

# Gardasil: A Deadly Risk Not Worth Taking

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Do you find something seriously wrong with this scenario?

Reports of faulty gas pedals, obstructive floor carpets, and failing breaks in Toyota and Lexus vehicles generated uproar across major media networks. For the 4-year period starting in 2006, the National Highway Traffic Safety Administration (NHTSA) had reported 5 deaths, 17 injuries and 13 crashes, and an additional 29 deaths between 2000 and 2005. There was no hesitation among the networks and federal officials to demonize Toyota for knowingly risking the lives of people solely to empty its dealership lots. Even Congress quickly called for a Congressional investigation, and Toyota took upon itself the responsibility to recall over 8 million vehicles.

As the NHTSA was collecting crash data on Toyota's lemons, the Centers for Disease Control's (CDC) Vaccine Adverse Events Reporting System (VAERS) database was gathering casualty data following vaccinations with Merck's human papilloma virus (HPV) vaccine, Gardasil. And it was clear that Merck was far ahead and winning its race against Toyota for the Lemon of the Decade Award. According to the vaccine watch organization Sanevax, since Gardasil's launch in 2006 until November 2012, the HPV vaccines have been associated with 121 deaths and over 27,485 medical injuries of young girls, some as young as 11 years old, in the CDC's monitoring system.

Unfortunately, vaccine injuries are not reported immediately and thoroughly as are automobile accidents and deaths. There are no vaccine police rushing to the scene of vaccine accidents to investigate the incidents and to record injuries and fatalities accurately. Consequently, only a fraction of vaccine adverse events reported by pediatricians, physicians, medical clinics and hospitals, make their way into the VAERS database. Few parents even know such a reporting system exists.

Gardasil, the human papillomavirus vaccine produced by Merck, was brought to market with great fanfare, widely proclaimed as the first ever anti-cancer vaccine. Merck created a market for Gardasil out of thin air with deceptive and dishonest advertising,[1] and thereby planted fear in the mind of consumers: fear of an enormous, yet unknown health crisis, an invisible time bomb waiting to explode and harm women everywhere. Whereas most vaccines and drugs undergo several years of clinical testing, including human trials, prior to FDA approval, Gardasil was on FDA fast track approval and underwent a mere six months of trial research. When criticized for their aggressive marketing, Merck

countered that they were performing a public service by raising awareness about the human papillomavirus and weren't selling anything.[2] Really?

This lie became public as Merck was caught lobbying the 50 states for mandatory Gardasil vaccination before it had even secured FDA approval![3] The fact is that there was never a need for Gardasil in the first place: regular Pap testing had already lowered the incidence of cervical cancer by 80% in the US to a few thousand cases a year and the vast majority of all HPV infections resolve of their own accord.[4]

But by lining the coffers of such groups as Women in Government (WIG), and, of course, the American Legislative Exchange Council (ALEC), Merck was able to influence legislation such that almost immediately after the vaccine was approved, it was part of the vaccine schedule recommended for all girls.[5] If it hadn't been for Governor Rick Perry's blunder of trying to mandate Gardasil for school attendance in Texas in the face of huge conflict of interest and a \$50 million contribution to his presidential campaign, Gardasil might have gone even further.[6]

There is something deeply wrong with a giant pharmaceutical company spending hundreds of millions of dollars to manipulate women and influence legislation in order to generate a revenue stream of billions of dollars a year for themselves at the expense of a gullible public. Because what is wrong with Gardasil isn't just that it is unnecessary. Gardasil is possibly the most dangerous vaccine on the market with the potential to injure, maim, or even kill the children who receive it.

The program of coercion to vaccinate every 11 to 26 year-old girl with Gardasil is relentless. This vaccine is given not just in doctor's offices, where doctors have been known to "fire" non-compliant patients, but in schools and colleges, where the pressure on girls and their parents to conform can be extreme. These institutions all have quotas — sometimes including financial rewards — and they are anxious to prove high rates of compliance.[7]

But there is no informed consent prior to vaccination, so most of these girls and their parents have no idea what they are risking by agreeing to vaccination with Gardasil. While Merck, the FDA, the CDC and the medical establishment all deny that there have been serious, life-altering adverse events associated with Gardasil, the fact is that compared with the mandated vaccines which are given with greater frequency, Gardasil still has the most adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) of any vaccine. And since reporting of adverse events is not mandatory in the US (although outbreaks of so-called vaccine-preventable illness are), it is likely that only 10% even get reported![8]

But what of the victims of Merck's war on cervical cancer? Alexis Wolf was a normal seventh grader in 2007. She had Type I diabetes, but had successfully

learned how to give herself insulin shots and eventually graduated to an insulin pump, which she also mastered easily. Alexis made the honor roll for the first time that year, and was rewarded with a trip to Germany over the summer to visit her grandparents. Her endocrinologist believed that the diabetes was under control and felt that Alexis would be perfectly capable of making the trip on her own and managing her diabetes herself. To make sure everything was in order prior to travel, Alexis' doctor recommended that she receive her first Gardasil vaccine.

