# **HPV VACCINES :**

# Not only unproven to protect against cervical cancer but

# **Dangerous & Unnecessary**

Researched and compiled by:

Sarah Kalell September 2015

*In response to request by CANSA to substantiate the claim that HPV Vaccines cause death, disability and chronic health problems* 

Disclaimer:

Nothing in this document should be construed as medical advice. Any person contemplating any medical intervention, including vaccination, should research their own information and educate themselves before taking any decision. Consultation with a suitably qualified medical professional is strongly recommended.

# CONTENTS

1.	Preamble1
	Where is the care and concern from CANSA for all those injured by the HPV vaccines?1 ${f 1}$
	Is CANSA's interest in HPV vaccination one of genuine care and concern?2
	But before you read this document2
2.	CANSA's References
	Conclusion on CANSA's References:4
3.	Cervical Cancer and the HPV (dis)connection4
	The FDA knew that most HPV infections are not associated with cervical cancer
	Number needed to treat = \$4,390,200 to "prevent" [sic] one cancer5
	National Cancer Institute (USA) confirms most high-risk HPV infections go away within 1 to 2 years and cancer takes between 10 and 30 years to develop5
	Further Proof that the FDA knew in 2003 that HPV is not the actual cause of cervical cancer 5
4.	Cervarix "Studies" as documented in product packaging6
5.	Gardasil Studies8
	Carcinogenesis not tested8
	Longest Clinical Trial only Four Years - Cervical Cancer actually takes decades to develop8
	Gardasil clinical trials - inadequate and methodologically flawed
	• Gardasil only tested in healthy individuals and not in the general population
	• Gardasil not tested for safety in conjunction with all the other 69 doses of 16 vaccines in the CDC schedule
	Patients were not warned about dangers of pre-existing conditions
	HPV Vaccines not tested for safety with oral contraceptives or other drugs10
	HPV Vaccines not tested for safety with regard to the menstrual cycle or menopause10

7.	The Dangers of Aluminium	11
	Aluminium content in HPV vaccines:	12
	The FDA Warning about Aluminium	13

The dangers of aluminum in immunotherapy	13
Summary of Aluminium Dangers and Controversy	14

8.	The Dangers of HPV Vaccines15		
	• How many reports of dead or seriously injured/permanently disabled girls does one need in order to initiate "peer reviewed research"?!		
	<ul> <li>How many "coincidences" does one need in order to initiate "peer reviewed research"?</li></ul>		
	If nothing else, this is the collection of news reports to watch to get the best overall picture of the HPV vaccine controversy		
	• If CANSA is so concerned about the health of the South African people, why has CANSA not carried out its own investigation into the adverse events that have been reported?		
	HPV Vaccine Injuries - the deadly statistics		
	• Please see Appendix C for a comprehensive listing of scientific studies and reports on the adverse events for HPV vaccines		
9.	HPV Vaccines not proven safe for Black Africans19		
10.	The South African Situation2		
11.	Why HPV vaccines are not needed20		
	Education is the key21		
12.	Why HPV might not be necessary for the development of cervical cancer after all 21		
	"But HPV does not completely explain what causes cervical cancer"		
	Why would only 1 in 10,000 HPV-infected women develop cervical cancer?		
13.	Peer-reviewed papers - another minefield 23		
14.	It is irresponsible NOT to take action23		
	Or is this how CANSA views the lives of South Africans?:24		
15.	At what point will you acknowledge the damage done by this vaccine? How many adverse events will it take? How many girls must die?		
	How much longer will you ignore the truth?24		
	Is ignoring all the adverse events CANSA's interpretation of 'educating the public'?24		

16.	References/Sources:
17.	Why we don't trust the pharmaceutical companies26
	Withholding data and studies26
	UK Drug Safety Agency Falsified Vaccine Safety Data For 6 Million – Millions of Children At Serious Risk
	Criminal Acts Committed by Pharmaceutical Companies28
	FDA Approval System does not Prevent Unsafe Drugs from Being Prescribed to Patients 28
18.	Why we don't trust the FDA or the CDC
	Simpsonwood - the Mercury Cover-up and the complete disregard for African children28
	The FDA approves basically everything these days29
	The CDC Deliberately Withheld Information and Lied About MMR and the Fact That They Had Evidence Linking it to Autism
	The CDC nor FDA has never studied vaccinated children against unvaccinated children30
19.	Conclusion

# Appendices

Appendix A : CANSA	A Resources	31
--------------------	-------------	----

Appendix B : Gardasil Vacci	nation - Evaluating The Risks Versus	s Benefits 34
-----------------------------	--------------------------------------	---------------

Appendix C : Comprehensive list of studies and reports on the deadly, serious and chron	nic
adverse effects of HPV vaccines	. 48

Appen	dix D : Gardasil/Cervarix/Silgard victims	56
	\$6,000,000 paid out to GARDASIL Victims	.56
	Truth About Gardasil	.56
	SANEVAX.ORG	.56
	Gardasil & Silgard Victims Archives	.56
	Cervarix Archives	.56
	Vaccine Victim Videos Archives - SaneVax, Inc	.57
	You Tube	.57
	Vaccination Information Network	.57
	Vaccine Injury Info	.57
	Brittany Fiste (Gardasil in 2007)	.57
	Gardasil: another victim's family speaks out (Brittany Fiste)	.57

Parent Urges Caution Over Cervical Cancer Vaccine After Daughter's Experience	57
The Murdering of Our Daughters - Dave Hodges - The Common Sense Show	58
6248 Permanent Injuries and 144 Deaths Following Gardasil HPV Vaccine:	58
HPV Vaccine Victim Sues Merck   Gardasil Dangers	58
My Girl Died As 'Guinea Pig' For Gardasil	60
Ashley Ryburn's life ruined by HPV Gardasil vaccine	60
HPV Gardasil Vaccine Proves Lethal - 140 Girls have now Died	60
Meet Nicole	60
The Dark Side Of Gardasil: My Story	60
Legal precedent in Colombia: Landmark decision for HPV vaccine survivor	60
Gardasil: A Deadly Vaccine - Gary Null PhD	61
All around the world, people are setting up web sites and Facebook pages for those injured by HPV vaccines	

Appendix E - South African Informed Consent	. 62
Could a 12 year old child understand what is written in this document?	62
It is an offence to provide a health service without informed consent	62

Appendix F :	Much of scientific lite	erature - maybe half	- maybe untrue	69
/ ppcnan i i		active maybe man		

Appendix G : Criminal Acts of Pharmaceutica	l Companies 70
---	----------------

# 1. Preamble

The following paragraph is on the CANSA web site:-

#### CANSA – leading the fight against cancer in SA

CANSA's purpose is to lead the fight against cancer in South Africa. Its mission is to be the preferred non-profit organisation that <u>enables research</u>, <u>educates the public</u> and <u>provides support</u> to all people affected by cancer.

Before I delve into the shocking reams of notifications of adverse events, deaths and compensation payouts with regard to the HPV vaccines, I'd like to put some thoughts together on the stated purpose of CANSA and the response from CANSA to my initial queries.

On 16<sup>th</sup> August 2015 I sent CANSA a variety of reports and links (including the results of adverse event reports which included 232 deaths on the CDC VAERS reporting system) showing that the HPV vaccines are at best, highly suspect and at worst, highly dangerous. I included links to specific cases where young girls had been damaged by an HPV vaccine and a highly detailed documentary on the damage that young girls had been subjected to in Denmark. There were also numerous other links to reports and scientific papers. Included in my information were specific questions that were not answered.

# Where is the care and concern from CANSA for all those injured by the HPV vaccines?

Instead of receiving a letter of concern in return, I received a response which displayed no sense of dismay, sorrow, empathy or any sense of caring curiosity about the information I had sent.

The response I received completely dismissed all of my information and questions and instead asked **me** to prove all of my claims via "unbiased peer reviewed research" and scientific information/references.

- Is this type of cold-hearted response "leading the fight against cancer"?
- Is this type of cold-hearted response "educating the public?"
- Does this type of response encourage donations to "enable research"?

So what is meant by "leading the fight against cancer"? Would the reader not conclude from this slogan that the organisation is a caring one, an organisation that wants to save lives?

Similarly, what image does "educate the public" conjure up? Would one not think that this is helping the public to understand health risks, to understand what is healthy and what is not? One would think that this should stem from a sense of caring?

Would not a caring person have responded to say that they would investigate my information and, at the very least, attempted to answer my questions?

# Is CANSA's interest in HPV vaccination one of genuine care and concern?

If CANSA truly had a <u>genuine</u> sense of wanting to help young women avoid cervical cancer and had a <u>genuine</u> concern for their health and welfare, shouldn't the response have been along the lines of "yes, we are aware of these reports and we are investigating them because we do not wish to put the young women of South Africa at risk of serious adverse events"?

Instead, CANSA (who presumably has access to scientific expertise and all the latest research) now expects me (a non-qualified medical or scientific professional) to prove my point with scientific evidence. Well, that is EXACTLY what I am about to do!

# But before you read this document.....

Before reading this document, I strongly suggest to the reader that they read/watch the following to get a basic understanding of why HPV vaccines need to be investigated:

- 1. Multiple TV News Reports : <u>https://www.youtube.com/watch?v=WCA5haGU6sl&app=desktop</u>
- 2. Appendix B : Evaluating the risks of HPV vaccines
- 3. Video proof of convulsions after injection with Gardasil:

School children in Mexico injured by Gardasil and Cervarix vaccines. This happened 8/31/15. <u>https://www.facebook.com/VaxTruth/posts/1052155548136861?hc\_location=ufi</u> https://www.facebook.com/AVPHMEX

<u>http://www.infowars.com/shocking-young-girls-convulse-on-the-floor-after-hpv-shot/</u> <u>http://inicio.aavp.es/</u> (refers to above report)

# 2. CANSA's References

In your email of 20<sup>th</sup> August 2015 you stated:

*"Find attached a few abstracts of peer-reviewed scientific research which categorically state that HPV vaccine prevents cervical cancer"* 

Of the five references you gave, none of them "categorically stated that HPV vaccine prevents cervical cancer". In fact, they stated:-

#### 1. HPV Vaccine : Current Status and future directions

"... and its effectiveness in preventing cervical cancer **though presumptive** is reasonably certain as per mathematical modelling"

[my bold emphasis]

In other words it is <u>presumed</u> effective, not <u>proven</u> effective. This is not scientific evidence.

#### 2. Current Status of Human Papillomavirus Vaccines

"It [cervical cancer] can have **several causes**; an infection with some type of human papillomavirus (HPV) is the greatest risk factor for cervical cancer".

"The HPV vaccine prevents infection with certain species of HPVs **associated with the development of cervical cancer...**"

This paper <u>confirms</u> that cervical cancer can have several causes and that HPV is **associated** with cervical cancer. Association is <u>not causation</u>.

3. Cost-Effectiveness of cervical cancer prevention in Central and Eastern Europe and Central Asia "The cost-effectiveness of human papillomavirus (HPV) 16/18 vaccination of 12 year-old girls was calculated for 28 countries under the assumption that vaccination prevents 70% of all cervical cancer cases ...."

Again, here we have the word "assumption". Upon what basis is the assumption made? "Assumption" is NOT "categorically" proven.

4. Review of the current knowledge on the epidemiology, pathogenesis, and prevention of human papillomavirus infection

"Human papillomavirus (HPV) infection is a central and necessary, although not sufficient, cause of cervical cancer. Besides HPV, the additional multiple risk factors related with the onset of cervical cancer are early-age sexual activities; high number of sexual partners, which is the most salient risk factor; suppression and alteration of the immune status; long-term use of oral contraceptives; and other hormonal influences".

"The therapeutic vaccination mode of prevention is a promising area of research, as revealed in preclinical trials, however, clinical trials based on large populations **are warranted before reaching a valid conclusion**".

Does the first sentence of the first quote really need repeating?!

Does the second sentence really need repeating?!

5. Hispanic mothers'..... this study merely assessed perceptions about HPV, cervical cancer and the HPV vaccine. No science, no study, nothing of any consequence.

#### See Appendix A for CANSA's references

#### **Conclusion on CANSA's References:**

- 1. None of these references proved that HPV vaccine prevents cervical cancer
- 2. The references are littered with the words "presumptive", "reasonably certain", "associated with", "assumption", "not sufficient".
- 3. The CANSA references prove the complete opposite and actually substantiate what I am trying to get across, and that is that the HPV vaccines <u>have not been proven to prevent cervical cancer</u>.
- 4. Furthermore, your references prove another vital point and that is that the mere presence of HPV is insufficient to cause cervical cancer. This fact is further proven by references below, including references from the FDA.

# 3. Cervical Cancer and the HPV (dis)connection

# The FDA knew that most HPV infections are not associated with cervical cancer

http://www.fda.gov/ohrms/dockets/dockets/07p0210/07p-0210-ccp0001-01-FDA-News-vol3.pdf (FDA News - FDA Approves Expanded Use of HPV Test - dated 31<sup>st</sup> March 2003)

In the above "FDA News", the FDA states:-

- 1. There are more than 100 types of HPVs
- 2. "Most women who become infected with HPV are able to eradicate the virus and suffer no apparent long-term consequences to their health. But a few women develop a persistent infection that can eventually lead to pre-cancerous changes in the cervix".
- 3. "Women who have normal PAP tests and no HPV infection are at very low risk (0.2%) for developing cervical cancer".
- 4. "Women who have an abnormal PAP test and a positive HPV test are at higher risk (6%-7% or greater) of developing cervical cancer if not treated".
- 5. "Nor is it intended to screen women under 30 who have normal PAP tests. Although the rate of HPV infection in this group is high, most infections are short-lived and not associated with cervical cancer".

 "50,000,000 women get PAP tests annually in the US. According to the American Cancer Society, in 2003, 12,200 women will be diagnosed with cervical cancer and 4,100 will die from the disease. With proper screening, cervical cancer is avoidable and, if caught early, curable"

Let's just run these numbers:-

12,200 women diagnosed with cervical cancer is equal to 0.0244% of women who get tested. Of these, 4,100 will die which equals 0.0082%. Every death, of course, is a tragedy. But every death is entirely preventable through safe, non-toxic means.

### Number needed to treat = \$4,390,200 to "prevent" [sic] one cancer

If we look at the "number needed to treat", even IF the treatment really did prevent the cancer (which is not proven and <u>cannot</u> be proven for reasons laid out further down), then we would have to vaccinate 12,195 women in order to "prevent" [sic] one death. In Dollar terms that's \$360 x 12,195 = \$4,390,200 to prevent one cancer.

# National Cancer Institute (USA) confirms most high-risk HPV infections go away within 1 to 2 years and cancer takes between 10 and 30 years to develop

http://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-fact-sheet

Even the NCI confirms the following:

"Most high-risk HPV infections occur without any symptoms, go away within 1 to 2 years, and do not cause cancer. Some HPV infections, however, can persist for many years. Persistent infections with high-risk HPV types can lead to cell changes that, if untreated, may progress to cancer."

Furthermore, the NCI confirms the length of time (between 10 and 30 years) that it takes to produce tumours:

"Researchers believe that it can take between 10 and 30 years from the time of an initial HPV infection until a tumor forms. However, even when severely abnormal cells are seen on the cervix (a condition called cervical intraepithelial neoplasia 3, or CIN3), these do not always lead to cancer. The percentage of CIN3 lesions that progress to invasive cervical cancer has been estimated to be 50 percent or less (20)."

### Further Proof that the FDA knew in 2003 that HPV is not the actual cause of cervical cancer

http://www.fda.gov/ohrms/dockets/dockets/07p0210/07p-0210-ccp0001-01-vol1.pdf

("Reclassification petition for Human Papillomavirus (HPV) DNA, Nested Polymerase Chain Reaction (PCR) Detection" published 7<sup>th</sup> March 2007)

If you go to page 7 of the referenced PDF document you will see:

The basis of this reclassification request is that the present regulatory classification of HPV DNA tests as devices intended for use in identifying and typing HPV infection to stratify women at risk for cervical cancer, thus assigned to class III, requiring submission and approval of PMAs [2], is no longer appropriate because continued designation of low-to-moderate risk HPV DNA test devices as class III devices contradicts the current understanding of HPV infection and its relationship to the development of cervical cancer. Based on new scientific information published in the past 15 years, it is now generally agreed that identifying and typing HPV infection that acute infections caused by HPV are self-limiting [1, 4-7]. It is the persistent HPV infection that may act as a tumor promoter in cancer induction [8-11]. Identifying and typing HPV is an important tool for following patients with persistent HPV infection. 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.

Let's repeat something for the sake of clarity:

"Based on new scientific information published in the past 15 years, it is now generally agreed that identifying and typing HPV infection <u>DOES NOT BEAR A DIRECT RELATIONSHIP TO</u> <u>STRATIFICATION OF THE RISK FOR CERVICAL CANCER</u>." [my capitals and underscore for emphasis]

Plus:

"Most acute infections caused by HPV are self-limiting".

Now the absolute final confirmation that HPV vaccines *can never, will never prevent cervical cancer*:

"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".

# 4. Cervarix "Studies" as documented in product packaging

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Cerva rix/pdf/CERVARIX-PI-PIL.PDF

#### 1. Studies in females 9 through 25 years of age

The 'studies' were carried out in "controlled" and "uncontrolled" "Clinical Trials". There is no definition of what the "controlled" or "uncontrolled" studies consisted of. The "control" groups were given **another vaccine (Hep A)** or a large dose of **Aluminium (500mcg)**. There were no groups where only a true placebo was given. I might not be a scientist but I can recognise when a study is not a true study and this was clearly one of them.

Adverse events were followed up via "solicited" and "unsolicited" means for 30 days. How scientific is this? The information package mentions a 7.4 year "follow-up" but does not state how long the follow-up was before the product was approved. It states "on-going".

But as stated previously, cervical cancer can take between 10 and 30 years to develop therefore unless a trial has been "on-going" for that length of time it is **impossible to state whether the vaccine can prevent cervical cancer**.

#### Questions:

- 1. **Unfair Comparison :** How can a study compare a new drug when the "control" groups have been injected with another vaccine or aluminium (which is a confirmed neurotoxin)? The study is therefore not comparing the drug to an inert substance. This then skews the findings of any adverse events. How can one know what the difference in adverse events is between the drug and doing nothing?! The answer of course is we can't!
- 2. Testing for carcinogenicity : in the product leaflet it states: "CERVARIX has not been evaluated for its carcinogenic or mutagenic potential"

In fact, no vaccines can be evaluated for carcinogenic or mutagenic potential as stated in this FDA document:

http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvacci nesandotherbiologics/vaccinesandrelatedbiologicalproductsadvisorycommittee/ucm319573.pd f

**4.2.1** Background: DNA Oncogenicity, DNA Infectivity, and DNA Integration : Small amounts of residual cell substrate DNA unavoidably occur in all viral vaccines as well as other biologics produced using cell substrates. There are several potential ways 15 DNA could be a risk factor. DNA can be oncogenic or infectious; in addition, it can cause insertion mutagenesis through integration into the host genome.

Therefore, how can ANY vaccine be declared "safe"? The answer is "they cannot".

3. **Insect cells and viral proteins in the vaccine** : the product package further states: "Each dose may also contain residual amounts of insect cell and viral protein (<40ng) and bacterial cell protein (<150ng)from the manufacturing process"

**Question:** Are young girls and parents advised of the fact that insect cells and viral proteins are in the vaccine they are about to receive?

Question: Are medical staff even AWARE of this fact?

4. FDA confirms that all vaccines are contaminated with foreign proteins and viruses which are tumorigenic :

http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/BiologicsResearchAreas/ucm127 327.htm

"In some cases the cell lines that are used [to produce vaccines] might be tumorigenic, that is, they form tumors when injected into rodents. Some of these tumor-forming cell lines may contain cancer-causing viruses that are not actively reproducing. Such viruses are hard to detect using standard methods. These latent, or "quiet," viruses pose a potential threat, since they might become active under vaccine manufacturing conditions. Therefore, to ensure the safety of vaccines, our laboratory is investigating ways to activate latent viruses in cell lines and to detect the activated viruses, as well as other unknown viruses, using new technologies. We will then adapt our findings to detect viruses in the same types of cell substrates that are used to produce vaccines. We are also trying to identify specific biological processes that reflect virus activity."

**Question:** Yet more evidence of the fact that all vaccines are contaminated. Are medical staff aware of this and are they informing the patients?

5. **Question : Aluminium - is it safe?** See section below on aluminium. This requires detailed analysis on its own.

# 5. Gardasil Studies

### **Carcinogenesis not tested**

As per the reference to carcinogenesis for CERVARIX, the same applies to GARDASIL:

<u>http://vaccines.procon.org/sourcefiles/Gardasil\_package\_insert.pdf</u> 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility GARDASIL has not been evaluated for the potential to cause carcinogenicity or genotoxicity.

### Longest Clinical Trial only Four Years -Cervical Cancer actually takes decades to develop

The following is absolute proof that the HPV vaccines have not been proven to prevent cervical cancer.

"The fact is that malignant cervical cancer takes decades to develop<sup>23</sup> and yet the longest clinical trial on Gardasil was only four years in duration<sup>4</sup>. In other words, Gardasil was never shown to prevent cervical cancer [emphasis added]. Furthermore, in all clinical trials conducted by Merck the cervical intraepithelial neoplasia (CIN) 2/3 precancerous lesion was used as the efficacy endpoint for evaluating the Gardasil<sup>4</sup>. What is the problem with using the CIN 2/3 lesion as the standard for efficacy? First, if the marketing claim for Gardasil is that the vaccine "protects against cervical cancer"<sup>125</sup>, then cervical cancer should have been used as the endpoint for efficacy, not a surrogate marker such as a CIN 2/3 precancerous lesion [emphasis added]. Second, in the natural course of cervical cancer, only a small fraction of the CIN 2 lesions will progress to CIN 3 lesions and only a small fraction of CIN 3 lesions will eventually progress to cervical cancer 6. Furthermore, even CIN 3 lesions are heterogeneous (there are early small lesions and old advanced lesions and we do not know what proportion of the small lesions, which serve as clinical endpoints in current studies, would persist to become large, advanced CIN3 lesions)<sup>7</sup>. Therefore, in any female population (and that includes those who have undergone Gardasil clinical trials) there are many more CIN 2 lesions than a combination of CIN 3 lesions and cervical cancers. As a result, the vast majority of the "CIN 2/3 or worse" cases used for evaluation of efficacy, and listed in Merck"s

report to FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC Background Document on Gardasil HPV Quadrivalent Vaccine 8), must have been CIN 2 lesions." [Source document : Gardasil-vaccination-risks-versus-benefits-FINAL1221.pdf] Appendix B

References: Merck&Co Inc. Gardasil product sheet, date of Approval 2006, p. 1-26. <u>http://www.merck.com/product/usa/pi\_circulars/g/gardasil/gardasil\_pi.pdf</u> Gherardi RK. [Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvantrelated syndrome]. Rev Neurol (Paris) 2003;159(2):162-4.

# Gardasil clinical trials - inadequate and methodologically flawed

"Gardasil clinical trials, all conducted by the manufacturer, were inadequate and methodologically flawed. The risks of Gardasil vaccination are not fully understood since an inadequate placebo was used in clinical trials and the follow-up period was too short.

In a safety evaluation study of Gardasil by Merck, the manufacturer used an inappropriate "placebo control" group in which results were pooled from a group that had received an aluminum salt adjuvant (amorphous aluminum hydroxyphosphate sulfate) together with the results from the group which had received conventional saline <sup>4</sup>. Altogether, bearing in mind that:

1) Gardasil is an aluminum-adjuvanted vaccine <sup>4</sup>,

2) aluminum is an experimentally demonstrated neurotoxin and <sup>17-21</sup>

**3)** on the basis of previous research, a plausible support for a specific role of aluminum adjuvants in various neurological as well as autoimmune disorders in humans has been established <sup>22-26</sup>,

..the rationale for such a "control-group" design remains tenuous [emphasis added]. In addition, the followup of trial participants was 2 to 6 months in duration <sup>4</sup>. During this period, a total of 245 adverse effects were reported in the group that received the vaccine compared with 218 for the "control" group <sup>4</sup>. Given that the aim of the study was to evaluate vaccine safety, the selected time frame should have been longer since potential auto-immune as well as neurological complications may take years to manifest <sup>27 28</sup>.

