



**British Society for Ecological Medicine Conference**  
Spring Scientific Meeting March 11, 2011  
Hallam Centre, London

**The Health Hazards of Disease Prevention -  
Vaccinations and Pharmacoprophylaxis**



## **Global Concerns about HPV Vaccines**

[Leslie Carol Botha](#), Vice-President, Public Relations, [SANE Vax Inc.](#) and Freda Birrell, Secretary, Sane Vax Inc were invited to present a power point titled: 'Global Concerns about HPV Vaccines' (link to PDF) at the BSEM Spring Meeting. Botha and Birrell are part of an international team who have joined together to bring to the attention of the media, politicians, medical experts and consumers their genuine concerns over the unnecessary devastation from adverse injuries and deaths occurring on a worldwide basis from HPV4-Gardasil (Merck Pharmaceutical Co) and HPV2 – Cervarix (GlaxoSmithKline). Botha is a women's health educator, broadcast journalist, author and publisher from Colorado, USA and Birrell is a political lobbyist from Scotland, representing the UK.

SANE Vax Inc. was formed in 2010 as a non profit organization focused on gathering peer-reviewed and government studies on vaccinations and the mechanisms of actions that may be causing adverse reactions and 'new medical conditions' to unsuspecting medical consumers. The name, S.A.N.E. Vax, stands for Safe, Affordable, Necessary and Effective Vaccinations and was chosen to attract physicians, and consumers starting to question vaccine safety and efficacy. 106 countries have visited the SANE Vax Inc. web site since its September 2010 debut.

The SANE Vax mission is to promote Safe, Affordable, Necessary & Effective vaccines and vaccination practices through education and information. We believe in science-based medicine. Our primary goal is to provide the information necessary for you to make informed decisions regarding your health and well-being. We also provide referrals to helpful resources for those unfortunate enough to have experienced vaccine-related injuries.

Freda Birrell opened the presentation by thanking BSEM Chairman, David Freed for the great honour to present research and data on Gardasil and Cervarix, stating it was a privilege to have been invited to the prestigious conference.

She introduced the first slide which reported HPV4 and HPV2 adverse injury and death statistics from the U.S. [VAERS](#) – Vaccine Adverse Events Reporting System database. As of February 2011, 94 deaths had been recorded and 21,634 adverse side effects had been reported – with an estimated 1 to 10% of the vaccine injured population filing with VAERS. Birrell explained that as this only represents between 1% and 10% of those victims filing a report, then by adding one or two zeros to these figures would raise the rates to an appalling level.

It was also noted that a young girl was a victim of sudden death post- Gardasil vaccination and if her father had not been present to resuscitate her, she too would have been part of the death statistics.

## Research Vaccine Adverse Event Reporting System – VAERS

VAERS ID: [415645](#) Vaccinated: 2010-10-07

Information has been received from a physician concerning a 14 year old female patient who on 07-OCT-2010 was vaccinated with the first dose of GARDASIL (lot number unspecified). On 09-OCT-2010 while the patient was at home, she had a sudden death and it was her father who resuscitated her. She had ventricular fibrillation. She spent one month and a half in intensive care and as a consequence of what happened to her, she had some motivity problems. They could not find a medical reason for what happened to her. She now had an automatic implantable defibrillator. She was now at home and taking beta-blocker treatment. The patient's outcome was unknown. Additional information has been requested.

### VAERS Reports HPV2 & HPV4 February 2011

Events	Total	Female	Male	Unknown
Reports	21,292	20,377	309	447
Deaths	94	74	2	14
Abnormal Pap Results - PV	372	372	N/A	N/A
Life-Threatening	402	393	6	3
ER Visit	8,617	8,455	84	78
Hospitalized	2,092	2,057	23	12
Did Not Recover	4,346	4,273	36	37
Disabled	689	682	3	4

## VAERS Reports HPV2 & HPV4 April 2011

Events	Total	Female	Male	Unknown
Reports	21,634	20,866	315	453
Deaths	94	78	2	14
Abnormal Pap Results - PV	376	376	N/A	N/A
Life-Threatening	422	412	7	3
ER Visit	8,733	8,562	93	78
Hospitalized	2,159	2,126	21	12
Did Not Recover	4,346	4,273	36	37
Disabled	714	709	1	4
Abortions – Spontaneous/Stillbirths	252	252	0	0

## List of Adverse Reactions reported to VAERS

Participants were asked to look carefully at the list of adverse reactions as reported to the U.S. Vaccine Adverse Reporting System (VAERS) and to take note of the many neurological and autoimmune conditions that have occurred post-vaccination and to previously healthy adolescent girls. It was pointed out that many of the girls were still seriously affected by illnesses following vaccination with Gardasil or Cervarix- and many of the girl's adverse reactions are lasting as long as the vaccine's efficacy. Medical authorities in the US and in the UK prefer to link these long term illnesses to 'conversion disorder' or 'psychogenic disorder' or at worst blame the parents for wishing their children to remain ill otherwise known as Munchausen's by Proxy Syndrome.

