

May 26, 2010

Will Merck's Gardasil HPV Vaccine be its Next Vioxx?

By Richard Gale and Gary Null

Progressive Radio Network, May 26, 2011

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.

During the same four year period while 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. Since Gardasil's launch in 2006, the vaccine has been responsible for 66 deaths and over 17,700 medical injuries of young girls, some as young as 11 years old. Six percent of reported events, or 1,100 girls, were serious enough to require emergency hospitalization.

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 are reported by pediatricians, physicians, medical clinics and hospitals, and make their way eventually into the VAERS database. Few parents even know such a reporting system exists.

Cindy Bevington has investigated and reported about Gardasil extensively. During a Progressive Radio Network interview, she reported on the hundreds

and 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.

Medalerts.org reports that a young woman vaccinated with Gardasil is ten times more likely to file a VAERS report compared to an influenza vaccination. HPV vaccines now account for 20 percent of all vaccine side effects aside from the H1N1 swine flu vaccine. America's daughters are twice as likely to have an emergency room visit. They are four times more likely to have a death sentence, five times more likely to receive a report of "did not recover," and seven times more likely be pronounced "disabled."

Besides the 66 deaths, Gardasil's serious side effects now include Guillain-Barre syndrome, lupus, seizures, anaphylactic shock, chronic fatigue, paralysis, blood clots, brain inflammation, blurred vision and blindness, convulsions, demyelinating encephalomyelitis, multiple sclerosis, pancreatitis and various digestive disorders. Last autumn a case of amyotrophic lateral sclerosis, better known as Lou Gehrig's disease, was reported. And a recent 2010 issue of the *Journal of Child Neurology* investigated the case of a 16-year old girl going blind following vaccination, a secondary symptom to multiple sclerosis.

In her January 2010 article on Vactruth.com, "Website Documents Over 300 Gardasil Horror Stories," Christina England, a journalist monitoring the politics and science of the HPV vaccines, relates the case of an employee at a large hospital who commented on the 1,000-plus girls who are manifesting psychotic symptoms for no apparent reason other than being vaccinated with Gardasil. Nevertheless, federal health agencies remain mute and dumb, and the CDC and the FDA continue to stand by their masters at Merck and preach their faith in Gardasil as "safe and effective and the benefits outweigh the risks."

One would expect that vaccine makers would undertake special precautionary measures when conducting clinical trials for women who are undergoing hormonal changes, such as premenstrual changes during

puberty and during various stages of pregnancy. The effects that Gardasil has on young girls entering sexual maturity remain unknown. The principle investigator for Gardasil's clinical trials, Dr. Diane Harper, has publicly stated that no efficacy and safety trials for any of the HPV vaccines were conducted on girls under the age of 15 years. Neither were trials conducted to determine Gardasil's safety on pregnant women.

Dr. Suzanne Garland at the Royal Women's Hospital in Melbourne published a study in 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 that there were 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.

Fortunately, the seriousness of HPV vaccination is becoming more apparent, via the efforts of the National Vaccine Information Center, NaturalNews.com, Mercola.com and the Progressive Radio Network, and concerns are being raised within the practicing medical community and among parents. For example, the otherwise pro-Big Pharma *Journal of the American Medical Association* (JAMA) printed an article in 2009 stating, "the rate of serious adverse events [of Gardasil] is greater than the incidence rate of cervical cancer." Given the high prestige of JAMA, this alone should be a sufficient warning to avoid HPV vaccines at any cost.

Once a vaccine is administered, the risk for potential damage cannot be recalled. It is not like returning your Toyota to avoid the possibility of a mechanical failure in the future. And the length of time a serious adverse effect might occur from Gardasil remains unknown. Christina Tassell, a 21-year-old National Honor Student died in her sleep a couple days after receiving Gardasil. There was no way the vaccine could be returned to her pediatric salesman after symptomatic complications began to surface.

Since Gardasil is administered in a series of three injections, adverse effects may occur after the second or third vaccination, or even months afterwards. One mother shared the condition of her 15-year-old daughter who two months after receiving her second vaccination began having seizures and complete memory loss. The mom writes, "her other symptoms were hair loss, joint pain, severe headaches, stomach pain and insomnia. When she

did sleep, she would have seizures for hours. We have taken her to numerous doctors but they have no idea what is wrong with her. She continues to struggle on a day to day basis and is on the 504 Disability Plan at school."