Aluminum is a well demonstrated toxin in biological systems <sup>29</sup> whose more specific impacts on the nervous system have been extensively documented <sup>17 18 20 21 30-39</sup>. Common symptoms of aluminum intoxication in both animals and humans include: progressive dementia, diminished performance in learning tasks, speech impairments, loss of psychomotor control, twitches, tremors, jerks, seizures, behavioural changes (paranoia, confusion, psychosis) and, in extreme circumstances, death <sup>21 39</sup>. Of note, recent research demonstrates that aluminum in levels comparable to those routinely found in vaccines can cause the death of motor neurons and induce impairments in motor function and decrements in spatial memory capacity in mice <sup>17 36</sup>. [emphasis added]."

[Source document : Gardasil-vaccination-risks-versus-benefits-FINAL1221.pdf] Appendix B

- Gardasil only tested in healthy individuals and not in the general population
- Gardasil not tested for safety in conjunction with all the other 69 doses of 16 vaccines in the CDC schedule

# Patients were not warned about dangers of pre-existing conditions

#### http://www.offtheradar.co.nz/vaccines/258-truth-about-gardasil-cynthia-janak.html

MERCK has made public their "exclusion" criteria for the Gardasil HPV vaccine in documents filed with ClinicalTrials.gov, for clinical trial #NCT01096134, a.k.a. "Mother Daughter Initiative." If these "exclusion criteria" were known by, and applied to families in the United States of America, prior to the vaccination of their child, virtually none of the 22,000 girls and boys listed by the CDC's VAERS reporting system as being injured by the Gardasil HPV vaccine, would have been allowed to be vaccinated, and 100 deceased HPV vaccinated children, would still be alive today. Family medical histories of children injured by the Gardasil HPV vaccine have been compiled by the non-profit group, "TRUTH ABOUT GARDASIL," who has issued this statement.

# After months and months of intensive research Truth About Gardasil has discovered that Merck the manufacturer of HPV vaccines have the potential to cause harm to people with certain preexisting conditions that are not mentioned in the Physicians Product Insert (1)

In the clinical studies (2, 3, 4, 5, 6) we have found that certain individuals have been excluded from the clinical study groups. They are:

- Allergies to any component of the vaccine
- History of a severe allergic reaction
- Known history of any allergies to food or medicine
- Immunocompromised, Immunodeficient or has an autoimmune condition
- History of any condition, therapy, lab abnormality or other circumstance such that it is not in the best interest of the participant to participate
- Clinically significant disease or clinically significant findings during the screening medical history or physical examination that, in the investigator's opinion, would compromise the outcome of this study.
- Have a weakened immune system or other immune problems

Read the rest of the article here: <u>http://www.offtheradar.co.nz/vaccines/258-truth-about-gardasil-cynthia-janak.html</u>

# HPV Vaccines not tested for safety with oral contraceptives or other drugs

The only tests conducted were with regard to "immune response". Therefore, there has been no testing for safety in relation to oral contraceptives, HRT or any other prescription drug. <u>http://www.merck.com/product/usa/pi\_circulars/g/gardasil/gardasil\_pi.pdf</u>

# HPV Vaccines not tested for safety with regard to the menstrual cycle or menopause

No safety data exists that states it is safe for a menstruating woman or menopausal woman to be given an HPV vaccine.

# 6. Summary of evidence and absolute proof that HPV vaccines have not, and cannot, be proven to prevent cervical cancer

- 1. For the sake of repetition, none of the 5 references that CANSA gave substantiated the promised proof that HPV vaccines have been proven to prevent cervical cancer. In fact, these references confirm that other risk factors are required in order to progress to cervical cancer.
- 2. Cervical cancer takes between 10 and 30 years to develop as confirmed by the NCI (USA)
- 3. There have been zero studies of sufficient length of time to show any correlation between any vaccine and the vaccine preventing cervical cancer.
- 4. HPV vaccines have not demonstrated the prevention of one case of cervical cancer.
- 5. HPV vaccines have only demonstrated to prevent mostly CIN2 lesions, of which only a small fraction will progress to CIN3 lesions and only a small fraction of CIN3 lesions eventually progress to cervical cancer.

Reduction in HPV prevalence--no evidence to support HPV vaccination reduces HPV prevalence <a href="http://www.ncbi.nlm.nih.gov/pubmed/24368836">http://www.ncbi.nlm.nih.gov/pubmed/24368836</a> No evidence that the vaccine reduces incidence of HPV

# 7. The Dangers of Aluminium

"1) The biggest problem of all: Ingested aluminum cannot be used to determine safe levels of injected adjuvant, because aluminum adjuvant is in the form of nanoparticles, which do not dissolve into ionic form. Aluminum absorbed from ingestion is in dissolved ionic form, which is rapidly removed by the kidneys. Nanoparticles cannot be removed by the kidneys (they are too large), especially when they have adsorbed antigen. We provide a detailed explanation here: http://vaccinepapers.org/al-adjuvant-nanoparticles-can-travel-brain/ The nanoparticulate nature of aluminum adjuvant, and its transport by macrophages renders Keith and Mitkus completely irrelevant and worthless. But we will proceed with describing the other problems anyway..."

"Nanoparticulate adjuvant aluminum is different from ionic aluminum. Consequently, the only scientifically-valid way to establish the safety of injected aluminum adjuvant, is to study the effect of injected aluminum adjuvant. Oral aluminum toxicity is not relevant.

Only three studies of injected aluminum adjuvant neurotoxicity have ever been done (all by the Shaw laboratory at the University of British Columbia):

Aluminum Adjuvant Injection Experiment #1: 100mcg/kg Aluminum Adjuvant Injection Experiment #2: 300mcg/kg Aluminum Adjuvant Injection Experiment #3: 550mcg/kg

These studies show that the same or lower dosages of Al adjuvant given to human infants cause serious neurological harm to mice.

Why do the vaccine advocates resort to using oral-ingestion studies to make the case for the safety of injected AI adjuvant? It's because they have no studies showing that injecting AI adjuvant is safe. In fact, there is overwhelming evidence that injected aluminum adjuvant travels to the brain, and has unique dangers due to its nanoparticulate form. See this article: http://vaccinepapers.org/al-adjuvant-nanoparticles-can-travel-brain/"

http://vaccinepapers.org/rigorous-defense-al-adjuvant-wrong/

Aluminum forces the undeveloped and immature immune system of infants and children to produce greater amounts of humoral immune cells (TH2) and antibodies, before their immune systems have a chance to adapt to the world in which they've barely had a chance to live in.

Under these circumstances, the activity of aluminum appears to play a vital role in disrupting the maturation of the immune system in infants and children through its effects on TH2 and therefore, on TH1 and TH3.

What effect this has on their overall health in the short or long term is unknown, but this model appears to help us understand how we may be contributing to the development of chronic illness in infants and children with the use of aluminum in vaccines. We also have little understanding of what might happen to the overall health of their immune systems if parents wait until later in life to expose them to vaccines containing aluminum, or if they're exposed in smaller doses one at a time.

How much of a role does injected aluminum play, either acting alone, or in conjunction with other vaccine ingredients and environmental toxins, in the selection and subsequent development of chronic illnesses, in a susceptible population of children, through the disruption of TH1, TH2, TH3? There is no science to answer this question because no one has investigated this issue.

We have no scientific studies in infants, children or adults to help us understand the nature of the progression of TH1, TH2 and TH3 immune responses to any of the injected materials in vaccines.

You cannot do research on questions that enough people don't believe is worth asking, or are afraid of what the answers might show if the proper studies were done.

Lawrence B. Palevsky, MD, FAAP Pediatrician <u>http://www.nvic.org/Doctors-Corner/Lawrence-Palevsky/Aluminum-and-Vaccine-Ingredients.aspx</u>

### Aluminium content in HPV vaccines:

CERVARIX - **500mcg** per 0.5ml dose GARDASIL Quadrivalent - **225mcg** per 0.5ml dose GARDASIL 9 - **500mcg** per 0.5ml dose GARDASIL 2 - **500mcg** per 0.5ml dose

NB: babies who follow the CDC immunisation schedule are injected with nearly 5000mcg (5mg!) of aluminum by 18 months of age.

### The FDA Warning about Aluminium

(a) The aluminum content of large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN) therapy **must not exceed 25 micrograms per liter** ([micro]g/L).

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=201.323

#### This means for a 6 pound baby 11-14mcg would be toxic.

The American Academy of Pediatrics warning about Aluminium

According to the American Academy of Pediatrics : "Aluminum is now being implicated as interfering with a variety of cellular and metabolic processes in the nervous system and in other tissues". "Aluminum toxicity in infants and children (RE9607)," Pediatrics (March 1996);97(3):413-416

The CDC warns about Aluminium

The CDC, like the FDA, is also aware the aluminium is dangerous. For example, in June 2000, Dr Tom Verstraeten, CDC epidemiologist, made the following comment to a group of concerned scientists: "The results [for aluminium] were almost identical ethylmercury because the amount of aluminium [in vaccines] goes along almost exactly with the mercury." He was referring to a landmark study that found "statistically significant relationships" between both aluminium and mercury in vaccines and neurodevelopmental delays. Dr John Clements, WHO vaccine advisor, provided another telling statement: "Aluminum is not perceived, I believe, by the public as a dangerous metal. Therefore, we are in a much more comfortable wicket in terms of defending its presence in vaccines".

Source: Clements, J "Workshop on aluminum in vaccines" presented by National Vaccine Program Office, Dept. of Health and Human Services, San Juan, Puerto Rico (May 11-12, 2000). As noted in David Ayoub's presentation "Aluminum, vaccines and autism : deja vu!" National Autism Association Annual Conference, Atlanta, GA (November 11, 2007)."

# The dangers of aluminum in immunotherapy

#### Abstract

Sub-cutaneous immunotherapy is an effective treatment for allergy. It works by helping to modify or re-balance an individual's immune response to allergens and its efficacy is greatly improved by the use of adjuvants, most commonly, aluminium hydroxide. Aluminium salts have been used in allergy therapy for many decades and are assumed to be safe with few established side-effects. **This assumption belies their potency as adjuvants and their potential for biological reactivity both at injection sites and elsewhere in the body. There are very few data purporting to the safety of aluminium adjuvants in allergy immunotherapy and particularly so in relation to longer term health effects. There are, if only few, published reports of adverse events following allergy**  immunotherapy and aluminium adjuvants are the prime suspects in the majority of such incidents. Aluminium adjuvants are clearly capable of initiating unwanted side effects in recipients of immunotherapy and while there is as yet no evidence that such are commonplace it is complacent to consider aluminium salts as harmless constituents of allergy therapies. Future research should establish the safety of the use of aluminium adjuvants in sub-cutaneous allergy immunotherapy.

Keywords: Aluminium adjuvant; Immunotherapy; Allergy; Adverse events

Contrary to the view of a recent otherwise informed commentary [5] aluminium adjuvants are not 'harmless salts'! They are far from being benign participants in vaccination and immunotherapy and their reactivity's have been associated with adverse events in the recipients of such therapies. Adverse reactions to aluminium adjuvants might have been avoided if there had been a requirement to demonstrate the safety of their use in humans. However, no such regulations exist and the amount of aluminium salt which is included as an adjuvant is wholly determined by its immuno-efficacy in tandem with the respective antigen or allergen. Indeed it is an anomaly of many trials of the safety of aluminium-adjuvanted vaccines and immunotherapies that the (essentially toxic) aluminium adjuvant is considered to be the appropriate placebo in such clinical trials [6].

http://www.aacijournal.com/content/10/1/4

# Summary of Aluminium Dangers and Controversy

#### In summary:

Here is a very well-balance article by Dr Sears on the subject of aluminium:

He states: "If I could sum up the aluminum controversy in three sentences, it would be this. There is good evidence that large amounts of aluminum are harmful to humans. There is no solid evidence that the amount of aluminum in vaccines is harmful to infants and children. No one has actually studied vaccine amounts of aluminum in healthy human infants to make sure it is safe. Should we now stop and research this matter? Or should we just go on and continue to hope that it is safe?"

http://www.askdrsears.com/topics/health-concerns/vaccines/vaccine-faqs

#### See also Appendix B for more information on the dangerous effects of aluminium.

# 8. The Dangers of HPV Vaccines

The more I read the response from CANSA to my enquiry, the more I find it <u>completely incomprehensible</u> that CANSA has clearly ignored the wealth of reports and information about adverse events concerning the HPV vaccines that have been flooding in since their introduction in 2006.

Here is one such report in 2008 reporting on 10 deaths: <u>https://cogforlife.org/2008/07/01/judicial-watch-fda-reports-10-more-deaths-to-gardasil/#more-681</u>

CANSA's stance is in <u>complete contrast</u> to a growing number of scientists, doctors, physicians, parents and countries who are stepping forward with reports, opinions, evidence, assessments and action that show they do not accept the safety claims of the vaccine manufacturers or the CDC.

This list includes:

Japan : withdraws support for HPV vaccine due to infertility side-effects: <u>http://www.thesleuthjournal.com/japan-withdraws-support-for-hpv-vaccines-due-to-infertility-side-effects/</u>

> Yet the CDC says HPV vaccines DON'T negatively affect fertility: http://www.cdc.gov/vaccines/who/teens/vaccines/vaccine-safety.pdf There is no evidence to suggest that HPV vaccine causes fertility problems.

"No evidence to suggest"? Really? Is this just a case of not looking in the right direction?

#### Scotland : a petition has been lodged to investigate the effects of the HPV vaccine

http://www.scotsman.com/news/health/holyrood-urged-to-take-lead-on-cancer-vaccine-issue-1-3834667

"But the European Medicines Agency recently launched a review into the HPV vaccine. And Freda Birrell of the UK Association of HPV Vaccine Injured Daughters (AHVID) says there is a growing "pattern" of illness emerging among young girls since the jab was introduced in 2008. "Many UK girls have become seriously ill after being inoculated," she states in the petition which has been lodged at the Scottish Parliament.

*"We feel that serious concerns regarding the safety and efficacy of Gardasil and Cervarix have not been addressed."* 

"Birrell says her organisation has been contacted by more than 130 families since 2008; more than half of these have come forward since the start of last year, indicating the rate is accelerating.

She added: "They were all saying the same thing – that after they had the jabs they suddenly started feeling very unwell and these illnesses were never going away. They were staying with them."

READ THE LIST OF COMMENTS FROM PARENTS WHOSE DAUGHTERS HAVE BEEN INJURED FROM THESE VACCINES. ARE ALL THESE PEOPLE MAKING UP THEIR STORIES?!

#### Ireland : Trouble with the Gardasil vaccine in Ireland

http://www.regret.ie/

#### Colombia : No-one is listening to parents in Colombia - parents protest

http://healthimpactnews.com/2015/parents-of-hpv-vaccine-victims-protest-in-the-streets-of-colombia/

#### United Kingdom : More reports of adverse events from the UK

http://www.independent.co.uk/life-style/health-and-families/thousands-of-teenage-girls-report-feeling-seriously-ill-after-routine-school-cancer-vaccination-10286876.html

#### France : Only 45% of doctors recommend HPV vaccines

http://vaccinefactcheck.org/2015/05/25/mainstream-media-vigorously-debates-vaccine-safetyin-france/ France banned advertising for Gardasil in 2010 (see "Spain" link below".

#### European Medical Agency Review :

http://www.bbc.com/news/health-33504211

Spain : Joins growing list of countries to file criminal complaints against Gardasil manufacturer https://socioecohistory.wordpress.com/2015/02/28/gardasil-vaccine-spain-joins-growing-list-ofcountries-to-file-criminal-complaints/

Denmark : documentary on Gardasil injuries to a large group of young girls <u>https://www.youtube.com/watch?v=GO2i-r39hok&feature=youtu.be</u>

India : Why India has stopped giving HPV vaccines

http://articles.mercola.com/sites/articles/archive/2010/12/29/why-india-has-stopped-givinghpv-vaccines.aspx

"In India, civil society groups have long been voicing their concerns regarding the safety and efficacy of the two HPV vaccines, along with the aggressive promo-tion of the vaccines and the need to investigate reported deaths and adverse events post vaccination."

CANSA asked me for "peer-reviewed research/scientific reference that supports and proves that HPV vaccines are deadly.... and that the HPV vaccine was directly responsible for the disability/disabilities that are claimed to result from the HPV vaccine..."

• How many reports of dead or seriously injured/permanently disabled girls does one need in order to initiate "peer reviewed research"?!

Does CANSA support the typical response when faced with a potential vaccine injury that "there is no proof that the vaccine caused the death/injury"?

What **would** constitute "proof" in order for CANSA to be convinced? Does the injury have to happen immediately the HPV vaccine is administered to the patient? Even then, most doctors <u>refuse to accept that</u> <u>the vaccine was responsible</u>. "It's a coincidence" is the oft-heard response.

How many "coincidences" does one need in order to initiate "peer reviewed research"?

### If nothing else, this is the collection of news reports to watch to get the best overall picture of the HPV vaccine controversy

https://www.youtube.com/watch?v=WCA5haGU6sI&app=desktop

If the reader of this document only uses one link or reference as listed here, then this 17 minute report has to be the one. This video is a collection of TV news reports (published in 2012) on the increasing numbers of adverse reports and includes:-

- 1. JAMA references to the 12424 adverse events reported, of which 6.2% were serious, which included:
  - a. Hospitalisation
  - b. Permanent disability
  - c. Deaths
  - d. Paralysis
  - e. Blood clots
- 2. Confirmation that the FDA knew that cervical cancer was rare and preventable through screening
- 3. Confirmation that women with existing HPV infection have a 44.6% increased risk of developing pre-cancerous lesions if injected with an HPV vaccine.
- 4. Reports of injuries and deaths a few hours after receiving the HPV vaccine
- 5. Reports on Sky News, CBS and CNN (when the mainstream TV news screens this adverse information then one knows it is serious because the mainstream TV channels derive most of their advertising income from the pharmaceutical companies)
- 6. Reports by Judicial Watch concerning seizures, strokes and heart problems following administration of Gardasil
- 7. Reports by NVIC stating that serious adverse events from HPV vaccines are 30 times higher than in other vaccines administered to the same age group
- 8. 29 fatalities in 2 years
- 9. Interviews with a number of girls who have been seriously disabled by the vaccine
- 10. Interviews with doctors who express concern about the HPV vaccines

https://www.youtube.com/watch?v=WCA5haGU6sI&app=desktop

• If CANSA is so concerned about the health of the South African people, why has CANSA not carried out its own investigation into the adverse events that have been reported?

# HPV Vaccine Injuries - the deadly statistics

As of July 2015, the following adverse events have been reported to VAERS:

Description	Total
Disabled	1,357
Deaths	232
Did Not Recover	7,883
Abnormal Pap Smear	602
Cervical Dysplasia	268
Cervical Cancer	104
Life Threatening	<b>696</b>
Emergency Room	12,677
Hospitalized	4,083
Extended Hospital Stay	272
Serious	5,532
Total Adverse Events	40,215

It is widely acknowledged and accepted that :

- 1. Most doctors do NOT report adverse events
- 2. Many doctors do not even know about the VAERS reporting system
- 3. Patients are not told about the VAERS reporting system
- 4. Most doctors will not associate (and refuse to associate) adverse reactions with vaccines
- 5. Parents are dismissed by doctors when trying to get help for their vaccine injured children
- 6. As a result, it is acknowledged that the adverse events reported to VAERS can be anything between 1% and 10% of the true numbers of adverse events.

The following is taken from the GARDASIL product leaflet:

#### 6.2 Postmarketing Experience

The following adverse events have been spontaneously reported during post-approval use of GARDASIL. 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.

- 1. Blood and lymphatic system disorders: Autoimmune hemolytic anemia, idiopathic thrombocytopenic
- 2. purpura, lymphadenopathy.
- 3. Respiratory, thoracic and mediastinal disorders: Pulmonary embolus.
- 4. Gastrointestinal disorders: Nausea, pancreatitis, vomiting.
- 5. General disorders and administration site conditions: Asthenia, chills, death, fatigue, malaise.
- 6. Immune system disorders: Autoimmune diseases, hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.
- 7. Musculoskeletal and connective tissue disorders: Arthralgia, myalgia.
- 8. Nervous system disorders: Acute disseminated encephalomyelitis, dizziness, Guillain-Barré
- 9. syndrome, headache, motor neuron disease, paralysis, seizures, syncope (including syncope associated
- 10. with tonic-clonic movements and other seizure-like activity) sometimes resulting in falling with injury,

- 11. transverse myelitis.
- 12. Infections and infestations: cellulitis.
- 13. Vascular disorders: Deep venous thrombosis.

http://www.merck.com/product/usa/pi\_circulars/g/gardasil/gardasil\_pi.pdf

• Please see Appendix C for a comprehensive listing of scientific studies and reports on the adverse events for HPV vaccines.

# 9. HPV Vaccines not proven safe for Black Africans

Are black South African parents alerted to the study done by researchers from Duke University who found that although African-American women are twice as likely as Caucasian women to die from cervical cancer, HPV vaccines target strains of HPV that are far less likely to infect them? Are black South African girls being subjected to unnecessary risks even more so than white South African girls?

The available vaccines only protect against four strains of HPV, which, according to the study African American women are half as likely as White women to carry. Neither Merck nor GlaxoS mithKline has addressed the lack of coverage for HPV strains prevalent in African American women. Merck is currently testing an updated HPV vaccine that fights nine dangerous strains instead of four—6, 11, 16, 18, 31, 33, 45, 52 and 58. Although their preliminary study results are promising, the disparity will likely remain.

"The most disconcerting part of this new vaccine is it doesn't include HPV 35, 66 and 68, three of the strains of HPV of which African-American women are getting the most," said study co-author, Cathrine Hoyo. "We may want to rethink how we develop these vaccines, given that African-Americans tend to be underrepresented in clinical trials."

Shouldn't these studies and questions confirm that at the very least, black populations should refrain from HPV vaccines until further evidence is provided that they are safe and effective?

Ref: The findings, presented on Oct. 28, 2013, at the 12th annual International Conference on Frontiers in Cancer Prevention Research hosted by the American Association for Cancer Research. The research was supported by the National Cancer Institute (R01CA142983 and R01CA142983-02S1). The authors reported no conflicts of interest. http://www.dukehealth.org/health\_library/news/hpv-strains-affecting-african-american-women-differ-from-vaccines

# **10. The South African Situation**

#### **Questions:**

- 1. Who is giving "Informed Consent"? Please read Appendix E.
- 2. Could a 12 year old child understand this document?
- 3. Is the child/woman being tested for the correct strain of HPV?
- 4. Is the child/woman already 'infected' with the vaccine strain of HPV? If so, the patient is 44.6% more likely to develop high-grade precancerous lesions.
- 5. Is the child/woman pregnant?
- 6. Is the child/woman on oral contraceptives?
- 7. Why are parents not being told about the potential adverse effects of this vaccine including the negative effect on fertility?
- 8. Is the patient or parent given a copy of the product package insert?
- 9. Are all the patients monitored for 15 minutes afterwards to check for adverse reactions?
- 10. Are patients and parents aware that a booster shot will be required because the immunity doesn't last?
- 11. Are patients/parents being informed that a PAP smear is still required in order to screen for cervical cancer because the vaccine doesn't cover all the HPV strains?
- 12. Why is SA not looking for a cheaper alternative such as the vinegar test?
- 13. Who is following up on the health of the child after vaccination?
- 14. How are adverse events monitored and recorded?
- 15. Who will be held accountable for the devastating adverse effects of this vaccine?
- 16. What research has been done on the effects of the HPV vaccine and HIV infected women?
- 17. Is the SA government prepared for lawsuits against them for withholding vital information on the dangers of this vaccine?
- 18. Or is the government/pharmaceutical industry/medical industry relying on the fact that most people won't have the resources with which to initiate lawsuits?

# 11. Why HPV vaccines are not needed

The HPV vaccine is administered to mostly healthy young girls for whom the statistical chances of developing cervical cancer are virtually zero **provided they get regular cervical screening.** 

Even with the administration of the HPV vaccine, the product packaging confirms that <u>this is not a</u> <u>substitute for regular screening</u> and that regular cervical screening should still take place because the vaccine is not intended to protect against all 100 (or more) strains of HPV.

So whilst the incidence of cervical cancer is high in South Africa (estimated at 6000 per year), the incidence can be dramatically reduced by a fully functional screening service <u>which is required anyway as per the</u> <u>advice in the HPV vaccine product leaflets</u>. All the experts agree : the vaccine is NOT a substitute for regular PAP smears.

For the sake of repetition, I refer here again to the statistics on HPV infection and abnormal PAP smears:

Even the NCI confirms the following:

"Most high-risk HPV infections occur without any symptoms, go away within 1 to 2 years, and do not cause cancer. Some HPV infections, however, can persist for many years. Persistent infections with high-risk HPV types can lead to cell changes that, if untreated, may progress to cancer."