Abortion,/Stillbirth/Miscarriage, Addison's Disease, Adrenal failure, Adrenal issues, Allergies, Anxiety/Panic attacks, Appetite loss, Arthritis, Asthma attacks, Autistic - like symptoms, Autoimmune Disease (Lupus / Mixed Connective Tissue Disease), Back pain, Bacterial Vaginosis, Bladder issues, Bleeding gums, Blindness, Bloating, Blood Sugar Issues, Bloody stools, Brain fog, Brain Inflammation, Brain lesions, Bronchitis, Cervical cancer, Chemical sensitivity, Chest pains, Convulsions, Chronic Fatigue Syndrome, Constipation, Cytomegalovirus (CMV), Death, Degenerative disk disease, Dehydration, Depression, Diabetes, Diarrhea, Dizziness, Dyslexia, Dysplasia, Early Onset of Menopause, Enlarged fallopian tubes, Enlarged liver, Epstein Barr Virus (EBV), Extreme pain in the tailbone area, Fainting, Fatigue, Fertility problems, Fever, Fever blisters, Fibromyalgia, Food allergies, Gallbladder issues, Genital Warts, Gray film on teeth, Guillain-Barre Syndrome, Hair growth in strange places, Hair loss, Hallucinations, Hand / Leg Weakness, Hashimoto's Disease, Head pressure, Headache, Hearing loss (Permanent), Hearing loss (Temporary), Hearing sensitivity, Heart Palpitations, Heart arrhythmia, High levels of metals in blood: aluminium, mercury Hot / Cold Intolerance, HPV, Infertility, Insomnia, Itching, IUD discomfort, Joint pain, Kidney Failure, Kidney issues, Knee pain, Leaky Gut Syndrome, Light sensitivity, Lip spots, Liver Failure, Loss of bladder control, Lupus, Memory Loss (long-term), Memory Loss (short-term), Menstrual cycle changes, Metallic taste in mouth, Migraines, Miscarriage, Mood Swings, Moles (Increase in number of), Mononucleosis, Multiple Sclerosis (MS), MS-like symptoms, Muscle aches, Muscle spasms, Muscle tension, Nausea, Neurological reactions to fungal metabolites, Neurological symptoms, Night sweats, Non-Hodgkin's Lymphoma, Numbness, Other types of cancer, Ovarian failure, Paleness, Paralysis, Pancreatitis, PCOS (Poly-Cystic Ovarian Syndrome), Pelvic Inflammatory Disease (PID), Pelvic pain, Personality changes, Pins / Needles in Extremities, Pleural effusion, Pneumonia, Postural Orthostatic Tachycardia Syndrome (Orthostatic Intolerance), Random twitching of extremities Rash, Raynaud's Phenomenon (loss of blood circulation to hands and/or feet), Regression, Rheumatoid arthritis, Ruptured ovarian cysts, Seizures, Sensitivity to commercially processed citric acid, MSG, sulfur and other additives, Severe nerve pain syndrome, Shortness of breath, Sleep Apnea, Slurred speech, Smell sensitivity, Sore throat, Sound sensitivity w/

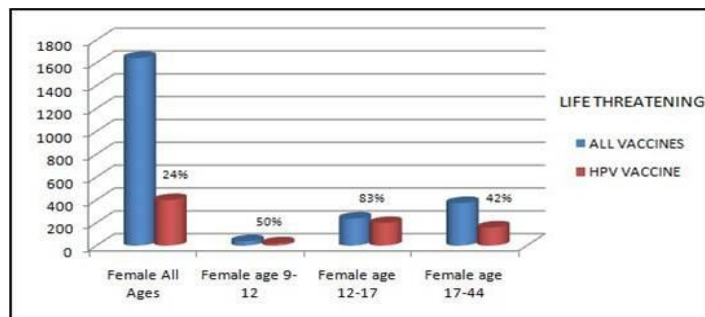
Anxiety, Stomach ache, Stomach pain, Sudden drops in blood pressure, Swelling / Edema, Swollen lymph nodes, Thyroid Issues, Thrombosis Toothaches/Teeth Changes, Tremors: hand and/or leg, Uterine spasms, Urinary Tract Infection (UTI), Vision changes - long term, Vision loss (Permanent), Vision loss (Temporary), Vision Problems - abnormal pupillary function / dilation, Vomiting blood, Weight gain or loss (20 – 30 lbs.)

## VAERS DATA 6/1/06 – 12/31/10

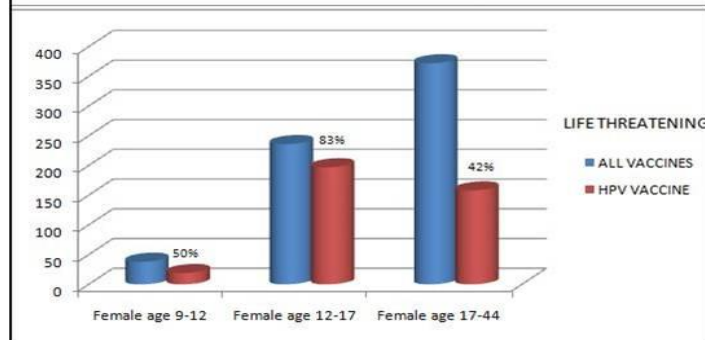
The following graphs based on VAERS data identifies how serious the HPV vaccines adverse reactions are in comparison with the 73 vaccines administered in the US. The graphs also identified the age groups affected. It is obvious HPV vaccine adverse reactions have a higher incident rate than any of the other vaccines recommended for these age groups.

### Life Threatening Incidents Post HPV Vaccination

Life threatening incidents post HPV Vaccines in relation to all other vaccines



Life threatening incidents post HPV Vaccines in relation to 9 other vaccines administered in this age group.

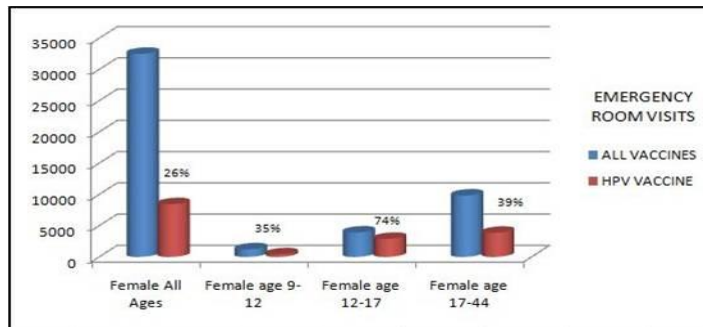


Graphs reflect all reports to the US VAERS DATABASE from June of 2006 (Gardasil released on the market) until December 31, 2010. We have compared the % of adverse effects from the HPV Vaccines to the 73 other vaccines reported to VAERS during the same time period.

