## HPV VACCINATION

## Abstract

This document provides an overview of HPV virus and it's spread and outcome, HPV Vaccine Safety, side effects of the HPV Vaccine, concerns raised about the HPV vaccine, pharma irregularities and vaccine compensations

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1.	Disea	ase overview, prevalence, and mortality rate	3					
1.1.	What	is HPV?	3					
1.2.	How p	revalent is HPV and how does HPV spread?	3					
1.3.	What	are severe outcomes of HPV?	3					
1.4.	4. Who is at risk from severe outcomes of HPV? 4							
1.5.	What	is the mortality rate for HPV?	5					
2.	Vacc	ine safety	6					
2.1.	When	were HPV vaccines introduced? troduction of HPV Vaccine in India	<b>6</b> 6					
2.2.	Side e	ffects of HPV Vaccine	8					
2.3.	Count	ries that suspended/restricted/discontinued HPV vaccine over	er concerns 12					
	2.3.1 2.3.2 2.3.3	Japan United States Denmark	12 12 12 13					
	2.3.3	Israel	13					
	2.3.5	Australia	13					
	2.3.6	Colombia	14					
	2.3.7	Sweden	14					
	2.3.8	Mexico	14					
	2.3.9	New Zealand	14					
	2.3.10	Spain	14					
	2.3.11	Ireland	15					
3.	Vacc	ine effectiveness	15					
3.1.	HPV- v	vaccine effectiveness and Myth of eradicating disease	15					
4.	Phar	ma Irregularities	16					
4.1.	India		16					
4.2.	4.2. United States 17							

5.	Compensation	18
5.1.	U.S.	18
5.2.	Japan	22
6.	Media reports of vaccine injury from India	22
7.	Summary	26

### Disease overview, prevalence, and mortality rate 1. 1.1.What is HPV?<sup>i</sup>

Human papillomavirus (HPV) is a sexually transmitted infection (STI) that is passed between people through skin-to-skin contact during sexual activity. There are over 200 varieties of HPV, more than 40 of which are passed through sexual contact and can affect genitals, mouth, or throat.

## **1.2.How prevalent is HPV and how does HPV spread**<sup>1</sup>?

HPV infection causes genital warts, some of which can turn into cancer. For the most part, however, HPV infection is benign. More than 90 percent of HPV infections cause no clinical symptoms and are selflimited, meaning the virus is cleared by the body via natural immunological defenses. More than 90 per cent of HPV infections - cases of anogenital warts - are caused by low-risk HPV types 6 and 11 that cause no clinical symptoms and are self-limited, meaning the virus cleared naturally by the body. HPV is not transmitted through bodily fluids such as semen or saliva, but through skin-to-skin contact. This happens most easily through sexual contact, such as vaginal, anal and oral sex. HPV can enter the body through any mucous membrane, such as mouths, lips, anus and parts of the genitals.

Whereas high-risk HPV types 16, 18 and others could lead to abnormalities that are a precursor to cancer. However, in most cases HPV goes away on its own within two years without any serious health problems and most women with even with high-risk HPV infection do not develop cancer. When it does not go away it either leads to genital warts or cancers in the anus, vulva, vagina which are preventable. HPV also causes cervical smear abnormalities in women.

In most cases, HPV goes away on its own within two years without any serious health problems. But when HPV does not go away, it can cause health problems like genital warts and other HPV-related cancers. In women, certain HPV types cause a proportion of cancers of the anus, vulva, and vagina, which are preventable. HPV also causes cervical smear abnormalities in women.

## 1.3.What are severe outcomes of HPV<sup>2</sup>?

High-risk HPV types (types 16, 18, and others) can cause cervical cell abnormalities<sup>3</sup> that are precursors to cancers.

- Type 16 is associated with approximately 50 percent of cervical cancers worldwide
- Types 16 and 18 together are linked to 70 percent of cervical cancers.

<sup>&</sup>lt;sup>1\_1</sup>https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf

<sup>&</sup>lt;sup>2</sup> Cervical cancer in India and HPV vaccination - PMC (nih.gov)

<sup>&</sup>lt;sup>3</sup> https://www.theepochtimes.com/health/evidence-of-serious-adverse-events-in-what-is-believed-to-be-one-of-the-mosteffective-vaccines 4972564.html?

- Types, 31, 33, 45, 52, and 58, are linked with another 15 percent of cervical cancers and 11 percent of all HPV-associated cancers.
- Non-oncogenic HPV serotypes-6 and 11 contribute over 90% of benign genital infections such as genital warts. Oncogenic HPV serotypes have also been implicated in the causation of anal, vulvar, vaginal, penile and oropharyngeal cancers

Infection with a high-risk HPV type is associated with a higher chance of the development of cervical cancer but, by itself, HPV infection is not the sole risk factor to cause cancer. There are many other factors. HPV infection is measured by means of HPV DNA detection in cervical cells (fresh tissue, paraffin-embedded or exfoliated cells). The relative frequency of HPV-16/18 increases with the severity of the lesion.

The lag period between the oncogenic HPV infection and the invasive cervical cancer is 15–20 years

## 1.4. Who is at risk from severe outcomes of HPV?

HPV infection causes genital warts, some of which can turn into cancer. For the most part, however, HPV infection is benign.

More than 90 percent of HPV infections cause no clinical symptoms and are self-limited, meaning the virus is cleared by the body via natural immunological defenses.

Infection with a high-risk HPV type is associated with a higher chance of the development of cervical cancer but, by itself, HPV infection is not the sole risk factor to cause cancer. There are many other factors like smoking, HIV infection<sup>4</sup>

HPV infection is most prevalent among sexually active women between 18-30 years of age. There is significant reduction in its prevalence after 30 years of age. However, cervical cancer is more common in women older than 35 - this suggests infection at a young age and slow progression to cervical cancer with the high-risk oncogenic HPV types.

Cervical cancer is associated with poor genital hygiene, early age of marriage, repeated pregnancies, and multiple sexual partners<sup>5</sup>. Long-term use of hormonal contraceptives, high parity, early initiation of sexual activity, multiple sex partners, tobacco smoking and co-infection with HIV have been identified as established cofactors

Cervical cancer is the uncontrolled growth of abnormal cells in the lining of the cervix. The cervix is part of the female reproductive system and the lower part of the womb, forming the opening from the womb to the vagina

<sup>&</sup>lt;sup>4</sup> <u>https://www.cancer.org/cancer/cervical-cancer/causes-risks-prevention/what-</u>

 $<sup>\</sup>underline{causes.html \#:} \\ \texttt{causes.html \#:} \\ \texttt{ca$ 

<sup>&</sup>lt;sup>5</sup> https://empirediaries.com/2023/01/26/hpv-vaccines-in-india/

## 1.5. What is the mortality rate for HPV?

- In the US, the current age standardized death rate from cervical cancer according to WHO data is 1.7/100,000, which equates to 99.99% survival rate
- In India it is 15.2/100,000, which equates to 99.98% survival rate for India.