So where is the media in reporting on this Big Pharma-created medical catastrophe? Where are the *New York Times* and Rupert Murdoch's media empire? Why aren't our health officials at the FDA, the CDC and Secretary Kathleen Sebelius at the HHS taking precautionary measures, and why aren't our elected officials on the Hill demanding a Congressional investigation of a product threatening our daughter's lives and health that is greater than handing the family's Toyota's car keys over to a teenager?

According to Cindy Bevington, after she investigated the reasons why the *New York Times* and the Associated Press are failing to report on the medical fraud that is so clearly evident with HPV vaccination, she found people with the Associated Press married to persons at Medscape and WebMD, two of the most popular medical and drug information resources funded by Merck and GlaxoSmithKline. In addition, James Murdoch is on the Board of Directors of GlaxoSmithKline, and Reuters' CEO sits on Merck's board. "So of course the mainstream media aren't going to report it," Bevington remarked.

But what is worse and should instill greater outrage is that we are not dealing with a pharmaceutical company with a relatively clean and innocent record--if such a pharmaceutical entity actually exists--but we are facing Merck. In the case of Toyota, there is reason to consider the automaker a first time offender. Until the recent recall, Toyota had a near unblemished reputation for manufacturing safe, reliable and popular vehicles for many years.

Merck on the other hand has proven itself to be a notorious repeat offender. One would expect that any drug maker steeped in a well-documented record of criminality and fraud would immediately raise a red flag to federal health officials when one of its products shows every indication of threatening the health and lives of young American girls over the course of four years. Usually when a crime is committed, repeat offenders are among the first to be investigated.

There should be no hesitation in viewing Merck as the pharmaceutical industrial complex's most dangerous serial killer. Vioxx alone accounted for over 44,000 deaths and 120,000 serious medical injuries behind a trail of deception and corporate cover-ups by withholding clinical information and documents confirming Vioxx's adverse effects. The company has been charged with intentionally hiding the liver-damaging effects of its cholesterol

drug, and intentionally withholding the release of clinical data that revealed failures of another cholesterol product. It has dumped vaccine waste and toxic chemicals in water supplies. In 2008, it paid out \$650 million for over-billing Medicaid. An Australian civil suit has been filed against the company for publishing fake medical journals; the *Australasian Journal of Bone and Joint Medicine* and six others were simply phony surrogates for Merck advertising. Finally, the drug giant was caught in a huge scheme of scientific fraud when it was discovered that in-house writers were secretly being used to compose so-called "independent" studies to support their research in peer-reviewed medical journals.

However, we should never underestimate the depth of Merck's pockets and its power and influence to persuade our federal regulators and elected officials to comply with its financial bidding and lobbying demands. Clearly Merck is a leader in the pharmaceutical cartel and a major force in the drug lobbying industry, if not the entire American medical regime.

In the shadows of Merck's lawsuits and payouts, Merck has been in dire need of a blockbuster drug. In order to position itself as the first to bring an HPV vaccine to market, Merck commenced with a marketing campaign founded upon misinformation and deception. It hired the world's largest advertising master of deception, the PR monster firm Edelman, best known for its early misinformation campaign for its client R.J. Reynolds on behalf of the tobacco industry. Another major Edelman client is Pharmaceutical Research and Manufacturers of America (PhRMA), the principal lobbying organization for the pharmaceutical industry that helped leverage Obamacare to care more for Big Pharma's revenues and shareholder interests than the health of the nation's citizens. According to Bloomberg News, Merck spent over \$840,000 to infiltrate the internet with information leading to the launch and advertising of Gardasil to parents of daughters and young adult women. Their intention was primarily twofold. First, it was necessary to educate the American public about the dangers HPV as the single leading cause of cervical cancer. And second, it was not in Merck's commercial interests to offer the nation with factual statistical science that would guide parents to make informed decisions on whether to have their daughters vaccinated or not; rather it was a disinformation campaign, piggy-backing on previous success campaigns related to STDs and HIV, to instill fear about a dreaded HPV killer, disguised in the veneer of being a distinctly "sexually transmitted" viral disease.

