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THURSDAY, AUGUST 29TH, 2019

HEALTH

Australia rolls out Gardasil 9 amid reports that HPV vaccination is causing death, injury, and infertility

BY ANNETTE GARTLAND ON OCTOBER 12, 2017 • (2 COMMENTS)

There are updates at the end of this article about Colton Berrett, who passed away on January 5, 2018, and a court ruling in the US that states that the death of 21-year-old Christina Richelle Tarsell was caused by Gardasil.



The new HPV vaccine, Gardasil 9, which is mostly given to teenage girls, but also to boys, has been given federal approval in Australia.

The rollout comes amid increased reports of deaths and dangerous injuries associated with HPV vaccination.

One major concern is that HPV vaccination may be causing premature ovarian failure (POF) in adolescent girls.

Another is that there is more than twice as much aluminium in Gardasil 9 than in the original vaccination.

The Gardasil vaccinations contain strains of the human papillomavirus (HPV) and its manufacturer, Merck, say they protects against cervical cancer.

Questions are being asked, however, about the efficacy of HPV vaccines – and whether cervical cancer is even caused by HPV.

The Australian government says Gardasil 9 will be available free to 12- and 13-year old from next year. The Therapeutic Goods Administration (TGA) approved the vaccine on January 3 this year.

The Australian sponsor of Gardasil 9 is the Merck subsidiary, Merck Sharp & Dohme (Australia) Pty Limited.

The European Commission granted a marketing authorisation for Gardasil 9, which is valid throughout the European Union, in June 2015 and the Food and Drug Administration (FDA) approved it for use in the United States in December 2014. It is also already in use in New Zealand.



The original Gardasil vaccine contains LI protein from only four HPV types: 6, 11, 16, and 18. It is approved for use in 132 countries and, to date, more than 208 million doses have been distributed worldwide.

Gardasil was first given to teenage girls in Australia in 2007, and has been given to boys aged 13 to 15 since 2013. It was approved on June 16, 2006,



for females aged from 9 to 26 years and males aged from 9 to 15 years.

Most of the Australian media leapt enthusiastically onto the story of the Gardasil 9 rollout with such headlines as "Schoolkids to get anti-cancer vaccine" and talk of protection against "almost all cervical cancers".

The co-creator of the HPV vaccines, lan Frazer, told reporters in Sydney last Sunday: "The new vaccine will make sure that even more people are protected against cancer."

He added: "There's a real prospect that over time, the viruses that cause the cancer will disappear from the community and the cancer will go too."



Objectors to the rollout, and the use of Gardasil in general, point to the dangers of the vaccination and the fact that Lucy Turnbull (*pictured left*), who is the wife of the Australian prime minister, is on the board of the biotechnology company Prima BioMed.

lan Frazer (*pictured below*) used to be the head of Prima's scientific advisory board and was last year appointed as chairman of the Australian Medical Research Advisory Board.



Merck says its sales of Gardasil and Gardasil 9 in the second quarter of 2017 were worth 469 million dollars; an increase from 393 million dollars over the same period in 2016.

The company says Gardasil 9 will protect against nine types of the HPV virus: 6, 11, 16, 18, 31, 33, 45, 52 and 58.

It does state, however, that Gardasil 9 "does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening" and those vaccinated "should not discontinue anal cancer screening if it has been recommended by a health care provider".

In October last year, on the advice of the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control (CDC) in the US recommended that 11- to 12-year-olds receive two doses of HPV vaccine at least six months apart rather than the previously recommended three doses.

Teenagers and young adults who started the series of vaccinations later, at ages 15 to 26 years, would continue to need three doses of the HPV vaccine, the CDC said.

HPV vaccination is also given via the GlaxoSmithKline product Cervarix.

The FDA approved the marketing of Gardasil to females aged 9 to 26 in June 2006, and to males aged 9 to 26 in October 2009.

There is widespread concern about adverse effects caused by the original Gardasil vaccination. They include paralysis, narcolepsy, respiratory dysfunction, cognitive impairment, involuntary movements, blood clots, and a rapid heartbeat. Concerns are amplified now that Gardasil 9 is being rolled out in yet another country.

Reports to the Vaccine Adverse Event Reporting System (VAERS) in the US relating to all HPV vaccination globally total 51,968 up to June this year. A total 41,829 were related to Gardasil and 5,337 to Gardasil 9.

A total 3,579 of the reports related to Cervarix, and this included 17 deaths, 74 cases of life threatening injury, and 226 cases of permanent disability.

A total 328 deaths were reported in relation to all HPV vaccination globally, including 266 that cited Gardasil and five that cited Gardasil 9. There were 834 reports of life threatening illness, and 2,011 cases of permanent disability.

The CDC points out that a report to VAERS "does not necessarily mean that the vaccine caused the reported adverse event – only that the adverse event happened sometime following vaccination".

In Australia, 4,115 adverse reactions have been reported to the TGA since Gardasil was first used in the country.

Legal action over alleged side-effects from HPV vaccination has been taken in the US, France, Spain, and Denmark, and more than 250 cases are underway.

Plaintiffs have won damages in cases in the US and France.

Merck itself states in its "Warnings and Precautions" about Gardasil 9: "Because vaccinees may develop syncope¹, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended.

"Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion."

In the "Post-Marketing Experience" section of the insert (https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts /ucm426457.pdf)produced for Gardasil 9, Merck gives a disturbing list of possible side-effects.²

Vaccine injury compensation

The National Vaccine Injury Compensation Program (https://www.hrsa.gov/sites/default/files/vaccinecompensation/data/statisticsreport.pdf) (VICP) in the US reports that, from January 1 to December 31, 2015, 89,696,704 HPV vaccinations were given in the country.

As of October 2 this year, 264 vaccine injury petitions were filed. Compensation was given in 123 cases, and the remaining 141 claims were dismissed.