Country	Incidence per 100,000 women (age-standardized)	Mortality per 100,000 women (age-standardized)	Mortality ranking among all cancers (all ages)	Pap screening coverage (%)
Australia	4.9	1.4	17th	60.6 (All women aged 20-69 y screened every 2 y)
Netherlands	5.4	1.5	16th	59.0 (All women aged > 20 y screened every 5 y)
US	5.7	1.7	15th	83.3 (All women aged > 18 y screened every 3 y)
France	7.1	1.8	15th	74.9 (All women aged 20-69 y screened every 2 y
Canada	6.6	1.9	14th	72.8 (All women aged 18-69 y screened every 3 y; Annual if at high risk)
Spain	6.3	1.9	15th	75.6 (All women aged 18-65 y screened every 3 y
UK and Ireland	7.2	2	16th	80 (All women aged 25-64 y screened every 5 y)
Israel	5.6	2.1	14th	34.7 (All women aged 18-69 y screened every 3 y)
Germany	6.9	2.3	13th	55.9 (Women aged 20-49 y screened every 5 y)
China	9.6	4.2	7th	16.8 (All women aged 18-69 y screened every 3 y)
Viet Nam	11.5	5.7	4th	4.9 (All women aged 18-69 y screened every 3 y)
Russia	13.3	5.9	7th	70.4 (All women aged 18-69 y screened every 3y)
Brazil	24.5	10.9	2nd	64.8 (All women aged 18-69 y screened every 3 y)
Thailand	24.5	12.8	2nd	37.7 (All women aged 15-44 y ever screened
Pakistan	19.5	12.9	2nd	1.9 (All women aged 18–69 y screened every 3 y)
South Africa	26.6	14.5	2nd	13.6 (All women aged 18-69 y screened every 3 y
India	27	15.2	lst	2.6 (All women aged 18-69 y screened every 3 y)
Cambodia	27.4	16.2	Ist	None
Nepal	32.4	17.6	1st	2.4 (All women aged 18-69y screened every 3 y
Nigeria	33	22.9	2nd	None
Ghana	39.5	27.6	İst	2.7 (All women aged 18-69 y screened every 3 y)
Uganda	47.5	34.9	Ist	None

The cervical-cancer death-rate in the control group of the study can be used to calculate the risk in the population without any screening program. There were 64 deaths in 8 years in the population of 31,488 making for an absolute risk of 2.5/10,000/year. The absolute risk reduction in this case works out to be

## 0.00013.

Incidence rate is 0.0147% and mortality of 0.0092% at 55 to 59 years of age.

## 2. Vaccine safety<sup>6</sup>

## 2.1. When were HPV vaccines introduced?<sup>7</sup>

<u>Three HPV vaccines</u>—bivalent HPV vaccine (Cervarix, 2vHPV), quadrivalent HPV vaccine (Gardasil,

4vHPV), and 9-valent HPV vaccine (Gardasil 9, 9vHPV)—have been licensed by the FDA.

- Gardasil and Cervarix are two unproven and hazardous HPV vaccines purported to prevent cervical cancer, marketed in India by MSD Pharmaceuticals Pvt. Ltd. (subsidiary of Merck) and GlaxoSmithKline Ltd.
- Merck's original Gardasil vaccine was designed to prevent infections from four strains (types 6, 11, 16, and 18).
- On June 8, 2006, after the FDA's fast-tracked review, <u>Gardasil was approved</u> for use in

females ages 9 to 26 for the prevention of cervical, vulvar, and vaginal cancers.

• <u>Cervarix, developed by GlaxoSmithKline</u>, is a bivalent vaccine against HPV types 16 and 18. Cervarix was approved for use in the US on October 16, 2009.

## 2.1.1 Introduction of HPV Vaccine in India<sup>89</sup>

## 2008- 2009

- 2 HPV vaccines have been made available in India,
  - A quadrivalent vaccine (Gardasil), which supposedly protects against 4 strains of HPV,
  - A bivalent vaccine (Cervarix), which supposedly protects against 2.
- Demonstration projects initiated in Andhra Pradesh and Gujarat in 2009 introduced HPV vaccination in public health services in India.

## 2016 - 2020

Delhi was the first state in India to initiate a public HPV vaccination program for school children, on the occasion of National Cancer Awareness Day (November 7, 2016).<sup>12</sup> This program invited girls age 11 to 13 years to get vaccinated at the Delhi State Cancer Institutes (East and West). A total of 1,200 doses have been administered as of March 2017 in a hospital setting along with mothers being offered the <sup>10</sup>Papanicolaou smear and mammography services.

<sup>&</sup>lt;sup>6</sup> https://vaccineimpact.com/2015/study-hpv-infections-not-necessary-for-development-of-cervical-cancer-are-hpv-vaccines-worthless/

<sup>&</sup>lt;sup>7</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6180758/

<sup>&</sup>lt;sup>8</sup> https://pubmed.ncbi.nlm.nih.gov/34429233/

<sup>&</sup>lt;sup>9</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3385284/</u>

<sup>&</sup>lt;sup>10</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6180758/</u>

On November 23, 2016, the government of Punjab also initiated HPV vaccination in a campaign in the Bathinda (incidence 17.5 per 100,000 women) and Mansa (17.3 per 100,000 women) districts. In phase 1, nearly 10,000 girls studying in class 6 of government schools were covered.<sup>13</sup> A total of 261 schools in Bathinda and 187 schools in Mansa were involved in the program. In total, 5,851 girls were vaccinated at Bathinda and 4,002 at Mansa, constituting 97.5% and 98.5% coverage, respectively.

- <u>https://www.who.int/india/news/detail/12-07-2017-punjab-launches-hpv-vaccine-with-who-support</u>
- <u>https://pib.gov.in/PressReleasePage.aspx?PRID=1885597#:~:text=National%20Technical%20Adv</u> <u>isory%20Group%20for,routine%20introduction%20at%209%20years</u>
- <u>https://theprint.in/health/delhi-1st-state-to-launch-hpv-vaccine-for-cervical-cancer-sees-numbers-fall-blame-pandemic/814106/</u>
- <u>https://www.who.int/india/news/detail/12-07-2017-punjab-launches-hpv-vaccine-with-who-support</u>
- <u>https://timesofindia.indiatimes.com/city/chandigarh/health-minister-launches-hpv-vaccine-campaign/articleshow/61568416.cms</u>
- <u>https://www.hindustantimes.com/cities/delhi-news/lg-office-asks-govt-to-set-up-delhi-labour-welfare-board-101679767695805.html</u>
- <u>https://main.mohfw.gov.in/sites/default/files/Approved%20Minutes%20of%20NTAGI%20meeting%20held%20on%20December%2019%202017.pdf</u>
- In 2018, Sikkim state in India introduced human papillomavirus (HPV) vaccine for 9-13-year-old girls, primarily through school-based vaccination, targeting approximately 25,000 girls
- Nonavalent vaccine was licensed in 2018.