Furthermore, the NCI confirms the length of time (between 10 and 30 years) that it takes to produce tumours:

"Researchers believe that it can take between 10 and 30 years from the time of an initial HPV infection until a tumor forms. However, even when severely abnormal cells are seen on the cervix (a condition called cervical intraepithelial neoplasia 3, or CIN3), these do not always lead to cancer. The percentage of CIN3 lesions that progress to invasive cervical cancer has been estimated to be 50 percent or less (20)."

As with developed countries and their success with reducing cervical cancer to the lowest percentage of cancers in women, should we rather not be <u>educating women about the need for regular screening</u> and instead of spending millions of Rands on a dangerous and useless/unproven vaccine, rather <u>set up a better</u> <u>screening service? Which is in any case required for this vaccine!!</u>

### **Education is the key**

Education is a far more powerful tool than just mindlessly injecting toxic substances into unsuspecting patients.

- With education comes awareness.
- With awareness comes responsibility.
- With responsibility comes empowerment.
- With empowerment comes action.
- With action comes results.

# 12. Why HPV might not be necessary for the development of cervical cancer after all

### "But HPV does not completely explain what causes cervical cancer"

http://www.cancer.org/cancer/cervicalcancer/detailedguide/cervical-cancer-what-causes

"But HPV does not completely explain what causes cervical cancer. Most women with HPV don't get cervical cancer, and certain other risk factors, like smoking and HIV infection, influence which women exposed to HPV are more likely to develop cervical cancer."

## Why would only 1 in 10,000 HPVinfected women develop cervical cancer?

#### Abstract Backgroup

#### Background

In 1952 Papanicolaou et al. first diagnosed and graded cervical carcinomas based on individual "abnormal DNA contents" and cellular phenotypes. Surprisingly current papilloma virus and mutation theories of carcinomas do not mention these individualities. The viral theory holds that randomly integrated, defective genomes of papilloma viruses, which are often untranscribed, cause cervical carcinomas with unknown cofactors 20–50 years after infection. Virus-free carcinomas are attributed to mutations of a few tumor-suppressor genes, especially the p53 gene. But the paradox of how a few mutations or latent defective viral DNAs would generate carcinomas with endless individual DNA contents, degrees of malignancies and cellular phenotypes is unsolved. Since speciation predicts individuality, we test here the theory that cancers are autonomous species with individual clonal karyotypes and phenotypes. This theory postulates that carcinogens induce aneuploidy. By unbalancing mitosis genes aneuploidy catalyzes chain reactions of karyotypic evolutions. Most such evolutions end with non-viable karyotypes are stabilized by clonal selections for cancer-specific autonomy. http://www.molecularcytogenetics.org/content/6/1/44

#### "This hypothesis raises four questions:

- Why would only 1 in 10,000 HPV-infected women develop cervical cancer?
- Why would cervical cancers only develop 20 to 50 years after infection? In other words, why would the virus not cause cancers when it is biochemically active and causing warts, namely before it is neutralized by natural anti-viral immunity?
- Why are cervical carcinomas individually very distinct from each other in terms of malignancy, drug-resistance, cell histology, as originally described by Papanicolaou et al. in Science in 1952, although they are presumably caused by the same viral proteins?
- Why are cervical carcinomas that are presumably generated by Human Papillomavirus proteins not immunogenic and thus not eliminated by natural antibodies?

Despite over 25 years of research on the HPV causes cancer hypothesis, there are no direct answers to these questions.

Instead poorly defined "co-factors" are mentioned as "collaborators" of HPV in the causation of carcinomas. Poorly defined cellular mutations are mentioned as the causes of the cervical carcinomas of HPV-negative women.

# *Moreover, about 30% of cervical cancers are virus-free.* In these cases the virus couldn't even theoretically be responsible for the cancer.

According to the karyotypic carcinoma theory this discrepancy is the result of the facts that HPV infection and carcinogenesis are two entirely independent events:

• No specific correlation exists between HPV and cervical carcinoma. HPV is very common, about 70 to 80% endemic in the American population. The rest of the population is HPV-free. The virus is typically sexually transmitted at young age. Since cervical carcinomas occur in both HPV-positive and HPV-negative females, there is no specific correlative evidence that HPV plays any role in causing cervical cancer. • There is also no specific functional correlation between HPV-infection and carcinogenesis. As shown from the clonal karyotypes of cervical cancers, cancers originate from a major rearrangement of the karyotypes of normal cells. Since this is true for cervical carcinomas of HPV-positive and of HPV-negative females – and is indeed true for all cancers – there is no functional evidence that HPV plays a role in the development of carcinomas. This conclusion is consistent with the fact that carcinomas with new clonal karyotypes arise only 20 to 50 years (!) after infection by HPV, which we discuss next.

<u>Thus there is neither a specific correlation between the presence and/or the functions; or lack of functions of HPV and carcinogenesis."</u>

http://healthimpactnews.com/2015/study-hpv-infections-not-necessary-for-development-of-cervicalcancer-are-hpv-vaccines-worthless/

# **13.** Peer-reviewed papers - another minefield

In terms of giving credibility to any industry-sponsored studies or trials, here is a short report on the statement made by Mr Richard Horton, Editor-in-Chief of the Lancet who said "much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness". http://www.collective-evolution.com/2015/05/16/editor-in-chief-of-worlds-best-known-medical-journal-half-of-all-the-literature-is-false/

Furthermore, Dr Marcia Angell, a physician and longtime Editor in Chief of the New England Medical Journal (NEMJ), which is considered to another one of the most prestigious peer-reviewed medical journals in the world, makes her view of the subject quite plain: "It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the New England Journal of Medicine" (source)

See report in Natural Medicine, Appendix F.

Read also "Bad Pharma" and "Bad Medicine" by Ben Goldacre.

# **14.** It is irresponsible NOT to take action

South African Medical Journal On-line version HPV Vaccine : why the rush? Louis-Jacques van Bogaert

National Health Laboratory Service and University of Limpopo, Polokwane, South Africa. louis.vanbogaert@nhls.ac.za

http://www.scielo.org.za/scielo.php?pid=S0256-95742014000800006&script=sci\_arttext

http://ww2.cfo.com/risk-management/2012/01/the-value-of-life-statistically-speaking/

For example, either as a parent or a child, most likely you have been exposed to programs that contain some of these issues. Inoculating children to prevent infectious disease transmission is good for society from both health and financial perspectives, but some initially healthy children may suffer adverse reactions, injury, or even death. For vaccines, the enormous societal benefits trump the tragedies of the few. And in order to keep the vaccine costs affordable, the U.S. government administrates and pays all vaccine compensation claims through its Vaccine Lawsuit Injury Compensation program. Inoculation requirements and the accepted reasons to opt out vary by state. In 2011, the National Vaccine Injury Compensation Program received over 1,000 new claims and awarded 250 plaintiffs more than \$228 million for injuries and deaths from the vaccines administered to both adults and children.

# 15. At what point will you acknowledge the damage done by this vaccine? How many adverse events will it take? How many girls must die?

How much longer will you ignore the truth?

Is ignoring all the adverse events CANSA's interpretation of 'educating the public'?

# **16.** References/Sources:

http://www.renewamerica.com/columns/janak/071212 FDA and HPV, when did they know the truth?

http://www.renewamerica.com/columns/janak/071220 FDA and HPV, when did they know - follow up

https://cogforlife.org/2008/07/01/judicial-watch-fda-reports-10-more-deaths-to-gardasil/#more-681

http://www.fda.gov/ohrms/dockets/dockets/07p0210/07p-0210-ccp0001-01-vol1.pdf HiFi DNA Tech application : "Reclassification Petition for Human Papillomavirus (HPV) DNA, Nested Polymerase Chain Reaction (PCR) Detection" published 7<sup>th</sup> March 2007 [referenced in the "Renew America" articles]

http://www.fda.gov/ohrms/dockets/dockets/07p0210/07p-0210-ccp0001-01-FDA-News-vol3.pdf FDA Approves Expanded Use of HPV Test, 31<sup>st</sup> March 2003 [referenced in the "Renew America" articles]

http://www.cancer.org/cancer/cervicalcancer/detailedguide/cervical-cancer-what-causes " HPV does not completely explain what causes cervical cancer"

http://healthimpactnews.com/2015/study-hpv-infections-not-necessary-for-development-of-cervicalcancer-are-hpv-vaccines-worthless/ http://www.molecularcytogenetics.org/content/6/1/44

https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Cerva rix/pdf/CERVARIX-PI-PIL.PDF Product package for CERVARIX

http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandothe rbiologics/vaccinesandrelatedbiologicalproductsadvisorycommittee/ucm319573.pdf Cells derived from human tumours for vaccine manufacture

<u>http://vaccines.procon.org/sourcefiles/Gardasil\_package\_insert.pdf</u> Merck : Gardasil product package

http://vaccinepapers.org/rigorous-defense-al-adjuvant-wrong/ Aluminium - the dangers A more rigorous defense of Al Adjuvant, and why it is wrong

http://www.askdrsears.com/topics/health-concerns/vaccines/vaccine-faqs Aluminium in vaccines

http://www.judicialwatch.org/blog/2010/10/gardasil-law-under-fire/

A Virginia lawmaker has introduced legislation to repeal an outrageous state law that requires young girls to receive a controversial cervical cancer vaccine linked to dozens of deaths and thousands of adverse reactions nationwide.

<u>http://www.judicialwatch.org/?s=Vaccine</u> List of reports on adverse effects of HPV vaccines and more

<u>http://www.thesleuthjournal.com/?s=hpv+vaccine</u> List of more reports on the adverse effects of HPV vaccines

<u>http://sanevax.org/</u> <u>http://www.nvic.org/Vaccines-and-Diseases/hpv.aspx</u> <u>http://www.nvic.org/NVIC-site-search-result.aspx?q=gardasil%20deaths</u>

http://www.collective-evolution.com/2015/07/17/genetically-modified-virus-in-hpv-vaccines-causes-twice-the-adverse-effects/

http://www.offtheradar.co.nz/vaccines/258-truth-about-gardasil-cynthia-janak.html HPV vaccines can harm those with certain pre-existing conditions>

The Vaccine Safety Manual - Neil Z Miller For concerned families and Health Practitioners

# 17. Why we don't trust the pharmaceutical companies

The first, and undoubtedly the biggest, reason is that there is no incentive for the pharmaceutical companies to produce safer vaccines. They are legally exempt from being sued for vaccine damages in the USA. Culminating in the 1980s, there were so many lawsuits that the USA vaccine program was in 'danger' of collapsing.

So instead of investigating the dangers of the vaccines and making them safer (or banning them altogether), the USA government introduced the National Childhood Vaccine Injury Act in 1986 to remove the danger of litigation from the pharmaceutical companies to a "vaccine court".

This vaccine court has now paid out approximately \$3billion in compensation to vaccine injured children/people.

# Withholding data and studies

"The most infamous case of publication bias is a 1980 study in which heart attack patients were split into two groups: One group received a drug called lorcainide, while the other group received a placebo. Researchers wanted to find out whether lorcainide cures dangerous abnormal heart rhythms, which it does. But during the study, nine of the lorcainide patients died, compared with just one of the placebo patients. Lorcainide's maker stopped production soon after for unrelated commercial reasons, and consequently the researchers never published their report. They believed the deaths to be "an effect of chance."

But physicians continued prescribing drugs similar to lorcainide. Finally, in 1993, the researchers apologized for withholding the study, which they said could have "provided an early warning of trouble ahead." But the damage was done: Throughout the '80s, an estimated 20,000 to 75,000 people died in the U.S. each year from the inappropriate prescription of antiarrhythmic drugs, according to a 2003 editorial by Kay Dickersin and Drummond Rennie in The Journal of the American Medical Association."

"Sometimes the bias is more subtle. Results get published, but negative details are left out.

In 2001, Ellen Roche, a 24-year-old technician at Johns Hopkins University, volunteered for a study to find out how healthy people's bodies avoid asthma attacks. Doctors would give her a dose of the drug hexamethonium to induce a mild attack, her healthy body would fend off that attack, and doctors would observe how her body did it. Instead, she began to cough, her lung tissue broke down, and her kidneys failed. She was dead within a month. A study performed way back in 1978 had discovered this kind of reaction to hexamethonium—but the paper that was published didn't mention it.

Knowing about negative results is not just useful; it is essential to good science."

http://www.newsweek.com/2014/11/21/medical-science-has-data-problem-284066.html Big Pharma plays hide the ball with data

# UK Drug Safety Agency Falsified Vaccine Safety Data For 6 Million – Millions of Children At Serious Risk

http://nsnbc.me/2013/07/28/uk-drug-safety-agency-falsified-vaccine-safety-data-for-6-million/ "Professor Sir Kent Woods Instructs Medical Professionals Not To Report Adverse Reactions.

In advice dated 2nd September 2008 issued by the UK MHRA in Professor Kent Woods name Professor Woods primed health professionals to expect the most common adverse reactions would be "psychogenic". Professor Woods then advised medical professionals not to report an adverse reaction if it "may" be psychogenic.

"Psychogenic" means that the symptom of the adverse reaction is to be treated as "all in the minds" of the British schoolgirls receiving GSK's Cervarix vaccine – that is: the result of emotional or mental stress from the administration of the vaccine.

In other words – and feminists please take note – the male dominated MHRA was telling medical professionals to dismiss adverse reactions in schoolgirls because women are prone to that sort of thing – you know – women are silly, emotional and prone to hysteria and mass hysteria.

"This advice was not only counterproductive but unscientific and improper from a drug safety perspective. Professors Woods and Breckenridge must know that."

Adverse reactions to all pharmaceuticals are heavily under-reported. Because of that medical professionals are constantly and generally encouraged to file adverse reaction reports to improve drug safety monitoring. Professor Woods' advice was encouraging them not to."

# Criminal Acts Committed by Pharmaceutical Companies

See also Appendix G for a list of criminal acts committed by various pharmaceutical companies for selling drugs "off-label", for promoting drugs even though the dangers of those drugs were well-known, fraud, bribery, poor manufacturing practices, failure to disclose safety data and more.

### FDA Approval System does not Prevent Unsafe Drugs from Being Prescribed to Patients

Also documented in Appendix G are cases of drugs/products that were approved as safe by the FDA, which were subsequently proven deadly. <u>This proves that the process for the approval of drugs/vaccines is</u> <u>inadequate to prevent unsafe medication from being prescribed to patients.</u>

# **18.** Why we don't trust the FDA or the CDC

### Simpsonwood - the Mercury Cover-up and the complete disregard for African children

http://www.whale.to/a/blaylock.html#Mercury\_neurotoxicty\_

An article (originally printed in 2004 in *World Natural Health Organisation* and *Nexus Magazine*)by Dr Russell Blaylock giving details of a meeting held in Georgia, USA (7<sup>th</sup>/8<sup>th</sup> June 2000) to discuss a study by a Doctor Thomas Verstraeten, then representing the CDC.

The group's purpose was to evaluate Dr Verstraeten's results and data and make recommendations with regard to the prevailing vaccine policy. Here is a quote from the report:

#### Difficulties for children in the third world

Now this next statement should shock everyone, but especially the poor who in any way think that these "vaccinologists" experts have their best interest in mind. Dr. Johnson says on page 17, "We agree that it would be desirable to remove mercury from U.S. licensed vaccines, but we did not agree that this was a universal recommendation that we would make because of the issue concerning preservatives for delivering vaccines to other countries, **particularly developing countries**, in the absence of hard data that implied that there was in fact a problem."

So, here you have it. The data is convincing enough that the American Academy of Pediatrics and the American Academy of Family Practice, as well as the regulatory agencies and the CDC along with these organizations all **recommend its removal as quickly as possible because of concerns of adverse effects of mercury on brain development, but not for the children in the developing countries**. I thought the whole idea of child health programs in the United States directed toward the developing world was to give poor children a better chance in an increasingly competitive world. This policy being advocated would increase the neurodevelopmental problems seen in poor children (also in this country) of developing countries, impairing their ability to learn and develop competitive minds. Remember, there was a representative of the World Health Organization (WHO), Dr. John Clements, serving on this panel of "experts". He never challenged this statement made by Dr. Johnson.

It also needs to be appreciated that children in developing countries are at a much greater risk of complications from vaccinations and from mercury toxicity than children in developed countries. This is because of poor nutrition, concomitant parasitic and bacterial infections and a high incidence of low birth weight in these children. We are now witnessing a disaster in African countries caused by the use of older live virus polio vaccines that has now produced an epidemic of vaccine related polio, that is, polio caused by the vaccine itself. In, fact, in some African countries, polio was not seen until the vaccine was introduced.

The WHO and the "vaccinologist experts" from this country now justify a continued polio vaccination program with this dangerous vaccine on the basis that now that they have created the epidemic of polio, they cannot stop the program. In a recent article it was pointed out that this is the most deranged reasoning, since more vaccines will mean more vaccine-related cases of polio.

Read the report further to find out that they understood that mercury was seriously implicated in the negative effect of neurological development but that they **chose not to tell anyone**.

# The FDA approves basically everything these days

http://www.forbes.com/sites/matthewherper/2015/08/20/the-fda-is-basically-approving-everythingheres-the-data-to-prove-it/ 20<sup>th</sup> August 2015

20<sup>th</sup> August 2015

"Right now, it only looks like this trend will continue. A new bill called the 21st Century Cures Act attempts to further speed up approvals and remove red tape.

But the risks of speeding up approvals should be pretty clear, too. In the late 1990s and early 2000s, there was a boom of new drug approvals. In 1999, the FDA approved two drugs that became synonymous with drug safety scandals: Vioxx, which was withdrawn from the market by Merck, and Avandia, made by GlaxoSmithKline, which later had its use severely restricted. The approval boom is good only so long as it doesn't trigger another drug safety conference."

# The CDC Deliberately Withheld Information and Lied About MMR and the Fact That They Had Evidence Linking it to Autism

http://www.morganverkamp.com/august-27-2014-press-release-statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/.

"I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal Pediatrics. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed." CDC Whistleblower, William Thompson

# The CDC nor FDA has never studied vaccinated children against unvaccinated children

Here is the video link to prove it:

https://www.youtube.com/watch?v=uNWTOmEi\_6A

Sen. Bill Posey asks the question twice: "have you studied vaccinated children versus unvaccinated children?" . Dr Coleen Boyle - CDC replies "We have not studied vaccinated against unvaccinated".

# **19.** Conclusion

How can any parent, after researching the controversies about the HPV vaccine, fail to appreciate that this vaccine is not just worthless, it is potentially dangerous and deadly?

Why would any woman of sound mind, after reading this document, CHOOSE to get this vaccine when the safer option is to remain with regular PAP smear screening?

How can any nurse, doctor or scientific professional put their hand on their heart and inject a vulnerable 9 year old girl (or boy) with this toxic poison and say "don't worry, it's safe and effective"?

How can CANSA (or anyone in authority in South Africa) continue to promote this useless and deadly vaccine to vulnerable, poor, black girls without giving them true informed consent and without it weighing on their conscience?

# **Appendix A : CANSA Resources**

# Med J Armed Forces India. 2015 Apr;71(2):171-7. doi: 10.1016/j.mjafi.2015.02.006. Epub 2015 Mar 13. HPV vaccine: Current status and future directions.

Kumar S1, Biswas M2, Jose T3.

Author information

#### Abstract

HPV Vaccine was introduced to prevent cervical cancer known to be caused by infection with one or more of the high risk subtypes of the Human papilloma virus (HPV). Since introduction, trials have proven its efficacy in preventing Cervicalintraepithelial neoplasia (CIN) beyond doubt and its effectiveness in preventing cervical cancer though presumptive is reasonably certain as per mathematical modelling. It also prevents other HPV related anogenital and oropharyngeal malignancies in both sexes. HPV vaccines have courted many controversies related to its efficacy, safety, ideal age of vaccination, use in HPV infected individuals and use in males. The currently available vaccines are based on L1 Viral like particles (VLP) and hence highly species specific, thermolabile, costly and are purely prophylactic. The quest for a cheaper, thermostable and broad spectrum vaccine has led to many newer prophylactic vaccines. Therapeutic vaccines were born out of the inescapable necessity considering high HPV related morbidity projected in the non HPV naïve population. Therapeuticvaccines would immediately reduce this burden and also help in the management of HPV related cancers alone or as part of combination strategies. Ongoing research is aimed at a total control over HPV related malignancies in the near future. KEYWORDS:

Cervical cancer; Cervical intraepithelial neoplasia; Humoral immune response; Papillomavirus vaccines; Viral like particles

#### Clin Exp Vaccine Res. 2014 Jul;3(2):168-75. doi: 10.7774/cevr.2014.3.2.168. Epub 2014 Jun 20. Current status of human papillomavirus vaccines. Kim KS1, Park SA1, Ko KN1, Yi S1, Cho YJ1.

#### Author information

#### Abstract

Cervical cancer is a malignant neoplasm arising from cells that originate in the cervix uteri. It is the second most prevalentcancer among women. It can have several causes; an infection with some type of human papillomavirus (HPV) is the greatest risk factor for cervical cancer. Over 100 types of HPVs have been identified, and more than 40 types of HPVs are typically transmitted through sexual contact and infect the anogenital region. Among these, a number of HPVs types, containing types 16 and 18, are classified as "high-risk" HPVs that can cause cervical cancer. The

HPVs vaccine prevents infection with certain species of HPVs associated with the development of cervical cancer, genital warts, and some less common cancers. Two HPVs vaccines are currently on the global market: quadrivalent HPVs vaccine and bivalent HPV vaccine that use virus-like particles as a vaccine antigen. This review discusses the current status of HPVs vaccines on the global market, clinical trials, and the future of HPVs vaccine development.

#### **KEYWORDS**:

Clinical trial; Papillomavirus vaccines; Uterine cervical neoplasms; Virus-like particle vaccines

Vaccine. 2013 Dec 31;31 Suppl 7:H71-9. doi: 10.1016/j.vaccine.2013.04.086. Cost-effectiveness of cervical cancer prevention in Central and Eastern Europe and Central Asia. Berkhof J1, Bogaards JA2, Demirel E2, Diaz M3, Sharma M4, Kim JJ4. Author information Abstract We studied the cost-effectiveness of cervical cancer prevention strategies in the Central and Eastern Europe and Central Asia (CEECA) region. The cost-effectiveness of

human papillomavirus (HPV)16/18 vaccination of 12 year-old girls was calculated for 28 countries, under the assumption that vaccination prevents 70% of all cervical cancer cases and that cervical cancer and allcause mortality rates are stable without vaccination. At three-dose vaccination costs of I\$ 100 per vaccinated girl (currency 2005 international dollars), HPV16/18 vaccination was very cost-

effective in 25 out of 28 countries using the country's gross domestic product (GDP) per capita as costeffectiveness threshold (criterion by World Health Organization). A three-dose vaccination cost of I\$ 100 is within the current range of vaccine costs in European immunization programs, and therefore our results indicate that HPV vaccination may be good value for money. To evaluate the cost- effectiveness of cervical cancerscreening combined with vaccination, we calibrated a published simulation model to HPV genotype data collected in Slovenia, Poland, and Georgia. The screening interval was varied at 3, 6, and 10 years starting at age 25 or 30 and ending at age 60. In Slovenia and Poland, combined vaccination and 10-yearly HPV (DNA) screening (vaccination coverage 70%, screening coverage per round 70%) was very costeffective when the cost of three-dose vaccination was I\$ 100 per vaccinated girl. More intensive screening was very cost-effective when the screening coverage per round was 30% or 50%. In Georgia, 10-yearly Pap screening was very cost-effective in unvaccinated women. Vaccination combined with 10-yearly HPV screening was likely to be cost- effective if the three-dose vaccination cost was I\$ 50 per vaccinated girl. To conclude, cervical

cancer prevention strategies utilizing both HPV16/18 vaccination and HPV screening are very cost- effective in countries with sufficient resources. In low-resource settings, low vaccine pricing is essential for strategies of combined vaccination and screening to be cost-effective. This article forms part of a regional report entitled "Comprehensive Control of HPV Infections and Related Diseases in the Central and Eastern Europe and Central Asia Region" Vaccine Volume 31, Supplement 7, 2013. Updates of the progress in the field are presented in a separate monograph entitled "Comprehensive Control of HPV Infections and Related Diseases" Vaccine Volume 30, Supplement 5, 2012.