In March 2013, the advocacy group Judicial Watch (https://www.judicialwatch.org/press-room/press-releases/hpv-vaccine-injuries-and-deaths-is-the-government-compensating/) said it had received documents (http://www.scribd.com/doc/131306945/HPV-Claims-3-7-2013) from the Department of Health and Human Services stating that the VICP had awarded \$5,877,710 dollars to 49 people who made injury claims about HPV vaccination. Forty-seven of the claims were for alleged injury caused by HPV vaccination and, in two cases, the claimants alleged that the vaccine caused death.

In June 2008, Judicial Watch published a special report (https://www.judicialwatch.org/documents /2008/JWReportFDAhpvVaccineRecords.pdf) detailing Gardasil's approval process, side effects, safety concerns, and marketing practices.

The watchdog expresses its concern about the facts detailed in the FDA's adverse event reporting associated with Gardasil.

"Merck has waged an aggressive lobbying campaign with state governments to mandate this HPV vaccine for young girls. Given all the questions about Gardasil, the best public health policy would be to reevaluate its safety and to prohibit its distribution to minors. In the least, governments should rethink any efforts to mandate or promote this vaccine for children."

'Sacrificial virgins'

In the first part of a recently released documentary entitled "Sacrificial Virgins", experts state that there is no proof that HPV vaccination of girls can prevent cervical cancer in later life and question whether HPV actually causes cervical cancer.

The film also documents deaths from the vaccination and the severe side-effects that have occurred.

The filmmakers say there have been hundreds of documented deaths following HPV vaccination.



One of the deaths that may have been caused by Gardasil is that of Jasmin Soriat, a 19-year-old student from Vienna in Austria.

Jasmin exhibited neurological symptoms after receiving a second dose of the vaccine, and suffered respiratory failure three weeks later. She died in her sleep.

Former government forensic pathologist Dr Johan Missliwetz, who has taken early retirement, conducted the autopsy on Jasmin Soriat's body. He said that he couldn't find a reasonable cause of death, but had two suspicions: "one is a genetic disorder of the heart and the other one, it had to do with vaccination".

When Missliwetz reported his findings to the drug regulatory authorities he received numerous phone calls from senior members of the medical

establishment in Austria.

"Many professors called me up and said I should stop talking about vaccination death," he said.

This was extraordinary, he says, as he had done thousands of autopsies in the past, and no one had ever telephoned him about them.



British teenager Ruby Shallom from Bracknell, Berkshire, who is also featured in "Sacrificial Virgins", received her first HPV vaccination in 2014.

She is now paralysed in three limbs.

Ruby says in the documentary that the only one of her limbs that works now is her left arm. She says she still goes out to see friends, but the pain and fatigue she suffers make this difficult.

Weeks after receiving the HPV vaccine, Ruby started to suffer from dizziness, headaches, stomach spasms, and fatigue.

In May 2016, she woke up with no feelings in her legs at all.

Ruby is now often too weak to even lift her head. She is unable to feed or dress herself, and is incontinent.





In the "Sacrificial Virgins" documentary, Peter Duesberg, a professor of molecular biology at the University of California in Berkeley in the US, says that scientific studies have found that cervical cancers are not caused by HPV.



Duesberg (*pictured left*) says HPV doesn't replicate in cervical cancer cells. He says that when HPV is found in some cervical cancer cells, it is a "passenger virus" that plays no role.

He says it is "fossils" of HPV DNA that are being detected and they come from previous infection that could date back decades.

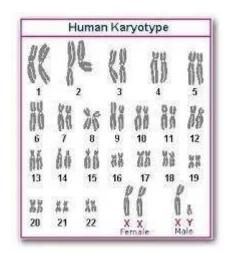
HPV vaccination should be stopped, Duesberg says, until there is proof that it protects against cancer. It has, he says, more side-effects than any other vaccine.

"Other vaccines combined have less adverse effects than this one."



Christian Fiala (*pictured left*), who specialises in obstetrics and gynaecology in Vienna, says in the documentary that no one has shown that the HPV vaccine actually reduces the rate of cervical cancer.

"As long as we have no proof that cervical cancer is caused by HPV, as long as we only have an association, it is fundamentally useless to vaccinate against HPV because the chances are the cervical cancer is not caused by HPV, in which case the cancer will occur whether there is HPV or not."



Fiala and Duesberg are two of the authors of a paper

(https://molecularcytogenetics.biomedcentral.com/articles/10.1186/1755-8166-6-44) entitled "Individual karyotypes at the origins of cervical carcinomas".

A karyotype (http://www.tutorvista.com/content/biology/biology-iii/cell-reproduction/karyotype.php) is the number, size, and shape of chromosomes in any given organism.

In their report, which was published in October 2013, Duesberg and Fiala state that neither genetic predisposition nor HPV

infections are necessary for the development of cervical cancer.

"All cervical cancer cells investigated during the course of this study contained new abnormal karyotypes. The clonality (genetic makeup) of these new abnormal karyotypes indicates the cervical cancers originated with these karyotypes – NOT from a virus," the authors state.

They say that, based on their findings, "it is expected that a vaccine against human papilloma viruses will have no effect on the occurrence of cervical carcinomas".



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In Part 2 of "Sacrificial Virgins", the filmmakers examine what exactly in the HPV vaccines might be causing such serious side-effects. They focus on two young British women who suffered adverse reactions and ask whether additional aluminium content in the vaccines, which was not studied in the safety trials, could be to blame.

Gardasil	Gardasil 9		
225 mcg A/	AHS (aluminum adjuvant)	500 mcg	
9.56 mcg	Sodium Chloride	9.56 mcg	
.78 mcg	L-Histidine	.78 mcg	
50 mcg	Polysorbate 80	50 mcg	
35 mcg	Sodium Borate	35 mcg	
<7 mcg	Yeast Protein	<7 mcg	

enco tables	COST FORCES CHICARTHON	TADORESC PERM
20 mcg	HPV 6 L1 protein	30 mcg
40 mcg	HPV 11 L1 protein	40 mcg
40 mcg	HPV 16 L1 protein	60 mcg
20 mcg	HPV 18 L1 protein	40 mcg
	HPV 31 L1 protein	20 mcg
	HPV 33 L1 protein	20 mcg
	HPV 45 L1 protein	20 mcg
	HPV 52 L1 protein	20 mcg
	HPV 58 L1 protein	20 mcg

In Part 3, they document litigation about HPV vaccination around the world, including a class action in Japan.