The trip went well, but Alexis seemed different to her mother when she returned, perhaps a bit distant. Alexis received her second Gardasil vaccine after coming home, and shortly thereafter her personality changed entirely. For a relatively shy girl, Alexis immediately became very gregarious, hugging everyone all the time. But she also became agitated, troubled, and started having difficulty keeping food down. It reached the point where she threw up a number of times a day, which is especially dangerous for a diabetic. There began a series of appointments with many, many doctors: the GP, the endocrinologist, the cardiologist, the gastroenterologist, and numerous different diagnostic tests. But nothing they did or recommended seemed to help. Alexis was struggling to get through her days, usually carrying a bucket with her at all times just in case. She had terrible insomnia, was eating excessively, and was falling further and further behind in school.

In January 2008, Alexis received her third Gardasil shot – within 2 weeks she was in the hospital. Her behavior had worsened to the point where she was considered bipolar and she was put on a series of antipsychotic medications. Her mother didn't believe that this was a psychological problem. She knew that something else had to be wrong, knew that there had to be some medical explanation for what was going on.

After weeks and months in and out of different hospitals with no improvement and her condition growing more desperate, Alexis at long last was seen by a doctor who recognized that she was having seizures – something all the previous doctors had overlooked. This led to more tests – EEGs, MRI imaging, and spinal taps — and finally a conclusion that seemed to make sense: encephalitis, traumatic brain injury, and seizure disorder. But why? Alexis' mother had an additional conclusion which was so crystal clear in hindsight – her daughter was normal before she received the Gardasil vaccine and had worsened with each one. The Gardasil vaccine had left Alexis with brain damage.

We spoke with Tracy Wolf, Alexis' mother, about their ordeal. While maintaining a cheerful optimism, Tracy admitted that she could never have foreseen how their lives would change completely. After Alexis' seizure disorder was identified and she was put on anti-seizure medication, her physical symptoms improved to a certain extent, but she was completely altered. Alexis has deteriorated from being a normal child to one who is only functioning at a fourth grade level.

Forced to enter Special Education instead of rejoining her previous class, Alexis became enormously frustrated and school became an ordeal for everyone.

Since Alexis turned 18, Tracy finally gave up and pulled her out of school, realizing that it really could not offer Alexis anything but misery. The stress on their family has been enormous. The pressure caused the Wolf's marriage to dissolve, and Tracy is now raising both their daughters by herself, with their father living in a different state. Alexis needs almost constant supervision, and Tracy can only leave her alone for short periods of time. They have applied for special services that could possibly be helpful, but the waiting list is long. Alexis doesn't understand why things are so different, why her little sister is learning to drive but she can't.[9]

Unlike with other types of injuries, a vaccine victim cannot simply sue the company responsible for the problem. Since 1986, all cases of vaccine injury must be brought to the Office of Special Master at the US Court of Federal Claims, commonly called the vaccine court. This court was established to create a non-adversarial situation in which children injured by vaccines could receive compensation. But the Department of Health and Human Services has completely distorted the intent of this legislation, and turned it into a highly adversarial proceeding. Injuries listed on a table are supposed to be automatically compensated, but they have removed a lot of injuries from the table over the years, and have listed new vaccines, such as Gardasil, with no specific injuries attributable to the vaccine. So the burden is on the victim to prove causation because there is no presumption of any injury.

In conversation with William Ronan, a lawyer retained by Alexis' family, he shared that his law firm currently is handling 12 – 15 Gardasil cases that are being evaluated and another 6 cases already filed in the vaccine court. Interestingly, out of all the types of Gardasil-related injuries, the cases Ronan represents all fall into two main categories: autoimmune and neurological. When the injuries are neurological, doctors frequently can't put their finger on what is wrong, and end up sending the girls to a psychiatrist.

Ronan maintains that it is impossible for all of these girls suddenly to have developed mental problems or simply to be imagining that they have been harmed since receiving the Gardasil vaccine. While not anti-vaccine himself, he has seen too many girls have serious adverse reactions to Gardasil. He runs a two-person law firm in Kansas City, and without advertising, has received at least 20 to 30 calls regarding Gardasil injuries. Ronan believes his experience is just the tip of the iceberg — anyone actually advertising legal services for Gardasil victims would be inundated with a huge number of cases.