### 2021

 MSD Pharmaceuticals Pvt. Ltd, a wholly owned subsidiary of Merck & Co. Inc., launched of India's first gender-neutral human papillomavirus (HPV) vaccine—Gardasil 9 <u>https://www.livemint.com/companies/news/msd-india-launches-9-valent-human-papillomavirus-vaccine-gardasil9-11632914111895.html</u>

### 2023

• **The Drugs** Drugs Controller General of India (DCGI) granted market authorisation to Serum Institute of India (SII) to manufacture 'CERVAVAC' an indigenously-developed India's first Quadrivalent Human Papillomavirus vaccine (qHPV) against cervical cancer.

https://www.livemint.com/news/india/serum-institute-s-qhpv-vaccine-against-cervical-cancer-gets-india-regulator-dgci-s-nod-11657630152069.html

- <u>https://indianexpress.com/article/explained/explained-health/explained-cervavac-indias-first-indigenously-developed-vaccine-for-cervical-cancer-8125663/</u>
- Vaccination of girls against<sup>11</sup> cervical cancer likely to begin in six states in June'23
   The government is likely to begin administering anti-cervical cancer vaccine in girls aged
   nine to 14 years in six states in June 2023. In the first phase of the vaccination campaign,
   2.55 crore girls are targeted to be administered the human papillomavirus (HPV) vaccine in
   Karnataka, Tamil Nadu, Mizoram, Chhattisgarh, Maharashtra, and Uttar Pradesh.

https://www.deccanherald.com/national/vaccination-of-girls-against-cervical-cancer-likelyto-begin-in-six-states-in-june-sources-1190504.html

• HPV Vaccine In The National Program: Is It A Sound Move?

https://empirediaries.com/2023/01/26/hpv-vaccines-in-india/

## 2.2. Side effects of HPV Vaccine

Some of the side effects of the HPV vaccine for which compensation has been awarded include but are not limited to the following<sup>12</sup>:

- Acetabular labrum tear
- Acute Disseminating Encephalomyelitis (ADEM)
- Aggravation of multiple sclerosis (MS)
- Aplastic Anaemia
- Autoimmune limbic encephalitis
- Blood Clots
- Cardiac Arrest
- Cardiomyopathy
- Cardiac Arrythmia
- Cerebral Vasculitis
- Demyelinating disorders
- Demyelinating encephalitis
- Developmental delays
- Dizziness
- Epilepsy
- Epstein Barr virus (reactivated)
- Fainting

 $<sup>^{11}\ {\</sup>tt https://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(23)00118-3.pdf}$ 

<sup>&</sup>lt;sup>12</sup> <u>https://www.uscfc.uscourts.gov/aggregator/sources/8</u>

- Fatigue
- Guillian-Barre Syndrome (GBS)
- Headaches
- Henoch Schonlein Purpura
- Hip impingement syndrome
- Joint pain
- Juvenile Amyotrophic Lateral Sclerosis (ALS)
- Macrophagic Myofasciitis (MFF)
- Myocarditis
- Neuromyelitis Optica (NMO)
- Neurogenic bladder
- Neurological Injury
- Neutrophilic urticaria
- Optic Neuritis
- Pancreatitis
- Photophobia
- Polyarthritis
- Polyarthralgia pain syndrome
- Rheumatoid arthritis
- Snapping hip syndrome
- Subarachnoid haemorrhage
- Systemic Juvenile Idiopathic Arthritis
- Transverse Myelitis
- Ulcerative Colitis
- Urticaria
- Vitiligo
- Vomiting
- Weston Hurst disease
- Death

## Hidden Toxicity of Human Papillomavirus Vaccine Ingredients

Recent publications originating from Italy, Japan, Australia, Columbia, India, Ireland, Denmark, Mexico, Norway, Sweden, Canada, France, the USA, and the United Kingdom have reported post-HPV vaccination phenomena that share overlapping clinical features with chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME), fibromyalgia (FM), postural orthostatic tachycardia syndrome (POTS), complex regional pain syndrome (CRPS), small fiber neuropathy (SFN), and autonomic dysfunction (AD). Typical symptoms include (but are not limited to) prolonged generalized fatigue, chronic headaches, widespread generalized pain, tremors, orthostatic fainting, postural tachycardia, alterations in gastrointestinal motility, gait disturbance, anxiety, paresthesia's, sleep disturbance, learning impairment, difficulty in concentration, and other cognitive phenomena.

https://clinmedjournals.org/articles/jrdt/journal-of-rheumatic-diseases-and-treatment-jrdt-5-075.php?jid=jrdt Given below are some references of HPV vaccine injury cases:

### Australia

#### • Adolescent Premature Ovarian Insufficiency

Three young women who developed premature ovarian insufficiency following quadrivalent human papillomavirus (HPV) vaccination presented to a general practitioner in rural New South Wales, Australia. The unrelated girls were aged 16, 16, and 18 years at diagnosis. Each had received HPV vaccinations prior to the onset of ovarian decline. Vaccinations had been administered in different regions of the state of New South Wales and the 3 girls lived in different towns in that state. Each had been prescribed the oral contraceptive pill to treat menstrual cycle abnormalities prior to investigation and diagnosis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528880/

US

#### • Human papilloma virus vaccine and primary ovarian failure

Post-vaccination autoimmune phenomena are a major facet of the autoimmune/inflammatory syndrome induced by adjuvants and different vaccines, including HPV, have been identified as possible causes. https://pubmed.ncbi.nlm.nih.gov/23902317/

#### • Birth Defects

http://www.judicialwatch.org/files/documents/2010/VAERS-052009-to-092010.pdf

 Human papillomavirus vaccination syndrome--small fiber neuropathy and dysautonomia could be its underlying pathogenesis

Inexplicit adverse reactions have been described after the injection of the newer vaccines vs. human papillomavirus (HPV). The symptoms more often reported are chronic pain with paresthesias, headaches, fatigue, and orthostatic intolerance. Adverse reactions appear to be more frequent after HPV vaccination when compared to other type of immunizations

https://pubmed.ncbi.nlm.nih.gov/25990003/

- Severe somatoform and dysautonomic syndromes after HPV vaccination Case study and review of literature.<u>https://link.springer.com/article/10.1007/s12026-016-8820-z</u>
- Cardiac arrest 3 days after receiving 2nd dose of the HPV vaccine. https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2015vv0929-90-0

### Denmark

• Increased Neurological and Autoimmune Events After HPV Vaccines

A Danish review of 79,102 female and 16,568 male subjects, found HPV vaccines had significantly increased rates of serious nervous system disorders. Postural orthostatic

tachycardia syndrome (POTS) and complex regional pain syndrome (CRPS) were judged "definitely associated" with the HPV vaccine.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7047375/

## India

On November 23, 2016, the government of Punjab also initiated HPV vaccination in a campaign in the Bathinda (incidence 17.5 per 100,000 women) and Mansa (17.3 per 100,000 women) districts. In phase 1, nearly 10,000 girls studying in class 6 of government schools were covered.<sup>13</sup> A total of 261 schools in Bathinda and 187 schools in Mansa were involved in the program. In total, 5,851 girls were vaccinated at Bathinda and 4,002 at Mansa, constituting 97.5% and 98.5% coverage, respectively. Although 28 minor adverse events were reported, consisting of fainting (n = 16), dizziness (n = 5), vomiting (n = 5), and headache (n = 2).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6180758/

 119 adverse effects were reported – headache, dizziness, nausea, syncope <u>https://www.assamcancercarefoundation.org/about-us/pdfs/current-status-of-human-papillomavirus-vaccination.pdf</u>

https://www.globalresearch.ca/serious-injuries-merck-gardasil-hpv-vaccine-significantlyunderreported-study-shows/5746442 -