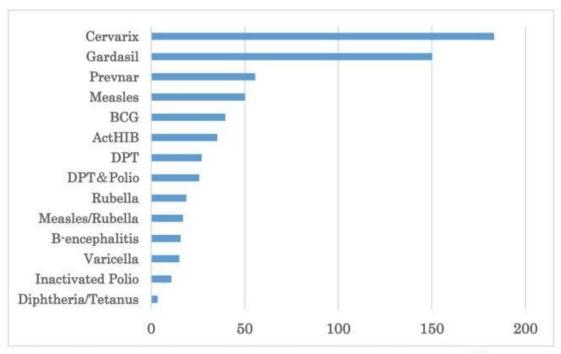


Fig. 2: Severe ADRs from HPV vaccines and other vaccines in Japan⁶⁻⁸⁾ (ADRs/10⁶ inocul.)

BCG: Bacille Calmette Guerin; DPT: diphtheria-pertussis-tetanus

In early 2015, the Association of HPV Vaccine Injured Daughters (https://www.facebook.com/AHVID.UK/) (AHVID) was set up in the United Kingdom.

In a survey among 94 AHVID members, 27 girls reported same-day reactions to the HPV vaccine, 22 reported reactions within seven days, and 16 reported reactions with thirty days. Eight girls have a confirmed diagnosis of complex regional pain syndrome (CRPS).

In Ireland there are hundreds of reports of adverse effects of Gardasil vaccination. About 150 families, whose daughters suffered serious adverse reactions, formed a support group called R.E.G.R.E.T (https://www.regret.ie/). Within two months the group's numbers had swelled to four hundred.

"The primary goal of the parents in the group is to get help for their daughters who, like many girls around the world, have experienced 'Reactions and Effects of Gardasil Resulting in Extreme Trauma'," R.E.G.R.E.T. says.

"Many are not receiving effective medical treatment and cannot attend school regularly due to the debilitating health

conditions they still suffer from."

R.E.G.R.E.T. members prioritise raising awareness about the safety issues surrounding HPV vaccination "so that other parents can be in a position to make a truly informed decision on this issue".

The group says the information provided by Ireland's Health Service Executive about HPV vaccination is "incomplete and biased, downplaying the safety issues while exaggerating its effectiveness".

As is the case in most countries, those in Ireland who are trying to raise awareness, and are fighting for justice for those injured by HPV vaccination, are repeatedly dismissed as "anti-vaxxers" and get little support from politicians or the media.

In 2015, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) conducted a safety review of HPV vaccination and held to its position that the benefits outweigh the risks.

However, there is scepticism among leading doctors in several countries in Europe, and notably Denmark, about the safety of HPV vaccination.

Approximately 1,300 female patients who received HPV vaccination have been referred to specialist centres in Denmark with symptoms of CRPS or postural orthostatic tachycardia syndrome (POTS), in which the heart rate increases abnormally, causing dizziness, fainting, chest pain, headache, and weakness.

The PRAC says that the "available evidence does not support that CRPS and POTS are caused by HPV vaccines" and "therefore there is no reason to change the way the vaccines are used or amend the current product information".

In May last year, the deputy director of the Nordic Cochrane Centre in Denmark, Karsten Juhl Jørgensen, and others filed an official complaint (http://nordic.cochrane.org/news/complaint-filed-european-medicines-agency-over-maladministration-related-safety-hpv-vaccines) about how the EMA handled the HPV safety issue.

Colton Berrett



Colton Berrett was paralysed after receiving three Gardasil vaccinations. He was just 13 years old. He was diagnosed with transverse myelitis, a rare clinical syndrome in which an immune-mediated process causes neural injury to the spinal cord.

A sports enthusiast from an early age, Colton loved baseball, riding motorcycles, indoor skydiving, skiing, and especially motorcoss.

Two weeks after his third Gardasil vaccination, in February 2014, Colton started to get severe neck ache. He felt nauseous and exhausted.



When his parents took him to the hospital the next morning, his mother had to hold his head up, and he could no longer move his right arm.



Colton became paralysed from the neck down, and, at one stage, was only able to communicate with his eyebrows. He was in intensive care for more than twelve weeks.

While he is now able to do some sporting activities, his right arm is still paralysed and he has only minimal function in the left one. He has to have a breathing apparatus with him at all times, and needs help to carry it.



Japan

The Japanese government no longer recommends HPV vaccination.

In a letter sent to the World Health Organisation's Global Advisory Committee on Vaccine Safety (GACVS) in November last year, the private medical supply supervisory system, Medwatcher Japan (http://www.yakugai.gr.jp/en/), refuted the statement made by the GACVS in October 2015 about the safety of HPV vaccination.

In its very detailed refutation, Medwatcher Japan gives a list of reported adverse effects of HPV vaccination.

These effects, Medwatcher Japan says, include diverse, complex, multi-system symptoms such as seizures; disturbance of consciousness; systemic pain including headache, myalgia, arthralgia, back pain and other pain; and motor dysfunction such as paralysis, muscular weakness, exhaustion, and involuntary movements.

The watchdog also cites numbness and sensory disturbance; autonomic symptoms including dizziness, hypotension, tachycardia, nausea, vomiting, and diarrhoea; respiratory dysfunction including dyspnoea and asthma; endocrine disorders such as menstrual disorder and hypermenorrhoea; hypersensitivity to light and sound; and psychological symptoms including anxiety, frustration, hallucinations, and overeating.

The other side-effects listed by Medwatcher Japan are higher brain dysfunction and cognitive impairments that include

memory impairment, disorientation, and loss of concentration; and sleep disorders, hypersomnia, and sudden sleep attacks.

