone who has ever had a life-threatening allergic reaction to yeast, to any other component of HPV vaccine, or to a previous dose of HPV vaccine should not get the vaccine." Which of the reactions reported to VAERS constitute a "life-threatening allergic reaction" and which, if any, of the children and young adults who experienced reactions should receive additional doses of vaccine? At the October 2006 ACIP meeting, CDC staff stated that only "three serious reports were reported to VAERS after HPV vaccination in females 14 and 16 years of age. One of these patients had vasovagal syncope and was hospitalized overnight for observation." [7]CDC's summary of the first 76 VAERS reports suggests that CDC doesn't regard the remaining reports as "serious." CDC needs to clarify which of the reactions reported to VAERS constitute contraindications to further vaccination with GARDASIL and make this information available to the public and to prescribing physicians.

7. What were the short and longer-term outcomes for the individuals who experienced the reactions reported to VAERS? Is there information available that would help to predict the characteristics that predispose one to be at greatest risk of experiencing a serious reaction?

8. The CDC's Vaccine Information Sheet indicates that allergy to yeast is a reason to avoid taking GARDASIL. Merck notes that contraindications to the vaccine include "hypersensitivity to the active substances or to any of the recipients of the vaccine. Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL should not receive further doses of GARDASIL." The prescribing information provided by Merck does not specifically note that yeast allergy is a contraindication to taking GARDASIL. Government regulators and the manufacturer need to address the discrepancy between these documents and clarify the issues related to yeast allergy and make this information readily available to the public and prescribing physicians.

9. Additionally, Merck notes that vaccine ingredients include 225 mcg of aluminum (as amorphous aluminum hydroxyphosphate sulfate adjuvant), 0.78 mg of L-histidine, 50 mcg of polysorbate 80, and 35 mcg of sodium borate. These ingredients are not listed on the CDC's VIS sheet. The public needs this information so that they can identify whether they have "hypersensitivities" to any of the ingredients and whether they are at risk of experiencing a serious allergic reaction. Hypersensitivities and known allergic reactions are critical pieces of information that need to be communicated to prescribing physicians in order to make the safest possible vaccination decisions.

Government regulators including the CDC and FDA, in combination with Merck, should address the above safety concerns as soon as possible. Medical groups advocating use of GARDASIL should effectively communicate to physicians and patients the potential risks of using GARDASIL along with precautions to improve the safety of patient care.

ADVERSE EVENTS REPORTED BY October 6, 2007:
(ARTICLE_ID=58004 (c) 2007 WorldNetDaily.com)

Another eight deaths in just the past few months are being connected to Gardasil, Merck & Co.'s vaccine that targets the sexually transmitted human papillomavirus and is being considered by many states as mandatory for all schoolgirls, according to documents released by Judicial Watch.

There also have been another 1,824 adverse reactions to the drug, bringing the "known total" of such problems to 3,461, according to the public interest group that investigates and prosecutes government corruption.

"In light of this information, it is disturbing that state and local governments might mandate in any way this vaccine for young girls," said Tom Fitton, the group's president. "These adverse reactions reports suggest the vaccine not only causes serious side effects, but might even be fatal."

WND previously has reported how Merck was lobbying state lawmakers to require the vaccination, but gave that up after its activities were unveiled.

WND also reported when a key researcher into human papillomavirus, which is targeted by Gardasil, reported it needed more testing, and how even the Centers for Disease Control suggested the vaccine should not be mandatory.

The dispute primarily has been over proposed state and other governmental requirements that schoolgirls be vaccinated against an infection transmitted only by sexual contact.

The target of the vaccine is cervical cancer, since studies show that those who have HPV have a higher chance of later developing cervical cancer. However, opponents note that such cancers develop most often in older women, while the plan is to require girls as young as 11 or 12 years old to be inoculated. They cite the lack of evidence that the vaccine would have an impact later in life.

Judicial Watch said it obtained documents from the U.S. Food and Drug Administration under the Freedom of Information Act detailing the new 1,824 cases.