Copyright © 2013 Elsevier Ltd. All rights reserved. KEYWORDS:

Central Asia; Central Europe; Cost effectiveness; Eastern Europe; HPV; Mathematical model; Screening; Vaccination

Eur J Cancer Prev. 2014 May;23(3):206-24. doi: 10.1097/CEJ.0b013e328364f273. Review of the current knowledge on the epidemiology, pathogenesis, and prevention of humanpapillomavirus infection.

## Asiaf A1, Ahmad ST, Mohammad SO, Zargar MA.

## Author information

## Abstract

Human papillomavirus (HPV) infection is a central and necessary, although not sufficient, cause of cervical cancer. BesidesHPV, the additional multiple risk factors related with the onset of cervical cancer are early-age sexual activities; high number of sexual partners, which is the most salient risk factor; suppression and alteration of the immune status; long-term use of oral contraceptives; and other hormonal influences. The tumor-suppressor proteins p53 and pRb are degraded and destabilized through ubiquitination by viral oncoproteins E6 and E7. Over 95% of cervical

cancer cases worldwide test positive for oncogenic HPV DNA. Although cervical screening procedures have been successful in reducing the disease burden associated with HPV infection because of lack of resources or inadequate infrastructure many countries have failed to

reduce cervical cancer mortality. Therefore, prevention may be a valuable strategy for reducing the economic and disease burden of HPVinfection. At present, two successful

prophylactic HPV vaccines are available, quadrivalent (HPV16/18/6/11) 'Gardasil' and bivalent (HPV16/18) 'Cervarix' for vaccinating young adolescent girls at or before the onset of puberty. Recent data indicate that

vaccination prevents the development of cervical lesions in women who have not already acquired the vaccine-specificHPV types. Moreover, several therapeutic vaccines that are protein/peptide-based, DNA-based, or cell-based are in clinical trials but are yet to establish their efficacy; these vaccines are likely to provide important future health benefits. The therapeutic vaccination mode of prevention is a promising area of research, as revealed in preclinical trials; however, clinical trials based on large populations are warranted before reaching a valid conclusion. This review summarizes the studies on the epidemiology of HPV infection, the pathogenesis of viral oncoproteins in the oncogenesis of cervical cancer, the economic and health burden of HPV-related diseases, and, finally, focuses on the results of recent clinical vaccination trials.

### J Adolesc Health. 2013 May;52(5 Suppl):S69-75. doi: 10.1016/j.jadohealth.2012.09.020. Hispanic mothers' and high school girls' perceptions

## of cervical cancer, human papilloma virus, and the human papilloma virus vaccine.

## Morales-Campos DY1, Markham CM, Peskin MF, Fernandez ME.

## Author information Abstract PURPOSE:

Cervical cancer incidence and mortality are higher for Hispanic women than for women in other population groups. However, the incidence could be reduced if teenaged Hispanic girls received the human papillomavirus (HPV) vaccine before they become sexually active. Unfortunately, few Hispanic girls receive this vaccine, which prevents cervical cancer. This study assessed Hispanic mothers' and girls' perceptions about cervical cancer, HPV, and the HPV vaccine. Results show factors that affect whether Hispanic high school girls receive the vaccine.

## METHODS:

Twenty-four Hispanic mothers and 28 Hispanic girls from an urban school district in southeast Texas each participated in one of eight focus groups. Bilingual moderators facilitated the mothers' groups in English and Spanish and the girls' groups in English. We analyzed transcripts of the discussions and identified themes using the grounded theory approach.

### **RESULTS:**

Our analysis found several themes that affect whether Hispanic girls get the HPV vaccine: gaps in knowledge; fears and concerns about the vaccine; sociocultural communication practices; and decision-making about HPV vaccination. Both mothers and girls had limited knowledge about cervical cancer, HPV, and the vaccine. Some girls who received thevaccine said they wished their mothers had involved them in making the decision.

## CONCLUSIONS:

Findings may help in developing school or community-based educational programs for Hispanic families. Such programs should provide information on the HPV vaccine and the link

between HPV and cervical cancer, and they should assist mothers and girls in communicating to make informed decisions about the vaccine.

## Appendix B : Gardasil Vaccination - Evaluating The Risks Versus Benefits

### GARDASIL VACCINATION: EVALUATING THE RISKS VERSUS BENEFITS

Lucija Tomljenovic, PhD, Neural Dynamics Research Group, Dept. of Ophthalmology, University of British Columbia, 828 W. 10th Ave, Vancouver, BC

January 2011

All drugs are associated with some risks of adverse reactions and vaccines are no exception. In weighing risks versus benefits, one has to keep in mind that vaccines represent a special category of drugs since they are generally given to healthy individuals. If there are uncertain benefits from a vaccine, only a small level of risk of harmful effects may be acceptable. If the benefits are certain, then a greater risk of side effects may be tolerated. Here I review the current evidence which indicates that the former case, applies to Gardasil, the quadrivalent human papillomavirus (qHPV) vaccine:

1) The efficacy of Gardasil in preventing cervical cancer has not been demonstrated and the marketing campaign has been misleading. The efficacy of Gardasil remains unsubstantiated since the vaccine hasn't been adequately tested on the primary age group to which it is currently given.

Merck promoted Gardasil primarily as a vaccine against cervical cancer, rather than promoting it as a vaccine against HPV infection or sexually transmitted diseases <sup>1</sup>.

According to recent reports published in two highly respected scientific journals, *Nature Biotechnology* and *Journal of American Medical Association (JAMA):* 

"Most genital infections are asymptomatic and resolve spontaneously, but the virus can persist and cause precancerous lesions that can become malignant over the subsequent 20-30 years." (Nature Biotechnology, 2007 <sup>2</sup>)

"So how should a parent, physician, politician, or anyone else decide whether it is a good thing to give young girls a vaccine that partly prevents infection caused by a sexually transmitted disease (HPV infection), an infection that in a few cases will cause cancer 20 to 40 years from now? (JAMA, 2009 <sup>3</sup>)

The fact is that malignant cervical cancer takes decades to develop <sup>23</sup> and yet the longest clinical trial on Gardasil was only four years in duration <sup>4</sup>. In other words, Gardasil was never shown to prevent cervical cancer [emphasis added]. Furthermore, in all clinical trials conducted by Merck the cervical intraepithelial neoplasia (CIN) 2/3 precancerous lesion was used as the efficacy endpoint for evaluating the Gardasil 4. What is the problem with using the CIN 2/3 lesion as the standard for efficacy? First, if the marketing claim for Gardasil is that the vaccine "protects against cervical cancer" <sup>125</sup>, then cervical cancer should have been used as the endpoint for efficacy, not a surrogate marker such as a CIN 2/3 precancerous lesion [emphasis added].

Second, in the natural course of cervical cancer, only a small fraction of the CIN 2 lesions will progress to CIN 3 lesions and only a small fraction of CIN 3 lesions will eventually progress to cervical cancer 6. Furthermore, even CIN 3 lesions are heterogeneous (there are early small lesions and old advanced lesions and we do not know what proportion of the small lesions, which serve as clinical endpoints in current studies, would persist to become large, advanced CIN3 lesions)<sup>7</sup>. Therefore, in any female population (and that includes those who have undergone Gardasil clinical trials) there are many more CIN 2 lesions than a combination of CIN 3 lesions and cervical cancers. As a result, the vast majority of the "CIN 2/3 or worse" cases used for evaluation of efficacy, and listed in Merck's report to FDA Vaccines and Related Biological Products Advisory Committee (*VRBPAC Background Document on Gardasil HPV Quadrivalent Vaccine*<sup>8</sup>), must have been CIN 2 lesions.

In a review of the literature from 1950-1992, **it was noted that 60% of CIN 1 lesions regressed, 30% persisted, 10% progressed to CIN 3, and only 1% progressed to invasive cancer**. The corresponding approximations for CIN 2 were 40%, 40%, 20%, and 5%, respectively. The likelihood of CIN 3 regressing was 33% and that of progressing to invasive cancer was greater than 12% <sup>6</sup>.

The author of the study, Andrew G Östör, MD, from the Departments of Obstetrics and Gynaecology and Pathology, University of Melbourne noted 6:

"It is obvious from the above figures that the probability of an atypical epithelium becoming invasive increases with the severity of the atypia, but does not occur in every case. **Even the higher degrees of atypia may regress in a significant proportion of cases. As morphology by itself does not predict which lesion will progress or regress, future efforts should seek factors other than morphological to determine the prognosis in individual patients." [emphasis added]** 

The above remark leads us to a third reason why a surrogate morphological marker is not an adequate endpoint for assessing the efficacy of cervical cancer vaccines <sup>9</sup>:

"CIN 2 is not a true biologic entity but an equivocal diagnosis of pre-cancer, representing an admixture of HPV infection and pre-cancer. The existence of CIN 2 biopsy results as a clinical entity may be the consequence of the inaccuracies of colposcopy and colposcopically directed biopsy, which could result in less than-perfect representation of the underlying disease state." [emphasis added]

Furthermore, the same report by the National Cancer Institute (NCI 9) states that:

"That CIN2 is the least reproducible of all histopathologic diagnoses may in part reflect sampling error..."

Finally, according to second report by the NCI 10:

"Approximately 40% of undiagnosed CIN 2 will regress over two years" (this also precisely corroborates the findings of the study by Östör)

**Gardasil is marketed as the vaccine that prevents cervical cancer**<sup>125</sup>. This statement is incorrect. Based on the above NCI findings, we can conclude that the data presented in the *VRBPAC Background Document on Gardasil HPV Quadrivalent Vaccine*<sup>8</sup> only supports the claim **that Gardasil can prevent "an equivocal diagnosis of pre-cancer, representing an admixture of HPV infection and pre-cancer" - about half of which are self-reversing to normal cases and do not reflect actual cervical cancer. [emphasis added]** 

There was yet another important oversight in assessing the efficacy of Gardasil. Most cervical cancers are believed to be linked to infection with genital HPV types 6, 11, 16, and 18<sup>2311</sup>. According to NCI, the only reliable HPV genotyping method is a "*PCR system with short target sequences" 12 or alternatively, " 'sentinel-base' genotyping by PCR*"<sup>13</sup> Ironically, these HPV genotyping methods were never used to determine the HPV type associated with precancerous lesions in the clinical trials for evaluation of the efficacy of Gardasil to prevent type-specific HPV infections.

# 2) Cervical cancer is a rare disease in developed countries which invalidates the recommendations for universal immunization with any HPV vaccine. The incidence of cervical cancer has dropped

# substantially since implementation of regular Pap screening procedures. Currently, in the US, the death rate from cervical cancer (2.4/100,000 women) is lower than the rate of reported serious adverse events, including death, from Gardasil (3.34/100,000 doses distributed)

Although rare, the severity of cervical cancer should not be understated. Advanced cervical cancer is a deadly disease, especially in areas where the resources and infrastructure to fully implement Papanicolaou (Pap) smear tests are limited such as Latin America, Africa, India and South Asia<sup>2</sup>. **Regardless, in the past** four decades, industrialized countries such as the US, have cut cervical cancer mortality and incidence rates by 74% largely through the use of the Pap smear<sup>2</sup> [emphasis added].

Thus, as noted by Diane Harper, MD, Professor and Vice Chair, Obstetrics and Gynecology, Community and Family Medicine and Informatics and Personalized Medicine, who conducted the phase 2 and phase 3 trials for Gardasil, authoring their publications, in developed countries such as the US, which have regular Pap screening programs in place, the HPV vaccine will do little to decrease the already very small cancer rate. In fact, Harper noted that **if women who are vaccinated stop going for Pap smears, the incidence rate for cervical cancer would increase**<sup>14</sup>. [emphasis added]

Based on L1-encoded virus-like particles, Gardasil should protect against the HPV genotypes 16 and 18, which are thought to account for 70% of cervical cancers <sup>2</sup>. Since Gardasil does not even claim to protect against all cases of cervical cancer but only those "caused by HPV strains 16 & 18", it does not replace the need for a regular pap smear [emphasis added].

More crucially, however, for deciding whether a risk of adverse effects from the HPV vaccine is worth taking, much depends on the perceived benefit from the vaccine relative to that risk. If benefits are indeed substantial, then many individuals would be willing to accept the risk. **However, if the benefit of the vaccine has not been demonstrated and is in fact only speculative, and if a majority of those women who are persistently infected with HPV are not likely to develop cancer providing they are adequately screened <sup>23</sup>, then most reasonably they will only be willing to accept very small risk of harm from the vaccine. Data from clinical safety trials argue against small risks from Gardasil vaccination [emphasis added]. In a paper published in JAMA, Slade et al. (2009) <sup>11</sup> report that from June 1, 2006, through December 31, 2008, the US Vaccine Adverse Event Reporting System (VAERS) received 12, 424 reports of adverse reaction following receipt of Gardasil amongst which, 772 (6.2%) were serious, including 32 deaths. Given the overall reporting rate of 53.9 reports per 100,000 vaccine doses distributed <sup>11</sup>, the estimated rate of reported serious adverse events from Gardasil is 3.34/100, 000 doses distributed. This rate is higher than the death rate from cervical cancer in the US which stands at 2.4/100, 000 women (according to CDC statistics, <sup>15</sup>** 

Harper poses an important question <sup>14</sup>:

"Would a parent accept such a rate of serious adverse events if the same cancer prevention can occur with continued Pap screening? Is there any acceptable level of risk of serious adverse events, including death, to prevent genital warts?" [emphasis added]

The later claim was in reference to one of the vaccine's other claimed benefits.

## 3) Most HPV infections are benign and resolve spontaneously without causing cervical cancer

According to Harper <sup>16</sup>:

"70% of all HPV infections resolve themselves without treatment within a year. Within two years, the number climbs to 90%. Of the remaining 10% of HPV infections, only half will develop into cervical cancer."

These numbers are consistent with those above quoted from Nature Biotechnology<sup>2</sup>:

"Most genital infections are asymptomatic and resolve spontaneously, but the virus can persist and cause precancerous lesions that can become malignant over the subsequent 20-30 years."

In addition, in a recent JAMA editorial, Charlotte Haug, MD, PhD, emphasized <sup>3</sup>:

"The virus does not appear to be very harmful because almost all HPV infections are cleared by the immune system. In a few women, the HPV infection persists, and some women may develop precancerous cervical lesions and eventually cancer. It is currently impossible to predict in which women this will occur and why. Likewise, it is impossible to predict exactly what effect vaccination of young girls and women will have on the incidence of cervical cancer 20 to 40 years from now."

Thus, again, there appears to be little rationale in support of universal immunization with any HPV vaccine.

4) Gardasil clinical trials, all conducted by the manufacturer, were inadequate and methodologically flawed. The risks of Gardasil vaccination are not fully understood since an inadequate placebo was used in clinical trials and the follow-up period was too short.

In a safety evaluation study of Gardasil by Merck, the manufacturer used an inappropriate "placebo control" group in which results were pooled from a group that had received an aluminum salt adjuvant (amorphous aluminum hydroxyphosphate sulfate) together with the results from the group which had received conventional saline 4. Altogether, bearing in mind that:

- 1) Gardasil is an aluminum- adjuvanted vaccine <sup>4</sup>,
- 2) Aluminum is an experimentally demonstrated neurotoxin and <sup>17-21</sup>
- 3) On the basis of previous research, a plausible support for a specific role of aluminum adjuvants in various neurological as well as autoimmune disorders in humans has been established <sup>22-26</sup>,

...the rationale for such a "control-group" design remains tenuous [emphasis added].

In addition, the follow-up of trial participants was 2 to 6 months in duration 4. During this period, a total of 245 adverse effects were reported in the group that received the vaccine compared with 218 for the "control" group 4. Given that the aim of the study was to evaluate vaccine safety, the selected time frame should have been longer since potential auto-immune as well as neurological complications may take years to manifest <sup>27 28</sup>.

Aluminum is a well demonstrated toxin in biological systems <sup>29</sup> whose more specific impacts on the nervous system have been extensively documented <sup>17 18 20 21 30-39.</sup>

Common symptoms of aluminum intoxication in both animals and humans include: progressive dementia, diminished performance in learning tasks, speech impairments, loss of psychomotor control, twitches, tremors, jerks, seizures, behavioural changes (paranoia, confusion, psychosis) and, in extreme circumstances, death <sup>21 39</sup>. Of note, recent research demonstrates that aluminum in levels comparable to those routinely found in vaccines can cause the death of motor neurons and induce impairments in motor function and decrements in spatial memory capacity in mice <sup>17 36</sup>. [emphasis added].

Consistent with the above experimental data, a host of neurodegenerative complications and diseases such as Alzheimer's <sup>21 38 40</sup>, Parkinson's disease, amyotrophic lateral sclerosis (ALS; <sup>40 41</sup>), multiple sclerosis (MS; <sup>23</sup> <sup>42</sup>), Gulf War Syndrome (GWS; <sup>25 26</sup>) and epilepsy <sup>43</sup> have been linked to aluminum exposure.

In addition, cases of motor neuron disease and multiple sclerosis (MS) after immunization with Gardasil have been reported <sup>44</sup>. All of these reports also indicate an immune-mediated reaction which is not surprising given the immunostimulatory role of aluminum adjuvants <sup>23-25</sup>. At the 134th annual meeting of the American Neurological Association in Baltimore, Oct. 11-14, 2009,

researchers described a case of rapidly progressive disease leading to the death of a 14 year old girl. Catherine Lomen-Hoerth MD, Director of the Amyotrophic Lateral Sclerosis at the University of California-San Francisco reported the following <sup>44</sup>:

"Pathological features support the temporal association of the clinical presentation and vaccination and provides supporting evidence that **immune-mediated reactions to the nervous system are potential risks after Gardasil vaccination**. Our patient received three doses of Gardasil with symptom onset 2 months after her last dose. Despite treatment with aggressive immunosuppression, her weakness relentlessly progressed and **she died of respiratory failure 21 months after the onset of her weakness**." [emphasis added]

Post-mortem evaluations revealed widespread infiltrates of T lymphocytes and macrophages in the grey and white matter at all levels of the spinal cord. The researchers also reported **extensive demyelination (MS symptoms) and severe loss of motor neurons**<sup>44</sup>. [emphasis added]

In September 2009, investigators presenting at the 25th **European Committee for Treatment and Research in Multiple Sclerosis** annual meeting **reported cases of autoimmune disorders after immunization with Gardasil.** Lead investigator Maria Bouktsi from the Interbalkan European Medical Centre in Thessaloniki, Greece told Medscape Neurology that her team is questioning whether **the immunostimulatory effects of the HPV-like particles of the vaccine are triggering adverse effects in vulnerable patients**<sup>44</sup>. It is the same question that researchers asked in a recent issue of Multiple Sclerosis (2009)<sup>45</sup>. Ian Sutton, MB ChB(Hons), MRCP(UK), PhD, FRACP from St. Vincents Hospital, New South Wales, Australia, and his team have reported five cases of multiple sclerosis after vaccination with Gardasil<sup>45</sup>. The team reported that patients presented with multifocal or atypical demyelinating syndromes within 21 days of immunization. These researchers have also noted that this was an unusually rapid development of disease that is not normally seen in the general population 45 [emphasis added].

In summary, a placebo group containing a demonstrated neurotoxic substance such as aluminum, invalidates the conclusion that Gardasil is not associated with a significant rate of adverse reactions (as claimed by the manufacturer, Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC)<sup>46</sup>).

5) Since 2006 when it was first approved, Gardasil has been associated with 20, 915 adverse reactions in the US alone. These included 89 deaths, over 1000 cases that required emergency hospitalization, and 382 abnormal pap tests <sup>47-49</sup>. Could the vaccine exacerbate the very disease it is claimed to prevent?

**VAERS is a passive and voluntary reporting system with only 1 to 10% of the population filing, according to** National Vaccine Information Center (NVIC) estimates <sup>50</sup>. For this reason, surveillance studies based on VAERS reports may grossly underestimate the true rate of adverse reaction from vaccines. If correct, this would imply that **Gardasil could be associated with as many as 200,000 to 2,000,000 adverse reactions** [emphasis added]. Many people don't report to VAERS because they are not aware that the database exists and paradoxically, this includes doctors. According to Rosemary Matthis, mother of Lauren Brooke Mathis, who received her first Gardasil injection at the age of 13 years <sup>51 52</sup>:

"Prior to Gardasil, I did not know what VAERS was. When my daughter became ill, I found out about VAERS by research performed on the internet. **My daughter's doctors did not even know what it was** and they did not file a report until I filed one myself and told them **they were obligated by law to file a report**. How can the #'s be accurate if doctors don't file the reports? I even had to explain

what VAERS is. Shouldn't VAERS and the adverse side effects of vaccines be taught in medical school or shouldn't the doctors receive periodic newsletters from the CDC explaining VAERS and its importance?" [emphasis added]

According to the information from the FDA and the CDC on Gardasil and its Safety <sup>46</sup>:

"Since Gardasil was approved, the **great majority (94%) of adverse events** reported to VAERS after receiving this vaccine have **not** been **serious**. These reports **include syncope (fainting)**, pain at the injection site, headache, nausea, and fever. **Fainting is common after injections and vaccinations, especially among adolescents**. Falls after syncope may sometimes cause serious injuries such as head injuries, which can be **prevented** with simple steps, such as **keeping the vaccinated person seated for up to 15 minutes after vaccination**." [emphasis added]

The above claim suggests that fainting is apparently common with vaccines (especially among adolescents who incidentally, are targeted by this vaccine) and thus not a reason for concern. The statement by the CDC and the FDA also implies that simple prevention can resolve any potential resulting injuries. **It would also suggest that unless an adverse event is observed within 15 min of vaccination, it most likely did not occur as a result of Gardasil vaccination. This statement is misleading since neurological complications may take anywhere from weeks to years to be fully manifested <sup>27 28</sup>. As such, this claim by the CDC and the FDA effectively downplays safety concerns over Gardasil. This is a crucially important matter to consider since recommendations by the FDA and the CDC profoundly affect practicing physicians. According to parent's reports <sup>51 52</sup>:** 

"My 17 year old daughter, with prompting from her new adolescent pediatrician, received the first Gardasil vaccine on 4/23/09. She was told the side effects were: pain and redness at the injection site and possible fainting so she would need to stay in the office for 15 minutes following the injection. The next day, 4/24/09 she began having symptoms of dizziness, nausea and abdominal pain. On the 5th day of symptoms, we called the pediatrician and she said that it could not be due to the Gardasil because it was too long past the injection and she felt it was viral." [emphasis added]

It is obvious that physicians will not report to VAERS if they are not adequately informed on vaccine side effects. This not only leads to underestimation of case reports but also the inability to provide adequate treatment to those adversely affected by the vaccine:

"On the 5th day of symptoms, we called the pediatrician and she said that it could not be due to the Gardasil because it was too long past the injection and she felt it was viral. We called the doctor again in June because the symptoms had progressed to: numbness and tingling to feet, joint pain, muscle weakness, stabbing pain to her back and feet, headaches, skin sensitivity, brain fog, chest pain, shortness of breath, racing pulse, extreme fatigue, visual disturbances. We saw the ediatrician and she referred us to Dr. Steven Linder, **neurologist... he diagnosed her extreme foot pain as peripheral neuropathy which was a result of the Gardasil vaccine. We sought the help from several different doctors who had little else to offer because they did not know how to deal with Gardasil side effects<sup>5152</sup>." [emphasis added]** 

# The above statement highlights the fact that the risks of Gardasil vaccination are not fully understood since the vaccine clinical trials were inadequate.

In recognition of this risk, Spanish health authorities have withdrawn tens of thousands of doses of a Gardasil vaccine after two teenagers who received the shots were hospitalized hours after receiving them <sup>53</sup>. Similarly, in April 2010 the government of India called a halt to trials of HPV vaccine in the country. This followed reports of ethical violations within the trials and public outcry at deaths and side effects

reported from use of the vaccine by a fact finding visit led by India?s civil society groups to the areas concerned <sup>54</sup>.