## Others

• Human papillomavirus vaccination syndrome--small fiber neuropathy and dysautonomia could be its underlying pathogenesis

The symptoms more often reported are chronic pain with paresthesias, headaches, fatigue, and orthostatic intolerance. Adverse reactions appear to be more frequent after HPV vaccination when compared to other type of immunizations. Different isolated cases and small series have described the development of complex regional pain syndrome (CRPS), postural orthostatic tachycardia syndrome (POTS), and fibromyalgia after HPV vaccination. These are illnesses often difficult to diagnose that have overlapping clinical features. <u>https://pubmed.ncbi.nlm.nih.gov/25990003/</u>

- **Postural tachycardia syndrome after vaccination with Gardasil** https://onlinelibrary.wiley.com/doi/10.1111/j.1468-1331.2010.03021.x
- Anti-NMDA receptor encephalitis, a newly identified autoimmune disorder causing severe neurological symptoms.
   After HPV vaccination, diagnosed with <u>anti-NMDA receptor encephalitis</u>, a newly identified autoimmune disorder causing severe neurological symptoms. https://sanevax.org/cervarix-one-mothers-experience-with-hpv-vaccine-damage/
- Potential cross-reactivity between HPV16 L1 protein and sudden death-associated antigens

34 pentamers from the viral capsid protein are shared with human proteins that, when altered, have been linked to short QT syndrome, arrhythmogenic cardiac disorders, cardiovascular diseases and sudden death.

https://pubmed.ncbi.nlm.nih.gov/21699023/

# 2.3. Countries that suspended/restricted/discontinued HPV vaccine over concerns

## 2.3.1 Japan

## Cervarix vaccine issues trigger health notice

The **Japanese** health ministry had issued a nationwide notice that cervical cancer vaccinations should no longer be recommended for girls aged 12 to 16 because several adverse reactions to the

medicines had been reported.

https://www.japantimes.co.jp/news/2013/06/15/national/cervix-vaccine-issues-trigger-health-notice/

• Lessons learnt in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective https://ijme.in/articles/lessons-learnt-in-japan-from-adverse-reactions-to-the-hpv-vaccine-amedical-ethics-perspective/?galley=html

In the spring of 2022, Japan announced it was relaunching its HPV vaccination drive.

## **2.3.2** United States<sup>13</sup>

The original Gardasil(approved in 2006) and Cervarix—are still used around the world, but both have been voluntarily discontinued in the United States. https://www.medscape.com/viewarticle/870853

2.3 to 2.5% risk of serious adverse reactions AND the 2.4 to 3.3% risk of developing a new medical condition potentially indicative of autoimmune disorders experienced by Merck's Gardasil 9 clinical trial participants. Cervical cancer rates are always quoted as # per 100,000. Given the above information, for every 100,000 people using Gardasil 9 there would be 2,300 serious adverse events.

The original Gardasil, still in use in certain parts of the world, was discontinued in the United States on May 8, 2017 following the introduction of Gardasil-9. Cervarix was voluntarily withdrawn in the U.S. on August 8, 2016, but is still in use in other countries.

<sup>&</sup>lt;sup>13</sup> <u>https://www.beasleyallen.com/article/hpv-vaccine-developer-speaks-out-against-gardasil-cervarix/</u>

Despite the CDC recommendations, the rate of HPV vaccination among teens in the United States is lower than almost every other developed country. Where European countries have HPV vaccination coverage ranging from 80% to 90%<sup>14</sup>, the United States hovers below 50%.<sup>15</sup>

## 2.3.3 Denmark

Documentary on HPV Vaccine Shows Lives of Young Women Ruined <u>https://healthimpactnews.com/2015/tv2-denmark-documentary-on-hpv-vaccine-shows-lives-of-young-women-ruined/</u>

https://oye.news/news/health/vaccines/the-vaccinated-girls-sick-betrayed/

http://www.wakingtimes.com/gardasil-firestorm-in-

denmark/?utm\_content=bufferd0247&utm\_medium=social&utm\_source=twitter.com&utm\_campaign= buffer

## 2.3.4 Israel

Criticism from Israel doctor on HPV vaccine is documented here in the link below

https://www.ageofautism.com/2013/09/hpv-vaccine-a-strong-criticism-from-leading-israeli-obgyndoctor.html

## 2.3.5 Australia

The <u>Australian government's cancer data</u><sup>16</sup> show the dramatic rise in cervical cancer in young girls vaccinated with Gardasil. Merck markets Gardasil as a prophylactic against cervical cancers despite the company's own pre-licensing studies <u>that showed a 44.6% INCREASE in cervical cancers</u> among girls exposed to HPV virus prior to vaccination (up to 30% may be exposed in the birth canal) <u>https://childrenshealthdefense.org/news/australian-data-cancer-epidemic-in-gardasil-girls/</u>

https://changingtimes.media/2019/05/26/hpv-vaccination-more-than-100-adverse-reaction-casesexcluded-from-public-database-in-australia/

In 2007, Australia reported an annual adverse drug reaction rate of 7.3/100,000, the highest since 2003, representing an <u>85 percent increase from 2006</u>.<sup>17</sup>

<sup>&</sup>lt;sup>14</sup> https://www.europeancancer.org/resources/199:hpv-vaccine-tracker.html

<sup>&</sup>lt;sup>15</sup> US 49.5% https://www.pediatricnursing.org/article/S0882-5963(18)30268-9/pdf

<sup>&</sup>lt;sup>16</sup> Cancer data in Australia, Cancer rankings data visualisation - Australian Institute of Health and Welfare (aihw.gov.au)

<sup>&</sup>lt;sup>17</sup> <u>Department of Health and Aged Care | Annual report: Surveillance of adverse events following immunisation in Australia, 2007</u>

Per the analysis of the Adverse Drug Reactions System (ADRS) database by the Australian Department of Health and Aging, this increase was "almost entirely due to" reports following the national rollout of the three-dose HPV vaccination program for young females in April 2007; 705 of the 1,538 adverse drug reactions reported that year were from the Gardasil vaccine.

https://www.theepochtimes.com/health/evidence-of-serious-adverse-events-in-what-is-believed-to-beone-of-the-most-effective-

vaccines\_4972564.html?utm\_content=bufferd98ca&utm\_medium=Social&utm\_source=twitter&utm\_ca mpaign=epochhealth

## 2.3.6 Colombia

200 girls were hospitalized following hpv vaccination in Colombia

## https://www.youtube.com/watch?v=1307z5xltrU

https://apnews.com/article/43b7d6db765c48d8b88d3f3221351546 https://www.scmp.com/news/world/article/1581501/hundreds-girls-colombian-town-sick-after-takinggardasil-vaccine

## 2.3.7 Sweden

The Centre for Cervical Cancer Prevention in Sweden has noted in its annual report a substantial increase in the incidence of invasive cervical cancer, especially during the two years 2014 and 2015

https://ijme.in/articles/increased-incidence-of-cervical-cancer-in-sweden-possible-link-with-hpv-vaccination/?galley=html

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4383348/ https://pubmed.ncbi.nlm.nih.gov/30037785/