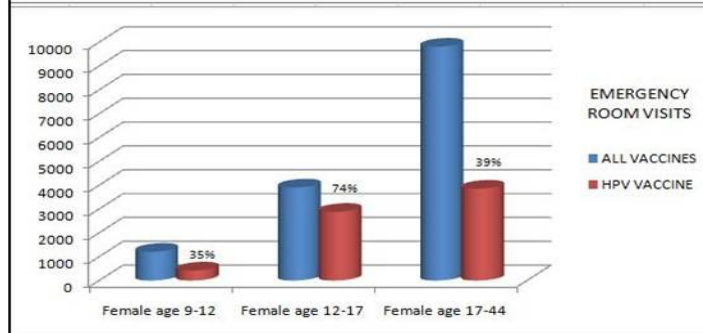
- HPV Vaccines make up 24% of all LIFE THREATENING reports filed during this time period.
- HPV Vaccines make up 50% of LIFE THREATENING reports for females age 9-12 compared to the 9 vaccines recommended by the CDC for this age group.
  - 9 Other Vaccines administered in this age group:
    1. Tetanus and Diphtheria toxoids and acellular pertussis vaccine (Tdap)
    2. Meningococcal conjugate vaccine, quadrivalent (MCV4)
    3. Influenza vaccine (seasonal)
    4. Pneumococcal vaccines
    5. Hepatitis A vaccine (HepA)
    6. Hepatitis B vaccine (HepB)
    7. Inactivated poliovirus vaccine (IPV)
    8. Measles, mumps, and rubella vaccine (MMR)
    9. Varicella vaccine

## Emergency Room Incidents Post HPV Vaccination

Emergency room visits post HPV Vaccines in relation to all other vaccines



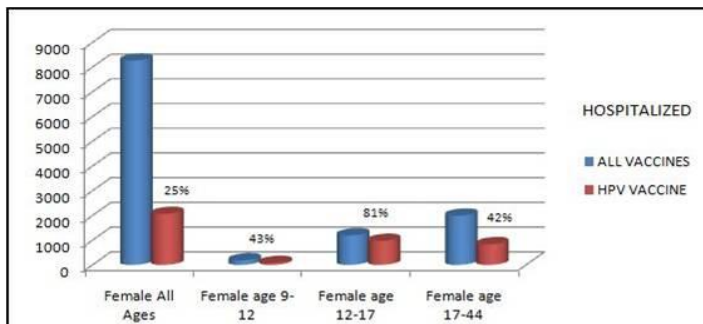
Emergency Room visits post HPV Vaccines in relation to 9 other vaccines administered in this age group.



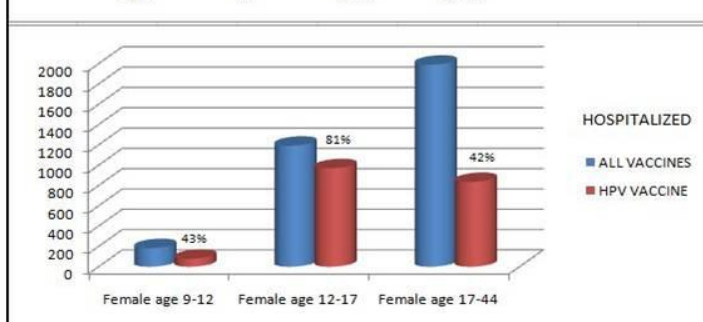
- HPV Vaccines make up 26% of all EMERGENCY ROOM VISIT reports filed during this time period.
- HPV Vaccines make up 35% of the EMERGENCY ROOM VISITS for females ages 9-12 compared to the 9 vaccines recommended by the CDC for this age group.
- HPV Vaccines make up 74% of the EMERGENCY ROOM VISIT for females age 12-17 out of all reports combined.

## Hospitalization Post HPV Vaccination

Hospitalizations post HPV Vaccines in relation to all other vaccines



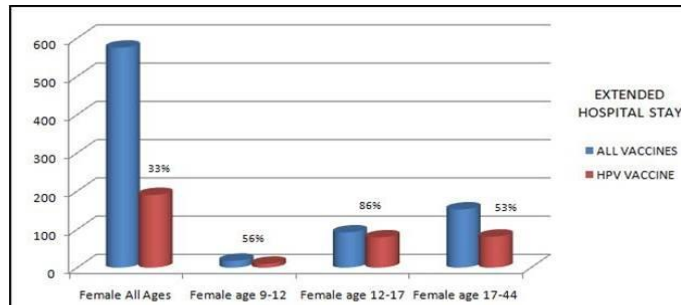
Hospitalizations post HPV Vaccines in relation to 9 other vaccines administered in this age group.



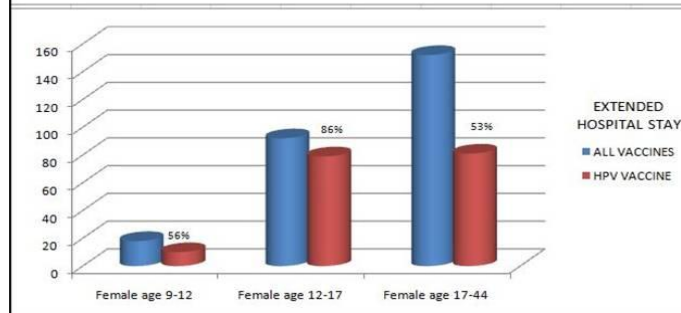
- HPV Vaccines make up 25% of all HOSPITALIZED reports filed during this time period.
- HPV Vaccines make up 43% of the HOSPITALIZED compared to the 9 vaccines recommended by the CDC for this age group.

## Extended Hospital Stay Post HPV Vaccination

Extended hospital stay post HPV Vaccines in relation to all other vaccines



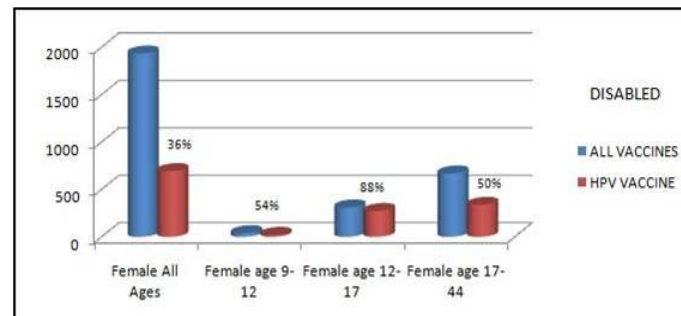
Extended hospital stay post HPV Vaccines in relation to 9 other vaccines administered in this age group.