In a recent letter to the editor of the *European Journal of Neurology* Svetlana Blithshteyn, MD of the Department of Neurology, State University of New School of Medicine and Biomedical Sciences, Buffalo, NY, US described a case of Postural Tachycardia Syndrome (POTS) following vaccination with Gardasil. POTS is thought to be an auto-immune disease <sup>55</sup>. The symptoms include dizziness, exercise intolerance, fatigue, nausea and loss of appetite, which in this case has lasted months. The patient had no other relevant factors or events preceding the symptoms onset apart from Gardasil vaccination <sup>55</sup> [emphasis added]:

"There was no family history of cardiac, autoimmune or autonomic disorders. Other than vaccination with Gardasil 2 weeks prior to symptom onset, there were no other factors or events preceding the illness"

This is a significant piece of research as symptoms of **fainting and dizziness are the most common adverse event to Gardasil** and have been, somewhat dismissively, reported as "psychogenic", as Blithshteyn remarks <sup>55</sup>:

"It is probable that some patient who develop POTS after immunization with Gardasil or other vaccines are simply **undiagnosed or misdiagnosed**, which leads to **under-reporting** and a paucity of data on the incidence of POTS after vaccination in literature" [emphasis added].

Finally, the finding that Gardasil was associated with abnormal Pap smears <sup>47-49</sup> suggests that the vaccine in some individuals may exacerbate the risk for developing cervical cancer. In fact, according to Merck's *VRBPAC Background Document on Gardasil HPV Quadrivalent Vaccine*, the manufacturer expressed "concern" regarding the administration of Gardasil to girls who are already affected with HPV strains 16 and 18. Merck indicated that if the cervical cancer vaccine was administered to such girls, it would increase their risk of developing cervical cancer by 44.6% (page 13, VRBPAC 8). Despite this warning by Merck, no screening is being done to rule out the presence of strain 16 or 18 of the HPV in girls before vaccination. [emphasis added]

6) Gardasil contains sodium-borate (70 ug/mL) which, according to a 2005 listing at The National Library of Medicine (NLM) of the National Institutes of Health, is no longer commonly used in medicinal products due to its high toxicity <sup>56</sup>. Symptoms of sodium borate poisoning include: collapse, seizures, coma, death, muscular spasms, dullness, lethargy, circulatory depression, central nervous system depression, kidney damage, nausea, vomiting, diarrhea, fever, low blood pressure <sup>57</sup>.

Although **boric acid** was used to disinfect and treat wounds in the past, such practice was subsequently discontinued because patients who received such treatment repeatedly, got sick and some died <sup>56</sup>. Boric acid is still contained in some vaginal suppositories used for yeast infections, however, this is not a standard treatment <sup>56</sup>. Furthermore, at a recent **European Diagnostics Manufacturing Association (EDMA)** meeting, several new additions to the **Substance of Very High Concern (SVHC)** candidate list in relation to the Registration, Evaluation, Authorisation and restriction of Chemicals Regulations 2007 (REACH) were discussed <sup>58</sup>. The registration and review completed as part of REACH **has changed the classification of Sodium Tetraborate CAS 1303-96-4 to: Highly Toxic** <sup>59</sup>. **Sodium borate is commonly used in insecticides** and acute, accidental sodium borate poisoning usually occurs when someone swallows such products <sup>56</sup>. Although large doses of sodium borate are needed for acute intoxication via ingestion exposure (Estimated lethal dose 15 to 20 grams <sup>57</sup>), there is no data available on toxicity following injection exposure in humans [emphasis added].

Post-marketing surveillance data suggests that there is a common pattern of adverse reactions from Gardasil. The following symptoms appear to be common among individuals who reported adverse reactions after they had received Gardasil: sudden fainting, collapse, seizures, pulmonary embolisms, difficulty breathing, paralysis, muscular spasms, memory loss, confusion, speech impairments, behavioural changes, fatigue, chest pain, arrythmias, vomiting and diarrhea, dizziness, headaches, nausea, increased incidence of upper respiratory tract infections, vision problems, hypersensitivity to light, irritability, depression, and changes in menstrual cycle <sup>11 44 51 52 55 60.</sup>

7) Gardasil contains polysorbate 80 (100 ug/mL), a non-ionic detergent suspected to cause sudden unconsciousness, arrythmias, chest pain, nausea, headaches, vomiting and diarrhea, dizziness, confusion, breathing irregularities, diminished resistance to infection and increased incidence of upper respiratory tract infections, in users of Darbepoetin Alfa, a drug which is also administered by injection <sup>61-63</sup>.

Polysorbate 80 is a non-ionic surfactant used widely in foods, pharmaceutical preparations, and cosmetics because of its effectiveness at low concentrations and presumed relative low toxicity <sup>64 65</sup>. **Darbepoetin Alpha** (brand name: Aranesp) which is normally given to chronic renal failure and cancer patients to treat anemia <sup>65</sup> (by stimulating the bone marrow to produce red blood cells), **contains 0.005% of polysorbate 80** <sup>66</sup>, which is half of the amount of **polysorbate 80 in Gardasil** (0.01%) <sup>4</sup>.

In addition to suspected side effects cited above, studies have shown that polysorbate 80 at clinicallyrelevant concentrations (10-30 ug/mL, 10-3x less than the amount in Gardasil) increases the cytotoxicity of hydrogen peroxide in vitro 64. Result suggests that polysorbate 80 may increase the susceptibility of cells to oxidative stress because it decreases the cellular concentration of glutathione <sup>64</sup>.

Polysorbate 80 may also affect fertility as indicated in a study by Gajdova et al. (1992<sup>67</sup>). In this case, neonatal female rats were exposed to polysorbate 80 (trade name Tween 80) on days 4 to 7 after birth. Treatment with polysorbate 80 accelerated maturation, prolonged the oestrus cycle and induced persistent vaginal oestrus in these rats. The relative weight of the uterus and ovaries was decreased relative to the untreated controls. Squamous cell metaplasia of the epithelial lining of the uterus and cytological changes in the uterus were indicative of chronic oestrogenic stimulation. Ovaries were without corpora lutea and had degenerative follicles<sup>67</sup>. Given that neonatal female rats were used in this experiment, the extrapolation of the study results to young female adults exposed to polysorbate 80 may not be adequate. Nonetheless, many adverse reactions from Gardasil include changes in menstrual cycle (including heavy periods, absence of periods, irregular cycle, severe PMS symptoms, etc.) which would suggest that the vaccine may interfere with female hormone levels, the ovarian cycle and subsequently-fertility. In addition, some female users of Darbepoetin Alpha reportedly experienced abnormal menstrual cycles even after not having regular cycles for a long time<sup>63</sup>. All of these outcomes are consistent with the effects of polysorbate 80 on neonatal female rats, hence the relevance of the study by Gajdova et al. (1992<sup>67</sup>) should not be dismissed [emphasis added].

The use of non-ionic surfactants in biological systems aids drug delivery (by making water non- soluble drugs more bioavailable) since it has the effect of permeating cellular membranes <sup>64 65 68</sup>. However, in addition to making a drug more bioavailable, polysorbate 80 could also make potentially toxic components such as sodium borate and aluminum more bioavailable as well, thereby effectively lowering the toxicity threshold levels which are normally associated with administration of single compounds. In other words, much smaller amounts of aluminum and sodium borate would be required to produce cytotoxicity if co-injected with a surfactant such as polysorbate <sup>80</sup>. Insofar there have been no studies to evaluate the systemic effects of co- administrating three potentially toxic compounds (aluminum, sodium borate and polysorbate <sup>80</sup>) via injection to animals or humans, hence, their administration via Gardasil to girls aged 9- 26 years worldwide constitutes what can be considered as a big "public health experiment" [emphasis added].

## 8) Professional medical association (PMAs) including the American College of Obstetricians and Gynecologists, the American Society for Colposcopy and Cervical Pathology, the Society for Gynecologic Oncologists, and the American College Health Association received funding from Merck in educational campaigns to promote vaccine use

A recent report in *JAMA* by Sheila Rothman, PhD, from sociomedical sciences and David Rothman, PhD, from social medicine, both at the Columbia College of Physicians and Surgeons, New York City, provides compelling evidence that Merck funded educational programs by PMA as a marketing strategy to promote vaccine use <sup>1</sup>. In a reference to this paper, the accompanying editorial in JAMA states <sup>3</sup>:

"The article illustrates how the Society of Gynecologic Oncology, the American Society for Colposcopy and Cervical Pathology, and American College Health Association helped market the vaccine and influenced decisions about vaccine policy with the help of ready-made presentations, slide sets, e-mails, and letters.... These educational programs strongly promoting HPV vaccination began in 2006, more than a year before the trials with clinically important end points were published. How could anyone be so certain about the effect of the vaccine? This matters because the voices of experts such as the professional medical associations are especially important with a complex issue such as this." [emphasis added]

Rothman and Rothman note 1:

"By making this vaccine's target disease cervical cancer, the sexual transmission of HPV was minimized, the threat of cervical cancer to all adolescents maximized, and the subpopulations most at risk practically ignored." [emphasis added]

"Rather than concentrating on populations in geographical areas with excess cervical cancer mortality, including African Americans in the South, Latinos along the Texas-Mexico border, and whites in Appalachia, the marketing campaign posited that every girl was at equal risk,"

"The marketing campaign that followed, according to Merck's chief executive officer, proceeded "flawlessly." **In 2006, Gardasil was named the pharmaceutical "brand of the year" for building "a market out of thin air**." [emphasis added]

Merck had also bankrolled efforts to pass state laws across the US which would mandate Gardasil for girls as young as 11 or 12. In one such instance, Texas governor Rick Perry circumvented his state legislature and signed an executive order making HPV vaccination compulsory for 11- to 12-year-old girls. A report in Nature Biotechnology further adds <sup>2</sup>:

"Adding fuel to the resulting outcry, it was revealed that Merck had contributed \$6,000 to Perry in the past and now employed Mike Toomey, a former Perry chief of staff, as its lobbyist. Surrounded by a chorus of disapproval, Merck cracked. **As Nature Biotechnology went to press, the company announced a cessation** of all efforts to lobby for US state laws requiring compulsory vaccination." [emphasis added]

Merck's marketing strategies were condemned even by those who were in favour of the vaccine:

"Merck is hammered for the fact that it is spending huge lobbying dollars to make the vaccine mandatory. Even those who strongly favor the vaccine, such as Dr. Joseph A. Bocchini, chairman of the committee on infectious diseases of the American Academy of Pediatrics, are stunned at the degree to which Merck has pushed its \$400 vaccine as a mandatory measure, rather than opting to phase in the vaccine at lower cost and with measures for informed consent and tiered pricing <sup>5</sup>." [emphasis added]

Similar marketing strategies were also seen in France where they were eventually stopped by the action of government health authorities. On August 31st 2010, **Merck's marketing partner for Gardasil, Sanofi-Pasteur, was officially prohibited from advertising Gardasil for cervical cancer prevention in France**. The Director General of the French Agency for Safety of Health Products (AFSSAPS) found the sponsor of several Gardasil ads to be in direct violation of French public health codes <sup>69</sup>.

These violations included, but were not limited to:

**1) Claiming longer efficacy than was actually proven**. "The ads stated an 8.5 year efficacy period when, in fact, the only data of validated efficacy is limited to a maximum assessment of the effectiveness of 4.5 years";

**2)** Making false claims: the ads in question replaced the officially approved use of Gardasil for "the prevention of low-grade lesions" with statements indicating Gardasil be used for "the prevention of premalignant genital lesions, cancers of the cervix and external genital warts." [emphasis added]

According to the French Committee on Immunization Practices (CTV) and the High Council of Public Health (HCSP), " *the vaccines impact on the incidence and mortality of cervical cancer will only become apparent in the long term, in fifteen to twenty years*<sup>69</sup>."

In spite of bad publicity, Merck's business strategy suggests that **the manufacturer increasingly aims on** expanding the market to include women ages 19 to 26, who have been less likely to get the vaccine <sup>70</sup>:

"We see tremendous opportunity" said Bev Lybrand, Merck's senior vice president of vaccines in a recent news report. "We have a number of programs under way to get after these women." [emphasis added]

Further reports suggest that **Merck is counting on Gardasil to help offset declining sales of cholesterol drugs Vytorin and Zetia** after a study found they may work no better at unclogging arteries than a cheaper medicine <sup>70 71</sup>. There were also safety concerns over Zetia and **the manufacturer was accused of withholding important safety and efficacy information in an effort to protect sales** <sup>71</sup>. Sales of the asthma treatment Singulair, Merck's top-selling drug, have also slowed over safety concerns <sup>70</sup>.

"Gardasil needs to be doing better," said Barclays Capital analyst Tony Butler in New York. The vaccine "has become increasingly more important from a profit standpoint because of the concerns over Singulair and Vytorin and Zetia." [emphasis added]

SUMMARY: Clinical trials on Gardasil have been largely inadequate, the efficacy of the vaccine in preventing cervical cancer has not been demonstrated, the benefits of vaccination have been exaggerated and safety concerns downplayed, thus preventing parents from making informed decisions for their children. Routine immunization against cervical cancer with Gardasil is not supported by the current data. The benefit of vaccination is uncertain and the risks of serious adverse effects are substantial.

**Gardasil can prevent "an equivocal diagnosis of pre-cancer,** representing an admixture of HPV infection and pre-cancer" - about half of which are self-reversing to normal - **not cervical cancer**.

Most genital infections are asymptomatic and resolve spontaneously, but the virus can persist and cause precancerous lesions that can become malignant over the subsequent 20-30 years.

Merck's longest median duration of follow-up in clinical trials: 4 years.

# Gardasil post marketing reports of adverse effects in the US according to VAERS (SK note: these figures are as @ January 2011, the current figures for July 2015 are much higher and are referenced in this document)

20,915 adverse reactions 89 deaths >1000 serious adverse reactions requiring emergency hospitalization 382 abnormal pap tests

**Gardasil (polysorbate 80, 0.01%) adverse reaction symptoms**: sudden fainting, collapse, seizures, pulmonary embolisms, DEATH, difficulty breathing, twitches and tremors, paralysis, back spasms, memory loss, fatigue, chest pain, arrythmias, vomiting and diarrhea, dizziness, headaches, nausea, increased incidence of upper respiratory tract infections, vision problems, hypersensitivity to light, irritability, depression, and changes in menstrual cycle.

**Darbepoetin Alfa (polysorbate 80, 0.005%):** sudden unconsciousness, arrythmias, chest pain, nausea, headaches, vomiting and diarrhea, dizziness, confusion, breathing irregularities, diminished resistance to infection, and increased incidence of upper respiratory tract infections.

**Sodium borate**: collapse, seizures, coma, death, muscular spasms, dullness, lethargy, circulatory depression, central nervous system depression, kidney damage, nausea, vomiting, diarrhea, fever, and low blood pressure.

**Aluminum ("placebo control" in Gardasil clinical trials**): progressive dementia, diminished performance in learning tasks, speech impairments, loss of psychomotor control, twitches, tremors, jerks, seizures, behavioural changes (paranoia, confusion, psychosis) and, in extreme circumstances, death.

# "In addition, just as pizza bearing cheerleader drug reps are a poor substitute for medical education, pharmaceutical company lobbying is a poor substitute for well-reasoned public health policymaking <sup>5</sup>."

## **References:**

- 1. Rothman SM, Rothman DJ. Marketing HPV vaccine: implications for adolescent health and medical professionalism. *JAMA* 2009;302(7):781-6.
- 2. Flogging gardasil. Nat Biotechnol 2007;25(3):261.
- 3. Haug C. The risks and benefits of HPV vaccination. JAMA 2009;302(7):795-6.
- 4. Merck&Co Inc. Gardasil product sheet, date of Approval 2006, p. 1-26.
- http://www.merck.com/product/usa/pi\_circulars/g/gardasil/gardasil\_pi.pdf
  5. McGee G, Johnson S. Has the spread of HPV vaccine marketing conveyed immunity to common sense? *Am J Bioeth* 2007;7(7):1-2.
- 6. Ostor AG. Natural history of cervical intraepithelial neoplasia: a critical review. Int J Gynecol Pathol 1993;12(2):186-92.
- 7. Schiffman M, Rodriguez AC. Heterogeneity in CIN3 diagnosis. Lancet Oncol 2008;9(5):404-6.
- 8. FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Background Document: Gardasil™ HPV Quadrivalent Vaccine. May 18, 2006 VRBPAC Meeting, p. 1-30. www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4222B3.pdf
- Castle PE, Stoler MH, Solomon D, Schiffman M. The relationship of community biopsy-diagnosed cervical intraepithelial neoplasia grade 2 to the quality control pathology-reviewed diagnoses: an ALTS report. Am J Clin Pathol 2007;127(5):805-15.
- 10. Castle PE, Schiffman M, Wheeler CM, Solomon D. Evidence for frequent regression of cervical intraepithelial neoplasia-grade 2. *Obstet Gynecol*2009;113(1):18-25.
- 11. Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, Sutherland A, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. *JAMA* 2009;302(7):750-7.
- 12. National Cancer Institute (NCI). HPV Genotyping. https://www.fbo.gov/index?s=opportunity&mode=form&id=da396b97ad6eb7ec4f7d511f85d9e3

25&tab=core&\_cview=06, Accessed Jan 25<sup>th</sup> 2010.

- 13. Gharizadeh B, Zheng B, Akhras M, Ghaderi M, Jejelowo O, Strander B, et al. Sentinel-base DNA genotyping using multiple sequencing primers for high-risk human papillomaviruses. *Mol Cell Probes* 2006;20(3-4):230-8.
- 14. Chustecka Z. HPV Vaccine: Debate Over Benefits, Marketing, and New Adverse Event Data. *Medscape Med News* 2009. http://www.medscape.com/viewarticle/707634
- 15. Centers for Disease Control and Prevention (CDC). Cervical Cancer Rates by Race and Ethnicity (last reviewed: February 4, 2010). http://www.cdc.gov/features/dscervicalcancer/
- 16. Alliance for Human Research Protection (AHRP). Archive for the "Dr. Diane Harper" Category, Correction for Gardasil Blog 117 from AHRP, Monday, November 30th, 2009. http://easydiagnosis.com/blog/?cat=198
- 17. Shaw CA, Petrik MS. Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration. *J Inorg Biochem* 2009;103(11):1555-62.
- 18. Walton JR. Brain lesions comprised of aluminum-rich cells that lack microtubules may be associated with the cognitive deficit of Alzheimer's disease. *Neurotoxicology* 2009;30(6):1059- 69.
- Campbell A, Becaria A, Lahiri DK, Sharman K, Bondy SC. Chronic exposure to aluminum in drinking water increases inflammatory parameters selectively in the brain. *J Neurosci Res* 2004;75(4):565-72.
- 20. Bishop NJ, Morley R, Day JP, Lucas A. Aluminum neurotoxicity in preterm infants receiving intravenous-feeding solutions. *N Engl J Med* 1997;336(22):1557-61.
- 21. Exley C. Aluminium and Alzheimer's Disease: The science that describes the link. 1st ed. Amsterdam: Elsevier Science, 2001; p.452
- Exley C, Swarbrick L, Gherardi RK, Authier FJ. A role for the body burden of aluminium in vaccineassociated macrophagic myofasciitis and chronic fatigue syndrome. *Med Hypotheses* 2009;72(2):135-9.
- 23. Gherardi RK. [Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvantrelated syndrome]. *Rev Neurol (Paris)* 2003;159(2):162-4.
- 24. Gherardi RK, Coquet M, Cherin P, Belec L, Moretto P, Dreyfus PA, et al. Macrophagic myofasciitis lesions assess long-term persistence of vaccine-derived aluminium hydroxide in muscle. *Brain* 2001;124(Pt 9):1821-31.
- 25. Israeli E, Agmon-Levin N, Blank M, Shoenfeld Y. Adjuvants and autoimmunity. *Lupus* 2009;18(13):1217-25.
- 26. Agmon-Levin N, Paz Z, Israeli E, Shoenfeld Y. Vaccines and autoimmunity. *Nat Rev Rheumatol* 2009;5(11):648-52.
- 27. Authier FJ, Cherin P, Creange A, Bonnotte B, Ferrer X, Abdelmoumni A, et al. Central nervous system disease in patients with macrophagic myofasciitis. *Brain* 2001;124(Pt 5):974-83.
- 28. Classen JB. Childhood immunisation and diabetes mellitus. NZ Med J 1996;109(1022):195.
- 29. Carson BL. Aluminum Compounds. Review of Toxicological Literature, Abridged Final Report. Integrated Laboratory Systems, Research Triangle Park, North Carolina, 2000:84 p. http://ntp.niehs.nih.gov/ntp/htdocs/Chem\_Background/ExSumpdf/Aluminum.pdf
- 30. Gies WJ. Some objections to the use of alum baking-powder. JAMA1911;57(10):816-21.
- Bowdler NC, Beasley DS, Fritze EC, Goulette AM, Hatton JD, Hession J, et al. Behavioral effects of aluminum ingestion on animal and human subjects. *Pharmacol Biochem Behav* 1979;10(4):505-12.
- 32. Banks WA, Kastin AJ. Aluminum-induced neurotoxicity: alterations in membrane function at the blood-brain barrier. *Neurosci Biobehav Rev* 1989;13(1):47-53.
- el-Sebae AH, Abdel-Ghany ME, Shalloway D, Abou Zeid MM, Blancato J, Saleh MA. Aluminum interaction with human brain tau protein phosphorylation by various kinases. *J Environ Sci Health B* 1993;28(6):763-77.
- 34. Yokel RA, Allen DD, Meyer JJ. Studies of aluminum neurobehavioral toxicity in the intact mammal. *Cell Mol Neurobiol* 1994;14(6):791-808.
- 35. Fewtrell MS, Bishop NJ, Edmonds CJ, Isaacs EB, Lucas A. Aluminum exposure from parenteral nutrition in preterm infants: bone health at 15-year follow-up. *Pediatrics* 2009;124(5):1372-9.
- 36. Petrik MS, Wong MC, Tabata RC, Garry RF, Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *Neuromolecular Med* 2007;9(1):83-100.
- 37. Platt B, Fiddler G, Riedel G, Henderson Z. Aluminium toxicity in the rat brain: histochemical and immunocytochemical evidence. *Brain Res Bull* 2001;55(2):257-67.
- 38. Walton JR. Aluminum in hippocampal neurons from humans with Alzheimer's disease. *Neurotoxicology* 2006;27(3):385-94.
- 39. Tomljenovic L. Aluminum and Alzheimer's disease: after a century of controversy, is there a

plausible link? Journal of Alzheimer's Disease 2010;23(4), in press.

- 40. Perl DP, Moalem S. Aluminum and Alzheimer's disease, a personal perspective after 25 years. *J Alzheimers Dis* 2006;9(3 Suppl):291-300.
- 41. Perl DP, Moalem S. Aluminum, Alzheimer"s Disease and the Geospatial Occurrence of Similar Disorders. *Reviews in Mineralogy & Geochemistry* 2006;64:115-34.
- 42. Exley C, Mamutse G, Korchazhkina O, Pye E, Strekopytov S, Polwart A, et al. Elevated urinary excretion of aluminium and iron in multiple sclerosis. *Mult Scler* 2006;12(5):533-40.
- 43. Exley C. Aluminium and Medicine. In: Merce ALR, Felcman J, Recio MAL, editors. *Molecular and Supramolecular Bioinorganic Chemistry: Applications in Medical Sciences*. New York: Nova Biomedical Books, 2009:45-68.
- 44. Gandey A. Report of Motor Neuron Disease After HPV Vaccine. *Medscape Med News* 2009. http://www.medscape.com/viewarticle/711461
- 45. Sutton I, Lahoria R, Tan IL, Clouston P, Barnett MH. CNS demyelination and quadrivalent HPV vaccination. *Multiple Scerosis* 2009;15:116–19.
- 46. Centers for Disease Control and Prevention (CDC). Information from FDA and CDC on Gardasil and its Safety (Archived), 2008. http://www.cdc.gov/vaccinesafety/Vaccines/HPV/HPVArchived.html
- 47. Vaccine Adverse Event Reporting System (VAERS). VAERS data. http://vaers.hhs.gov/data/data/, Accessed Sept 5<sup>th</sup> 2010.
- 48. S.A.N.E. VAX, Inc. S.A.N.E Vax Objects to FDA Ruling for Gardasil Use for Anal Cancer in 9 to 26 year olds, December 27, 2010. http://sanevax.org/blog/?p=1568
- 49. Free Press Release. HPV Vaccine (Gardasil and Cervarix) VAERS Reports Injury Statistics Increasing at Rapid Rate. December 13, 2010. http://www.free-press-release.com/news-hpvvaccine-gardasil-and-cervarix-vaers-reports-injury-statistics-increasing-at-rapid-rate-1292290323.html
- 50. National Vaccine Information Center (NVIC). An Analysis by the National Vaccine Information Center of Gardasil & Menactra Adverse Event Reports to the Vaccine Adverse Events Reporting System (VAERS), February 2009.
- http://www.nvic.org/Downloads/NVICGardasilvsMenactraVAERSReportFeb-2009u.aspx 51. S.A.N.E. VAX, Inc. Gardasil/Silgard Victims from the United States.
- http://sanevax.org/victims/gardasil-silgard-usa.shtml, Accessed Jan 25<sup>th</sup> 2010. 52. Vaccine Information Coalition (VIC). Gardasil Injuries. http://www.vacinfo.org/gardasil.htm, Accessed Jan 25<sup>th</sup> 2010.
- 53. AFP. Spain withdraws cervical cancer shot after illnesses, Feb 10, 2009. http://www.google.com/hostednews/afp/article/ALeqM5gIPeSOSkC3zU3Xd4HMRiovY9ri-Q
- 54. Sarojini NB, Srinivasan S, Madhavi Y, Srinivasan S, Shenoi A. The HPV Vaccine: Science, Ethics and Regulation *Econom Polit Weekly* 2010;45(48):27-34.
- 55. Blitshteyn S. Postural tachycardia syndrome after vaccination with Gardasil (letter to the editor). *European Journal of Neurology* 2010.
- 56. Medline Plus, A service of the U.S. National Library of Medicine, National Institutes of Health (NIH). Boric acid poisoning, Update Date: 1/30/2009.
- http://www.nlm.nih.gov/medlineplus/ency/article/002485.htm 57. Mallinckrodt Baker Inc. Sodium borate, Material Safety Data Sheet (MSDS), Effective Date:
- 02/15/08. http://www.jtbaker.com/msds/englishhtml/s3122.htm 58. The European Diagnostic Manufacturers Association (EDMA). Comments for Annex XV SVHC Dossiers, Boric acid, Disodium tetraborate, anhydrous, Tetraboron disodium heptaoxide, hydrate. April 2010.