This is how the mother of Brittany Bell understood the ads about Gardasil and how she was persuaded to relieve her fears by having her 12-year old daughter vaccinated. Two months after receiving the vaccine, the former cross country runner collapsed and now suffers paralysis in her legs. And

how did Merck respond to the growing number of incidences of paralysis in vaccinated girls? One Merck spokesperson, responded to the media with expected corporate sociopathic logic: since paralysis is not one of Gardasil's adverse effects and it is not a listed complication on the package insert--so the logic goes--the tragic events of paralysis could not be related to Gardasil.

Since the FDA's standard for vaccine approval is so remarkably low, and there is no financial reason or incentive for the vaccine industry to raise the bar on conducting safety trials, serious vaccine adverse effects may take a while, even years, to be officially investigated and confirmed. For example, ever since Gardasil's 2006 launch upon the public, there have been incidences of girls having seizures. At the time, seizures were not listed as an adverse effect on the vaccine's product packaging and labeling. As seizure rates increased, Merck eventually conceded to include it; but it was not until mid-2009 that they did so, and during the previous three years pediatricians were blind and unknowingly administering a vaccine related to seizures.

In the wake of all the evidence confirming Gardasil's serious life-threatening risks, how are we to understand Merck's adamant stance on the health benefits of its vaccine, and the CDC's and FDA's commitment to HPV vaccines being "safe and effective and the benefits outweigh the risks?" How scientifically valid are these claims?

Merck's Gospel of Twisted Science

Cindy Bevington is an investigative reporter who won acclaim for bringing attention to the whistleblowing facts behind the HPV vaccines after interviewing Dr. Diana Harper. During Bevington's interview, Dr. Harper stated that "giving [the HPV vaccines] to 11 year olds is a great big public health experiment." Dr. Harper is highly qualified to know the truth. She is a world expert in HPV virus, having studied over 100 strains of this particular virus for 20 years. During her professorship at Dartmouth School of Medicine, she was the principal investigator for the clinical trials conducted for both Merck's Gardasil and a competitor vaccine, Cervarix, manufactured by GlaxoSmithKline, which was approved in the US in late 2009. As the principal investigator, Dr. Harper was responsible for the research, the recruiting of participants into the trials, and the review of the clinical data for interpretation and publication.

First, in contradiction to what we are being told through Merck's advertising campaign, Gardasil is not a cancer vaccine. There are no clinical studies whatsoever proving that the vaccine prevents cancer at all. In fact the

National Institutes for Health states that the virus does not lead directly to cervical cancer. What HPV does is influence cellular abnormalities, which if not detected via a pap smear, could potentially turn cancerous. However, according to Dr. Harper, 70 percent of HPV infections resolve themselves in one year, and 90 percent resolve themselves in two years without treatment. A recent study from New Zealand indicates that 95 percent of HPV infections naturally disappear due to the body's immune system.

This is not to suggest HPV infections are rare; in fact, 80 percent of women by the age 50 will have been infected with one of many strains. Gardasil only protects against two of those strains--types 16 and 18--that account for approximately two-thirds of cervical cancers. But HPV infections are not in any way associated with the alarm and fear promulgated by Merck and our federal and state health agencies. In fact, HPV infection is easily treated and cervical cancer prevention has been statistically proven to be more effective with regular pap smear exams instead of a vaccine. Dr. Anne Szarewski at the Cancer Research UK conservatively told the British newspaper *The Telegraph* that "a [pap smear] screening program is as effective as a vaccination program;" equally important, nobody ever died or was physically disabled from a pap smear, which is also far cheaper and more cost-effective. Cindy Bevington has further reported that the vaccine makers' own clinical studies show that unless a girl is tested negative for HPV at the time of her vaccination, HPV vaccination can actually backfire and increase her risk of a current infection progressing towards cervical cancer.

During a special April 29 Progressive Radio Network broadcast about the dangers and politics of Gardasil and GlaxoSmithKline's Cervarix HPV vaccine, Bevington outlined Merck's and the CDC's fabrication of a mythology to instill fear in parents leading to mandatory vaccine enforcement. What is not being told to the public, according to Bevington's research, "is that anyone can get HPV. It is not a sexually transmitted disease even though that's what the government tells you and that's the first thing on the CDC's website.

Professional journal articles and studies have shown documented cases of babies testing positive for HPV as well as nuns who have never had sex, as well as adolescent boys who happen to have it under their fingernails. That is because HPV is transmitted via the skin. [Merck's and the CDC's] vaccine campaigns simply highlight the easiest most common mode of transmission, which is sexual."