In some cases, the watchdog says, "these symptoms impair learning and result in extreme fatigue and decreased motivation, negatively impacting everyday life".



Sixty-three Japanese women have launched a class action lawsuit over injuries they suffered after HPV vaccination.

Gardasil 9 vaccination 'may not result in protection in all vaccine recipients'



Merck says Gardisal 9 will protect girls against cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11.

It says the girls will also be protected against a number of precancerous or dysplastic lesions.

Boys, it says, will be protected against anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts caused by HPV types 6 and 11; and a number of precancerous or dysplastic lesions.

The company states that Gardasil 9 "has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity" and "has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58".

Merck adds that "vaccination with Gardasil 9 may not result in protection

in all vaccine recipients".

One of the things that Judicial Watch highlights in its 2008 special report (http://www.judicialwatch.org/documents /2008/JWReportFDAhpvVaccineRecords.pdf) is that women who already unknowingly have HPV and are vaccinated with Gardasil could suffer massive outbreaks of genital warts. The watchdog details several cases, including cases of outbreaks of warts on the face, hands, and feet.

Premature ovarian failure

In January 2016, the American College of Pediatricians said there were "legitimate concerns (http://www.acpeds.org/the-college-speaks/position-statements/health-issues/new-concerns-about-the-human-papillomavirus-vaccine)" about the Gardasil vaccination possibly causing premature ovarian failure (POF) in adolescent girls. These concerns, the college says, should be addressed.

The college also cites cases of amenorrhea (the absence of menstrual periods).

It stated: "Since licensure of Gardasil® in 2006, there have been about 213 VAERS reports ... involving amenorrhea, POF or premature menopause, 88 percent of which have been associated with Gardasil®.

"The two-strain HPV2, CervarixTM, was licensed late in 2009 and accounts for 4.7 percent of VAERS amenorrhea reports since 2006, and 8.5 percent of those reports from February 2010 through May 2015."

The college draws a comparison with the pre-HPV vaccine period from 1990 to 2006, during which no cases of POF or premature menopause and 32 cases of amenorrhea were reported to VAERS.

The college says that, since 2006, 76 percent of reports of ovarian failure, premature menopause, and/or amenorrhea are associated solely with Gardasil.

"When VAERS reports since 2006 are restricted to cases in which amenorrhea occurred for at least four months and is not associated with other known causes like polycystic ovary syndrome or pregnancy, 86/89 cases are associated with Gardasil®, 3/89 with CervarixTM, and 0/89 with other vaccines administered independently of an HPV vaccine."

Using the same criteria, the college says, there are only seven reports of amenorrhea between 1990 and 2005 and only two of those were associated with any one vaccine type.

A study (http://casereports.bmj.com/content/2012/bcr-2012-006879.abstract) entitled "Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination" was published in the British Medical Journal in 2012.

It details the case of a 16-year-old girl in Australia who presented with a history of five months of amenorrhoea, preceded by approximately 12 months of oligomenorrhoea (infrequent menstrual periods).

After the development of amenorrhoea, the girl experienced hot flushes. She said that the alteration in her menstrual pattern had started after HPV vaccination.

The study says New South Wales Health confirmed that three HPV vaccinations were administered to the girl in the high-school vaccination programme in February, May, and August 2008.

The authors of the study, Deirdre Therese Little and Harvey Rodrick Grenville Ward, said the chief identifiable causes of premature ovarian failure were excluded.

"There was no past or present history of significant other illness, stressors or surgery, no known exposure to radiation or toxins and no other medications were being taken during or preceding this time," the authors state.

"She was a non-smoker. There was no known family history of genetic abnormalities, premature menopause or of autoimmune disease."

Little and Ward say that results consistent with premature ovarian insufficiency (POI) in a 16-year-old girl have significant consequences for her future health and for her prospects of motherhood.

They say that if the young woman taken oral contraceptives as prescribed for correction of her oligomenorrhoea/amenorrhoea, her diagnosis of premature ovarian insufficiency, also known as primary ovarian insufficiency, may not have been determined for perhaps some years.

"The possibility of its link to an adverse pharmaceutical event might also have been lost."

The study cites anecdotal evidence from high-school students that suggests that one in three girls aged 16 are taking an oral contraceptive (OC) to control their menstrual cycle, for acne management, or for contraception.

Given the prevalence of the use of oral contraceptives in this age group, combined with the possibility of initial OC prescription for the management of oligomenorrhoea, conditions affecting menstrual function in the age group would be undetected and undiagnosed, the researchers say.

"Menstrual abnormalities and particularly ovarian insufficiency at this time may therefore be under-reported as possible adverse events following vaccination or other medication."



In an interview in a video entitled "Truth and Gardasil", Deirdre Little (*pictured left*) talks about the 16-year-old's case and how she discovered that, according to the TGA, Merck did not conduct any studies about ovarian effects of the Gardasil vaccine or ongoing effects on fertility.

The teenager from New South Wales came to Little for a second opinion, and the doctor then started researching the safety of Gardasil.

"I found that the research that I was seeking on its safety for rats and its safety, much more importantly, for humans just wasn't there. There was an absence of research on egg-bearing capacity in vaccinated females.

"And a lot of other girls have been coming and saying 'my periods have become irregular; my periods have become scant since I had the Gardasil vaccination'."

Little says there are a hundred strains of HPV, about 14 of which can cause cancer.

She say of the TGA: "If they are taking responsibly for authorising this drug they also have a responsibility to be able to answer questions, and the main question is 'Is this drug safe for the fertility of my daughter?'."

Little says the rate of anaphylactic reactions to Gardasil vaccination per dose is 2.6 per 100,000 doses.



She refers to the scandal over Merck's drug Vioxx. The company was sentenced in a criminal case to pay a fine of \$321,636,000 after pleading guilty to violating the Food, Drug and Cosmetic Act for introducing a misbranded drug into interstate commerce.

Merck made false statements about the drug's cardiovascular safety and promoted it for the treatment of rheumatoid arthritis before that use was approved by the FDA.