## 2.3.8 Mexico

Girls convulsed on the floor after receiving hpv vaccines in 2015

https://www.bitchute.com/video/yuNwLqwBJUyB/

## 2.3.9 New Zealand

Three New Zealand girls killed following Gardasil vaccination <u>https://envirowatchrangitikei.wordpress.com/2017/03/15/hpv-vaccination-gardasil-kills-three-new-</u> <u>zealand-girls-and-debilitates-hundreds-of-</u> <u>others/?fbclid=IwAR1Vrm3auFin\_lJevMyvBMfphD2\_AIDRhqaz0aEF9fFTo\_ndt0hmj76J4QY</u>

## 2.3.10 Spain

Concerns raised about Gardasil in Spain

https://www.reuters.com/article/tb-merck-gardasil-suspension-idUSLA56308620090210 https://www.healthplanspain.com/blog/health-news/414-concerns-raised-about-hpv-vaccine.html

## 2.3.11 Ireland

Almost 650 girls in Ireland reported requiring medical intervention or treatment after receiving the HPV vaccine

https://www.irishtimes.com/news/health/almost-650-girls-needed-medical-intervention-after-hpv-vaccine-1.3217346

### **Other References:**

https://www.youtube.com/watch?v=8dxvXPd8BpE

## 3. Vaccine effectiveness

## **3.1. HPV- vaccine effectiveness and Myth of eradicating disease**

An analysis of the clinical trials of HPV vaccines to prevent cervical cancer raises doubts about the vaccines' effectiveness. The analysis, published by the Journal of the Royal Society of Medicine, assessed 12 published Phase 2 and 3 randomized controlled efficacy trials of the HPV vaccines Cervarix and Gardasil. The researchers found that the trials were not designed to detect cervical cancer, which takes decades to develop. Women in the trials were followed up for six years or less, apart from one trial extension to just under nine years.

The researchers also found that the trial populations had limited relevance and validity for real world settings. The women in the trials were older than the target population

https://www.rsm.ac.uk/media-releases/2020/doubts-raised-about-effectiveness-of-hpv-vaccines

No autoimmune safety signal after vaccination with quadrivalent HPV vaccine Gardasil <a href="https://pubmed.ncbi.nlm.nih.gov/22540172/">https://pubmed.ncbi.nlm.nih.gov/22540172/</a>

**Can HPV Vaccine Prevent Cervical Cancer?** <u>https://childrenshealthdefense.org/defender/truth-hpv-vaccine-part-3-et/</u>

One of the lead HPV vaccine developers for Merck's Gardasil, Dr. Diane Harper, came clean and warned that Gardasil was not only ineffective and unnecessary, it was dangerous. Harper mentioned the medically known fact that 98 percent of HPV warts among sexually active women heal on their own within a year or two.

https://www.organicconsumers.org/news/lead-developer-hpv-vaccines-comes-clean-warns-parentsyoung-girls-its-all-giant-deadly-scam https://www.beasleyallen.com/article/hpv-vaccine-developer-speaks-out-against-gardasil-cervarix/

Cervical cancer takes twenty or more years to develop and the vaccines have just not been around that long to prove their efficacy in preventing cancer.

## 4. Pharma Irregularities

## 4.1.India

Supreme Court admits writ petition against licensing and trials with "Cervical Cancer" vaccines implicating the Drugs Controller of India, PATH, ICMR and others ordering Government of India to immediately respond

https://www.countercurrents.org/mehta070113.htm

### Untested cancer vaccine on sale

Days after the death of four tribal girls in Andhra Pradesh after the alleged administration of HPV vaccine for prevention of cervical cancer, it turned out that the vaccines were being sold over the counter without comprehensive country-specific safety trials held. https://www.tribuneindia.com/2010/20100328/main7.htm

## Can't penalize US NGO for violating drug trial norms

https://indianexpress.com/article/india/india-others/cant-penalise-us-ngo-for-violating-drug-trialnorms/

### It's a PATH of violations, all the way to vaccine trials

https://www.thehindu.com/news/national/its-a-path-of-violations-all-the-way-to-vaccine-trials-house-panel/article5083151.ece

https://www.ecchr.eu/en/case/indian-supreme-court-asks-pharmaceutical-companies-for-specificdetails-on-clinical-trials/

https://main.icmr.nic.in/sites/default/files/reports/HPV\_PATH\_final\_report.pdf

### Supreme Court seeks Centre's reply on plea to ban pentavalent vaccine

https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/supreme-court-seekscentres-reply-on-plea-to-ban-pentavalent-vaccine/articleshow/22223639.cms

https://www.hindustantimes.com/delhi/sc-asks-govt-to-respond-to-pil-on-pentavalent-vaccine/storyiI7BHrYktdrPOe7hmIWDSI.html

## https://www.deccanherald.com/content/354868/sc-takes-up-pil-against.html

A woman of Patunia panchayat lodged a complaint with Dharmasala police alleging that her threemonth-old baby boy died after being administered a faulty pentavalent vaccine. https://www.newindianexpress.com/states/odisha/2022/aug/02/baby-dies-after-being-given-faultyvaccine-in-fazilpur-2483224.html

Poonawalla suggests that the deaths may have occurred due to human error while administering the vaccine or due to some other illness,

https://punemirror.com/pune/cover-story/human-error-may-have-caused-vaccine-deaths-sayscyrus/cid5110869.htm

The study demonstrated an increase in reports of sudden unexplained deaths within 72 hours of administering PV compared to DTP vaccine.

https://www.dnaindia.com/india/report-pentavalent-vaccine-caused-more-deaths-than-dpt-study-2594255

Pentavalent vaccine: Doing more harm than good? https://www.expresspharma.in/amp/pentavalent-vaccine-doing-more-harm-than-good/

GSK's 69 Infanrix deaths are not explicable as coincidence.

https://www.ageofautism.com/2015/01/gsks-69-infanrix-deaths-are-not-explicable-as-coincidence.html

## 4.2.United\_States

## Lawsuit alleges Gardasil Contains "Dangerous and Undisclosed Ingredients,"

The lawsuit alleges Gardasil contains "dangerous and undisclosed ingredients," including HPV L1-DNA fragments and phenylmethylsulfonyl fluoride (PMSF). According to the complaint, HPV L1-DNA fragments make the vaccine "more potent and dangerous than intended," and phenylmethylsulfonyl fluoride is a "toxic nerve agent that is not intended for human consumption or injection."

https://www.wisnerbaum.com/blog/2021/july/gardasil-contains-dangerous-and-undisclosed-ingr

## **Merck Gardasil Clinical Trials**

In the Merck Gardasil vaccine clinical trials, Merck "spiked" the placebo with <u>amorphous aluminum</u> <u>hydroxyphosphate sulfate (AAHS)</u>, a <u>neurotoxin</u>. The result was that approximately equal numbers of subjects in the vaccine group and the placebo group suffered adverse reactions. This allowed the adverse reactions in both groups to appear similar and give the impression that <u>Gardasil HPV</u> <u>vaccine</u> was "as safe as a placebo," or as safe as salt water. In fact, significant numbers of subjects in both treatment groups suffered many serious medical conditions, including symptoms of autoimmune disease

https://www.wisnerbaum.com/prescription-drugs/gardasil-lawsuit/merck-gardasil-clinical-trials