The question of whether or not girls as young as 9 years old, which is the minimum age approved by the FDA, should receive the vaccine is the most disturbing. Dr. Harper has categorically stated that no efficacy or safety trials have ever been conducted on girls under age 15. Furthermore, young girls

don't get cervical cancer. So is there any credible rationale for vaccinated girls at such a young age other than increasing revenue streams?

In her lecture to the 2010 Vaccine Conference sponsored by the National Vaccine Information Center, Dr. Harper lectured that the safety issues with Gardasil are so serious that the rate of serious adverse events is greater in the US than the incidence rate of cervical cancer. The incidence of cervical cancer is so low, there is almost no supporting evidence to conclude massive vaccination would lower the rate. In her analysis of Harper's findings, Bevington states, "in the US to even touch cervical cancer rates in this country, you would have to vaccinate every single 11 year old in the US every year for 70 years to even drop [the cervical cancer rate] by one percent."

Merck's Legislative Zombies

In 2007, almost every state had legislation filed to mandate the HPV vaccine. It is rather extraordinary that so many states would have state officials in unison calling for mandatory vaccination. Well, it might appear rather odd and remarkable until the extent to which Merck's greedy tentacles reach the fringe corners of state governments are fully recognized.

Women in Government is a nonprofit organization with a stated mission to bring elected women state legislators and business leaders together. In reality WIG is little more than a well-funded shell for the pharmaceutical and energy industries. Over 50 percent of its corporate sponsors are Big Pharm firms, including the two HPV vaccine manufacturers Merck and GlaxoSmithKline. The organization also hosts a "Business Council", a six member advisory group consulting state women legislators about critical business issues. Three of the six Council members represent the pharmaceutical industrial complex, and not surprisingly these include Merck's Executive Director of Health Policy and GlaxoSmithKline's Director of Public Policy. The third drug member is Digene Corporation's VP for Women's Health. Who is Digene, a firm very few people have heard of? It is certainly not one of the larger multi-national pharmaceutical firms among WIG's corporate sponsors. It turns out Digene is the company that manufactures Gardasil.

The WIG's recent report, "A Roadmap for Success: The State of Cervical Cancer Prevention in America 2010," which is being disseminated through state health departments and women's health organizations, is nothing more than a fidgeting and arrangement of data about the severity of cervical cancer and rates of infections leading to the conclusion that vaccinating all girls in the US will eradicate HPV infection.

Individual state initiatives to mandate the HPV vaccine can be traced back to WIG. Texas governor Rick Perry is perhaps the most rabid among state governors seeking mandatory vaccination. Perry's former chief of staff is now a Merck lobbyist and Perry himself received Merck donations for his reelection campaign. The former chief's mother, state representative Diana White Delisis is WIG's state director. Now that the FDA approved Gardasil for males from 9 to 26 years of age to protect against genital warts and extremely rare penile and anal cancers, the Texas Medical Association voted this month in favor of vaccinating young boys as young as 9 years of age.

Efforts are still being made in some states to mandate HPV vaccines. In New York, Liz Kreuger, a leading voice in WIG, sponsored a State Senate bill for mandatory vaccination. Fortunately that bill was placed on hold last February.

WIG, however, is not the only state legislative organization that has been won over by Merck and GlaxoSmithKline. The National Foundation for Women Legislators and the National Conference of State Legislators each include the two HPV vaccine makers as sponsoring corporate members. Along with WIG, Merck's viral propaganda has infected almost every state health department.

In the June 2008 issue of the *Journal of Law, Medicine and Ethics*, three scholars representing Johns Hopkins Institute of Bioethics, George Washington School of Medicine, and Georgetown University's Law Center determined that the evidence for the benefits of HPV vaccines on public health provides no rationale whatsoever for making it mandatory. In fact, such a mandate would be unethical and unconstitutional.