It is estimated that Vioxx may have caused between 88,000 and 139,000 heart attacks and between 26,000 and 42,000 deaths before it was withdrawn. Some have estimated the likely deaths to be much higher, reaching as many as 120,000.

Merck has also been disciplined for falsely representing its cholesterol drug Vyatorin.

Little is concerned about the fast-tracking of Gardasil in Australia.

"Considering that the Pap smear programme in Australia had already reduced cervical cancer by about 70 percent, and was continuing to do so, it's hard to be definitive, and hard to really understand, the reasons for introducing a universal vaccination programme."

She says that, in Merck's clinical research about Gardasil, vaccinated rats were killed after giving birth to their first litter, "so we don't know how many more litters they may or may not have been able to have in their lifespan; we don't know when they would have gone through menopause, and we also don't know how many pups would have been in each litter after that".

She says that the human studies that were done prior to the release of Gardasil failed to look at any effects on human fertility or on ovarian capacity and function, and failed to discriminate between those women who were taking the contraceptive pill and those who weren't.

As a GP, Little says she doesn't think there is enough information in the handouts provided by the Australian government for any parent to give valid, informed consent to Gardasil vaccination.



Another study (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528880/)conducted in 2014 by Little and Ward, entitled "Adolescent Premature Ovarian Insufficiency Following Human Papillomavirus Vaccination", documents the cases of three young women, also from New South Wales, who developed premature ovarian insufficiency after HPV vaccination.

Two of the girls were aged 16 when diagnosed and one was 18. Each girl had been prescribed the oral contraceptive pill to treat menstrual cycle abnormalities prior to investigation and diagnosis.

"Preservation of reproductive health is a primary concern in the recipient target group," Little and Ward said.

"Since this group includes all prepubertal and pubertal young women, demonstration of ongoing, uncompromised safety for the ovary is urgently required. This matter needs to be resolved for the purposes of population health and public vaccine confidence."



In 2013, two sisters from Wisconsin in the US – Madelyne and Olivia Meylor – filed a federal claim, saying they believed that Gardasil vaccination caused them to suffer premature ovarian failure, but the claims were dismissed by a federal judge in Washington, D.C. in 2016.

The judge said that some of the women's symptoms appeared to begin before they were vaccinated in their early teens, but didn't rule on whether ovarian failure is a legitimate injury caused by Gardasil.

Merck said in a statement at the time: "Nothing is more important to Merck than the safety of our medicines and vaccines."

The company added: "The safety and efficacy of Gardasil was established in clinical trials involving more than 25,000 females and males."

Merck said it had continued to evaluate safety in several large post-licensure surveillance studies involving more than 500,000 people following the administration of more than a million doses of vaccine.

The company said it had reviewed the post-licensure reports of POI after administration of Gardasil and had concluded that the evidence did not support a causal relationship to the vaccine.

"There have been no reports of adverse reactions of POI in subjects who received Gardasil in clinical trials. A medical history of POI has been reported by a small number of trial participants who received Gardasil or placebo; the number of medical history reports of POI is similar for Gardasil and placebo recipients."

TGA says Gardasil does not cause premature ovarian failure

The Australian Medical Association (AMA) said in a statement (https://ama.com.au/ausmed/no-link-between-gardasil-and-infertility-tga) in May 2013 that the TGA had found no evidence to link the HPV vaccine to premature ovarian failure and infertility.

It quoted the Health Minister, Tanya Plibersek, as saying the TGA found that there was no "plausibly biological basis" for drawing a link between Gardasil and premature ovarian failure.

Plibersek said the TGA did not think there were grounds for undertaking long-term surveillance of ovarian function among vaccinated girls and women.

"The TGA has not identified a possible safety signal for premature ovarian failure following Gardasil vaccination," the minister wrote.

"In addition, the TGA does not consider that a plausible biological basis for a causal relationship between the administration of Gardasil vaccine and the occurrence of premature ovarian failure has been established."

In her answer, Ms Plibersek said oligomenorrhoea and amenorrhoea were "common occurrences" in teenage girls and young women, and could have many possible causes.

She said that, out of 6.7 million doses of Gardasil distributed in Australia between 2006 and the end of 2012, the case reported by Dr Little was the only incident about which the TGA had been informed that involved a possible link between the vaccine and POF.

"The TGA considers there is insufficient evidence of a safety signal with Gardasil to warrant undertaking a specific long-term follow up of ovarian function in a cohort of vaccinated girls and women," the minister wrote.

She said the TGA reported that it had been advised of 1,983 suspected adverse events following vaccination with Gardasil, including 1,585 where Gardasil was the sole vaccine administered.

The minister said the TGA found that the majority of adverse reactions were "mild and well recognised": nearly one in five involved headaches, and 18.4 per cent involved reactions at the site of the injection, including bruising, pain, swelling or a rash. Other reactions were nausea, dizziness, fatigue and lethargy, and fever.

There were 167 cases (9.1 per cent) where the recipient of the vaccine fainted, and 19 reported instances of anaphylactic reaction.

The AMA says the incidence of genital wart cases among young women has plunged since the nationwide HPV programme began in 2007.

It says a study in the British Medical Journal found rates of diagnosis among women aged 21 years or younger had plummeted from 11.5 per cent in 2007 to 0.85 per cent in 2011, a fall of almost 93 per cent.

The AMA stated: "Internationally, the GAVI Alliance – a global joint public and private partnership partially funded by the Australian Government – has announced plans to vaccinate 30 million girls in 40 of the world's poorest countries against HPV after negotiating a deal with manufacturers for supplies at just \$4.40 a dose, a big discount on its cost in developed countries."

US study says HPV vaccination is not affecting fertility

In a study (https://www.ncbi.nlm.nih.gov/pubmed/28881394) published in Paediatric and Perinatal Epidemiology in September 2017, researchers from Boston in the US and Aarhus in Denmark stated that HPV vaccination "had little effect on fecundability overall" and "HPV vaccination was positively associated with fecundability among women with a history of sexually transmitted infections".