The work is slow-going. Evidence of harm caused by vaccines is crucial, but there aren't a lot of published medical studies about safety to back up this claim. Those that exist are funded by the manufacturer and tend to be overly

favorable. Possibly the strongest argument against Merck, according to Ronan, is their failure to warn girls of the risk involved when getting the Gardasil vaccine. Merck clearly knew that this drug could cause neurological dysfunction, yet did not adequately address this in the product insert. Also, it is well known that girls who already have an HPV infection are more likely to be harmed by the vaccine, but the manufacture does not make this clear and does not recommend testing. Ronan summed up his view of vaccinating young girls with Gardasil:

*“The real issue is: what is the benefit of this vaccine? Do the benefits outweigh the risks? There is a risk of a seizure disorder or an autoimmune disorder versus the benefit that it might reduce cervical cancer. But Gardasil doesn’t eliminate the need for regular Pap testing, which is already safe, and there isn’t good evidence that it prevents cervical cancer. In evaluating risk and benefit, when all the facts are known it becomes a pretty easy decision – the vaccine is more dangerous than any benefit. Unfortunately, medical professionals tend to read and listen to information provided by the manufacturers, which doesn’t adequately present the risks involved, so they actually aren’t sufficiently informed to advise their patients.”*

Ronan’s own daughter had to fight off an aggressive attempt by her doctor to get the Gardasil vaccine, so he understands the pressure that girls are under to just go along instead of asking questions.[10]

We interviewed Dr. Meryl Nass, board certified internal medicine practitioner and vaccine specialist, who agrees that Gardasil was rushed to market without adequate safety testing. Three years after approval for girls, the company likewise received approval to vaccinate boys age 9 and above with no new studies and very little data to justify this action. Regarding Gardasil’s adverse effects, Dr. Nass said,

*“Children don’t usually die suddenly when they are healthy but there are certainly lots of teenage girls who have died relatively suddenly after Gardasil or developed severe neurologic reactions. Therefore, if you are going to try to balance safety and efficacy when you prescribe something like a vaccine, you have to know how effective it’s going to be. Does this really prevent cervical cancer in young women? And does it prevent it in women who have already been exposed to these viruses? ... So I don’t know how other doctors prescribe something like Gardasil ... Basically, they make an assumption that since the FDA has licensed it ... the manufacturer would only market something that’s safe, doctors go ahead and prescribe. And what they may not be aware of is that it is extremely hard to link a side effect to a vaccine, for many reasons. Getting a judgment against a manufacturer is very difficult and it has become more difficult due to some recent litigation that reduced manufacturer liability for vaccines in general.”[11]*

Gardasil’s doctrine is already so entrenched after only six years that it is a

formidable task to challenge the official story that this vaccine is safe and effective, because the truth is too unsettling. The remarkable claims of Gardasil's benefits to women in the war on cancer are full of holes and not supported by the science, even that science funded by Merck itself. It is important to deconstruct the falsehoods and half-truths that masquerade as facts about Gardasil.

□ **THERE IS NO HUMAN PAPILLOMAVIRUS HEALTH CRISIS.**

Cervical cancer in the United States has been at record lows for the past two decades. Currently only an estimated 3,600 women die of cervical cancer each year. The spectacular success in lowering the death rate from cervical cancer can be attributed to annual Pap screening – between 1955 and 1992 deaths from cervical cancer declined 74% and continue to decline annually by 4%. [12] Part of the success of Pap screening lies in the fact that cervical cancer, unlike most other cancers, is very slow growing. With screening, there is ample opportunity to catch and successfully treat cervical cancer before it gets out of hand. It would be unlikely, then, for any further treatment to improve upon this already very low rate of cervical cancer death.

When government officials and vaccine advertising make wild claims of high death rates associated with cervical cancer, according to neuroscientists Dr. Lucija Tomljenovic at the University of British Columbia, 88% of these deaths occur in developing countries without adequate pap smear screening programs.

□ **HUMAN PAPILLOMAVIRUS INFECTION DOES NOT USUALLY LEAD TO CANCER**

It is estimated that virtually all women in the US experience a series of human papillomavirus infections throughout their lifetimes. What the makers of Gardasil try to hide is the well-documented fact that 90% of all HPV infections go away of their own accord within two years without causing any disease and with no treatment or intervention of any kind.[13]

□ **GARDASIL DOES NOT PREVENT CANCER**

The end point of all the efficacy studies for Gardasil was not, in fact, prevention of cancer. Researchers couldn't actually assess the development of cervical cancer following the vaccine because this process normally takes 20 to 40 years and their studies stopped after just five. So instead, Merck's scientists decided that the presence of atypical cervical cells was a valid "surrogate end point," or substitute for cancer. They used this hypothesis despite the fact that there is no evidence that the types of cervical lesions they chose as their end point would eventually lead to cancer.[14] Merck has never acknowledged that their entire premise for the efficacy of Gardasil rests on pure speculation. In fact, many if not most atypical cervical cells resolve on their own without intervention.[15]

□ **GARDASIL IS NOT 98% EFFECTIVE AT PREVENTING HIGH-GRADE CERVICAL LESIONS.**

Results of Merck's efficacy study published in a 2007 article in the New England Journal of Medicine claim that Gardasil is 98% effective at preventing high-grade cervical lesions. Subsequently, Merck and the CDC have lowered that figure to 70%. But the article itself reveals that Merck manipulated the data by excluding women and girls who did not follow the exact protocol. When all women in the study were considered, vaccine efficacy dropped to 44%. But even these numbers only actually reflect cervical lesions associated with HPV 16 and 18. When Merck looked at Gardasil's ability to prevent all cervical lesions, Gardasil was only 17% effective!<sup>[16]</sup> And again, their definition of "effective" rests solely on the unfounded assumption that certain types of cervical lesions turn into cancer.