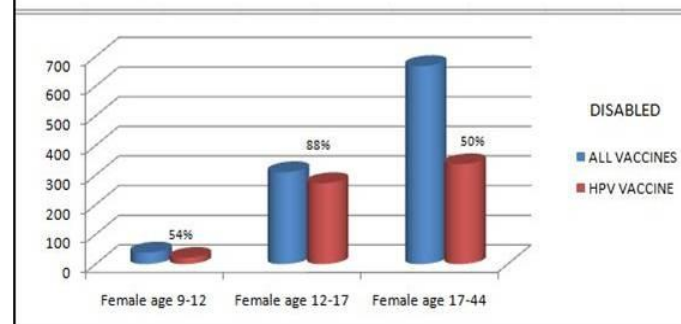
- HPV Vaccines make up 33% of all EXTENDED HOSPITAL STAY reports filed during this time period.
- HPV Vaccines make up 56% of the EXTENDED HOSPITAL STAY for females age 9-12 compared to the 9 vaccines recommended by the CDC for this age group.

## Disabling Events Post HPV Vaccination

Disabling events post HPV Vaccines in relation to all other vaccines



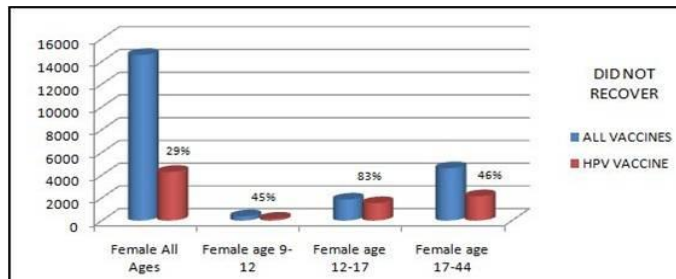
Disabling events post HPV Vaccines in relation to 9 other vaccines administered in this age group.



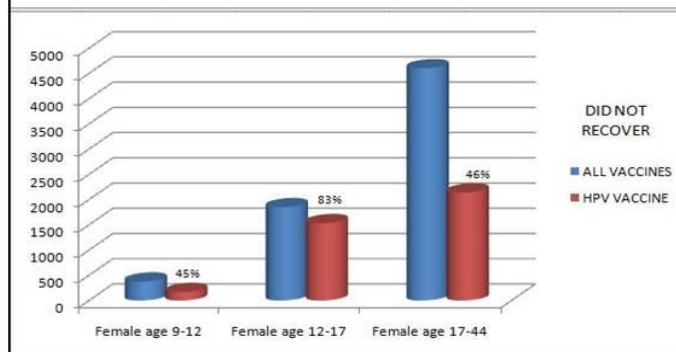
- HPV Vaccines make up 36% of all DISABLED reports filed during this time period.
- HPV Vaccines make up 54% of the DISABLED for females age 9-12 compared to the 9 vaccines recommended by the CDC for this age group.

## Percentage of those Not Recovered Post HPV Vaccination

Percentage of those who have not recovered post HPV Vaccines in relation to all other vaccines



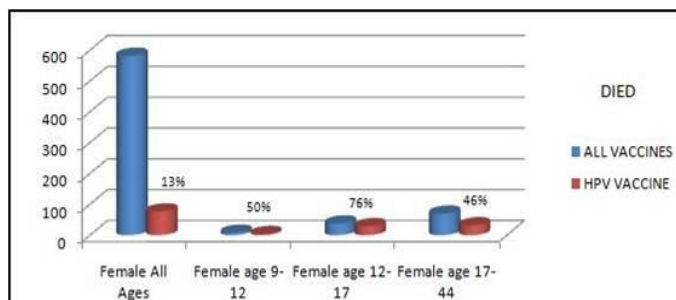
Percentage of those who have not recovered post HPV Vaccines in relation to 9 other vaccines administered in this age group.



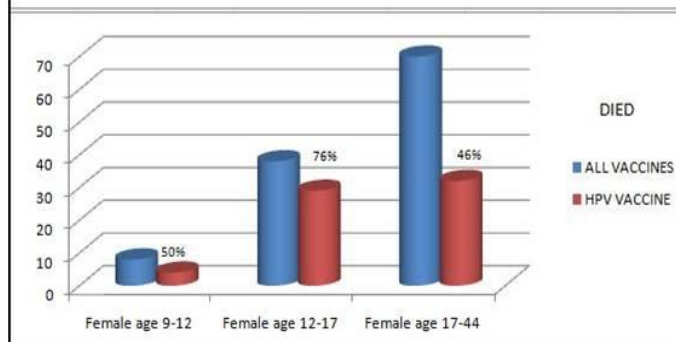
- HPV Vaccines make up 45% of the DID NOT RECOVER for females age 9-12 compared to the 9 vaccines recommended by the CDC for this age group.
- HPV Vaccines make up 83% of the DID NOT RECOVER for females age 12-17 of all reports combined.
- HPV Vaccines make up 46% of the DID NOT RECOVER for females age 17-44 of all reports combined.

## Percentage of Deaths Post HPV Vaccination

Deaths post HPV Vaccines in relation to all other vaccine deaths



Deaths post HPV Vaccines in relation to 9 other vaccines administered in this age group.



- HPV Vaccines make up 13% of all DEATH reports filed during this time period.

- HPV Vaccines make up 50% of the DEATHS for females age 9-12 compared to the 9 vaccines recommended by the CDC for this age group.
- HPV Vaccines make up 76% of the DEATHS for females age 12-17 compared to the vaccines recommended by the CDC for this age group.

Additional graphs detailing HPV vaccine adverse events in relation to other vaccines events available at:

<http://sanevax.org/pdf/BSEM%20Conference%20Global%20Concerns%20about%20HPV%20Vaccines%202011.pdf>

## Research

### Cervical Cancer Gardasil

- *The finding of HPV viral DNA integrated in most cellular genomes of cervical carcinomas supports epidemiologic data linking this agent to cervical cancer however, direct causation has not been demonstrated.*

#### **Cervical Cancer Prevention, Health Professional Version** Published by the National Cancer Institute (NCI)

The next paragraph in the *NCI Cervical Cancer Prevention* states HPV infections dropped by 42% with no precancerous lesions being demonstrated during an eight month study of women whose partners consistently used condoms. 90% of women pass HPV within two years.