Those cases include as many as eight deaths related to the vaccine, on top of the three deaths reported earlier among 1,637 earlier reports of adverse effects.

Among the new information Judicial Watch found:

"Information has been received concerning a 17 year old female who in June 2007 was vaccinated with a first dose of Gardasil During the evening of the same day, the patient was found unconscious (lifeless) by the mother. Resuscitation was performed by the emergency physician but was unsuccessful. The patient subsequently died."

"Information has been received concerning a 12 year old female with a history of aortic and mitral valve insufficiency who on 01-MAR-2007 was vaccinated IM into the left arm with a first does of Gardasil On 01-MAR-2007 the patient presented to the ED with ventricular tachycardia and died."

"Initial and follow-up information has been received from a physician concerning an 'otherwise healthy' 13 year old female who was vaccinated with her first and second doses of Gardasil. Subsequently, the patient experienced paralysis from the chest down, lesions of the optic nerve At the time of the report, the patient had not recovered."

The flood of adverse reactions during 2007 reported to the FDA through the Vaccine Adverse Event Reporting System, included 347 serious reactions.

"Of the 77 women who received the vaccine while pregnant, 33 experienced side effects ranging from spontaneous abortion to fetal abnormities. Other serious side effects continue to be reported including, paralysis, Bells Palsy, Guillain-Barre Syndrome, and seizures," Judicial Watch said.

And these numbers may not even include all the cases, Judicial Watch said. It filed a lawsuit this week against the FDA for failing to fully respond to its requests for information involving the vaccine.

Specifically Judicial Watch wanted access to correspondence between Merck and the FDA regarding the vaccine, communications between the FDA and GlaxoSmithKline, which is working on a similar vaccine, called Cervarix, and reports by consumers, health professionals and others regarding problems with the HPV vaccine.

When the organization's investigation into the HPV vaccine issue arose, and the first reports starting coming in, Fitton described it as "a catalog of horrors."

One earlier report, No. 275438-1, describes the reaction as coronary artery thrombosis, sudden cardiac death. "Given Gardasil vaccine dose #1 3/12/07. Collapsed and died on 3/26/07 Echocardiogram revealed very enlarged right ventricle, small left ventricle as well as large blood clots within both the right atrium & right ventricle."

Another report noted that the woman was vaccinated and "died of a blood clot 8 hours after getting the Gardasil vaccine."

Officials with the Abstinence Clearinghouse noted in a position paper that groups including the Texas Medical Association, the American Academy of Pediatrics, the Association of American Physicians and Surgeons, and the American Academy of Environmental Medicine have come out publicly against mandatory vaccination.

"The reasoning of these medical associations is clear. They are not opposed to medical progress, and certainly support all efforts to combat life-threatening diseases. The problem, as these organizations see it, lies in the fact that the drug only went through three and a half years of testing, leaving the medical community somewhat in the dark as to what serious adverse effects might result in the long term," the group said.

"Along with the potential of serious adverse effects is the question of efficacy. There is evidence that after approximately four years, the vaccine's potency significantly declines. The long-term value of the vaccine has yet to be determined; if it wears off within six years, will girls and women need to repeat the battery of injections they originally received?" the organization wondered.

Michigan was the first state to introduce a plan to require the vaccine to be given to young girls, but the proposal failed. Ohio also considered a failed plan in 2006.

Then in 2007, after Merck's aggressive lobbying campaign and contributions to Women in Government, lawmakers in at least 39 states and the District of Columbia worked on sponsoring such plans.

September 26, 2007

Merck Set to Donate Cancer Vaccine Doses

By LINDA A. JOHNSON
http://www.lasvegassun.com/sunbin/stories/thrive/2007/sep/26/092603125.html
AP Business Writer

TRENTON, N.J. (AP) - Drug maker Merck & Co. plans to donate enough doses of its cervical cancer vaccine, Gardasil, to inoculate 1 million women in some of the world's poorest countries.