More damning is Merck's own acknowledgement that in their controlled studies, a percentage of girls actually developed serious cervical lesions following Gardasil. The vaccine seemed to cause the most lesions in girls with pre-existing HPV 16 or 18 infections, but also in girls who had no pre-existing HPV infections.<sup>[17]</sup> At the very least, screening girls for HPV 16 or 18 infections would give HPV-positive girls the chance to avoid developing cervical lesions by declining the vaccine. Yet not only does Merck not recommend testing for HPV prior to vaccination with Gardasil, they have actually discouraged this practice, presumably so as not to draw attention to the danger.<sup>[18]</sup> Anything to maintain the fantasy that this is a safe and effective vaccine.

□ **GARDASIL DOES NOT PREVENT HUMAN PAPILLOMAVIRUS**

Gardasil is designed to prevent only 4 HPV strains: 16 and 18, which can cause cervical cancer, and 6 and 11, which can cause genital warts. However, there are 150 other types of HPVs, at least 15 of which can cause cancer, and Gardasil provides no protection against these other strains.<sup>[19][20]</sup> Does Merck's so-called consumer education ever mention any of this? Of course not. Why would you have your daughter vaccinated if you knew the protection was so limited?

□ **VACCINATING PREPUBESCENT GIRLS WITH GARDASIL WILL NOT PROTECT THEM AGAINST HPV OR CERVICAL CANCER.**

Despite the sanctimonious advertising which suggests that both mothers and daughters can empower themselves through Gardasil, Merck's own studies show that the vaccine is only effective for 5 years.<sup>[21]</sup> So if your 11 year-old daughter gets the Gardasil vaccine, it will have stopped working by the time she is 16. But since Merck doesn't give out this information voluntarily, these girls and their mothers will be in the dark.

□ **GARDASIL VACCINATION DOES NOT ELIMINATE THE NEED FOR ANNUAL PAP SCREENING**

In portraying Gardasil as a treatment that will prevent 98% of cervical cancer, the strong implication is that vaccinated girls will no longer be at risk of cervical cancer at all. As we have already seen in Finland, this can lead to the false

assumption that there is no longer a need for annual Pap testing. When women in Finland stopped getting Pap screens, cervical cancer increased to 4 times the incidence in only 5 years![22] This complacency about risk, started and fostered by Gardasil advertising, is also likely to lead to an actual increase in cervical cancer in the US as more females receive the vaccine and stop taking actions that have been proven to be protective.

□ **THERE IS NO EVIDENCE THAT GARDASIL IS EFFECTIVE IN BOYS AT PREVENTING GENITAL WARTS AND ANAL CANCER.**

Merck's study of HPV vaccine efficacy in males published in the New England Journal of Medicine states that Gardasil is 89% effective against genital warts and 75% effective against anal cancer. Given the fact that there are approximately 300 annual deaths from of anal/rectal cancer among men in the United States, one wonders how Merck was able to prove such a huge reduction in such a rare problem. As with the female group, external lesions substituted for actual cancer with no proof that lesions of that type actually lead to cancer at all. Yet, Merck's statistics regarding their cancer substitute penile/perianal/perineal intraepithelial neoplasia (PIN) listed in their appendix to the article show that in men who did not have HPV prior to vaccination, both the vaccinated group and the placebo group had the same number of these types of lesions, making the observed efficacy of Gardasil minus 98%! And for HPV strain 18-related genital lesions, there were actually more lesions in the vaccinated group than the placebo group. So as in the previous study, Merck's impressive numbers for the efficacy of Gardasil in men can only be attained by excluding one-quarter of the study participants. When everyone is included and all outcomes are assessed, the efficacy drops to zero![23]

□ **GARDASIL IS NOT SAFE**

Most significantly, Gardasil has been associated with an unacceptable number of serious, life-altering adverse events following vaccination. According to World Health Organization data, the rate of serious adverse reactions reported to the VAERS system is 2.5 times higher than the current age-standardized death rate from cervical cancer. According to an evaluation performed by Sanevax, of the 75 FDA approved vaccines, the HPV vaccines account for 60% of the entire VAERS database of adverse events. This includes 64% of all reported deaths and 65% of life threatening reactions. An additional 82% of all cases of permanent disability for women under 30 years of age is attributed to the HPV vaccines. Adverse reactions include seizures, anaphylaxis, paralysis, transverse myelitis, Lou Gehrig's disease (ALS), acute disseminated encephalomyelitis (ADEM), opsoclonus-myoelonus syndrome (uncontrollable movement of the eyes back and forth and jerking movements of the extremities), brachial neuritis, loss of vision, postural tachycardia syndrome, facial palsy, deep vein thrombosis, pulmonary embolism, chronic fatigue syndrome, blindness, pancreatitis, speech problems, short term memory loss, miscarriage, multiple sclerosis, autoimmune disorders, Guillain-Barre Syndrome, abnormal Pap smears and even cervical cancer.[24][25][26] **Yes, you read that correctly – VAERS reports 41 cases of**