- It is not a single infection, but multiple *persistent* infections that may cause cervical cancer. ...therefore it is the *persistent* infection, not the virus that determines cervical cancer risk.

**Dr. Sin Hang Lee -Pathologist, Milford Hospital  
Director, Milford Medical Laboratory, Milford, CT**

- Non cancerous types of HPV: 6 & 11  
Cancerous types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 69, 73, 82

#### **Cervical Cancer Prevention, Health Professional Version** Published by the National Cancer Institute (NCI)

- It is estimated that 25,000,000 women may have been previously exposed to HPV

**CDC extrapolation of population figures for that  
age group multiplied by the percentage of infected (potentially)—**

- The [May 2006 FDA VRBPAC Report](#) states if a woman is pre-exposed to HPV and if she is administered the HPV vaccines incidences of cervical cancer increase:

**44.6% - Post-Gardasil®  
32.5% - Post-Cervarix®**

*May 2006 VRBPAC Report*

- In a September 2008, [FDA Closing Statement on Gardasil](#) it was noted that 73.3% of girls in the clinical trials developed “new medical conditions” post vaccination.<sup>2</sup>

*September 2008 FDA Closing Statement on Gardasil*



- Cervical cancer is a major lethal malignancy in underdeveloped countries, but not in the U.S. The Centers for Disease Control and Prevention (CDC) record showed that 3,976 women died from cervical cancer in the U.S. in 2006.

The current type-specific HPV vaccines have claimed to be almost 100% effective against infection by HPV-16 and HPV-18, and perhaps also against HPV-31 and HPV-45 infections. However, we do not know if these four HPV types are the most prevalent carcinogenic HPV genotypes in the U.S. According to two published reports – one by the CDC, HPV-52 not HPV-16 or HPV-18 was found to be the most prevalent “carcinogenic” genotype infecting young American women.<sup>1</sup>

**Dr. Sin Hang Lee -Pathologist, Milford Hospital  
Director, Milford Medical Laboratory, Milford, CT  
*Consumer-Engaged Prevention of Cervical Cancer***

- Screening via Gynecologic Examinations and Cytologic Screening based on solid evidence, screening via regular gynecologic examinations and cytologic test (Papanicolaou smear) with treatment of precancerous abnormalities decreases the incidence and mortality of cervical cancer.

Screening is not beneficial in detecting invasive cancer in women younger than 25 years because of the low prevalence of invasive disease, and the harms outweigh the benefits. Screening is not beneficial in women older than 60 years if they have had a history of recent negative tests.

***Cervical Cancer Prevention, Health Professional Version***  
**National Cancer Institute**

- In the natural history of cervical cancer development 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 progress to cervical cancer. Therefore, there are many more CIN 2 lesions than CIN3 lesions and cervical cancers combined in any female population, including the subjects enrolled in the Gardasil™ clinical trials. As a result, the overwhelming majority of the “CIN 2/3 or worse” cases used for evaluation of efficacy and listed in the VRBPAC Background Document on Gardasil™ HPV Quadrivalent Vaccine presented at the May 18, 2006 VRBPAC meeting must have been CIN 2 lesions.<sup>1</sup>

***S.A.N.E. Vax, Inc. Asks FDA to Rescind Approval of Gardasil™:  
Inappropriate Endpoint and Unreliable HPV Genotyping Methods Used for Vaccine's Efficacy  
Evaluation***

## **Research**

### **Gardasil**


### **Cervarix**

Birrell introduced the next slide which was a VAERS report of a 12 year old UK subject vaccinated with Cervarix. The Medical and Healthcare Products Regulatory Agency (MHRA) reference number was identified on the original report in VAERS which gave proof of identity that it was a UK subject. Many cases of visual problems are being experienced after vaccination with Cervarix in the UK including six cases of blindness, 1 case of blindness unilateral, 2 cases of colour blindness and many other serious visual problems. It also should be noted that the MHRA database only represents a percentage of victims reporting symptoms after vaccination.

## **HPV2 Cervarix ® – approved for use in the UK in June 2008 Approved for use in the US in October 2009**

Following her concern of the serious visual problems which were being reported Birrell sent many of the UK visual VAERS reports to her own optician and also to Dr Susan Blakeney of

the College of Optometrists. In November 2010 Dr Blakeney included in the Optometrists Bulletin the following information which would be brought to the attention of around 13,000 opticians in the UK. This is an extract of the article which also states that the MHRA regards this vaccination programme as completely safe.

<p><b>Cervarix</b></p> <p>A colleague has asked me to highlight the possible visual side effects which may occur after vaccination with Cervarix, a human papillomavirus vaccine to prevent cervical cancer<sup>1</sup>. These are rare but may include photophobia, blurred vision or visual impairment (MHRA suspected adverse reaction analysis dated 29/7/10 – accessible using the link below). Symptoms may occur several days after the vaccination which makes it difficult to definitely link them with the drug and it is important to note that these are reported even if there was merely a suspicion of causality. The MHRA safety analysis dated October 2010 states that 'The human papillomavirus (HPV) immunisation programme has now completed its second successful year and is ready to enter its third. With at least 4.5 million doses of Cervarix administered up to the end of July 2010 to girls aged 12–18 years across the UK, the vaccine has been shown to have an excellent safety profile. Most Yellow Card reports have related either to the signs and symptoms of recognised, minor side effects listed in the product information, or to the injection process and not the vaccine itself (ie, psychogenic in nature). The balance of risks and benefits of Cervarix remains positive'.</p> <p>As for all suspected side effects to any medication these can be reported to the MHRA via their yellow card scheme which can be accessed directly at</p> 	<p><b>“A colleague has asked me to highlight the possible visual side effects which may occur after vaccination with Cervarix®, a human papillomavirus vaccine to prevent cervical cancer. These are rare, but may include photophobia, blurred vision or visual impairment. (MHRA suspected adverse reaction analysis dated 29/7/10)”</b></p> <p>Dr. Susan Blakeney, Optometric Advisor, College of Optometrists</p>
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Visual problems are also experienced after vaccination with Gardasil since it came on to the market in 2006. These are the statistics:

**Dec 2010 VAERS Reports on Gardasil®  
Blindness/Visual Problems/Visual Impairment**

<b>Blindness/Blindness cortical</b>	<b>56</b>
<b>Blindness unilateral</b>	<b>11</b>
<b>Optic nerve disorder/glioma/injury/optic neuritis/ Retrobulbar/neuropathy</b>	<b>49</b>
<b>Associated problems:</b>	
Vision blurred/visual acuity reduced/or transiently/ Visual acuity tests/abnormal	<b>303</b>
<b>Visual brightness/disturbance/evoked potentials/</b>	<b>213</b>
Abnormal/normal/visual field defect/visual field tests/ Abnormal/normal/visual impairment/visual tracking /Abnormal	

Birrell continued in her final part of the presentation to further report that the MHRA is consistent in its attempt to let medical professionals and consumers believe that side effects are only experienced for between 7-10 days. The National Health Service informs girls and parents that side effects are quite mild. Yet from data downloaded from VAERS on a sample of 52 UK Cervarix cases a totally different story is related by Grace Filby who analyzed these reports:

**Cervarix® HPV vaccine long term adverse events in Great Britain**  
**by Grace Filby BA(Hons) CertEd FRSA, Independent Researcher**  
**Thursday, October 21, 2010**

**The MHRA view is that Cervarix® side effects only last 7 - 10 days**  
**The NHS informs girls and parents that side effects are 'quite mild'.**

The following data on the US Govt's VAERS database, America's vaccine safety watchdog, shows a different view of the facts.

No. of British girls reported to VAERS in this sample:	52
No. of British girls reported to VAERS by MHRA in this sample:	51
No. of cases marked Disabling:	14
No. of cases marked Life Threatening:	4
No. of Deaths:	1
No. of cases with symptoms 0-1 day after vaccination:	27
No. of cases with concurrent medical conditions and/or medications:	19
No. of cases long-lasting (>7-10 days):	38
No. of cases "quite mild:"	0

**VAERS Comprehensive Analysis**  
**Adverse Injuries According to Age Groups**

**The HPV vaccination program is targeting adolescent girl's at the most fragile time of their lives.**

**[Leslie Carol Botha](#), Women's Health Educator;  
 Vice- President of Public Relations, SANE Vax Inc.**

Botha presented the following graphs that reflect the number of adverse reactions reported to VAERS over the lifetime of a medical consumer. As a women's health educator and author, she has spent 30 years researching and documenting the endocrine system's affect on adolescent health and behaviors. Her colleague, Janny Stokvis, Netherlands first found the correlation between an increase vaccine adverse reactions and menarche. It is important to note that the numbers of reported vaccine side effects are higher amongst males until adolescence when there is a significant increase in the female adolescent age group –

particularly at the time when the endocrine system is establishing its own natural rhythm for reproduction. Also note that the numbers of reports increase after 6/01/06 substantially after the introduction of Gardasil to the consumer market in June 2006.

	Submission date on/before 05/31/06		05/31/06 Difference %		Submission Date on/after 06/01/06		06/01/06 Difference %	
	male	female			male	female		
0 - 2 year olds	35269	30754	4515	12.8%	14540	12457	2083	14.3%
3 - 5 year olds	12918	11713	1205	9.3%	6738	6232	506	7.5%
6 - 9 year olds	2758	2469	289	10.5%	2190	2223	33	1.5%
10 - 12 year olds	2352	2538	186	7.3%	2924	3690	766	20.8%
13 – 17 year olds	3642	4308	666	15.5%	3227	10546	7319	69.4%
18-44 year olds	14519	29831	15672	52.5%	8093	25306	17213	68.0%

**VAERS Comprehensive Analysis**  
**Numbers without HPV given as a single vaccine but including reports where HPV is given in combination with other vaccines**

	Submission date on/before 05/31/06		05/31/06 Difference %		Submission Date on/after 06/01/06		06/01/06 Difference %	
	male	female			male	female		
0 - 2 year olds	35269	30753	4516	12.8%	14522	12442	2083	14.3%
3 - 5 year olds	12918	11713	1205	9.3%	6737	6227	510	7.6%
6 - 9 year olds	2758	2469	289	10.5%	2190	2215	25	1.1%
10 - 12 year olds	2352	2536	186	7.3%	2915	3974	259	8.2%
13 – 17 year olds	3642	4281	639	14.9%	3189	5447	2258	41.5%
18-44 year olds	14519	29759	15672	52.4%	8056	17700	9644	54.5%

**VAERS Comprehensive Analysis  
NUMBERS WITHOUT HPV VACCINES INVOLVEMENT**

	Submission date on/before 05/31/06		05/31/06 Difference %		Submission Date on/after 06/01/06		06/01/06 Difference %	
	male	female			male	female		
0 - 2 year olds	35269	30753	4516	12.8%	14507	12428	2079	14.3%
3 - 5 year olds	12918	11713	1205	9.3%	6735	6222	513	7.6%
6 - 9 year olds	2758	2469	289	10.5%	2189	2209	20	0.9%
10 - 12 year olds	2350	2521	171	6.8%	2878	2553	325	11.3%
13 – 17 year olds	3641	4228	587	13.9%	3130	3151	21	0.7%
18-44 year olds	14517	29738	15581	52.4%	8027	16639	8612	51.8%

**HPV Vaccines Mechanisms of Action  
What is Triggering HPV Stimulation?**

The FDA has acknowledged studies on the interaction between Gardasil, estrogen and HPV stimulation have not been conducted.

**Research**

- Estrogen**
- Oral Contraceptives**
- Hormone Influence on Chronically Ill**
- Head & Neck Cancer**
- Polysorbate 80**
- Histamine Metabolism during the Menstrual Cycle**

**Post-HPV Vaccine Licensure Studies**

- Women diagnosed with cervical cancer report longer duration and more recent use of combined oral contraceptives (COCs). It is unclear whether COC use is associated with upstream events of human papillomavirus (HPV) infection prior to development of clinical disease.” The studies objective...“was to assess the association of contraceptive use on the risk for prevalent HPV infection in a cohort of long-term hormonal contraceptive (HC) users.