## Judicial Panel Consolidates Dozens of Lawsuits Against Merck's HPV Gardasil Vaccine

https://childrenshealthdefense.org/defender/merck-gardasil-hpv-vaccine-lawsuits-multidistrictlitigation/

Gardasil Cervical Cancer Lawsuit Claims Merck Falsely Represented HPV Vaccine's Effectiveness <a href="https://www.aboutlawsuits.com/gardasil-cervical-cancer-lawsuit/">https://www.aboutlawsuits.com/gardasil-cervical-cancer-lawsuit/</a>

## 5. Compensation

## 5.1. U.S.

Below is a list of court judgments from US wherein compensation was awarded to HPV vaccine recipients following adverse events:

- 1. Court awarded over \$ 860,000 in lump sum payments, and several thousand dollars in recurring annual payments, after a woman suffered neurological injury and/or transverse myelitis following HPV vaccination (Link: <u>https://casetext.com/case/good-v-secy-of-health-human-servs</u>)
- Person suffered GBS and/or acute disseminating encephalomyclitis ("ADEM") as a result of receiving the Tdap, hep. B, IPV, MMR, hep. A, and HPV vaccines. Court has directed over \$1 million lumpsum & thousands of dollars recurring annually as compensation (Link: <u>https://ecf.cofc.uscourts.gov/cgibin/show\_public\_doc?2012vv0729-74-0</u>)
- 3. Lady suffered from neuromyelitis optica (NMO) following administration of flu & HPV. Court ordered over \$1 million lump sum and several thousand dollars in recurring payments as compensation. (Link: <a href="https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2012vv0630-164-0">https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2012vv0630-164-0</a>)
- 4. A woman developed demyelinating disorders following HPV vaccines. Court awarded damages, including \$1.9 million lump sum and ~\$150,000 in recurring annual payments for life. (Link: <a href="https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2012vv0298-139-0">https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2012vv0298-139-0</a>)
- 5. Court ordered over \$38,000 in damages after person suffered from vitiligo following HPV vaccination. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2017vv1096-45-0</u>)
- "Petitioner had proven, by a preponderance of the evidence, that her sJIA was caused by her HPV vaccinations". Child suffered systemic juvenile idiopathic arthritis following HPV. Court ordered ~1.3 million dollars lumpsum & ~\$38,000 in lifetime annual payments. (Link: <a href="https://ecf.cofc.uscourts.gov/cgi-bin/show">https://ecf.cofc.uscourts.gov/cgi-bin/show</a> public doc?2011vv0549-88-0)
- 7. Child suffered from autoimmune limbic encephalitis, intractable epilepsy & developmental delays following HPV. Court ordered damages: \$1.5 million lumpsum & over \$120,000 in recurring annual payments. (Link: <a href="https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2009vv0293-176-0">https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2009vv0293-176-0</a>)
- 8. A female suffered ulcerative colitis after HPV vaccination, Court ordered \$800,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2013vv0529-55-0</u>)
- 9. Petitioner suffered urticaria following HPV vaccine. Court ordered over \$166,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2013vv0044-74-0</u>)

- 10. Female died of cardiac arrest 3 days after receiving 2nd dose of the HPV vaccine. Court ordered \$175,000 in compensation following claim by the parents. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2015vv0929-90-0</u>)
- 11. Young child died following receipt of multiple vaccines including HPV. Court acknowledged vaccines as the cause of death. (Compensation amount unknown) (Link: https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2011vv0206-185-0)
- 12. Female died suddenly after HPV vaccination. Court ordered compensation of \$310,000 to her estate. (Link: https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2010vv0251-213-0)
- 13. Person died of myocarditis following HPV vaccination. Court ordered compensation of \$200,000. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2015vv0160-47-0</u>)
- 14. Female died from cerebral vasculitis following HPV vaccination. Court ordered \$200,000 compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2010vv0103-145-0</u>)
- 15. Female died from arrhythmia due to cardiomyopathy following HPV vaccine. Court ordered \$40,000 in damages. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.LALOUX.112612.\_0.pdf)

- 16. Female died of Weston Hurst disease, Acute Disseminated Encephalomyelitis ("ADEM"), juvenile Amyotrophic Lateral Sclerosis ("ALS") and/or a chronic progressive demyelinating encephalitis following HPV vaccination. Court ordered \$20,000 in compensation. (Link: <u>http://www.uscfc.uscourts.gov/sites/default/files/opinions/ZANE.INCZE121012.pdf</u>)
- 17. Female died due to aplastic anemia following HPV vaccination, Court ordered compensation of \$240,000. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/GOLKIEWICZ.IBARRA072611.pdf)

- 18. A woman suffered significant aggravation of pre-existing acute disseminated encephalomyelitis ("ADEM") and/or multiple sclerosis ("MS"), following HPV vaccination. Court ordered \$350,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2010vv0745-146-0</u>)
- 19. Minor child developed optic neuritis as a result of receiving the HPV, Hepatitis A, Meningococcal, and Tdap vaccinations. Court ordered over \$206,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2015vv1497-28-0</u>)
- 20. Minor child suffered from transverse myelitis ("TM"), encephalomyelitis ("ADEM"), neurogenic bladder, and subsequent conditions following receipt of flu, HPV & Hepatitis A vaccines. Court ordered \$185,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2014vv0572-25-0</u>)
- 21. Woman suffered from chronic neutrophilic urticaria following HPV vaccine. Court ordered \$210,000 in compensation. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.WHITING.061913...pdf)

22. Person suffered chronic joint pain & fatigue following receipt of the HPV vaccine. Court ordered \$28,500 in compensation. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.SNYDER.050813..pdf)

- 23. Person suffered pancreatitis and blood clots following receipt of HPV, TDaP & meningococcal vaccination. Court ordered \$25,000 in compensation. (Link: <a href="http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.GREGORY.041613...pdf">http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.GREGORY.041613...pdf</a>)
- 24. Person suffered from headaches, dizziness, photophobia, vomiting, subarachnoid \* hemorrhage after receiving HPV vaccine. Court ordered \$10,000 in compensation. (Link: http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.JOHNSON.022613...pdf)

25. Female suffered macrophagic myofasciitis ("MFF") after HPV vaccination. Court ordered \$350,000 in compensation. (Link: http://www.uscfc.uscourts.gov/sites/default/files/opinions/MORAN.RATNER020813.pdf)

26. Female died due to cardiomyopathy after receiving HPV vaccine. Court ordered \$40,000 in compensation. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.LALOUX.112612.\_\_0.pdf)

- 27. Girl suffered from acute disseminated encephalomyelitis (ADEM) after receiving HPV vaccine. Court ordered \$125,000 in compensation. (Link:
- <u>http://www.uscfc.uscourts.gov/sites/default/files/opinions/HASTINGS.SALLACH.103112.\_0.pdf</u>)
   28. Female developed a reactivated Epstein Barr virus infection and aplastic anemia after HPV vaccine. Court ordered \$70,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-</u>

bin/show public doc?2011vv0620-140-0)