## **cervical cancer following vaccination with Gardasil.**

Also, while Merck has not made pregnancy a contraindication for Gardasil vaccination, recent data released by VAERS reveal that Gardasil is by far the most dangerous vaccine to receive while pregnant, having caused more than 1300 adverse reactions in its five year existence compared to the next most dangerous vaccine frequently given to pregnant women, the flu vaccine, which has caused 200 adverse events over the past 20 years. Gardasil vaccination while pregnant has also been associated both with frequent miscarriage and a high rate of birth defects.[27] **But most tragically, as of November 2011, 4 more deaths have been added to the Gardasil toll, bringing the tally to 108 deaths due to the Gardasil vaccine!** [28]

### **□ THERE IS BIOLOGICAL EVIDENCE THAT GARDASIL IS ASSOCIATED WITH ENCEPHALOPATHY, AUTOIMMUNE DISORDERS AND DEATH**

Cindy Bevington has investigated and reported about Gardasil extensively. During a Progressive Radio Network interview, she remarked about the hundreds of emails she receives from girls, mothers and doctors around the US and other countries complaining about the HPV vaccines. Often she receives parents' requests "begging" for help because their pediatricians and physicians refuse to report their daughters' adverse events as vaccine related.

By the CDC's own admission, only 10 percent of adverse events get listed on VAERS. Even this very conservative figure has been refuted by independent analyses; actual records can be as low as 1 percent of all actual negative reactions for any given vaccine. It is therefore realistic to suspect that Gardasil is associated with between 177,000 and 1.7 million adverse effects among vaccinated American girls and young women.

Starting in mid 2011, discoveries about hidden Gardasil ingredients and the biological mechanisms contributing to the high rate of adverse events came to the public.

In 2009 a 13 year old girl came down with acute juvenile rheumatoid arthritis 24 hours after receiving the 3rd gardasil shot. Two years later, blood samples were sent to a Connecticut pathologist, Dr. Sin Hang Lee, for analysis. Now, normal HPV DNA should not last in the bloodstream long. It is removed by the body very rapidly because the bloodstream is the normal entry for the virus, rather the mucosal and skin systems are. Dr. Lee found the presence of HPV DNA unexpectedly. But more shocking was this was not any normal HPV DNA. It was genetically engineered and engineered in such a manner that it would firmly bind to the vaccine's aluminum adjuvant. Merck hid this ingredient from the public and the medical community. Gardasil's insert package at the time of Dr. Lee's finding stated there was no viral DNA in the vaccine--but Merck promptly removed this

lie after Dr. Lee's discovery went public. so here we have a vaccine, with genetically engineered DNA from a virus that causes cancer, having never been tested in trials and perhaps even unbeknownst to the FDA, being injected in millions and millions of girls all around the world. Furthermore, according to Dr. Lee, "based on medical literature and some of the FDA/Merck's own publications, adventitious (coming from an outside source) DNA in an injectable protein-based vaccine may increase the risk of autoimmune disorders and gene mutation which may lead to malignancies. In short, boys and girls receiving Gardasil are being injected with a biohazardous weapon.

The controversy over the safety of Gardasil took a major turn in 2012. Parents of two unrelated teenage girls, who believed their daughters died from the HPV vaccine, had the coroners send brain tissue samples sent to Drs. Chris Shaw and Lucija Tomljenovic at the University of British Columbia's Neural Dynamics Research Group for investigation. Neither teenager had a history of previous medical conditions nor drug use. One was a 14 year old Caucasian Canadian and the other a 15 year old from Maori decent in New Zealand. The only thing held in common was that both had received Gardasil. Prior autopsy analysis showed no signs of brain inflammation that could contribute to their sudden neurological death.

The University of British Columbia's findings, published in the journal Pharmaceutical Regulatory Affairs, were shocking. In all brain tissue specimens provided to the researchers, the vaccine's HPV16-L1 antigen, from the HPV virus, had penetrated the blood brain barrier of the teenagers thereby triggering an autoimmune reaction that affected the brain's cerebral vasculature that consequently led to brain blood vessel hemorrhaging. In other words the vaccine antigens, which should never have passed the blood brain barrier, crossed over and bound to the brain tissue walls of the blood vessels that signaled the immune system to target the brain vessels for destruction. These two cases of autoimmune vasculitis offers clear neurobiological evidence to explain why there have been so many deaths, permanent neurological disabilities, incidences of seizure and loss consciousness and encephalopathy due to Gardasil.