 $http://echa.europa.eu/doc/about/organisation/msc/msc\_rcoms2010/rcom\_disodium\_tetraborate$ 

## \_anhydrous/edma\_comments\_final.pdf

59. European Chemicals Agency. SVHC Support Document: Member State Committee draft support document for identification of disodium tetraborate, anhydrous as a substance of very high concern because of its CMR properties, June 2010.18.

http://echa.europa.eu/doc/candidate\_list/svhc\_supdoc\_disodium\_tetraborate\_anhydrous\_public ation.pdf 60. Vaccine Information Coalition (VIC). Gardasil: Memorial Document.

http://www.vacinfo.org/gardasil.htm

61. Drug Information Online. Darbepoetin Alfa. January 5, 2011.

- http://www.drugs.com/cdi/darbepoetin-alfa-polysorbate-80.html
- 62. Amgen Manufacturing Limited. Aranesp (darbepoetin alfa) For Injection, product information leaflet. Revised May 2010.

 $http://pi.amgen.com/united\_states/aranesp/ckd/aranesp\_pi\_hcp\_english.pdf$ 

63. Rx List, The Internet Drug Index. Aranesp patient information including side effects.

http://www.rxlist.com/aranesp-drug-patient.htm, Accessed Jan 25<sup>th</sup> 2010.

- 64. Tatsuishi T, Oyama Y, Iwase K, Yamaguchi JY, Kobayashi M, Nishimura Y, et al. Polysorbate 80 increases the susceptibility to oxidative stress in rat thymocytes. *Toxicology* 2005;207(1):7-14.
- Steele RH, Limaye S, Cleland B, Chow J, Suranyi MG. Hypersensitivity reactions to the polysorbate contained in recombinant erythropoietin and darbepoietin. *Nephrology* 2005;10:317–20.
- Boven K, Knight J, Bader F, Rossert J, Eckardt K, Casadevall N. Epoetin-associated pure red cell aplasia in patients with chronic kidney disease: solving the mystery. *Nephrol Dial Transplant* 2005;20 (Suppl 3):33-40.
- 67. Gajdova M, Jakubovsky J, Valky J. Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats. *Food Chem Toxicol*1993;31(3):183-90.
- 68. Li GF, Tan YF, Guo D, Wang L. Effect of Tween-80 on the permeability of rhodamine 123, a P-gp substrate across rat intestinal membranes in vitro. Nan Fang Yi Ke Da Xue Xue Bao 2008;28(4):579-81.
- 69. Legifrance gouv., Le Service Public De La Diffusion Du Droit. Décision du 31 août 2010 interdisant une publicité pour un médicament mentionnée à l'article L. 5122-1, premier alinéa, du code de la santé publique destinée aux personnes habilitées à prescrire ou délivrer ces médicaments ou à les utiliser dans l'exercice de leur art.

http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=?cidTexte=JORFTEXT000022839429& dateTexte&oldAction=rechJO&categorieLien=id

- 70. Bloomberg News. Merck Aims Gardasil to Women Least Likely to Benefit (Update2), October 17, 2008. http://www.bloomberg.com/apps/news?pid=newsarchive&sid=am85Fd2sVycU
- 71. Disability Insurance Resource Center. Canadians ingesting Ezetrol may be at risk. Updated March 17, 2008. http://www.lawyersandsettlements.com/case/ezetrol\_heart\_attack\_stroke.html

## Appendix C : Comprehensive list of studies and reports on the deadly, serious and chronic adverse effects of HPV vaccines

 Gardasil Vaccination : Evaluating the Risks versus Benefits : Lucija Tomljenovic <u>http://sanevax.org/wp-content/uploads/2011/02/Gardasil-vaccination-risks-vs-benefits-</u> <u>FINAL1221.pdf</u> Attached as Appendix XXX This document should be read before any other reference as it gives a complete overview of the history and dangers of Gardasil.

#### 2. Infertility linked to HPV Vaccine

There is evidence to suggest that these vaccines DO cause infertility : <u>http://www.ncbi.nlm.nih.gov/pubmed/23902317/</u> The conclusion of this study was: *"We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry".* 

http://www.washingtontimes.com/news/2013/nov/11/hpv-vaccine-cited-in-infertility-case/?page=all

## 3. Human papillomavirus vaccine and systemic lupus erythematosus.

http://www.ncbi.nlm.nih.gov/pubmed/23624585

"Data regarding type of vaccine, number of immunization, family and personal, clinical and serological features, as well as response to treatments were analyzed. In the reported cases, several common features were observed, such as personal or familial susceptibility to autoimmunity or adverse response to a prior dose of the vaccine, both of which may be associated with a higher risk of post-vaccination autoimmunity".

4. Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papilloma virus.

http://www.ncbi.nlm.nih.gov/pubmed/25882168

"CONCLUSIONS:

In a population referred for symptoms of orthostatic intolerance and other symptoms consistent with autonomic dysfunction that began in close temporal association with a quadrivalent HPV vaccination, we identified a 60% prevalence of POTS. Further work is urgently needed to elucidate the potential for a causal link between the vaccine and circulatory abnormalities and to establish targeted treatment options for the affected patients."

## 5. Hypothesis: Human papillomavirus vaccination syndrome—small fiber neuropathy and dysautonomia could be its underlying pathogenesis"

Yet another paper linking HPV vaccines to serious adverse effects: <u>http://link.springer.com/article/10.1007%2Fs10067-015-2969-z</u> Also, small fiber neuropathy has been recently recognized in CRPS, POTS, and fibromyalgia. This article forwards the hypothesis that small fiber neuropathy and dysautonomia could be the common underlying pathogenesis to the group of rare, but severe reactions that follow HPV vaccination. Clinicians should be aware of the possible association between HPV vaccination and the development of these difficult to diagnose painful dysautonomic syndromes.

#### 6. Guilllain-Barré Syndrome : 69 reports after Gardasil vaccination

http://www.greenmedinfo.com/article/there-were-69-reports-guillain-barr%C3%A9-syndrome-gbsafter-gardasil-vaccination-occurred-united

"Using data from Vaccine Adverse Event Reporting System, we identified 69 reports of Guillain-Barré Syndrome (GBS) after Gardasil vaccination that occurred in the United States between 2006 and 2009. The onset of symptoms was within 6 weeks after vaccination in 70% of the patients in whom the date of vaccination was known. The estimated weekly reporting rate of post-Gardasil GBS within the first 6 weeks (6.6 per 10,000,000) was higher than that of the general population, and higher than post-Menactra and post-influenza vaccinations. Further prospective active surveillance for accurate ascertainment and identification of high-risk groups of GBS after Gardasil vaccination is warranted."

# 7. Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papilloma virus.

#### http://www.ncbi.nlm.nih.gov/m/pubmed/25882168/

"CONCLUSIONS: In a population referred for symptoms of orthostatic intolerance and other symptoms consistent with autonomic dysfunction that began in close temporal association with a quadrivalent HPV vaccination, we identified a 60% prevalence of POTS. Further work is urgently needed to elucidate the potential for a causal link between the vaccine and circulatory abnormalities and to establish targeted treatment options for the affected patients."

## 8. HPV vaccines implicated in demyelinating syndromes http://msj.sagepub.com/content/15/1/116.short

"Vaccination is generally considered safe in patients with multiple sclerosis (MS). We report five patients who presented with multifocal or atypical demyelinating syndromes within 21 days of immunization with the quadrivalent human papilloma virus (HPV) vaccine, Gardasil<sup>®</sup>. Although the target population for vaccination, young females, has an inherently high risk for MS, the temporal association with demyelinating events in these cases may be explained by the potent immunostimulatory properties of HPV virus-like particles which comprise the vaccine. A prospective case– control study of patients with MS or clinically isolated demyelinating syndromes receiving the Gardasil<sup>®</sup> vaccine may provide relevant safety data in this population."

## 9. Reduction in HPV prevalence--no evidence to support HPV vaccination reduces HPV prevalence <u>http://www.ncbi.nlm.nih.gov/pubmed/24368836</u>

No evidence vaccine reduces incidence of HPV

#### 10. On the relationship between human papilloma virus vaccine and autoimmune disease,

http://www.thesleuthjournal.com/study-reveals-unavoidable-danger-hpv-vaccines/#more-36352 The study points out, "Along with the introduction of the HPV vaccines, several cases of onset or exacerbations of autoimmune diseases following the vaccine shot have been reported in the literature and pharmacovigilance databases, triggering concerns about its safety."

#### 11. Shocking statistics about the HPV Vaccine

http://www.thesleuthjournal.com/shocking-statistics-about-the-hpv-vaccine/#more-18226 "Six years after the introduction of Gardasil, "it appears there are more reports of abnormal pap smears, cervical dysplasia and cervical cancer in the HPV vaccine target market." In fact, the American Journal of Obstetetrics and Gynecology released a study in January 2013 of a "large cervical cancer screening trial" which found that "in a sub group of 12,852 young women, the HPV vaccine reduced HPV-16 infections by only 0.6%. The study also reported that the increase rate of infections by carcinogenic HPV types in vaccinated women is four to ten times higher than the reduction in HPV infections." To make that exceptionally clear, this means that if you get the Gardasil vaccine, you are more likely to contract the most dangerous, carcinogenic strains of HPV! These results should get drug makers arrested, not increased revenue.

A study published in Pediatrics magazine found that parents are increasingly refusing to give their teen daughters the Gardasil vaccine, while at the same time physicians are increasingly recommending the vaccine. Given it's shameful track record, why are more doctors recommending the HPV vaccine?

A Gardasil vaccine is only 'effective' against four types of HPV virus' and there are 150 types. Is it really worth the risk to have your child injected with Gardasil?"

#### 12. Former Merck Physician speaks out against Gardasil.

http://www.collective-evolution.com/2015/01/25/mercks-former-doctor-predicts-gardasil-to-become-the-greatest-medical-scandal-of-all-time/

"There is a long list of educated people speaking out about this vaccine. This time around, it's Dr. Bernard Dalbergue, a former pharmaceutical industry physician with Gardasil manufacturer Merck who has started to raise his voice against the HPV vaccine, along with the pharmaceutical industry as a whole. He joins a long list of experts from within the industry who have slammed the rampant manipulation and control of clinical research done by the pharmaceutical industry."

# 13. Detection of human papillomavirus (HPV) L1 gene DNA possibly bound to particulate aluminum adjuvant in the HPV vaccine Gardasil

http://www.sciencedirect.com/science/article/pii/S016201341200267X HPV DNA particles bound to aluminium adjuvant.

"The clinical significance of these residual HPV DNA fragments bound to a particulate mineral-based adjuvant is uncertain after intramuscular injection, and requires further investigation for vaccination safety."

# 14. Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination

Little DT1, Ward HR.

BMJ Case Rep. 2012 Sep 30;2012. pii: bcr2012006879. doi: 10.1136/bcr-2012-006879. http://www.ncbi.nlm.nih.gov/pubmed/23035167

#### Abstract

Premature ovarian failure in a well adolescent is a rare event. Its occurrence raises important questions about causation, which may signal other systemic concerns. This patient presented with amenorrhoea after identifying a change from her regular cycle to irregular and scant periods following vaccinations against human papillomavirus. She declined the oral contraceptives initially prescribed for amenorrhoea. The diagnostic tasks were to determine the reason for her secondary amenorrhoea and then to investigate for possible causes of the premature ovarian failure identified. Although the cause is unknown in 90% of cases, the remaining chief identifiable causes of this condition were excluded. Premature ovarian failure was then notified as a possible adverse event following this vaccination. The young woman was counselled regarding preservation of bone density, reproductive implications and relevant follow-up. This event could hold potential implications for population health and prompts further inquiry.

15. HPV Vaccine: A Strong Criticism from Leading Israeli OBGYN Doctor http://www.digitaljournal.com/pr/1481510#ixzz2fjvSqr59

Rochester, NY (PRWEB) September 22, 2013

The CBCD has learned that Dr. Uzi Beller, "an international authority on gynecological cancers who treats patients on a daily basis (1)", came out publicly against vaccinating 65,000, 14-year old girls in Israel with Gardasil (1). Dr. Beller voiced his criticism of Gardasil vaccination at "a meeting in Tel Aviv 10 days ago (with) 40 leading experts on gynecology, oncology, women's health, vaccines and other specialties (1)."

When describing his opposition to Gardasil vaccination, Dr. Beller said, "I am not at all against vaccines. I just underwent the oral polio vaccination as the Health Ministry instructed medical institutions to give the two drops to every doctor who is in direct contact with patients. But, HPV is different from all other vaccines. It is not a vaccination against cervical cancer but against a virus that in some cases causes a premalignant condition, and in a small number of cases, a malignancy (1)."

**16.** Acute disseminated Encephalomyelitis following vaccination against Human Papilloma Virus B. Wildemann, S. Jarius, M. Hartmann, J. U. Regula and C. Hametner

Neurology 2009;72;2132-2133

<u>http://holyhormones.com/wp-content/uploads/downloads/2010/04/ADEM\_post\_Gardasil1.pdf</u> We report a case of severe encephalitis evolving shortly after administration of a new vaccine against human papilloma virus (HPV) recently approved for the prevention of diseases caused by HPV types 6, 11, 16, and 18.

#### 17. HPV Vaccine Injuries and Deaths Now Being Reported from Central and South America http://healthimpactnews.com/2015/hpv-vaccine-injuries-and-deaths-now-being-reported-from-

central-and-south-america/

On May 22, 2015, 16-year old Karen Durán-Cantor diedafter complications related to new onset autoimmune disorders believed to have been triggered by two injections of Gardasil, the human papillomavirus vaccine currently being given to school age girls throughout the country. 18. Early cervical myelitis after human papilloma virus vaccination

Mireya Fernández-Fournier, MD, corresponding author Javier Díaz de Terán, MD, Antonio Tallón Barranco, MD, PhD, and Inmaculada Puertas, MD, PhD

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204223/ Discussion

The relationship between HPV vaccination and subsequent CNS inflammation remains unclear. A recent review summarizes 9 published cases of CNS demyelination following HPV vaccination; clinical syndromes vary and include myelitis, optic neuritis, and encephalitis.4 In the genesis of CNS inflammatory disorders post-HPV vaccination, both molecular mimicry between vaccine antigen and myelin proteins and toxic materials in vaccine components are seen as potential causative factors.5 There are previous reports of CNS inflammatory syndromes following HPV vaccination describing a 10-day to 5-month time lapse from vaccination to symptom onset, with a minimum of a 21-day interval in cases developing myelitis.

19. Suspected side effects to the quadrivalent human papilloma vaccine (Denmark) Brinth L1, Theibel AC, Pors K, Mehlsen J.

Dan Med J.2015 Apr; 62(4):A5064.

http://www.ncbi.nlm.nih.gov/pubmed/25872549

Abstract

INTRODUCTION:

The quadrivalent vaccine that protects against human papilloma virus types 6, 11, 16 and 18 (Q-HPV vaccine, Gardasil) was included into the Danish childhood vaccination programme in 2009. During the past years, a collection of symptoms primarily consistent with sympathetic nervous system dysfunction have been described as suspected side effects to the Q-HPV vaccine. METHODS:

We present a description of suspected side effects to the Q-HPV vaccine in 53 patients referred to our Syncope Unit for tilt table test and evaluation of autonomic nervous system function. RESULTS:

All patients had symptoms consistent with pronounced autonomic dysfunction including different degrees of orthostatic intolerance, severe non-migraine-like headache, excessive fatigue, cognitive dysfunction, gastrointestinal discomfort and widespread pain of a neuropathic character. CONCLUSION:

We found consistency in the reported symptoms as well as between our findings and those described by others. Our findings neither confirm nor dismiss a causal link to the Q-HPV vaccine, but they suggest that further research is urgently warranted to clarify the pathophysiology behind the symptoms experienced in these patients and to evaluate the possibility and the nature of any causal link and hopefully establish targeted treatment options.

20. Orthostatic intolerance and postural tachycardia syndrome as suspected adverse effects of vaccination against human papilloma virus
Brinth LS1, Pors K1, Theibel AC1, Mehlsen J2.
Vaccine. 2015 May 21;33(22):2602-5. doi: 10.1016/j.vaccine.2015.03.098.
Epub 2015 Apr 14.
<a href="http://www.ncbi.nlm.nih.gov/pubmed/25882168">http://www.ncbi.nlm.nih.gov/pubmed/25882168</a>
Abstract
BACKGROUND:
Infections with human papilloma virus (HPV) can result in cervical, oropharyngeal, anal, and penile cancer and vaccination programs have been launched in many countries as a preventive measure. We

report the characteristics of a number of patients with a syndrome of orthostatic intolerance, headache, fatigue, cognitive dysfunction, and neuropathic pain starting in close relation to HPV vaccination.

**METHODS:** 

Patients were referred for orthostatic intolerance following HPV vaccination. Symptoms of autonomic dysfunction were quantified by standardised questionnaire. The diagnosis of postural orthostatic tachycardia syndrome (POTS) rested on finding a sustained heart rate increment of >30 min(-1) (>40 min(-1) in adolescents) or to levels >120 min(-1) during orthostatic challenge. RESULTS:

35 women aged 23.3 ± 7.1 years participated. Twenty-five had a high level of physical activity before vaccination and irregular periods were reported by all patients not on treatment with oral contraception. Serum bilirubin was below the lower detection limit in 17 patients. Twenty-one of the referred patients fulfilled the criteria for a diagnosis of POTS (60%, 95%CI 43-77%). All patients had orthostatic intolerance, 94% nausea, 82% chronic headache, 82% fatigue, 77% cognitive dysfunction, 72% segmental dystonia, 68% neuropathic pain.

CONCLUSIONS:

In a population referred for symptoms of orthostatic intolerance and other symptoms consistent with autonomic dysfunction that began in close temporal association with a quadrivalent HPV vaccination, we identified a 60% prevalence of POTS. Further work is urgently needed to elucidate the potential for a causal link between the vaccine and circulatory abnormalities and to establish targeted treatment options for the affected patients.

21. Human papilloma virus vaccine and primary ovarian failure: another facet of the autoimmune/inflammatory syndrome induced by adjuvants Colafrancesco S1, Perricone C, Tomljenovic L, Shoenfeld Y.

1 Zabludowicz Center for Autoimmune Diseases Sheba Medical Center, Tel-Hashomer, Israel; Rheumatology Unit, Department of Internal Medicine and Medical Specialities, Sapienza University of Rome, Rome, Italy.

Am J Reprod Immunol. 2013 Oct;70(4):309-16. doi: 10.1111/aji.12151. Epub 2013 Jul 31

#### http://onlinelibrary.wiley.com/doi/10.1111/aji.12151/abstract;jsessionid=C63796AEE1A7579C33ECF F5E21D18FB8.f04t02

## Abstract

## PROBLEM:

Post-vaccination autoimmune phenomena are a major facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and different vaccines, including HPV, have been identified as possible causes.

## **METHOD OF STUDY:**

The medical history of three young women who presented with secondary amenorrhea following HPV vaccination was collected. Data regarding type of vaccine, number of vaccination, personal, clinical and serological features, as well as response to treatments were analyzed.

## **RESULTS:**

All three patients developed secondary amenorrhea following HPV vaccinations, which did not resolve upon treatment with hormone replacement therapies. In all three cases sexual development was normal and genetic screen revealed no pertinent abnormalities (i.e., Turner's syndrome, Fragile X test were all negative). Serological evaluations showed low levels of estradiol and increased FSH and LH and in two cases, specific auto-antibodies were detected (antiovarian and anti thyroid), suggesting that the HPV vaccine triggered an autoimmune response. Pelvic ultrasound did not reveal any abnormalities in any of the three cases. All three patients experienced a range of common non-specific post-vaccine symptoms including nausea, headache, sleep disturbances, arthralgia and a range of cognitive and psychiatric disturbances. According to these clinical features, a diagnosis of primary ovarian failure (POF) was determined which also fulfilled the required criteria for the ASIA syndrome. **CONCLUSION:** 

We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry.

#### 22. Case Study

Clin Exp Rheumatol. 2015 Jul-Aug;33(4):545-8. Epub 2015 May 11.

Autoimmune/auto-inflammatory syndrome induced by adjuvants (ASIA) after quadrivalent human papillomavirus vaccination in Colombians: a call for personalised medicine.

Anaya JM (1), Reyes B (1), Perdomo-Arciniegas AM (2), Camacho-Rodríguez B (2), Rojas-Villarraga A(1). 1) Centre for Autoimmune Diseases Research (CREA), Universidad del Rosario; and Mederi Hospital Universitario Mayor, Bogota, Colombia.

2) Banco de Sangre, Tejidos y Células, Hemocentro Distrital, Secretaría de Salud de Bogota, Bogota, Colombia.

#### Abstract

This was a case study in which 3 patients with autoimmune/auto-inflammatory syndrome induced by adjuvants (ASIA) after quadrivalent human papillomavirus vaccination (HPV) were evaluated and described. All the patients were women. Diagnosis consisted of HLA-B27 enthesitis related arthritis, rheumatoid arthritis and systemic lupus erythematous, respectively.

Our results highlight the risk of developing ASIA after HPV vaccination and may serve to increase the awareness of such a complication. Factors that are predictive of developing autoimmune diseases should be examined at the population level in order to establish preventive measures in at-risk individuals for whom healthcare should be personalized and participatory.

#### 23. Neurologic adverse events following vaccination

Prog Health Sci 2012, Vol 2, No 1 Neurologic adverse events vaccination Sienkiewicz D.\*, Kułak W., Okurowska-Zawada B., Paszko-Patej G. Department of Pediatric Rehabilitation of the Medical University of Bialystok, Poland Access to full article:

http://www.rescuepost.com/files/prog-health-sci-2012-vol-2-no1-neurologic-adverse-events-vaccination.pdf

#### Abstract

The present review summarizes data on neurological adverse events following vaccination in the relation to intensity, time of onset, taking into account the immunological and non-immunological mechanisms. The authors described the physiological development of the immune system and the possible immune system responses following vaccination. Toxic property of thimerosal – a mercury-containing preservative used in some vaccines was presented. The neurological complications after vaccination were described. The role of vaccination in the natural course of infectious diseases and the current immunizations schedule in Poland was discussed.

#### Conclusions

Despite the assurances of the necessity and safety of vaccinations, there are more and more questions and doubts, which both physicians and parents are waiting to be clarified. This paper describes several aspects of the immunization program of children. It includes: the physiological development of the immune system, the immunization schedule adopted in Poland in comparison with other countries, adverse reactions and complications following vaccination described in scientific publications, the natural course of infectious diseases in conjunction with the vaccination programs implemented and the problem of reporting adverse reactions following vaccination by medical personnel and parents. The proposal for changes in vaccination in Poland cited at the end of this paper is, according to the authors, part of the answer to the concerns and doubts. A second part would be extensive neuro-immunological research confirming or excluding the relationship of vaccines with the reported adverse events (early, late/long-term) and chronic diseases whose upward trend has been observed in recent decades in children.