The authors found: a demonstrable “association between the use of COCs for >6 years and prevalent HPV infection among 20- to 37-year-old women from Thailand after controlling for sexual behavior and cytological abnormalities. This finding is in agreement with other smaller cross-sectional studies conducted among college age women and women 20–29 years of age who report COC use for >4 years.” The summary “observed that long-term use of COCs of >6 years is associated with an increased risk of prevalent HPV infection in a cohort of HC and NHC users in Thailand.

*“Longitudinal studies examining the risk of HPV acquisition and particularly HPV persistence by contraceptive use are therefore urgently needed.”*

***The association of hormonal contraceptive use and HPV prevalence,***  
**26 OCT 2010**  
*International Journal of Cancer (IJC)*

- For months news headlines reported on the association between HPV and head and neck cancers suggesting that Gardasil may be a preventive for these cancers as well. However, Health Day News reported that estrogen stimulation may indeed be behind the HPV stimulation for head and neck cancers.

Rates of head and neck cancer are rising among some groups of people, including young women without any known risk factors. Now, a study suggests that estrogen may help the cancer spread by boosting the movement of precancerous cells in the mouth.

***Estrogen May Play Role in Rising Rates of Head, Neck Cancer***  
**January 4, 2011**  
*Health Day News*

- ***Hormonal status in protracted critically illness and in-hospital mortality.***

#### **Introduction**

The aim of the study was to determine the relationship between hormonal status and mortality in patients with protracted critical illness.

#### **Methods**

We conducted a prospective observational study in four medical and surgical intensive care units (ICUs). ICU patients who regained consciousness after 7 days of mechanical ventilation were included. Plasma levels of insulin-like growth factor 1 (IGF-1), prolactin, thyroid-stimulating hormone, follicle-stimulating hormone, luteinizing hormone, estradiol, progesterone, testosterone, dehydroepiandrosterone (DHEA), dehydroepiandrosterone sulfate (DHEAS) and cortisol were measured on the first day patients were awake and cooperative (day 1). Mean blood glucose from admission to day 1 was calculated.

#### **Results**

We studied 102 patients: 65 men and 37 women (29 of the women were postmenopausal). Twenty-four patients (24%) died in the hospital. The IGF-1 levels were higher and the cortisol levels were lower in survivors. Mean blood glucose was lower in women who survived, and DHEA and DHEAS were higher in men who survived.

#### **Conclusion**

Authors concluded results suggested that, according to gender, some endocrine or metabolic markers measured in the post-acute phase of critical illness have a prognosis value.

***Hormonal status in protracted critically illness and in-hospital mortality***  
*Critical Care 2011, 15:R47doi:10.1186/cc10010 -*

## **Pre-HPV Vaccine Licensure Studies**

- **Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection: the IARC multicentric**

#### **Background**

Use of oral contraceptives could increase risk of cervical cancer; however the effect of human papillomavirus (HPV), the main cause of cervical cancer, is not usually

taken into account. We aimed to assess how use of oral contraceptives affected risk of cervical cancer in women who tested positive for HPV DNA.

### **Interpretation**

Long-term use of oral contraceptives could be a cofactor that increases risk of cervical carcinoma by up to four-fold in women who are positive for cervical HPV DNA. In the absence of worldwide information about HPV status, extra effort should be made to include long-term users of oral contraceptives in cervical screening programmes.

#### ***Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection:***

[The Lancet, Volume 359, Issue 9312, 30 March 2002, Pages 1085-1092;](#)

- Although OC use may increase the risk of cervical cancer, human papillomavirus (HPV) is recognized as the major cause of this disease. Approximately 14 types of HPV have been identified as having the potential to cause cancer, and HPVs have been found in 99 percent of cervical cancer biopsy specimens worldwide.

A 2003 analysis by the International Agency for Research on Cancer (IARC) found an increased risk of cervical cancer with longer use of OCs. Researchers analyzed data from 28 studies that included 12,531 women with cervical cancer. The data suggested that the risk of cervical cancer may decrease after OC use stops. In another IARC report, data from eight studies were combined to assess the effect of OC use on cervical cancer risk in HPV-positive women. Researchers found a fourfold increase in risk among women who had used OCs for longer than 5 years. Risk was also increased among women who began using OCs before age 20 and women who had used OCs within the past 5 years. The IARC is planning a study to reanalyze all data related to OC use and cervical cancer risk.

#### ***Oral Contraceptives and Cancer Risk: Questions and Answers***

**Reviewed: 05/04/2006**

[National Cancer Institute](#)

- **Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats**

#### **Abstract**

Neonatal female rats were injected ip (0.1 ml/rat) with Tween 80 in 1, 5 or 10% aqueous solution on days 4-7 after birth. Treatment with Tween 80 accelerated maturation, prolonged the oestrus cycle, and induced persistent vaginal oestrus. 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.

#### **Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats**

Gajdová M, Jakubovsky J, Války J.

Institute of Preventive and Clinical Medicine, Limbová, Bratislava.

[NCBI, PubMed.gov, Food Chem Toxicol. 1993 Mar;31 \(3\):183-90](#)

- **Histamine metabolism during the menstrual cycle**

The urinary excretion of histamine and its metabolites methylhistamine (MeHi) and methylimidazoleacetic acid (MelMAA) were measured during the menstrual cycle in 9 healthy women, 1 allergic woman, and 3 nonpregnant women with anovulatory regular cycles. Simultaneous urinary analyses of luteinizing hormone (LH) and total estrogens were performed. The healthy women showed individual variations in the

excretion of histamine, MeHi and MelmAA. This observation has been interpreted as an expression of minor individual differences in the catabolism of histamine. At midcycle an increase in the urinary excretion of histamine metabolites was sometimes evident and a statistically significant correlation could be established between MeHi and estrogen in urine. These results may support previous findings of histamine release by estrogens in uterine tissue but may also reflect an elevated histamine formation.

