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| Our Feb/March 2014 cover | **From the Townsend Letter**[**February/March 2014**](http://www.townsendletter.com/FebMarch2014/FebMarch2014.html) |

**Gardasil: Child Abuse by Big Pharma**
by Gary Null, PhD, and Nancy Ashley

Gardasil, the human papilloma­virus vaccine produced by Merck, was brought to market in 2006 with great fanfare, widely proclaimed as the first ever anticancer vaccine. Having gained a strong foothold due to fast-tracking by the FDA and rushed to market ahead of completed safety studies and ahead of its competitor, Gardasil was already an entrenched, recommended vaccine by the time it was approved.1  Merck created a market for Gardasil out of thin air with deceptive and dishonest advertising, and thereby planted fear in the mind of consumers: fear of an unknown health crisis, an invisible time bomb waiting to explode and harm women everywhere.2  When criticized for its aggressive marketing, Merck countered that it was performing a public service by raising awareness about the human papillomavirus and wasn't selling anything.3  Really?  This lie became public as Merck was caught lobbying the 50 states for mandatory Gardasil vaccination prior to FDA approval.4

 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.5  But by lining the coffers of such groups as Women in Government (WIG), National Foundation for Women Legislators (NFWL), National Conference of State Legislatures (NCSL), 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.6  If it hadn't been for Governor Rick Perry's blatantly self-serving 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.7

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 itself 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" noncompliant 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.8  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!9

And what of the victims of Merck's war on cervical cancer? Alexis Wolf was a normal seventh-grader in 2007. She had type 1 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 thought 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 and 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 that 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's mother hadan 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's 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's seizure disorder was identified and she was put on antiseizure 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. When 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 Wolfs' marriage to dissolve, and Tracy is now raising both 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.10

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 Masters at the US Court of Federal Claims, commonly called the vaccine court. This court was established to create a nonadversarial 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 a lot of injuries have been removed from the table over the years, and new vaccines, such as Gardasil, are listed with no specific injuries attributable to them. 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's family, he shared that his law firm currently is handling 12 to 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 that 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 antivaccine 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 that 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 its 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.11

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, 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.12

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 US has been at record lows for the past two decades. Currently only an estimated 3600 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%.13 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 ervical cancer death.

•  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 2 years without causing any disease and with no treatment or intervention of any kind.14

•  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 it normally takes 20 to 40 years to develop and their studies stopped after 5. 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.15 Merck has never acknowledged that its 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.16

•  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. 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!17  And again, its 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 its controlled studies, a percentage of girls actually developed serious cervical lesions following Gardasil. The vaccine seemed to cause the most lesions in girls with preexisting HPV 16 or 18 infections, but also in girls who had no preexisting HPV infections.18  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, it has actually discouraged this practice, presumably so as not to draw attention to the danger.19 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.20,21 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 that the protection was so limited?

Vaccine manufacturers don't appear to consider that the human body, the immune system, and the world of viruses are in a constant state of seeking balance. While Gardasil may lower the incidence of these four particular HPV strains, there are numerous examples wherein vaccines – such as Haemophilus influenzae type B, which targets only one or two bacterial strains out of hundreds that exist – have actually created an increase in previously underrepresented strains.22 How does Merck know that the same thing won't happen with Gardasil?

•  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.23  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!24  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 proved 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 US, 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 cancer substitute penile/perianal/perineal intraepithelial neoplasia (PIN) listed in the 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!25

•  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. VAERS data show that Gardasil has been associated with 24,184 adverse effects since its debut in June 2006, including seizures, anaphylaxis, paralysis, transverse myelitis, Lou Gehrig's disease (ALS), acute disseminated encephalomyelitis (ADEM), opsoclonus-myoclonus 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-Barré syndrome, abnormal Pap smears, and even cervical cancer.26-28  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 with 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.29  But most tragically, as of November 2011, 4 more deaths were added to the Gardasil toll, bringing the tally to 108 deaths due to the Gardasil vaccine.30

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 to $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 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 siphoning 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 chool 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.31  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.32  France no longer permits advertising for Gardasil or Cervarix.33  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," 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.34 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*.35  Merck let 60,000 Americans die from Vioxx-related heart attacks before finally pulling the drug from the market when it 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 that she was doing the right thing, doing what Alexis's 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."



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