It seems that it would be worthwhile to apply the precautionary principle – the ethical principle (from 1988) according to which if there is a probable, although poorly known, risk of adverse effects of new technology, **it is better not to implement it rather than risk uncertain but potentially very harmful consequences**. (emphasis added)

## **Appendix D : Gardasil/Cervarix/Silgard victims**

There are so many victims of Gardasil / Cervarix and they or someone else has told their stories at the following web sites:

http://vaccineimpact.com/2015/13-year-old-world-championship-karate-student-forced-to-quit-aftergardasil-vaccine/ http://healthimpactnews.com/2014/gardasil-vaccine-one-more-girl-dead/ http://fox4kc.com/2014/08/08/girl-with-sore-throat-gets-hpv-vaccine-dies-hours-later/ http://sanevax.org/i-want-my-daughters-life-back-the-way-it-was-before-gardasil/ http://sanevax.org/cervarix-one-mothers-experience-with-hpv-vaccine-damage/

For anyone with an open mind, it doesn't take long to find reports of all types of vaccine injuries, not just HPV vaccine injuries. But for those who don't want to acknowledge this truth then "then is none so blind as those who will not see"

# \$6,000,000 paid out to GARDASIL Victims

http://www.washingtontimes.com/news/2014/dec/31/us-court-pays-6-million-gardasil-victims/?page=all

Here is a quote from the above article:

US Court pays \$6million to Gardasil victims

The facts appear to contradict the FDA's safety statements. The adverse reaction reports detail 26 new deaths reported between September 1, 2010 and September 15, 2011 as well as incidents of seizures, paralysis, blindness, pancreatitis, speech problems, short term memory loss and Guillain-Barré Syndrome. The documents come from the FDA's Vaccine Adverse Event Reporting System (VAERS) which is used by the FDA to monitor the safety of vaccines.

That's 26 reported deaths of young, previously healthy, girls after Gardasil vaccination in just one year.

## **Truth About Gardasil**

http://truthaboutgardasil.org http://truthaboutgardasil.org/memorial/

## SANEVAX.ORG

http://sanevax.org/victims-2/

## **Gardasil & Silgard Victims Archives**

http://sanevax.org/victims-2/gardasil-silgard-victims/

## **Cervarix Archives**

The bi-valent HPV vaccine, manufactured by GlaxoSmithKline, Cervarix. Czech Republic, India, Mexico, The Netherlands, Phillipines, United Kingdom, Spain (and South Africa), Japan

## Vaccine Victim Videos Archives -SaneVax, Inc.

http://sanevax.org/videos/vaccine-victim-videos/

## You Tube

https://www.youtube.com/results?search\_query=hpv+vaccine+dangers

## **Vaccination Information Network**

http://www.vaccinationinformationnetwork.com/gardasil-news/

## **Vaccine Injury Info**

http://vaccine-injury.info/gardasil.cfm Here are some stories ...

## Brittany Fiste (Gardasil in 2007)

Uploaded on 3 Jun 2009

https://www.youtube.com/watch?v=0gCVCP8BFrU

Brittney gives an emotionally charged overview of what her life has been like for the past two years. She struggles daily with the fact her life has been forever changed. A doctor frightened her into taking the Gardasil vaccine by telling her she could get an HPV through a "possible" lab accident at college - where her blood could mingle with someone elses who had an HPV. She was never told HPV's are sexually transmitted deseases. and having no other information, she allowed herself to be given a vaccine she never needed. Now she wishes the TRUTH to be told - more testing of this vaccine is warranted before another young woman is injured..

## Gardasil: another victim's family speaks out (Brittany Fiste)

Brittney Fiste - Written Testimony http://www.examiner.com/article/gardasil-another-victim-s-family-speaks-out-1

## Parent Urges Caution Over Cervical Cancer Vaccine After Daughter's Experience

NWT, Fri, 21st Aug

Listen to the radio interview here:

<u>http://oceanfm.ie/parent-urges-caution-over-cervical-cancer-vaccine-after-daughters-experience-nwt-fri-</u>21st-aug/

## Irish radio station

Irish mother speaks about her daughter's HPV vaccination experience. The R.E.G.R.E.T. group has grown from 6 members to 65 in a very short period of time.

## The Murdering of Our Daughters - Dave Hodges - The Common Sense Show

THECOMMONSENSESHOW.COM http://www.thecommonsenseshow.com/2013/09/17/the-murdering-of-our-daughters/

## 6248 Permanent Injuries and 144 Deaths Following Gardasil HPV Vaccine:

http://healthimpactnews.com/2013/6248-permanent-injuries-and-144-deaths-following-gardasil-hpv-vaccine-coincidence-or-scandal/

## HPV Vaccine Victim Sues Merck | Gardasil Dangers

http://articles.mercola.com/sites/articles/archive/2012/01/24/hpv-vaccine-victim-sues-merck.aspx **Naomi Snell**, a 28-year-old woman in Melbourne, Australia, is leading a class-action civil lawsuit against drug maker Merck after suffering autoimmune and neurological complications following injections with the HPV vaccine, Gardasil.

After receiving the first of three doses of the vaccine, Naomi suffered convulsions, severe back and neck pain, and lost her ability to walk.

Doctors actually diagnosed her with multiple sclerosis, which was later retracted and labeled a neurological reaction to the vaccine.

<u>Seven other women</u>, who say they have suffered various physical problems, including anaphylaxis and miscarriage, after receiving Gardasil may also join the civil lawsuit, and this is likely only the beginning, as Gardasil is being implicated in a growing number of serious, permanent and sometimes deadly adverse reactions.

Multiple Sclerosis-Like Symptoms and Paralysis Not Unusual After HPV Vaccination

Unfortunately, stories like Naomi's are all too common in relation to Gardasil.

One of the vaccine injury cases featured in the movie The Greater Good is that of <u>Gabi Swank, a 15-year-old honor student</u> who decided to get the Gardasil vaccine after seeing a "Be One Less" Gardasil vaccine advertisement on TV.

Like so many young girls, she wasn't warned about any possible side effects when she got the shots, which are given as a series of three injections.

At the time the documentary was filmed, she had already suffered two strokes and experienced partial paralysis. She also lost part of her vision and today suffers frequent seizures. When she was in high school, many days she had to use a wheelchair to get around school due to muscle pain and chronic fatigue.

A similar reaction happened to **<u>13-year-old Jenny Tetlock</u>**, who began seeing signs of trouble just one month after she was vaccinated against the HPV virus. Fifteen months later, a degenerative muscle disease left her nearly completely paralyzed.

Neurological symptoms such as these were also reported in a study done <u>in 2009 by neurologist Dr. Ian</u> <u>Sutton</u>. He reported five cases of multiple sclerosis-like symptoms emerging shortly after women received the Gardasil vaccine, noting:

"We report five patients who presented with multifocal or atypical demyelinating syndromes within 21 days of immunization with the quadrivalent human papilloma virus (HPV) vaccine, Gardasil. Although the target population for vaccination, young females, has an inherently high risk for MS, the temporal association with demyelinating events in these cases may be explained by the potent immuno-stimulatory properties of HPV virus-like particles which comprise the vaccine."

Further, Judicial Watch, a public interest group that investigates and prosecutes government corruption, recently issued an update on adverse reaction reports relating to Gardasil.

The documents obtained from the U.S. Food and Drug Administration (FDA) under the provisions of the Freedom of Information Act (FOIA) detail <u>26 new deaths reported to the government following HPV</u> <u>vaccination between September 1, 2010 and September 15, 2011.</u> That's 26 reported deaths of young, previously healthy, girls after Gardasil vaccination in just one year.

Other serious side effects reported during that time frame included:

Seizures Paralysis Blindness Pancreatitis Speech problems Short term memory loss Guillain-Barre syndrome Ovarian cysts Between May 2009 and September 2010, 16 deaths after Gardasil vaccination were reported. For that timeframe, there were also 789 reports of "serious" Gardasil adverse reactions, including 213 cases of permanent disability and 25 diagnosed cases of Guillain Barre Syndrome, Judicial Watch reported.

#### Serious Vaccine Reactions, Deaths, Often Labeled "Coincidence"

While it is not clear exactly what is causing so many adverse reactions, it is known that Gardasil contains genetically engineered virus-like protein particles as well as aluminum, which can affect immune function. Further, according to the vaccine manufacturer product information insert, the vaccine has not been evaluated for the potential to cause cancer or to be toxic to genes.

(SK Note Also see : <u>http://www.newsweek.com/2014/11/21/medical-science-has-data-problem-</u> 284066.html on genetically modified virus in HPV vaccine)

In fact, Merck only studied the Gardasil vaccine in fewer than 1,200 girls under 16 prior to it being released to the market under a fast-tracked road to licensure. To date, most of the serious side effects, including deaths, that occurred during the pre-licensure clinical trials and post marketing surveillance have been written off as a "coincidence" by Merck researchers and government health officials.

But on the National Vaccine Information Center's (NVIC) Web site, you can read about <u>Gabi Swank's</u> <u>Gardasil reaction</u> and other descriptions of women and girls who have suffered serious health deterioration after Gardasil shots and, in some cases, have died shortly after receiving this vaccine. The growing Gardasil vaccine injury toll has become too large to ignore:

Christina Tarsell, a 21-year-old college student majoring in studio arts at Bard College, who died suddenly and without explanation shortly after receiving the third Gardasil shot in June 2008.

Megan, a 20-year-old college student who died suddenly, without explanation, about one month after receiving her third Gardasil shot. No cause of death was found.

Ashley, a 16-year-old who became chronically ill after receiving Gardasil, and now suffers regular lifethreatening episodes of seizure-like activity, difficulty breathing, back spasms, paralysis, dehydration, memory loss and tremors.

## My Girl Died As 'Guinea Pig' For Gardasil

Jessica Ericzon, 17 July 20, 2008 <u>http://nypost.com/2008/07/20/my-girl-died-as-guinea-pig-for-gardasil/</u>

## Ashley Ryburn's life ruined by HPV Gardasil vaccine

https://www.youtube.com/watch?v=1j5zUFzRkws

## HPV Gardasil Vaccine Proves Lethal -140 Girls have now Died

https://www.youtube.com/watch?v=\_pTUtP0K4E4

## **Meet Nicole**

## VAXTRUTH.ORG

## http://vaxtruth.org/2013/09/meet-nicole/

On January 29th, 2011, I went to a gynecological appointment with my fiancé to discuss birth control pills... On January 29th, 2011, I went to a gynecological appointment with my fiancé to discuss birth control pills and get my first set of HPV Gardasil vaccinations. I believed the vaccine was important. I personally had never taken the time to research vaccinations or Gardasil. I believed it was a part of the 'healthcare' system. I had seen the commercials and wanted to be 'one less girl' affected by cervical cancer. I didn't know the ingredients, the real statistics on HPV, cervical cancer, or even how long it had been studied and tested. I knew nothing about the vaccine but trusted my doctors.

## The Dark Side Of Gardasil: My Story

YOUTUBE.COM https://www.youtube.com/watch?v=VzEgeCw-EAw

# Legal precedent in Colombia: Landmark decision for HPV vaccine survivor

http://sanevax.org/legal-precedent-colombia-landmark-decision-hpv-vaccine-survivor/

14 November 2014: A 15 year-old survivor of HPV vaccination, living in El Carmen de Bolivar, Colombia, South America, is the recipient of the first judgment issued by any High Court in the country in a case regarding complications occurring after HPV vaccination. In this landmark decision the court ruled that the fundamental rights of this girl and her newborn daughter have to be protected by Colombian health authorities.

## Gardasil: A Deadly Vaccine - Gary Null PhD

THEREFUSERS.COM http://therefusers.com/.../gardasil-a-deadly-vaccine.../...

## All around the world, people are setting up web sites and Facebook pages for those injured by HPV vaccines

Video proof of convulsions after injection with Gardasil:

School children in Mexico injured by Gardasil and Cervarix vaccines. This happened 8/31/15. https://www.facebook.com/VaxTruth/posts/1052155548136861?hc\_location=ufi https://www.facebook.com/AVPHMEX https://www.youtube.com/watch?v=228L5MmlEBo&feature=youtu.be http://www.infowars.com/shocking-young-girls-convulse-on-the-floor-after-hpv-shot/ http://inicio.aavp.es/ (refers to above report)

## **Appendix E - South African Informed Consent**

## WHAT THE SOUTH AFRICAN DEPARTMENT OF HEALTH MUST DO AND PROVIDE FOR PUBLIC AWARENESS ON THE HPV VACCINE TO ENSURE INFORMED CONSENT:

Parents are not informed as to which HPV vaccine is to be used in South Africa, on the HPV invitation letter signed by Dr Aaron Motsoaledi, the Minister of Health and Ms Motshega, Minister of Basic Education for the vaccination rollout in March 2014.

# Could a 12 year old child understand what is written in this document?

On the Basic Education Health, Human Papillomavirus (HPV) Vaccination Consent\* Form It states that -

#### "\*\*Girls who are 12 years and older can assent by signing in the space provided. "

Are we to understand that a child can make this medical decision without the consent of the parent and possible influence of the teacher or vaccine administrator?

#### According to medical protection.org

https://www.medicalprotection.org/southafrica/factsheets/consent-the-basics

"Correct as of December 2013

In terms of s129(2) of the Children's Act 38 (2005), a child may consent to his/her own medical treatment or the medical treatment of his/her child if he/she is over the age of 12 years and is of sufficient maturity to understand the risks of the treatment and the benefits associated with the treatment.

Respect for patients' autonomy is expressed in consent law; to impose care or treatment on people without respecting their wishes and right to self-determination is not only unethical, but illegal.

# It is an offence to provide a health service without informed consent

It is an offence to provide a health service to a user without their informed consent, under the National Health Act 2003 (there are some exceptions to this, such as in cases of emergency or when there is a risk posed to public health). In addition, the National Patients Health Charter (2008) states: "Everyone has a right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and the costs involved for one to make a decision that affects any one of these elements."

This form also states that the -

"1. The vaccine is safe with minimal risk to the girl. "

Below you will see that this statement is false and that informed consent cannot be given with the information that has been provided by the South African Department of Health.

This form also states that -

"8. If any of these problems get worse go to the nearest clinic or hospital and take the HPV immunisation card with you."

What if the "problems" are too severe for the child to travel to the nearest clinic or the clinic is closed? Is an emergency number provided in this case?

This form also states that -

"Please note that the HPV vaccination cannot be given to girls who are under 9 years, or if they have had a recent severe illness, or are very ill on the day of the vaccination. The HPV vaccination will also not be given to girls who are pregnant or have already had the HPV vaccination. "

What if the child is not yet aware they are pregnant?

Due to the misinformation that has been sent out by the South African Department of Health on the subject of the HPV vaccine, we cannot see how any parent is able to give informed consent, let alone a minor.

We therefore ask the following questions regarding informed consent on the HPV vaccine roll-out and the parent's information pack:

Are the vaccine package inserts or a copy of these inserts provided to parents to read prior to obtaining consent?

Have South African government health officials required any modifications to the HPV vaccine package inserts such as the below requirements made by the Japanese Ministry of Health? "Does the vaccine package inserts include stronger safety warnings to medical consumers regarding the possibility of Acute disseminated encephalomyelitis (ADEM), Guillain-Barre and neurological

ing the possibility of Acute disseminated encephalomyelitis (ADEM), Guillain-Barre and neurological problems."

On March 26, 2013, the Japanese Ministry of Health, Labor and Welfare informed GlaxoSmithKline they had 30 days to alter the package insert for Cervarix by adding the following to the Precau- tions/Adverse Reactions section:

"Acute disseminated encephalomyelitis (ADEM): Acute disseminated encephalomyelitis (ADEM) may occur. In such cases, pyrexia, headache, convulsion, movement disorder, and disturbed con- sciousness, etc., generally occur within several days to 2 weeks after vaccination. If ADEM is sus- pected, diagnosis should be made by MRI etc., and appropriate measures should be taken.

Guillain-Barre syndrome: Guillain-Barre syndrome may occur. If any symptoms such as flaccid paralysis originating from the distal extremities, decreased or absent tendon reflexes, appropriate measures should be taken."

This letter required the manufacturers of Gardasil and Cervarix to add the following to the 'Precautions' section of their package inserts within the next 30 days:

"Although the mechanisms of pathogenesis are unclear, severe pain which is not localized at the injection site (e.g. muscle pain, arthralgia and skin pain, etc.), numbness, weakness, etc., may occur after vaccination and these symptoms may persist for long time. Vaccine recipients and their guard- ians should be instructed to consult a healthcare provider who can provide appropriate medical care including making neurological and immunological differential diagnosis if any abnormalities are observed after vaccination."

## WHAT SA GOVERNMENT MUST DO AND PROVIDE FOR PUBLIC AWARENESS AND INFORMED CONSENT:

Other queries to Dr Motsoaledi, the South African Minister of Health

#### Do you, Dr Motsoaledi, believe in the right to informed consent?

South African parents have not been adequately informed of the serious potential risks involved, such as death, even if rare of the HPV to enable them to give informed consent.

(VAERS received 12 424 reports of AEFIs following qHPV distribution, a rate of 53.9 reports per 100,000 doses distributed. A total of 772 reports (6.2% of all reports) described serious AEFIs, including 32 reports of death. The reporting rates per 100,000 qHPV doses distributed were 8.2 for syncope; 7.5 for local site reactions; 6.8 for dizziness; 5.0 for nausea; 4.1 for headache; 3.1 for hypersensitivity reactions; 2.6 for urticaria; 0.2 for venous thromboembolic events, autoimmune disorders, and Guillain-Barré syndrome; 0.1 for anaphylaxis and death; 0.04 for transverse myelitis and pancreatitis; and 0.009 for motor neuron disease. Disproportional reporting of syncope and venous thromboembolic events was noted with data mining methods.)

http://www.ncbi.nlm.nih.gov/pubmed/19690307 and as stated and acknowledged on the American CDC (Centre of Disease Control) website

Are parents aware that data on the HPV efficacy against early stages of cervical cancer, are only available for females aged 15-17 years, not for 12-14 year-olds?

Are parents aware that a booster shot will be required since according to Dr. Diane Harper, the leading international developer of the HPV vaccines, "if you vaccinate a child, she won't keep im- munity in puberty and you do nothing to prevent cervical cancer." Dr. Harper emphasized the need for Gardasil booster shots, because it is still unknown how long the vaccine immunity lasts. More booster shots mean more money for Merck, obviously and more risk for children.

Are parents made aware that the most effective prevention to reduce the incidence of cervi- cal cancer is still the pap smear, which is by far the safer alternative and currently in the USA, one particular HPV blood test is starting to be recommended in place of the "Pap smear" test because it has been "shown" to give fewer false negatives than the "Pap smear".

http://consumer.healthday.com/women-s-health-information-34/misc-women-s-problem-news-707/fda-experts-debate-pap- smear-s-future-685746.html

Will parents be notified of the possible effect on fertility (primary ovarian failure) and post-vaccination autoimmune phenomena, which are a major facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and different vaccines, including HPV, have been identified as possible causes. (Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants; American Journal of Reproductive Immunology; Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y; doi: 10.1111/aji.12151.) http://www.ncbi.nlm.nih.gov/pubmed/23902317

"We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry.

Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination, BMJ Reports 2012, Deirdre Therese Little, Harvey Rodrick Grenville Ward, doi:10.1136/bcr-2012-006879.

Polysorbate 80 Causes Infertility, An Emulsifier That Can Damage Your Reproductive Health Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats. Gajdová M, Jakubovsky J, Války J., Food and Chemical Toxicology, 1993 Mar;31(3):183-90.

Will parents be notified that there was 200 events reported to the American Adverse affects VAERS detailing abnormal pap smears in girls who have had Merck's HPV Vaccination Gardasil?

Will parents therefore be advised to have their children have pap smears after receiving the HPV vaccine.

Will parents be made aware that the rate of deaths as a result of cervical cancer were already in decline in the developed world prior to the HPV vaccine? The American Cancer Society (ACS) notes that "between 1955 and 1992, the cervical cancer death rate declined by 74%" and adds that "the death rate from cervical cancer continues to decline by nearly 4% each year.

Are parents aware of the fast tracking of Gardasil (a mere six months of trial research) through the FDA without due scientific process and adequate research and conflicts of interest in how this vaccine came on the market? Merck was caught lobbying the 50 states for mandatory Gardasil vac- cination before it had even secured FDA approval.

That the study was funded solely by Merck, which manufactures Gardasil, and all of the authors had financial ties to Merck. Most significantly, in every clinical trial evaluating safety for both Gar- dasil and Cervarix, the so-called placebo groups were given injections that included an active alu- minum adjuvant. Though this is a common practice in vaccine trials, it is obviously a blatant means of biasing the results. Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome In- duced by Adjuvants; American Journal of Reproductive Immunology; Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y; doi: 10.1111/aji.12151.

Also, there are no restrictions with regard to conflicts of interest for the employees of the CDC or for those of the FDA (Kuehn, 2010). Each employee of either agency is allowed to own stock in drug companies. Dr. Julie Gerberding, former director of the U.S. Centers for Disease Control and Pre- vention, was named president of Merck & Co Inc's vaccine division in 2009.

#### Gardasil Profit:

2012 sales: \$1.900 billion 2011 sales: \$1.2 billion.

When you factor in all the information unknown to the public. Does science really have anything to do with why this drug is even on the market?

## Is there a cheaper alternative?

Researchers have been trying to find a cost-efficient method of detecting the cancer before it's too late. "After years of work, a group of scientists have developed an alternative test to Pap smears. The vinegar test is inexpensive and can be carried out with very little training and not much need for equipment. It involves swabbing the cervix with vinegar, which makes any pre-cancerous tu- mors turn white. The results can be seen within just minutes."

A total of 150,000 women living in the slums of Mumbai took part in the study. The results re- vealed that the vinegar test reduced cervical cancer deaths in the area by an overwhelming 31 percent. Experts predict that over 22,000 deaths in India and 72,600 deaths worldwide could be prevented as a result of this new method of screening.

http://www.medicalnewstoday.com/articles/261381.php

This can screen out those at risk from the 90-plus % of women who have no risk (and, in conjunc- tion with a cyrostatic (dry-ice cooled) probe, can also be used to treat the lesions found in those women with them), which should be used instead of either a "Pap smear" test or the recent FDA- approved blood test in developing countries as well as in those developed countries that wish to minimize their healthcare costs while maximizing the health of the people.

On the Basic Education Health, Guide for Educators, point 3.9 states,-

"All girls that were vaccinated will be observed for 15 minutes before they are returned to class. Have doctors, nurses and other medical staff, especially those that are administering the vaccines been issued with unified diagnostic criteria to help them recognize symptoms induced by the vaccine such as: ADEM GBS

Along with other symptoms as reported to VAERS such as: blood pressure decreased irregular heartbeat heartbeat decrease oxygen saturation decrease blood sodium decrease which were all common with syncope and tonic-clonic episodes (formerly known as grand mal seizures) loss of bladder control Syncope (fainting) Respiratory, thoracic and mediastina disorders

Other symptoms of note are weakness and tingling of the extremities on one or both sides.

Have doctors in targeted vaccine areas been alerted to the adverse effects and sometimes delayed symptoms of the HPV vaccine and provided with protocols on patient care and who to report adverse reactions to.

The updating of the labeling for Gardasil required by the FDA is an admission that these conditions do exist and are of concern.

Are parents and medical staff informed of VAERS and the reporting process of adverse HPV reactions.

How many reports of ADEM or GBS have been filed in South Africa after HPV vaccinations?

Who will be held accountable to any HPV vaccine adverse effects and is a policy in place to financially assist HPV vaccine damaged children for medical costs and other related costs?

Have you established treatment for HPV vaccine victims?

Set a policy in place to provide financial relief for HPV vaccine victims?

Set a policy in place to investigate all who have been inoculated with HPV vaccines?

Encouraged a protocol of South Africa's top neurological scientists obtaining information on ad- verse effects of the HPV vaccine with other countries such as Japan and Germany, amongst coun- tries who have questioned the safety of the HPV vaccine?

Are black South African parents alerted to the study done by researchers from Duke University who found that although African-American women are twice as likely as Caucasian women to die from cervical cancer, HPV vaccines target strains of HPV that are far less likely to infect them? Are black South African girls being subjected to unnecessary risks even more so than white South Afri- can girls?