- 29. Female suffered GBS after HPV vaccination, Court ruled that condition was caused by the vaccine and petitioner was entitled to compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2010vv0077-156-0</u>)
- 30. Female suffered from polyarthritis, polyarthralgia pain syndrome, seronegative rheumatoid arthritis, hip impingement syndrome, acetabular labrum tear, and snapping hip syndrome after HPV vaccine, Court ordered \$25,000 in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2014vv0438-40-0</u>)
- 31. Female suffered from GBS after HPV vaccine. Court concluded vaccine caused the condition and ordered \$1.4 million in compensation. (Link: <u>https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2011vv0140-123-0</u>)
- 32. Female fainted & suffered facial injuries following HPV vaccine. Court ordered ~\$32,000 in compensation. (Link:

http://www.uscfc.uscourts.gov/sites/default/files/opinions/MORAN.VANSCOY100213.pdf)

- 33. Female suffered pancreatitis following HPV vaccine. Court ordered ~\$68,000 in compensation. (Link: <u>http://www.uscfc.uscourts.gov/sites/default/files/opinions/HAMILTON-FIELDMAN.PARSONS.41613.pdf</u>)
- 34. Female suffered acute disseminated encephalomyelitis (ADEM) with transverse myelitis, as a result of receiving HPV, Hepatitis A & flu jabs. Court ordered \$90,000 in compensation. (Link: <a href="http://www.uscfc.uscourts.gov/sites/default/files/opinions/HAMILTON-FIELDMAN.TOCIO">http://www.uscfc.uscourts.gov/sites/default/files/opinions/HAMILTON-FIELDMAN.TOCIO</a>.032813.pdf)
- 35. Female suffered injury Henoch-Schonlein Purpura and other adverse effects, after HPV vaccination. Court ordered \$15,000 in compensation. (Link: <a href="http://www.uscfc.uscourts.gov/sites/default/files/opinions/MORAN.GRIFFIN052711.pdf">http://www.uscfc.uscourts.gov/sites/default/files/opinions/MORAN.GRIFFIN052711.pdf</a>)
- Female suffered from GBS following HPV & varicella jabs. Court ordered \$125,000 in compensation (Link: http://www.uscfc.uscourts.gov/sites/default/files/opinions/Millman.Nelson 9-73.pdf)
- 37. U.S. court pays \$6 million to Gardasil victims

https://m.washingtontimes.com/news/2014/dec/31/us-court-pays-6-million-gardasil-victims/

38. US, 2021: Court awarded over \$ 860,000 in lump sum payments, and several thousand dollars in recurring annual payments, after a woman suffered neurological injury and/or transverse myelitis following HPV vaccination.

https://casetext.com/case/good-v-secy-of-health-human-servs

**39.** Court orders over \$38,000 in damages after person suffered from vitiligo following HPV vaccination

https://ecf.cofc.uscourts.gov/cgi-bin/show\_public\_doc?2017vv1096-45-0

https://twitter.com/awakenindiamov/status/1612313411433406466?s=20&t=o5CQ0gBaK8AbMMKQT7 -jOA Big pharmaceutical companies have a history of paying hefty fines for illegal marketing of drugs & bribing of doctors

### Merck

Ever since gaining the FDA's approval in 2006, Merck has been heavily criticized for their overly aggressive marketing strategies and lobbying campaigns aimed at promoting Gardasil as a mandatory vaccine. Subsequently, questions have been raised as to whether it was appropriate for vaccine manufacturers to partake in public health policies when their conflicts of interests are so obvious. Some of their advertising campaign slogans, such as "cervical cancer kills x women per year" and "your daughter could become one less life affected by cervical cancer," seemed more designed to promote fear rather than evidence-based decision making about the potential benefits of the vaccine. <a href="https://pubmed.ncbi.nlm.nih.gov/23061593/">https://pubmed.ncbi.nlm.nih.gov/23061593/</a>

Merck Created Hit List to "Destroy," "Neutralize" or "Discredit" Dissenting Doctors https://www.cbsnews.com/news/merck-created-hit-list-to-destroy-neutralize-or-discredit-dissentingdoctors/

## Pfizer

### Pfizer Agrees to Settle Suit Over Diabetes Drug Rezulin

https://www.inquirer.com/philly/business/20100326\_Pfizer\_told\_to\_pay\_\_142\_1\_million.html

## Pfizer Inc was found to have committed racketeering fraud in the marketing of it's epilepsy drug Neurontin

https://www.inquirer.com/philly/business/20100326\_Pfizer\_told\_to\_pay\_\_142\_1\_million.html

### Pfizer Paid \$896 Million in Prempro Settlements

### https://archive.ph/TMGWB

American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay \$2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products,

## https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlementits-history

### **Pfizer's documents**

https://phmpt.org/pfizers-documents/

### Astra Zeneca

AstraZeneca Pleads Guilty In Cancer Medicine Scheme

https://archive.ph/0bQqg#selection-175.0-175.11

AstraZeneca to pay \$5.5 million for bribing doctors in China and Russia https://www.statnews.com/pharmalot/2016/08/31/astrazeneca-bribes-china-russia/

Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-label Drug Marketing https://www.justice.gov/opa/pr/pharmaceutical-giant-astrazeneca-pay-520-million-label-drug-marketing

## Johnson & Johnson

U.S. fines J&J \$9.75 mln over kickbacks to surgeon for overseas surgeries

U.S. fines J&J \$9.75 mln over kickbacks to surgeon for overseas surgeries | Reuters

## 5.2. Japan

State and drug makers sued over HPV vaccine damage https://www.japan-press.co.jp/s/news/index.php?id=9817 https://www.sadakafirm.com/blog/hpv-vaccine-lawyer-mark-sadaka-meets-with-11-japaneseattorneys/

## 6. Media reports of vaccine injury from India

**Controversial vaccine studies: Why is Bill & Melinda Gates Foundation under fire from critics in India** In 2009, several schools for tribal children in Khammam district in Telangana — then a part of undivided Andhra Pradesh — became sites for observation studies for a cervical cancer vaccine that was administered to thousands of girls aged between nine and 15. The girls were administered the Human Papilloma Virus<sup>18</sup> (HPV) vaccine in three rounds that year under the supervision of state health department officials. The vaccine used was Gardasil, manufactured by Merck. It was administered to around 16,000 girls.

Months later, many girls started falling ill and by 2010 five of them died. Two more deaths were reported from Vadodara, Gujarat, where an estimated 14,000 children studying in schools meant for tribal children were also vaccinated with another brand of HPV vaccine, Cervarix, manufactured by GSK.

https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/controversial-vaccinestudies-why-is-bill-melinda-gates-foundation-under-fire-from-critics-inindia/articleshow/41280050.cms?from=mdr

The HPV vaccine, administered to pre-pubescent girls to prevent cervical cancer, has received considerable bad press over its 14 years

<sup>&</sup>lt;sup>18</sup> https://ijme.in/articles/deaths-in-a-trial-of-the-hpv-vaccine/?galley=htmlhttps://www.youtube.com/watch?v=bg1NBTEhcU8

## Why has the controversy around the HPV vaccine still not died down?

## https://www.business-standard.com/article/health/why-has-the-controversy-around-the-hpv-vaccinestill-not-died-down-120021401998\_1.html

As many as 120 girls experienced reactions such as epileptic seizures, severe stomachache, headache and mood swings.