After discovering a biological association between the virus's antigen in the vaccine and encephalopathic conditions that most likely caused the girls' sudden death, Dr. Tomljenovic wrote to the British medical health authorities about her findings. The response shocking, and wreaked more of a faith based belief than scientific reason. According to the letter responding to Tomljenovic, the health officials in the UK had already made up their minds about HPV vaccine safety and no research can be provided to reconsider their views.

## **GARDASIL IS NOT SAFE IN PREGNANT WOMEN**

Dr. Suzanne Garland at the Royal Women's Hospital in Melbourne published a study in a 2009 issue of *Obstetrics and Gynecology* showing a "higher rate of congenital abnormalities in infants were noted in pregnant women who received the vaccine." A second study, according to Christina England, found slightly higher fetal deaths and rare cases of central nervous system malformations and neural tube defects in vaccinated pregnant women. Yet these kinds of studies only convince us of the seriously flawed and limited clinical trials conducted by Merck, and further confirms growing criticisms of the systemic failure in the FDA's approval process because of the millions of dollars the agency receives from the pharmaceutical cartel to expedite vaccine and drug launches and to require only the minimum of efficacy and safety information for approval.

## CONCLUSIONS

A vaccine against human papillomavirus was completely superfluous to women's health from its inception. As if the unreasonable risk associated with this vaccine weren't enough, Gardasil is also the most expensive recommended vaccine on the market at \$120 – \$150 per injection and three required doses. If this vaccine becomes mandated for school attendance, how are poor people and the uninsured to come up with the money? And as funding for government programs dries up, does it make any sense to take limited state health care dollars to vaccinate Medicaid-eligible girls with Gardasil instead of using the money for something that actually might be of benefit?

Since the ACIP arm of the FDA already approved Gardasil in 2007 for inclusion in the Vaccination for Children (VFC) program, which provides free immunizations to about 40-45% of children in the US due to their low income status, Merck's syphoning off of money from other health concerns is poised to become a reality. Vaccination of every 11 and 12 year old girl in the US with three doses of Gardasil in order to attend school would cost \$1.5 billion. To vaccinate these girls for a lifetime, once word gets out that the vaccine is only effective for five years, would cost \$7.7 billion.[29] Will there be any money left over for anything else, like Pap screening for poor women? Does this really seem like a good use of limited resources? Only to Merck and its well-compensated allies.

India banned the HPV vaccine a year ago due to vaccine-related deaths.[30] France no longer permits advertising for Gardasil or Cervarix.[31] So why hasn't the FDA, the CDC, the American Academy of Pediatrics, or Merck itself responded to the VAERS reports that Gardasil is not a safe vaccine? The argument, which is the same defense used by all the drug companies and government agencies against any adverse reaction to any vaccine, is that since the VAERS system uses voluntary, passive reporting, it does not prove that a sudden health problem – or even death — occurring after vaccination was in fact caused by the vaccine.

The only causal relationships acceptable to the powers that be are those that result from scientific studies. But these are often unacceptable to the rest of us since the majority are funded by the pharmaceutical companies themselves. So the fix is in. What can any injured child or concerned parent do in the face of this hard line – should they be required to set up their own scientific study? Obviously, neither Merck nor our own government are willing to spend money to prove that Gardasil is in fact dangerous – it is much simpler and infinitely more lucrative to just ignore the allegations and try to portray the victims as conspiratorial whiners.

Instead we get studies published in peer-reviewed journals such as, “**HPV Immunization in Adolescent and Young Adults: a Cohort Study to Illustrate What Events Might be Mistaken for Adverse Reactions,**”[32] from a lead author who received funding from Sanofi Pasteur (which partners with Merck for vaccines outside of the US) and GlaxoSmithKline (makers of the HPV vaccine Cervarix), while the other two authors received support from both Merck and GlaxoSmithKline. Sounds like objective science, right? Remember, Merck is the same company that intentionally kept the cardiac risks associated with Vioxx secret while aggressively advertising the product directly to consumers. The same company that so effectively fabricated a supposedly peer-reviewed journal to support Vioxx that even doctors couldn’t tell it wasn’t real – *The Australasian Journal of Bone and Joint Medicine*. [33] Merck let 60,000 Americans die from Vioxx-related heart attacks before finally pulling the drug from the market when they could no longer deny the truth, and cold-bloodedly set aside \$1.6 billion with the intention of fighting every claim for damages.

The CDC and the FDA maintain that Gardasil is an important cervical cancer prevention tool that could protect the health of millions of women. But the facts show that the opposite is true: in fact, Gardasil vaccination is not justified by the health care benefits – which are highly questionable and largely fraudulent – nor is it even economically feasible. Yet the lure of the money appears irresistible and seems to be clouding the thinking of everyone in a position to say no to the creeping, relentless advance of Gardasil. It is up to us, the victims, the parents, and the concerned friends and neighbors. We have to get the message out to as many people as we can and flood our legislators with notice that this vaccine is dangerous, should not be given to anyone, and at the very least cannot be mandated for school attendance.