The available vaccines only protect against four strains of HPV, which, according to the study African American women are half as likely as White women to carry. Neither Merck nor GlaxoS- mithKline has addressed the lack of coverage for HPV strains prevalent in African American women. Merck is currently testing an updated HPV vaccine that fights nine dangerous strains instead of four-6, 11, 16, 18, 31, 33, 45, 52 and 58. Although their preliminary study results are promising, the disparity will likely remain. "The most disconcerting part of this new vaccine is it doesn't include HPV 35, 66 and 68, three of the strains of HPV of which African-American women are getting the most," said study co-author, Cathrine Hoyo. "We may want to rethink how we develop these vaccines, given that African-Ameri- cans tend to be underrepresented in clinical trials."

Shouldn't these studies and questions confirm that at the very least, black populations should re- frain from HPV vaccines until further evidence is provided that they are safe and effective?

Ref: The findings, presented on Oct. 28, 2013, at the 12th annual International Conference on Frontiers in Cancer Prevention Research hosted by the American Association for Cancer Research. The research was supported by the National Cancer Institute (R01CA142983 and R01CA142983-02S1). The authors reported no conflicts of interest. http://www.dukehealth.org/health\_library/news/hpv-strains-affecting-african-american-women-differ-from-vaccines

Have other risks been explained to parents on vaccines? Such as the risk of autism and thimer- osal-containing vaccines?

A two-phase study evaluating the relationship between Thimerosal-containing vaccine administra- tion and the risk for an autism spectrum disorder diagnosis in the United States which provides new epidemiological evidence supporting an association between increasing organic-Hg exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an ASD diagnosis. It also explains, in concrete terms with examples, why certain other articles "missed" this linkage.

Ref: David A Geier, Brian S Hooker, Janet K Kern, Paul G King, Lisa K Sykes and Mark R Geier. Corresponding author: Mark R Geier mgeier@comcast.net. Translational Neurodegeneration 2013, 2:25 doi:10.1186/2047-9158-2-25 http://www.biomedcentral.com/content/pdf/2047-9158-2-25.pdf

World Health Organization estimate which clearly states that only 0.15% of those infected with carcinogenic HPV (high-risk HPV) will ever develop cervical cancer - much less die from it. According to Dr. Diane Harper, the leading international developer of the HPV vaccines, 70% of HPV infections resolve themselves without treatment in one year. After two years, this rate climbs to 90%. Of the remaining 10% of HPV infections, only half coincide with the development of cervical cancer.

We ask then, why is the South African Department of Health so single-minded on rolling this as yet, unproven to be safe, HPV vaccine?

MERCK Pharmaceuticals was found guilty by a court of law for having caused 27,000 heart at- tacks because of VIOXX. This same company now brings us GARDASIL for our children, claiming it will prevent cancer, but this HPV vaccine has now proven to bring about infertility in some, and autism-like symptoms and birth defects in the offspring of other.

Shouldn't the burden of proof of safety and efficacy be upon those manufacturing, selling, and regulating the product and not the exposed populations who increasingly are being told that these vaccines are safe? Will there be a cancer epidemic in the future because of these vaccines?

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

Dr Meryl Nass is a physician in private practice who is known for uncovering the use of anthrax as a biological weapon in Rhodesia. MOUNT DESERT ISLAND HOSPITAL, 10 Wayman Ln, Bar Harbor, ME 04609, (207) 288-5081 (Office)

## Regarding Gardasil's adverse effects, Dr. Nass said,

"Children don't usually die suddenly when they are healthy but there are certainly lots of teenage girls who have died relatively suddenly after Gardasil or developed severe neurologic reactions. Therefore, if you are going to try to balance safety and efficacy when you prescribe something like a vaccine, you have to know how effective it's going to be. Does this really prevent cervical cancer in young women? And does it prevent it in women who have already been exposed to these viruses? ... So I don't know how other doctors prescribe something like Gardasil ... Basically, they make an assumption that since the FDA has licensed it ... the manufacturer would only market something that's safe, doctors go ahead and prescribe. And what they may not be aware of is that it is extremely hard to link a side effect to a vaccine, for many reasons. Getting a judgment against a manufacturer is very difficult and it has become more difficult due to some recent litigation that reduced manufacturer liability for vaccines in general." Haug CJ, Human Papillomavirus Vaccination - Reasons for Caution, New England Journal of Medicine, August 21, 2008, 359; 861-

## Conclusions

From the start, a vaccine against the human papillomavirus was completely unnecessary. Aside from the unreasonable health risks that come with this vaccine, Gardasil is also the most expensive recommended vaccine on the market and in South Africa cost over 10 times more than what the government pays for a typical vaccine against childhood diseases - depending on the brand, one HPV shot could cost between R595 and R896 although the government will negotiate significantly lower prices than those in the private sector, it will still remain an expensive vaccine. The high vaccine cost can be linked to the monopoly pricing power of vaccine manufacturers seeking to recover high development costs. Their retention of exclusive patent rights and their power to keep vaccine prices high are aided by the absence of compulsory licenses, which could authorize the competitive development of cheaper biogenerics through developing country manufacturers.

http://mg.co.za/article/2013-06-07-life-saving-cancer-vaccine-will-be-difficult-to-implement Maybarduk P, Rimmington S: Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine? Am J Law Med 2009, 35:323-350. PubMed Abstract

Andrus JK, Sherris J, Fitzsimmons JW, Kane MA, Aguado MT: Introduction of human papillomavirus vaccines into developing countries - international strategies for funding and procurement. Vaccine 2008, 26(Suppl 10):K87-92. PubMed Abstract | Pub- lisher Full Text

Padmanabhan S, Amin T, Sampat B, Cook-Deegan R, Chandrasekharan S: Intellectual property, technology transfer and manufac- ture of low-cost HPV vaccines in India. Nat Biotechnol 2010, 28:671-8. PubMed Abstract | Publisher Full Text | PubMed Central Full Text

If HPV vaccines are as good as they should be, all of these questions should be easy to answer. South African citizens have a right to know. It is called the right to informed consent. What is more important to you, Dr Aaron Motsoaledi, - vaccine safety, or vaccine uptake?

# Appendix F : Much of scientific literature - maybe half - maybe untrue



## Shocking report – MAJOR PHARMACEUTICAL COMPANIES FALSIFY OR MANIPULATE TESTS ON DRUGS

Mr Richard Horton, Editor-in-Chief of a well-respected medical journal, *The Lancet*, declared 'Much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness.'

Dr Marcia Angell is a physician and longtime Editor-in-Chief of the *New England Medical Journal*, considered to be one of the most prestigious peer-reviewed medical journals in the world. Angell stated: 'It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of the *New England Journal of Medicine*.'

#### INTERESTING

Engaging in physical activity, such as walking, running or recreational sports, can improve cancer survival.

#### 028 | NATURALMEDICINE.CO.ZA

## SUPERFOODS GIVE AWAY

Answer this simple question and enter into a Lucky Draw to win one of four SuperFood hampers.

Who are the authors of, 'The Magic of Superfoods with Rawlicious Recipes for Radiant Health'.

Email your answer to lecia@naturalmedicine.co.za



Heart disease is a bigger killer for women than breast cancer, but many more women will fear breast cancer and not necessarily think about heart disease as a woman's issue.

## **Appendix G : Criminal Acts of Pharmaceutical Companies**

## Why we can't trust the FDA, the CDC and the pharmaceutical companies, and why we, as patients, need to check and verify information and data

- Below is a list of criminal cases against various pharmaceutical companies, together with details of the billions of dollars in fines. One has to ask the question why nobody went to jail for killing thousands of people?
- Also documented are cases of drugs/products that were approved as safe by the FDA, which were subsequently proven deadly. This proves that the process for the approval of drugs/vaccines is inadequate to prevent unsafe medication from being prescribed to patients.
- Patients are supposed to blindly 'trust their doctor', especially when vaccines are being administered. But how can we when drugs are approved as safe but subsequently proven unsafe and when the doctors are not given the truth about the safety and efficacy of the pharmaceutical products?

Item	Links	Details
1.	http://www.dcclothesline.com/2014/08/28/cdc- whistleblower-makes-official-statement-admits- cdc-hid-vaccine-link-autism/	<b><u>CDC committed fraud</u></b> by withholding information on the MMR vaccine showing a connection with the cause of autism. CDC whistleblower William Thompson has come forward with evidence of this fraud. Brian Hooker recorded conversation with William Thompson. This is the study:
	http://www.dcclothesline.com/2014/10/27/cdc- whistleblower-oh-godwhat/	https://www.ncbi.nlm.nih.gov/pubmed/14754936.
	http://www.ageofautism.com/2014/10/the-	William Thompson included in his statement:
	wakefield-complaint-the-hammer-falls.html http://www.rescuepost.com/files/ori- complaint_rev_1.pdf (34 page complaint sent to CDC by Brian Hooker and Dr Andrew Wakefield).	"I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal Pediatrics. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed"
	http://www.dcclothesline.com/2014/09/07/cdc- caught-billion-dollar-scheme-sell-vaccines/	For the African-American males, this was the increased risk of autism by earlier administration of the MMR vaccine:
	http://www.jeffereyjaxen.com/blog/congressma n-poesy-delivers-bombshell-cdc-whistle-blower-	MMR vaccination after 36 months - 1.0 risk of autism. (The rate of autism at that time.) MMR vaccination prior to 36 months - 3.36 fold increase in the risk of autism.

	evidence-to-us-house-calls-for-investigation https://sharylattkisson.com/cdc-scientist-we- scheduled-meeting-to-destroy-vaccine-autism- study-documents/ https://jonrappoport.wordpress.com/2015/07/3 1/open-letter-to-australian-pm-tony-abbott-the- mmr-vaccine/	For the "isolated autism" group (normally developing children), this was the increased risk of autism by earlier administration of the MMR vaccine:         MMR vaccination after 36 months - 1.00 risk of autism.         MMR vaccination prior to 36 months - 3.86 fold increase in the risk of autism.         In the data it was shown that the children at greatest risk in both subgroups were those children vaccinated by 18 months, demonstrating a clear trend that the earlier the MMR vaccination, the higher the risk of autism.         Congressman Poesy requests investigation into the CDC fraud:         http://www.jeffereyjaxen.com/blog/congressman-poesy-delivers-bombshell-cdc-whistle-blower-evidence-to-us-house-calls-for-investigation         Excellent letter by Jon Rappoport to the Australian Prime Minister:         https://jonrappoport.wordpress.com/2015/07/31/open-letter-to-australian-pm-tony-abbott-the-mmr-vaccine/         Vaccine/       Makes the valid point that if in 2004 the truth about MMR had been revealed instead of the CDC deliberately and illegally destroying it (except that William Thompson kept hard copies of the documents and then 'blew the whistle' when his conscience got the better of him), Australia should not have mandated the MMR vaccine.
2.	https://jonrappoport.wordpress.com/2014/03/1 8/welcome-to-the-medical-matrix-the-flu-isnt- the-flu/ http://whale.to/vaccine/cdc annual flu death I ie.html	How the CDC manufactures statistics on 'flu deaths and incidence.         "Doshi continued his assessment of published CDC flu-death statistics: "Between 1979 and 2001, [CDC] data show an average of 1348 [flu] deaths per year (range 257 to 3006)." These figures refer to flu separated out from pneumonia. This death toll is obviously far lower than the parroted 36,000 figure.         However, when you add the sensible condition that lab tests have to actually find the flu virus in patients, the numbers of flu deaths plummet even further."         CDC annual flu death lie         [2010 Jan] Sir Liam's Skeleton: the UK Department of Health Fabricates Flu Deaths to Boost Vaccination By John Stone         "Every year in the United States, on averageapproximately 36,000 people die from flu." CDC October 6, 2004         http://www.cdc.gov/flu/keyfacts.htm         Number of flu deaths 753 (2002) CDC       http://www.cdc.gov/nchs/data/nvsr/nvsr52/nvsr52 13.pdf         Every year, just prior to the impending "flu season," the CDC and their acquiescent media pawns terrorize the American public with false claims regarding annual flu deaths. The CDC boldly asserts that 36,000 people die every

		year from the flu. Such scare tactics are calculated to increase flu vaccine sales. However, according to the CDC's own official records documented in <u>National Vital Statistics Reports</u> , only a few hundred people die from influenza (flu) on an average year. And many of these deaths occur in people with preexisting conditions, weakened immune systems, and the elderly. <u>Annual Flu Deaths: The Big Lie By Neil Z. Miller</u> [2009 Oct] <u>Government Launches Deceptive Swine Flu Propaganda Blitz To Counter Growing Criticism from</u> <u>Scientific and Medical Community by Richard Gale &amp; Gary Null</u> If we take the combined figure of flu and pneumonia deaths for the period of 2001, and add a bit of spin to the figures, we are left believing that 62,034 people died from influenza. The actual figures determined by Peter Doshi, then at Harvard University, are 61,777 died from pneumonia and only 257 from flu. Even more amazing, among those 257 cases only 18 were confirmed positive for influenza. A separate study conducted by the National Center for Health Statistics for the flu periods between 1979 through 2002 revealed the true range of flu deaths were between 257 and 3006, for an average of 1,348 per year.
3.	http://www.justice.gov/opa/pr/johnson- johnson-pay-more-22-billion-resolve-criminal- and-civil-investigations http://www.johnsonandtoxin.com/payoff_settle ment.shtml	Johnson & Johnson - \$22billion. Off-label marketing, kickbacks to doctors and pharmacists. Risperdal, Invega and Natrecor. "The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust," said Attorney General Eric Holder. 4 <sup>th</sup> November 2013.
4.	http://healthimpactnews.com/2014/vaccine- scandals-and-criminal-cases-increase-in-2014/	<ul> <li>Merck, MMR, two whistleblowers regarding the efficacy of the mumps strain.</li> <li><i>"In a story that no mainstream media outlet reported in the beginning of September 2014, a Pennsylvania federal judge ruled in favor of whistleblowers who have accused Merck of lying about the efficacy of its mumps vaccine (currently only available in combo with MMR). We had to find this story posted on a couple of websites servicing attorneys.</i></li> <li>HPV Vaccine Supreme Court Trial for Fraud in India In a huge developing story that has been completely blacked out of the U.S. mainstream media, there is currently a case before the India Supreme Court regarding deaths and injuries occurring during drug trials carried out over Merck's HPV vaccine Gardasil. Vaccine trials were conducted on thousands of girls between the ages of 9 and 15. Many of the girls fell ill, and at least 7 died, and the lawsuit is alleging that in most of these cases, the girls and their parents did not even know what kind of vaccine trial they were participating in. </li> <li>Iowa State University Scientist Stands Trial for Fraud in HIV Vaccine: Cost to Taxpayers is Millions of Dollars</li> </ul>

In June of 2014 HIV vaccine researcher Dong-Pyou Han confessed to fraudulently injecting samples of rabbit blood with human antibodies to make an experimental HIV vaccine appear to have great promise, and earn \$19 million in grant money (funded by your tax dollars) from the National Institutes of Health (NIH).
Vaccine Manufacturer GSK Convicted of Fraud In a case that has been covered by the mainstream media this year, British manufacturer GlaxoSmithKline (GSK) has been fined by the Chinese government for a record Rmb3bn (nearly \$500 million) for bribing doctors to increase sales. The Wall Street Journal reports
Five of the company's managers, including Mark Reilly, its former top China executive, were convicted of bribery-related charges and received suspended prison sentences, a Glaxo spokesman said Friday. Glaxo still might be fined in the U.S. and U.K., and it faces several continuing investigations around the world.
<b>Flu Vaccine Fraud in Europe</b> Europe's biggest drugmaker Novartis had its offices in Italy searched by police in June of 2014 for information related to two flu vaccines. This one was covered by the mainstream media as Bloomberg reported:
Italian police searched two of the company's sites as part of a probe into possible fraud related to the purchase of the vaccines by the Health Ministry, one for a pandemic in 2009, according to an e-mailed statement from the police. The police allege Novartis inflated the cost of an additive to the vaccines, known as MF59, by six-fold. (Source.)
<b>Flu Injuries and Death Convictions in the U.S.</b> Most people in the U.S. do not realize that the U.S. government is forced to pay out damages to people injured and killed by vaccines on a regular, ongoing basis. The reason this is not generally known, is because the mainstream media never reports it, even though the information is public information posted every quarter on the U.S. Department of Health and Human Services' website.
We report these statistics and court convictions here at Health Impact News, and you can read the most recent report from 2014 here:

		http://healthimpactnews.com/2014/government-pays-damages-to-vaccine-victims-flu-shot-most-
		dangerous-with-gbs-and-death-settlements/ (Note the frequency of the damages paid to 'flu vaccine
		victims for Guillain Barre Syndrome).
5.	http://www.dailymail.co.uk/news/article-	24 <sup>th</sup> July 2015. Probe into claims NHS chiefs are paid thousands by drugs firms to use their products:
	<u>3172922/Probe-claims-NHS-chiefs-paid-</u> thousands-drugs-firms.html	Fraud watchdog launches investigation into 'serious allegations'. Read more:
		http://www.dailymail.co.uk/news/article-3172922/Probe-claims-NHS-chiefs-paid-thousands-drugs-
6	http://www.nytimes.com/2015/04/29/business/	firms.html#ixzz3hTqpBa4g
6.	takeda-agrees-to-pay-2-4-billion-to-settle-suits-	28 <sup>th</sup> April 2015 : Takeda Pharmaceutical has agreed to pay \$2.4 billion to settle thousands of lawsuits from patients and their family members who said that the company's diabetes drug Actos caused bladder
	over-cancer-risk-of-actos.html?_r=0	cancer, it announced on Tuesday.
7.	http://www.drugwatch.com/avandia/lawsuit.ph	<b>Avandia</b> - The type 2 diabetes drug Avandia is linked to severe heart problems, which have led to
<i>.</i>	<u>p</u>	lawsuits. If you suffered heart attack or failure after taking Avandia, you may be entitled to
		compensation.
		Serious cardiovascular side effects and potentially life-threatening complications from the diabetes drug Avandia prompted tens of thousands of patients in the United States to file lawsuits against
		GlaxoSmithKline, the drug's manufacturer. GlaxoSmithKline could face up to \$6 billion in liability for side effects litigation.
		According to a scientist for the U.S. Food and Drug Administration (FDA), Avandia is linked to as many as 100,000 heart attacks. Clinical studies show that the drug increases the risk of heart attack by 43 percent and can double the risk of heart failure after one year of treatment.
		During clinical trials, more people died as a result of a cardiovascular event taking Avandia than those taking a placebo, studies show. Despite these findings, Avandia's black-box warning label did not mention an increased risk of cardiovascular death until the FDA warned about the risks in 2007.
8.	https://en.wikipedia.org/wiki/List_of_largest_ph_ armaceutical_settlements	List of largest pharmaceutical settlements. Fraud, off-label promotion, kickbacks, monopoly practices, poor manufacturing practices, medicare fraud, failure to disclose safety data, criminal offences, making
0	http://www.drugwatch.com/2013/12/06/big-	false and misleading statements,
9.	http://www.drugwatch.com/2013/12/06/big- pharma-settlements/	Drugwatch – 2013 – settlements.

10.	http://www.lawyersandsettlements.com/lawsuit /gynecare_mesh.html#.VbuBwPn3CUI http://topclassactions.com/lawsuit-	Johnson & Johnson Johnson & Johnson has about 33,000 Gynecare lawsuits filed against its Ethicon division alleging Gynecare transvaginal mesh is defective. Rather than relieve women with Pelvic Organ Prolapse and Urinary Stress Incontinence, Gynecare Mesh side effects include severe pain, bleeding and infection. Some of the first transvaginal mesh or bladder sling products introduced in the US were made by Gynecare or Ethicon, which are subsidiaries of Johnson & Johnson. Various lawsuits.
11.	settlements/lawsuit-news/	various lawsuits.
12.	http://www.theguardian.com/business/2010/oct /27/glaxosmithkline-whistleblower-awarded- 96m-payout	<b>GSK</b> A whistleblower who exposed serious contamination problems at GlaxoSmithKline's (GSK) pharmaceutical manufacturing operations has been awarded \$96m (£60m).
		Cheryl Eckard's payment is thought to be the biggest ever handed to a US whistleblower. It was awarded after an eight-year fight, which ended yesterday, when GSK agreed to pay the US government \$750m to settle civil and criminal charges that it manufactured and sold adulterated drug products.
13.	http://www.stlmag.com/Simply-Thick-A- Tragedy-No-One-Saw-Coming/	FDA approved "Simply Thick" for use in infants without any testing of the product. 22 Infants died.
14.	http://healthland.time.com/2012/09/17/pharma -behaving-badly-top-10-drug-company- settlements/	GSK. Even the largest of settlements rarely dent the profits associated with the drugs involved: for example, the largest fine ever imposed on a drug company — July's \$3 billion judgment against GlaxoSmithKline (GSK) in part for illegally marketing the antidepressants Paxil and Wellbutrin and withholding data on the health risks of the diabetes medication Avandia — accounted for just 11% of associated revenue. Many other cases resulted in relatively smaller losses even when the fines were imposed as criminal penalties, as in the GSK case, and not just for civil law violations. Contrast such outcomes with those in most individual cases of fraud, in which all profits are typically confiscated as ill-gotten gains and the fraudster goes to prison.
15.	http://healthimpactnews.com/?s=MERCK+Crimin al+conduct	Long list of reports of criminal conduct by Merck, including: http://healthimpactnews.com/2014/gardasil-vaccine-spain-joins-growing-list-of-countries-to-file- criminal-complaints/
16.	http://www.naturalhealth365.com/big- pharma-Merck-pharmaceutical-sales- 1506.html	<ul> <li>More information on the criminal conduct of Merck, including:</li> <li>Where dollars and pharmaceuticals are concerned, it appears big pharma is more than willing to re-shape the truth. Legal action over Vioxx brought to light a number of deceitful acts by Merck, including:</li> <li>Creation of a peer-reviewed scientific journal to publicize "pro-Vioxx" articles.</li> </ul>

17.	http://www.naturalhealth365.com/drug -companies-big-pharma-1393.html	<ul> <li>Having an article ghost-written and then signed by a doctor as author, despite Merck staff characterizing the data it contained as "wishful thinking."</li> <li>Aggressive behavior toward reports.</li> <li>Seeding seminars with speakers who had pro-Vioxx opinions.</li> <li>The Daiichi Sankyo Co Ltd, along with its U.S. subsidiary, has been ordered to pay \$39 million to the federal government and individual state Medicaid programs.</li> </ul>
		The judgment comes in answer to a whistleblower lawsuit filed by former pharmaceutical salesperson Kathy Fragoules that accused the companies of paying kickbacks to physicians for prescribing its drugs.
18.	https://www.acatoday.org/content_css. cfm?CID=4767	Lawsuit against the AMA who were found guilty of trying to destroy the profession of chiropractice.
	http://www.dynamicchiropractic.com/ mpacms/dc/article.php?id=37334	The future of the chiropractic profession changed on Aug. 27, 1987, when federal court judge Susan Getzendanner found the American Medical Association (AMA) guilty of conspiring to destroy chiropractic. <sup>1</sup>
		The Iowa Plan's section "What Medicine Should Do About The Chiropractic Menace" includes a Part G titled "Undertake a positive program of 'containment" in which an often quoted phrase in chiropractic literature can be found: "If this program is successfully pursued, it is entirely likely that chiropractic as a profession will 'wither on the vine' and the chiropractic menace will die a natural but somewhat undramatic death. This policy of 'containment' might well be pursued along the following lines:
		<ul> <li>Encourage ethical complaints against doctors of chiropractic;</li> <li>Oppose chiropractic inroads in health insurance;</li> <li>Oppose chiropractic inroads in workmen's compensation;</li> <li>Oppose chiropractic inroads into labor unions;</li> <li>Oppose chiropractic inroads into hospitals; and</li> <li>Contain chiropractic schools."</li> </ul>
19.	http://www.forbes.com/sites/davidmari s/2012/10/10/fda-recall-points-to-	Wellbutrin 300mg generic. 10 <sup>th</sup> October 2012. Pay attention, as I can't say this seriously enough. Last week, the FDA took a drug off the market, and the reasons should send shivers of

serious-problems-at-the-fda/	fear down the backs of consumers, investors, generic drug companies – and the FDA.
	The FDA announced last week that the 300mg generic version of Wellbutrin XL manufactured by Impax Laboratories IPXL +% and marketed by Teva Pharmaceuticals was being recalled because it did not work. And this wasn't just a problem with one batch – this is a problem that has been going on with this particular drug for four or five years, and the FDA did everything it could to ignore it