Between 2013 and 2017, the researchers followed 3,483 women who were planning to conceive and 1,022 male partners for 12 months or until pregnancy was reported, whichever came first.

Participants reported whether they had been vaccinated against HPV and gave their age at vaccination.

The researchers found that HPV vaccination was more prevalent among females (33.9%) than males (5.2%) and concluded that there was "little overall association" between female or male vaccination and fecundability.

They discovered that, among females with a history of sexually transmitted infections or pelvic inflammatory disease (i.e. a group at high risk of exposure to HPV infection), those vaccinated against HPV had higher fecundability than those not vaccinated.

The researchers point out that "while rodent studies indicated no effect of HPV vaccination on fertility, no studies have examined this relationship in humans".

'Life sometimes feels like torture'

One of the young women in Australia whose life has been a nightmare since she received Gardasil vaccination is Asha Stubbs, who is originally from Albany, Western Australia, but lives in northern Queensland,.

Asha received her first two Gardasil injections in July 2007 and October 2007 when she was 15 years old. When she received her third injection in March 2008, she was 16.

Two weeks after that injection, she was diagnosed with idiopathic thrombocytopenic purpura (ITP), a rare autoimmune disorder in which a person's blood doesn't clot properly because the immune system destroys the blood-clotting platelets.

Asha had previously been in perfect health.



Asha with her mother Michelle.

After the second Gardasil shot, Asha was already suffering sore muscles all over her body. She developed bad stretch marks, and was bruising very easily.

When Asha was 19, the ITP turned into paroxysmal nocturnal hemoglobinuria (PNH), which is a rare and life-threatening blood disease in which red blood cells are destroyed and blood clots develop.

About six months later Asha was also diagnosed with myelodysplastic syndrome (MDS), in which the bone marrow does not produce sufficient healthy blood cells. She was told she was in the early stages of developing Acute myeloid leukaemia (AML).

Asha, who is now 25, hasn't been able to work for about six years, and has to have blood transfusions every six weeks.

She says that, when she tells her story, she is sometimes told that she is making it up, which, she says, is "heartbreaking". She says she now carries a huge level of resentment towards "Big Pharma" and the Australian government, "those who should have protected me and didn't". She says her existence sometimes feels like torture.

Asha's mother Michelle says that she had had no idea whatsoever that the Gardasil vaccination could have such a life-changing effect.

She says she is angry at the government "for letting this happen and not being here to help in the aftermath".

'HPV clears by itself'

One of the doctors who has spoken out publicly about the dangers of Gardasil is Diane Harper, who was a lead research scientist working on the clinical trials for Gardasil and Cervarix. She is now chair of the Department of Family and Geriatric Medicine at the University of Louisville in the US.

She also speaks about the short-lived nature of most HPV infection.

In the following video extract, Harper says that, of all the women who get a HPV infection, at least 70 percent of them will clear it themselves within the first year.

"Within two years, about 90 percent of all of those HPV infections are going to clear all by themselves."

In the case of the 10 percent of women that still had HPV infection, after three years half of those infections would have progressed to a CIN 2/3 pre-cancerous lesion.

"So, approximately 5 percent of HPV infections are going to go into a pre-cancerous lesion"

Harper says that, among women with CIN 3 lesions, it takes five years for about 20 percent of the lesions to become invasive carcinomas.

"It takes about thirty years for 40 percent of them to became invasive cervical carcinomas"



Harper told CBS News (http://www.cbsnews.com/news/gardasil-researcher-speaks-out/) that young girls and their parents should receive more complete warnings before receiving the Gardasil vaccine.

Sharyl Attkisson from CBS quotes Harper as saying that deaths associated with HPV vaccination are underreported.

"The risks of serious adverse events including death reported after Gardasil use ... were 3.4/100,000 doses distributed," Harper is quoted as saying.

"Gardasil has been associated with at least as many serious adverse events as there are deaths from cervical cancer developing each year."

Harper is also concerned that Merck's aggressive marketing of Gardasil may have given women a false sense of security, Attkisson writes.

She also points to the fact that Gardasil loses its effectiveness after about five years.

"If we vaccinate 11-year-olds and the protection doesn't last ... we've put them at harm from side effects, small but real, for no benefit," Harper told Attkisson.

Attkisson quotes Harper as saying that if women stop Pap screening after vaccination, the cervical cancer rate will actually increase per year.

"Should Gardasil not be effective for more than 15 years, the most costly public health experiment in cancer control will have failed miserably," Harper is quoted as saying.

Harper points out that she is talking about the US, where there is a successful Pap screening programme, and the situation in other countries may be different.

Merck said at this month's EUROGIN 2017 Congress in the Netherlands that final analyses of its clinical trial for Gardasil 9 indicated that there was "efficacy for up to six years following receipt of first vaccine dose, and antibody responses over five years".

'One More Girl'

Lucija Tomlinjenovic is a post-doctoral research fellow at the University of British Colombia, who has published numerous papers about the efficacy and safety of HPV vaccines.

She talks in a "One More Girl (https://www.youtube.com/watch?v=nablNgrwu9Q)" video clip about the side-effects of Gardasil.

She says that in the independent literature, there have been several reports documenting multiple sclerosis and encephalitis (brain inflammation), in girls who have received the Gardasil vaccine.

"Just because a study sponsored by the manufactures does not identify problems with the vaccine, does not necessarily mean that the vaccine is safe.

"In fact, if one looks at the manufacturer studies, they're often not designed to detect serious adverse events."

Tomlinjenovic cites a study done by a group of researchers sponsored by GlaxoSmithKline.

"They were looking at Cervarix ... and the authors acknowledged that none of the studies that they evaluated had been designed to detect autoimmune diseases, so obviously you're not going to find what you're not looking for."

In spite of these obvious flaws, Tomlinjenovic says, the researchers concluded that there was no evidence that Cervarix was associated with an increased risk for autoimmune diseases. "This is absurd because you haven't looked for it," Tomlinjenovic said.