The consequences of Merck's actions and the actions of the corporation's zombies in government health agencies and organizations, such as WIG, to promulgate scientific falsehood has had an immense impact on seducing local health facilities, hospital staffs, physicians and pediatricians. The efforts to mandate unproven and questionable vaccines, such as Gardasil, border on medical fascism. One story of a terrible casualty illustrates how far Merck's marketing campaign has reached:

One mother reports on the website Medications.com a story of her 13-year old daughter who was otherwise a physically active and healthy daughter until she became partially paralyzed after receiving a Gardasil vaccination. Her leg muscles shrank; her feet contorted as her muscular deterioration and nerve damage increased. She was taken to the best medical facilities: Case Western Hospital, the hospitals at Stanford University and the University of California at San Francisco, John Hopkins and others. Then the

mom shares some information indicative of Merck's marketing success. "This has been a very long, hard road and battle for my child. All because of vaccines. I was not fully informed of possible deaths or serious side effects linked to Gardasil. I did not give written consent; I was told this was practically mandated in other states and would soon be mandatory for all school girls age 11-12years old. I was told it was a good vaccine and led to believe I would not have to worry about my daughter having cervical cancer some day."

Merck's aggressive lobbying of federal and state officials has paid off. In 2008, Gardasil became one of the top five selling vaccines allowing the drug giant to cash in on \$2.7 billion in sales. It is also the most expensive vaccine on the market, costing almost \$400 for the series of three inoculations. Medical writer Judith Siers-Poisson has called it the "financial equivalent of the Holy Grail for the pharmaceutical company."

It is highly unlikely that Merck will ever reconsider its marketing assault to vaccinate the world's female population. Gardasil is already approved in over 100 countries. It is much easier for Merck to do what it has done best and has had the greatest success: cover-up their product's health risks and dangers, withhold clinical information, continue to ferret federal health officials and governments, and simply pay a fine if and when the company gets caught for its criminal behavior. Then it is back to business as usual to find another blockbuster drug to repeat their strategy all over again.

The Slow Backlash Against HPV Vaccination

Even if the US government and its health officials don't give a damn about the physical health and well-being of its citizens, and particularly its children, there are some countries that actually care population's health. India commenced with a 2-year study to determine the efficacy of Merck's Gardasil. Last April, the nation's health ministry suspended the study after 4 girls died and 120 serious complications were reported. To date, India has no plans to launch the vaccine on its young girls and women.

In Bhutan, Merck promised free Gardasil for the tiny Himalayan nation's female population. On May 14, the *Bhutan Observer* reported that the country's Drug Regulatory Authority, after witnessing events in India, ordered a halt to the vaccine until greater proof of safety can be produced. In Spain, the government recalled Gardasil after two serious hospitalizations occurred following inoculation. Yet in the US, we have thousands of Gardasil casualties, and nobody in government is doing anything about it. There is also some additional good news. Gardasil is now the mostly commonly declined vaccine, by 56 percent over other vaccines, among

parents. And the professional journal *Pediatrics* has reported on a 2009 survey showing that 1 out of 8 parents have refused at least one Gardasil vaccination recommended by their physicians or pediatricians. Therefore, we are witnessing the success of educating people about the dangers of vaccination and exposing the lies and fraud of the vaccine industry as the best chance available to preserve the health of children and young people.

The bad news is Merck is relentless in its pursuit for profits and no longer wants to limit Gardasil as a predatory revenue on girls and women used as crash test dummies. On the very day the FDA approved GlaxoSmithKline's HPV vaccine Cervarix in the US, it also approved Gardasil for boys 9 to 26 years old for genital warts. In May, Merck started marketing the vaccine towards America's sons. Again, it is fueled under the deceptive advertising that genital warts are sexually transmitted. And the FDA simply continues to mimic Merck's information campaign. The FDA's director Dr. Karen Midthun in the agency's press release states, "This vaccine is the first preventative therapy against genital warts in boys and men ages 9 through 26, and, as a result, fewer men will need to undergo treatment." The caveat of facts not mentioned by the FDA is that boys infected with HPV rarely have symptoms, and as with girls and women, infections disappear rapidly and naturally.

We are now 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 for the first time investigate objectively by a high scientific gold standard, independent from the vaccine manufacturers and the federal agencies, the long term safety and efficacy of individual vaccines and vaccines used in combination? 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?

Richard Gale is the Executive Producer of the [*Progressive Radio Network*](#) and a former Senior Research Analyst in the genomic industry.

Dr. Gary Null is the host of the nation's longest running public radio program on nutrition and alternative medicine, and a multi-award-winning director of progressive documentary films, including *Vaccine Nation* (2008) and *Autism: Made in the USA* (2009).