Tracy Wolf carries enormous guilt, blaming herself for ever agreeing to let Alexis get the Gardasil vaccine. She believed she was doing the right thing, doing what Alexis’ doctors had recommended. Too late, she realized that the doctors really didn’t know any more about this vaccine than she did. Tracy is now an advocate for informed consent. She tries to share her story with anyone who will listen to prevent this type of injury from happening to anyone else’s daughter. To all parents being asked to vaccinate their daughters – or even sons – with Gardasil, Tracy has this to say: “Please do your homework. Please educate yourself

about the risks of this vaccine. The risk of cervical cancer is so low and the success of regular Pap testing has been so great that there really is no need for this vaccine at all. There is no going back once your child has brain damage.”

We are faced with a paradoxical issue. Do we continue to create ever more vaccines, always with the assumption that their safety and efficacy have been proven and that there is no limit to how many of these vaccines can be introduced into a human body. Or do we step back make an concerted effort to investigate and reevaluate vaccines objectively with a high scientific gold standard, independent from the vaccine manufacturers and the federal agencies? It is critical that the long term safety and efficacy studies of individual vaccines be conducted as well as the safety of vaccines given in combination before licensing and public launch. However, we must be realistic. We are witnessing the power of Wall Street lobbyists acting for the banking industry who control almost every aspect of the financial reform bill. Hence there will be no real structural reform whatsoever. We saw the pharmaceutical and insurance industries' and their lobbyists control the healthcare debate. Again, the final bill represents no actual reform, virtually no preventative and regulatory measures to lessen the incidence of diseases. We observed the energy cartels and their lobbyists meeting secretly with Dick Cheney to assure the barons of coal, oil and nuclear energies can act on their own behalf without government interference. So the reality is that standing in the way to thwart any legitimate effort to evaluate vaccine efficacy and safety is once again the pharmaceutical industrial complex, their thousands of lobbyists, and the industry's serfs serving as heads of our regulatory health and oversight bodies.

The pharmaceutical financial game will continue, and injuries and deaths will continue to rise.

What chance is there then for scientific truth and ethical responsibility to protect citizens to emerge?

### **Sources:**

1. Herskovits B, Brand of the Year, February 1, 2007, *Pharmaceutical Executive Magazine*, <http://pharamexec.findpharma.com/pharmexec/Articles/Brahd-of-the-Year/ArticleStandard/Article/detal/401664>, accessed December 26, 2011.

2. Zimm A and Blum J, Merck Promotes Cervical Cancer Shot by Publicizing Viral Cause, *Bloomberg*, May 26, 2006, <http://www.bloomberg.com/apps/news?pid=2107001&sid=amVj.y3Eynz8>, accessed December 27, 2011.
3. Pettypiece S and Zimm A, Merck Stops Campaign to Mandate Gardasil Vaccine Use, *Bloomberg*, February 20, 2007, [http://www.bloomberg.com/apps/news?pid=2107001&sid=atbGQuDYx7\\_c](http://www.bloomberg.com/apps/news?pid=2107001&sid=atbGQuDYx7_c). accessed December 30, 2011.
4. Bevington C, Researcher, Diane Harper, Blasts Gardasil HPV Marketing, *Off The Radar*, <http://offtheradar.co.nz/vaccines/53-researcher-diane-harper-blasts-gardasil-hpv-marketing.html>, accessed September 15, 2011.
5. Siers-Poisson J, The Politics and PR of Cervical Cancer, Part III: Women in Government, Merck's Trojan Horse, *PR Watch*, July 18, 2007, <http://prwatch.org/node/6232>, accessed 12/27/11.
6. Siers-Poisson J, The Politics and PR of Cervical Cancer, Part III: Women in Government, Merck's Trojan Horse, *PR Watch*, July 18, 2007, <http://prwatch.org/node/6232>, accessed 12/27/11.
7. Levatin J, Why Do Doctors Push Vaccines? Tenpenny Integrative Health Center, December 24, 2011, <http://tenpennyimc.com/category/vaccines/>, accessed January 3, 2011.
8. Tomljenovic L and Shaw CA, Human Papillomavirus (HPV) Vaccine Policy and Evidence-Based Medicine: Are They at Odds? *Annals of Medicine* December 22, 2011; <http://informahealthcare.com/doi/abs/10.3109/07853890.2011.645353>, accessed December 23, 2011.
9. Interview with Tracy Wolf, January 3, 2012
10. Interview with William Ronan, January 5, 2012
11. Interview with Meryl Nass, January 5, 2012
12. Bevington C, Researcher, Diane Harper, Blasts Gardasil HPV Marketing, *Off The Radar*, <http://offtheradar.co.nz/vaccines/53-researcher-diane-harper-blasts-gardasil-hpv-marketing.html>, accessed September 15, 2011.
13. Cervical Cancer, *American Cancer Society*, [Cancer.org/cancer/cervical cancer/detailed guide](http://www.cancer.org/Cancer/CervicalCancer/DetailedGuide/index), <http://www.cancer.org/Cancer/CervicalCancer/DetailedGuide/index>, accessed October 15, 2011.
14. Rothman SM and Rothman DJ, Marketing HPV Vaccine: Implications for Adolescent Health and Medical Professionalism, *JAMA* 2009, 302(7); 781-786.
15. Tomljenovic L and Shaw CA, Human Papillomavirus (HPV) Vaccine Policy and Evidence-Based Medicine: Are They at Odds? *Annals of Medicine* December 22, 2011; <http://informahealthcare.com/doi/abs/10.3109/07853890.2011.645353>,