In a paper (http://www.tandfonline.com/doi/full/10.3109/07853890.2011.645353?scroll=top&needAccess=true) entitled "Human papillomavirus (HPV) vaccine policy and evidence-based medicine: Are they at odds?", published in the Annals of Medicine in December 2007,

Lucija Tomljenovic and Christopher A. Shaw write that, while the world's leading medical authorities state that HPV vaccines are an important cervical cancer prevention tool, "clinical trials show no evidence that HPV vaccination can protect against cervical cancer".

They add: "Similarly, contrary to claims that cervical cancer is the second most common cancer in women worldwide, existing data show that this only applies to developing countries.

"In the Western world cervical cancer is a rare disease with mortality rates that are several times lower than the rate of reported serious adverse reactions (including deaths) from HPV vaccination."

Other side effects

In an article published in the journal Clinical Rheumatology in 2015, researcher Manuel Martinez-Lavin stated that chronic pain conditions were more frequent after HPV vaccination.

He said that fibromyalgia and postural tachycardia syndrome appeared to be associated with the vaccination.

Another report, in the European Journal of Neurology, details the cases of six young women who developed POTS within weeks of receiving HPV vaccinations.

'Gardasil a risk to those already infected with HPV'

There are statements in documents sent to, and produced by the FDA, that say Gardasil vaccination brings a significantly higher risk of developing precancerous lesions to women already infected with HPV.

In its submission (http://www.fdalawblog.net/wp-content/uploads/archives/docs/hifi-dna-tech-Ilc.pdf) to the FDA in March 2007 for reclassification of a new device for Polymerase Chain Reaction (PCR) Detection, HiFi DNA Tech, who manufacture DNA test reagents, points to Merck's own trial date that states that vaccination with Gardasil of women who are already sero-positive and PCR-positive for vaccine-relevant genotypes of HPV has been found to increase the risk of developing high-grade precancerous lesions by 44.6 percent.

HiFi DNA Tech asked the FDA to change the classification of HPV tests from Class III to Class II.

The company cites a background document (https://web.archive.org/web/20100728043402/http://www.fda.gov:80/ohrms/dockets/ac/06/briefing /2006-4222B3.pdf) produced by the FDA's Vaccines and Related Biological Products Committee (VRBPAC) in May 2006.

Table 17. Study 013: Applicant's analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive <u>and</u> seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]

Endpoint	Gardasil™ N=2717			Placebo N=2725						
	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	Observed Efficacy	95% CI
HPV 6/11/16/18 CIN 2/3 or worse	156	31	278.9	11.1	137	19	247.1	7.7	-44.6%	<0.0, 8.5%

HiFi DNA Tech said; "It would be prudent to perform a sensitive HPV detection assay with accurate genotype determination on the patients to be vaccinated if prior HPV infection is suspected."

The background document says there is "compelling evidence" that HPV vaccination lacks therapeutic efficacy among women who have had prior exposure to HPV and have not cleared previous PCR-positive and sero-positive infection. This, the document states, represents approximately 6 percent of the overall study populations.

HiFi DNA Tech stated in its submission that, based on new scientific information published in the past 15 years, "it is now generally agreed that identifying and typing HPV infection does not bear a direct relationship to stratification of the risk for cervical cancer".

It added: "Most acute infections caused by HPV are self-limiting. It is the persistent HPV infection that may act as a tumour promoter in cancer induction."

HiFi DNA Tech states that "repeated sequential transient HPV infections, even when caused by 'high-risk' HPVs, are characteristically not associated with high risk of developing squamous intraepithelial lesions, a precursor of cervical cancer".

A woman found to be positive for the same strain (genotype) of HPV on repeated testing is highly likely suffering from a persistent HPV infection and is considered to be at high risk of developing precancerous intraepithelial lesions in the cervix, the company states.

"It is the persistent infection, not the virus, that determines the cancer risk."

HiFi DNA Tech says the FDA has accepted the above interpretation of current medical science, as reflected in its March 31, 2003, announcement on approval of the Digene HC2 High-Risk HPV DNA Test.

The FDA denied HiFi DNA Tech's reclassification submission. The company brought a lawsuit against that denial, but the Connecticut District Court's granted the FDA's motion to dismiss the case.

In December 2009, the United States Court of Appeals for the Second Circuit affirmed the district court's ruling.

HiFi had alleged that the FDA was arbitrary and capricious in its review of the company's product as a cancer-detection device rather than a virus-detection device.

The court ruled, however, that, based on the intended use for the device as defined by HiFi in its FDA application, the FDA reasonably determined that the device's intended use was to assess a woman's risk of developing cancer.

Doctors recommending HPV vaccination 'without urgency'

According to a study (http://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ltemID=774#.WdyugjvmjX6) published in the journal "Cancer Epidemiology, Biomarkers & Prevention", a journal of the American Association for Cancer Research, physicians often reported that they recommended HPV vaccination "inconsistently, behind schedule, or without urgency".

Researcher Melissa B. Gilkey, an assistant professor of population medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute in Boston, said: "Of the five communication practices we assessed, about half of physicians reported two or more practices that likely discourage timely HPV vaccination,"

Gilkey and her colleagues found that 27 percent of physicians across the US reported that they did not strongly endorse HPV vaccination, and 26 percent and 39 percent reported that they did not provide timely recommendations for vaccinating girls and boys, respectively.

"About 59 percent of the physicians recommended HPV vaccination more often for adolescents who they perceived to be at higher risk for getting an HPV infection, as opposed to recommending it routinely for all adolescents," Gilkey said.

"Only 51 percent of physicians recommended same-day vaccination at the time of visit."

WHO stands firm, but scandal is predicted

The World Health Organisation (WHO) stands firm against all the doubts raised about Gardasil and says 99 percent of cervical cancer cases are linked to genital infection with HPV.

It says that Gardasil and Cervarix are "highly efficacious" in preventing infection with HPV types 16 and 18, which, it says, are together responsible for about 70 per cent of cervical cancer cases globally.