Merck announced the gift Wednesday at the third annual Clinton Global Initiative conference in New York.

The Whitehouse Station-based company said at least 3 million doses of Gardasil are to be distributed over the next five years. The vaccine is given in three shots spread over six months.

Cervical cancer, caused by a sexually transmitted virus, is the No. 2 cause of cancer deaths worldwide, with nearly 500,000 new cases and 250,000 deaths each year. Most deaths occur in poor nations, where women rarely get tests to detect cervical cancer early, when it is most curable.

Merck plans to partner with a nongovernment organization to set up programs to distribute the vaccine in countries yet to be chosen.

"Our company is fully committed to making Gardasil available to those who need it," Margaret McGlynn, head of Merck Vaccines and Infections Diseases, said in a statement.

Gardasil is 99 percent effective in preventing infection by two strains of the human papilloma virus that together cause about 70 of cervical cancer cases. It also protects against 10 other strains that cause cancer, plus another two that cause genital warts but not cancer.

In the United States, Gardasil costs about $360 for three doses, plus any fee for a doctor visit.

Merck has the only cervical cancer vaccine approved in the United States, but rival GlaxoSmithKline PLC's vaccine, Cervarix, was approved Monday for sale in the 27 European Union member states and is awaiting U.S. approval.

Somebody should let these folks know that the hepatitis B vaccine was touted as being the first anti-cancer vaccine, which in fact was made by Merck, the company now claiming the HPV is the first anti-cancer vaccine. If they believe HPV causes hepatocelllular carcinoma (or is associated with leukemia), and if “HIV” causes 6 cancers (except of course for Kaposi’s sarcoma, the first AIDS-defining illness), then GARDASIL is not the first anti-cancer vaccine given (or mandated) in the U.S. It represents, perhaps, another first anti-cancer vaccine whose effectiveness will be evaluated at least 35 years from now, given the certainty of the Pankhurst analysis of the 35 year post polio era data where SV-40 was monitored for its ability to cause cancer in the carefully followed group described before.

Dear Mr. Andrew Maniotis,

Good afternoon, sir. Thank you for your reply. Yet I am still wondering, what does having HPV DNA really mean, then? I would assume it means in the past I was exposed to something of which I have now built natural immunit, thus the "normal" pap smears for several years. So WHY an HPV DNA test? I feel I was treated like a criminal. A total encroachment to my so called "civil" rights.

Obviously having HPV DNA (from 2006 testing) does not mean I am carrying active HPV, am I correct? I assume it means nothing. What would I ever tell a potential partner, or would I need to say anything at all? This type thing RUINS relationships! ALl based on fraudulent DNA testing.

The last guy I was with (for almost three years) knew about the HPV, and did not care. But that relationship ended due to his not being able to remain monogmous,etc. A typical latin womanizer. I do feel that I was used as a human lab rat by various doctors, and it infuriates me. I am in great health and take excellent care of myself. I do not smoke. I run everyday. I am actually in far better physical health than ANYONE I have ever met. I also have lots of energy. I am drug free and do not drink much alcohol. Most people I know are addicts of one thing or another, and most I know are not in good physical healtn. And most people I know are totally ingorant when it comes to just about anything besides what they see on their TV sets.

But there is this stigma with the HPV DNA thing, from the 2006 "testing" I was given without my consent, twice in six months by the same, uh. you know what female doctor. I cannot stand her. She makes me so mad. You cannot imagine the humiliation. If I was used as a medical lab rat, does this not give me legal grounds to sue the doctor who did this to me, or perhaps Digene Diagnostics? It really does not seem very fair. It has caused me extreme anxienty, depression, humiliation, stress, and humiliation. This is why I will never trust another doctor again. Most are such arogant and insenstive people. I am in Texas, and you can imagine how bad it is here. I hate Houston. We also have that creep Perry in office, who tried to mandate Gardasil vacccinations. Anyway, thank you so much for your reply. I really really appreciate it very much.

Regards,

Layla