- accessed December 23, 2011.
16. Lenzer J, Should Boys be Given the HPV Vaccine? The Science is Weaker than the Marketing, *Discover Magazine*, November 14, 2011.
  17. Tomljenovic L and Shaw CA, Human Papillomavirus (HPV) Vaccine Policy and Evidence-Based Medicine: Are They at Odds? *Annals of Medicine* December 22, 2011; <http://informahealthcare.com/doi/abs/10.3109/07853890.2011.645353>, accessed December 23, 2011.
  18. Erickson N, Dr. Sin Hang Lee: A case study in ethics don't pay, Sane Vax Inc, <http://sanevax.org/dr-sin-hang-lee-a-case-study-in-ethics-don%E2%80%99t-pay/>, accessed October 15, 2011.
  19. Human Papillomaviruses and Cancer, National Cancer Institute, September 7, 2011, <http://www.cancer.gov/cancertopics/factsheet/Risk/HPV/print>, accessed January 3, 2012.
  20. Haug CJ, Human Papillomavirus Vaccination – Reasons for Caution, *New England Journal of Medicine*, August 21, 2008, 359; 861-862.
  21. Tomljenovic L and Shaw CA, Human Papillomavirus (HPV) Vaccine Policy and Evidence-Based Medicine: Are They at Odds? *Annals of Medicine* December 22, 2011; <http://informahealthcare.com/doi/abs/10.3109/07853890.2011.645353>, accessed December 23, 2011.
  22. Ibid.
  23. Lenzer J, Should Boys be Given the HPV Vaccine? The Science is Weaker than the Marketing, *Discover Magazine*, November 14, 2011.
  24. Examining the FDA's HPV Vaccine Records, *Judicial Watch Special Report*, June 30, 2008, <http://www.judicialwatch.org/documents/2008/JWReportFDAhpvVaccineRecords.pdf>, accessed September 16, 2011.
  25. VAERS – Vaccine Adverse Event Reporting System. <http://vaers.hhs.gov/index>, accessed October 14, 2011.
  26. Botha LC, New Death Post-Gardasil Updated VAERS Figures & Report that HPV Vaccines Adverse Reactions are 50% Higher Than Other Age-Related Recommended Vaccines, November 29, 2011, Sane Vax, Inc., <http://sanevax.org/new-death-post-gardasil-updated-vaers-figures-report-that-hpv-vaccines-adverse-reactions-are-50-higher-than-other-age-related-recommended-vaccines/>, accessed December 4, 2011.
  27. Rubin S, Blog Entry for October 2011, National Vaccine Information Center, posted December 29, 2011, <http://medalerts.org/analysis/archives/394>, accessed December 30, 2011.
  28. Botha L, VAERS Reports with Percentage Increase, Sane Vax, Inc, <http://sanevax.org/november-14-2011-vaer-reports-with-percentage->

- increase/, accessed December 27, 2011.
29. Siers-Poisson J, The Politics and PR of Cervical Cancer, Part One: Setting the Stage, PR Watch, <http://prwatch.org/node/6186>, accessed December 27, 2011.
  30. Englund C, India has suspended the use of HPV Gardasil vaccines due to deaths, American Chronicle, April 11, 2010, <http://www.americanchronicle.com/articles/view/150425>, accessed December 27, 2011.
  31. England C, France Says “No” as They Ban Gardasil Ads, Sane Vax, Inc., January 11, 2011, <http://offtheradar.co.nz/vaccines/224-france-says-qnoq-as-they-ban-gardasil-ads.htm>, accessed December 28, 2011.
  32. Siegrist C et al, Human Papilloma Virus Immunization in Adolescent and Young Adults: A Cohort Study to Illustrate What Events Might be Mistaken for Adverse Reactions, *Pediatric Infect Dis J*. 2007 Nov;26(11):979-84.
- Grant B, Merck Published Fake Journal, *The Scientist*, 30th April 2009, <http://classic.the-scientist.com/blog/display/55671/>, accessed December 15, 2011.