However, Dr Bernard Dalbergue, a former physician who worked directly with Merck, voices the concerns of many medical professionals, and a growing number of other people worldwide, when he says, in an interview (http://ddata.over-blog.com/xxxyyy /3/27/09/71/2012-2013/Juin-2013/Dr-Dalbergue--Gardasil--plus-grand-scandale-de-tous-les-tem.pdf) with the French magazine Principes de Santé (Health Principles), which was published in April 2014, that the full extent of the Gardasil scandal needs to be assessed.

"Everyone knew when this vaccine was released on the American market that it would prove to be worthless ... I predict that Gardasil will become the greatest medical scandal of all time because, at some point in time, the evidence will add up to prove that this vaccine, technical and scientific feat that it may be, has absolutely no effect on cervical cancer and that all the very many adverse effects that destroy lives and even kill, serve no other purpose than to generate profit for the manufacturers.

"Gardasil is useless and costs a fortune In addition, decision makers at all levels are aware of it."



An AHVID collage of girls and young women who became ill after HPV vaccination.

- 1. Syncope is better known as fainting. It is a temporary loss of consciousness, usually related to insufficient blood flow to the brain.
 - 2. Insert (https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm426457.pdf)for Gardasil 9

6.2 Post-Marketing Experience

There is limited post-marketing experience following administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured similarly and contain the same antigens from HPV types 6, 11, 16, and 18. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure. The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL and may also be seen in post-marketing experience with

GARDASIL 9:

Blood and lymphatic system disorders: Autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy.

Respiratory, thoracic and mediastinal disorders: Pulmonary embolus.

Gastrointestinal disorders: Nausea, pancreatitis, vomiting.

General disorders and administration site conditions: Asthenia, chills, death, fatigue, malaise.

Immune system disorders: Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

Musculoskeletal and connective tissue disorders: Arthralgia, myalgia.

Nervous system disorders: Acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated with tonic-10 clonic movements and other seizure-like activity) sometimes resulting in falling with injury, transverse myelitis.

Infections and infestations: Cellulitis.

Vascular disorders: Deep venous thrombosis.

Comments from Asha and Michelle Stubbs are taken from a video (https://www.youtube.com/watch?v=EWI4Zs0_jOI&feature=youtu.be) published by the Australian Vaccination-skeptics Network Inc. in May this year.

Update 18/10/2017

The European Ombudsman, Emily O'Reilly, states in her decision, published on October 16, that "there was no maladministration by the European Medicines Agency in the handling of the referral procedure on HPV vaccines".

O'Reilly states that her inquiry did not identify any procedural issues that could have negatively affected the work and conclusions of the Pharmacovigilance Risk Assessment Committee in the referral procedure.

"The examination of the scientific evidence was complete and it was independent," O'Reilly stated.

She said she considered that the EMA's conflict of interest policy was fully complied with during the referral procedure on HPV vaccines.

"There were no identified conflicts of interest. The procedure in question was therefore deemed to have been conducted in full independence by the relevant scientific experts."

O'Reilly suggests that the EMA "continue to explore ways to explain to the public in more detail how its scientific committees arrive at scientific conclusions, and how differences in views that arise during the assessment are addressed".

She said this could be done, for example, by publishing more information online. She suggests that the EMA consider making publicly available lists of all relevant documents in its possession related to a specific referral procedure, or that it consider other ways of helping citizens to identify the documents they wish to obtain.

"Given the importance of ensuring citizens' trust in the procedures of bodies such as EMA, the Ombudsman suggests that EMA proactively makes public as much information as possible on the scientific work of its committees."

The EMA has agreed to review the confidentiality requirements imposed on experts so that they may discuss in public the

details of a scientific debate once that debate has been completed.

Further update on 07/01/2018: Colton Berrett passed away on January 5, aged just 17. He took his own life. Here is a statement from his mother.

Update 2/4/2018

A judge in the Office of Special Masters at the United States Court of Federal Claims has ruled that 21-year-old Christina Richelle Tarsell's death was caused by the HPV vaccine Gardasil.

Doctors determined that Christina Tarsell died from an arrhythmia induced by an autoimmune response to the HPV vaccine Gardasil, which she received just days before she died suddenly in June 2008.

Special Master Christian J. Moran stated in his judgement (https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2010w0251-200-0): "Ultimately, because of the finding that Christina began to experience arrhythmia after her HPV vaccination, Ms. Tarsell has presented preponderant evidence of a logical sequence of cause and effect, connecting the HPV vaccination to the ensuing arrhythmia."

The respondent in the case has proffered compensation of \$310,130: \$250,000.00 for Christina Tarsell's vaccine-related death; \$60,000.00 for past pain and suffering for Christina Tarsell's vaccine-related injury; and \$130 for past unreimbursable expenses related to Christina Tarsell's vaccine-related injury.

Vaccine manufacturers like Merck, who produce Gardasil, cannot be held liable under the law for injuries and deaths caused by their vaccines.

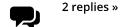
The only recourse the Tarsell family had was to file a claim against the Secretary of Health and Human Services.

• Heart arrhythmia, also known as irregular heartbeat or cardiac dysrhythmia, is a group of conditions in which the heartbeat is irregular, too slow, or too fast.

The Gardasil controversy: as reports of adverse effects increase, cervical cancer rates rise in HPV-vaccinated age groups (https://changingtimes.media/2018/09 /13/the-gardasil-controversy-as-reports-of-adverse-effects-increase-cervical-cancerrates-rise-in-hpv-vaccinated-age-groups/) September 13, 2018 In "Health"

Gardasil controversy: Freedom of Information disclosure reveals more deaths in Australia after HPV vaccination (https://changingtimes.media /2019/07/20/gardasil-controversy-freedom-of-information-disclosure-reveals-more-deaths-in-australia-after-hpv-vaccination/) July 20, 2019 In "Health"

HPV vaccination: more than 100 adverse reaction cases excluded from public database in Australia (https://changingtimes.media/2019/05 /26/hpv-vaccination-more-than-100-adverse-reaction-cases-excluded-from-public-database-in-australia/)
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