## https://www.deccanherald.com/content/63156/were-tribal-girls-guinea-pigs.html

Besides 7 deaths, over 120 girls experienced severe adverse events and many continued to do so even after 2 years of follow up. Many of the girls continue to suffer from stomachaches, headaches, giddiness, and exhaustion. There have been reports of early onset of menstruation, heavy bleeding and severe menstrual cramps and extreme mood swings, irritability, and uneasiness following the vaccination.

There were reports of deaths of four girls from Andhra Pradesh and two girls from Gujarat following the administration of the Human Papilloma Virus (HPV) vaccine. Sama along with Jan Swasthya Abhiyan and Anthra conducted a fact finding in March 2010 in Bhadrachalam, one of the areas in Andhra Pradesh, where the HPV vaccine was being administered.

## https://samawomenshealth.in/fact-finding-of-hpv-vaccine-demonstration-project-in-andhra-pradesh/

### Indian Parliament Comes Down Hard on Cervical Cancer Trial

https://www.science.org/content/article/indian-parliament-comes-down-hard-cervical-cancer-trial

Trials and tribulations: an expose of the HPV vaccine trials by the 72nd Parliamentary Standing Committee Report<sup>19</sup>

http://test.pharmabiz.com/news/govt-stops-phase-3-trial-of-hpv-vaccines-after-death-of-6-children-inap-gujarat-55908

### 72<sup>nd</sup> Parliamentary Report – Chapter XII –

<u>Scathing 72<sup>nd</sup> parliamentary report, Rajya Sabha, alleging criminal irregularities by PATH, Bill& Melinda</u> <u>Gates Foundation in collusion with Indian authorities for HPV Vaccine Trials criminals handling India's</u> <u>AEFI system.</u>

<sup>&</sup>lt;sup>19</sup> <u>https://pubmed.ncbi.nlm.nih.gov/24152343/</u>

- Department-Related Parliamentary Standing Committee on Health and Family Welfare released the 72<sup>nd</sup> report titled "Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)" dated 30<sup>th</sup> August 2013. The report has concluded that the program was to serve the ulterior, commercial interests of vaccine manufacturer to include the said vaccine in universal immunization programme which would have generated windfall profit for the manufacturer(s) by way of automatic sale year after year, without any promotional or marketing expenses.
- 1.1. The committee also concluded that the officers of Indian Council of Medical Research (ICMR), in an unauthorized manner, had signed Memorandum of Understanding (MoU) in 2007 even before the vaccines were approved for use in the country, which actually happened in the year 2008.
- 1.2. Important recommendations of the Parliamentary Committee asking for investigation and legal action against, PATH, Bill Gates and officials of ICMR are as under;

2.5 The Committee finds the entire matter very intriguing and fishy. The choice of countries and population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to commercially exploit a situation.

3.18. <u>The Committee feels that there was serious dereliction of duty by many of the</u> <u>Institutions and individuals involved. The Committee observes that ICMR</u> <u>representatives, instead of ensuring highest levels of ethical standards in research</u> <u>studies, apparently acted at the behest of the PATH in promoting the interests of</u> <u>manufacturers of the HPV Vaccine.</u>

4.6 The Committee's examination has proved that DCGI has also played a very questionable role in the entire matter. Initially, it took a call that since human subjects, as part of the studies, were receiving invasive intervention like immunization, clinical trial rules must be enforced. However, it remained as a silent spectator thereafter, even when its own rules and regulations were being so flagrantly violated. <u>The approvals of clinical trials</u>, marketing approval and import licenses by DCGI appear to be irregular. <u>Therefore, the role of DCGI in this entire matter should also be inquired into.</u>

6.17. The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role,

usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the consent and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends <u>that on the</u> <u>basis of the above facts, PATH should be made accountable and the Ministry should take</u> <u>appropriate action in the matter including taking legal action against it for breach of</u> <u>various laws of the land and possible violations of laws of the Country of its origin.</u>

6.26 The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM.

6.27. Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization.

6.37 The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was 'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency.

7.11.. <u>It is surprising that security and intelligence agencies did not raise an eyebrow on</u> <u>the way a foreign entity entered India virtually incognito through the backdoor.</u> The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in antinational and/or unlawful activities.

"7.13 Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/<u>demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents.</u>

1.3. Despite there being sufficient evidence of wrongdoings by PATH, BMGF, officials of ICMR, CDSCO and DCGI no action has been taken yet by the government of India After 11 years since the death of 8 girls, countless others injured, there seems to be a lack of political will to take action against these pharma mafia. This also clearly shows that the current administration which is promoting the HPV vaccines will ill intent and cannot be trusted.

## 7. Summary

## Vaccines do not provide lifelong immunity

Though vaccines are claimed to prevent cervical cancer, the truth is that cervical cancer takes twenty or more years to develop and the vaccines have just not been around that long to prove their efficacy in preventing cancer. But what is known with certainty is that if these vaccines are given to women who already are infected with the virus then they do raise the incidence of cervical cancer among those women.

Gardasil was first licensed in the USA in June 2006. This licensing was done on fast track with numerous conflicts of interests not only on the review board but also in that that the vaccine patent was held in PPP and the FDA itself as a part of the health department would benefit from the sales.

### No long-term studies for hpv vaccine

The vaccines are genetically engineered and their hazards are unknown even to the scientific communities. Though r-DNA has been detected in Gardasil in samples from many countries including India, in their application for licensing MSD pharmaceuticals claimed that there was no hazard because

there was no r-DNA. GlaxoSmithKline uses a novel technique for producing Cervarix which involves the use of insect cells. Their product information admitted to their vaccine containing insect cells and proteins only in July 2011 though the vaccine was already in use since 2007. These residues or adventitious agents enter the blood stream when the vaccine is injected and are acknowledged to have the capacity to cause infections, tumours, and cancer.

## Mortality Rate from hpv virus

In most cases HPV goes away on its own within two years without any serious health problems and most women with even with high-risk HPV infection do not develop cancer. When it does not go away it either leads to genital warts or cancers in the anus, vulva, vagina which are preventable.

Infection with a high-risk HPV type is associated with a higher chance of the development of cervical cancer but, by itself, HPV infection is not the sole risk factor to cause cancer. There are many other factors.

Survival rate of cervical cancer has been found to be 99.99% in the US and 99.99% in India

### Side Effects of hpv vaccines

Side effects of hpv vaccines include neurological injury, myocraditis, ovarian injuries. auto immune diseases, cervical cancer and death.

Given the above

- It is not surprising that prescription drugs are the third leading cause of death in US & Europe
- 1 in every 4 FDA approved drugs get recalled within 16 years<sup>20</sup>
- 71 of the 222 FDA drugs at the turn of the century were recalled<sup>21</sup>

Given this dubious history, and the fact that pharmaceutical products are the third leading cause of death, the government's obsession of mandating & advertising products of such pharmaceutical companies through vaccination campaigns should be questioned.

<sup>&</sup>lt;sup>20</sup> https://www.theamericanconservative.com/fda-failures-and-the-public-health-regime/

<sup>&</sup>lt;sup>21</sup> https://www.npr.org/sections/health-shots/2017/05/09/527575055/one-third-of-new-drugs-had-safety-problems-after-fda-approval?utm\_campaign=storyshare&utm\_source=twitter.com&utm\_medium=social