The allergic woman excreted constantly increased amounts of histamine and its metabolites, especially when her allergic symptoms became aggravated premenstrually. She was without any change in MelmAA excretion at midcycle but the MeHi excretion varied with the excretion of estrogens in the urine. The subjects with anovulatory menstrual cycles had low values of histamine and metabolites although within the normal variations.

***Histamine metabolism during the menstrual cycle***  
**Acta Obstet Gynecol Scand. 1976;55(4):297-304.**  
[NCBI PubMed.gov](#) –

The medical/mental health/pharmaceutical industries have overlooked the importance of menstrual cycle evaluation and endocrine system influence in practice/procedure/application and in the administration of drug and surgical therapies for far too long. There are numerous peer-reviewed studies on changes in immunity during the menstrual cycle that warrants further examination.

***HPV Mechanisms of Action in Women***  
**Leslie Carol Botha & Cynthia Janak**  
[FDA Presentation](#)  
**October 2010**

SANE Vax, Inc. is concerned about the role that estrogen plays not only in HPV stimulation but in histamine stimulation. Gardasil is the only vaccine to include L-Histidine – a synthetic histamine as one of the ingredients.

Estrogen dominance is becoming a major concern in western industrialized nations. Estrogen mimickers are found in plastics, foods, and household solvents. Estrogen has also been passed down from mother to daughter through birth control use and other vertical lines.

Gardasil and Cervarix are administered to an age group of young women ages 9 - 26 whose endocrine systems are fragile. Girls ages 9 to 16 are most vulnerable because many are going into menarche or who are experiencing irregular menstrual cycles (amenorrhea) until their reproductive system develops its own rhythm. Many are prescribed birth control pills to assist with the development of a regular cycle.

Estrogen production at this time of a woman's life is great – since the hormone is being secreted until ovulation takes place. Cycle length becomes a crucial factor in the amount of estrogen being produced. And since estrogen stimulates histamine production – higher amounts of histamine may be produced especially in girls with known or unknown pre-existing allergies and autoimmune disorders. The mechanism of action between estrogen, histamine, oral contraceptives and L-histidine must be studied. There is enough evidence to suggest that Gardasil is an endocrine and immune system disruptor.

There is also the challenge/re-challenge factor. The series of three vaccines are potentially providing a mechanism that is causing an inflammatory immune response. The strength of the immune system becomes more compromised during the follicular phase of the menstrual cycle and the stage becomes set for other potential inflammatory imbalances.



It is impossible to track whether a woman experienced a more severe reaction post HPV vaccination depending on the phase of her menstrual cycle. Most women do not keep track – and the data if recorded in a clinical setting is not used as a biomarker for any aspect of women's health. But there are many researchers and medical practitioners who question vaccination during the follicular phase of the cycle.

What is apparent is the high amounts of estrogen/histamine production in the luteal phase of the cycle and then the drop in hormones/immune system response in the follicular phase. Many of the victims are unable to cope with the onslaught of the vaccine toxins during the premenstrual phase – and they report adverse event relapses during this time. In other words, the toxic onslaught from the vaccine is so great – and the inflammatory immune stimulation so high during the luteal phase the immune system cannot cope with the response during the follicular phase.

Many girls are unable to recover and their endocrine and immune systems in particular are weakened with each passing cycle.

Aluminum exposure also affects neurological/endocrine system functioning. Each 0.5-mL dose of the Gardasil vaccine contains approximately 225 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant.) In a paper titled, *Brief Assessment of Aluminum Exposure and Endocrine Disruption*, Dan Laks, MS - addresses neuro/endocrine degeneration.

The brain is a main target of aluminum exposure and effect [1] where it induces neurodegeneration [2-4]. At high levels, aluminum has been demonstrated to inhibit prenatal and postnatal neurodevelopment in humans and animals [5-11]. Aluminum has been shown to target and accumulate in the hippocampus, the primary area of the brain associated with memory formation [12-14]. Aluminum exposure in human populations has been associated with deficits in cognitive function [15]. Aluminum neurotoxicity in children manifests symptoms of verbal impairment and regression [16]. Although the relationship between aluminum exposure and associated disease such as Alzheimer's disease [13, 17-23], amyotrophic lateral sclerosis [24], and Parkinson's disease [24, 25] remains to be fully elucidated, the specific toxicology of aluminum exposure on the endocrine system has been firmly established [26-31]. Aluminum deposits in the pituitary, parathyroid, and adrenals[32] and has been demonstrated to interfere with parathyroid hormone secretion[33-36], insulin like growth factor and T3 levels[ 37], and the reproductive system [28, 29, 31, 38].

It is thought that inflammation resulting from aluminum exposure may induce learning and memory deficits [39]. Certainly, targeted effects on the endocrine system may affect immune-modulation and produce a pro-inflammatory cascade that responds to targeted aluminum deposition in the hippocampus with resultant neurotoxicity.

***Brief Assessment of Aluminum Exposure and Endocrine Disruption***  
***Dan R. Laks MS, June 21, 2009***  
[SafeMinds.org](http://SafeMinds.org)

SANE Vax Inc. believes that the above studies warrant further examination in regards to HPV stimulation. An independent study on the relationship between estrogen, HPV, cancer and Gardasil needs to be conducted immediately. VAERS lists 554 reports of abnormal pap smears including CIN (dysplasia) and cervical cancer post-HPV vaccination.

SANE Vax believes that there is a mechanism of action stimulating HPV production. That the FDA has admitted the lack of clinical trials/studies on Gardasil's interaction with oral

contraceptives and the endocrine system is a blatant error and flaw in policy and procedure; one that may have cost too many girls their lives.

## Gardasil Marketing Campaign



### **Merck's 'One Less Girl to Get Cervical Cancer Campaign' becomes One More Girl Adversely Injured**

According to [Neon Tommy](#), the online publication for the Annenberg School for Communication and Journalism, USC, the promotion was successful. Merck's marketing techniques even earned Gardasil a "pharmaceutical brand of the year" award from Pharmaceutical Executive for its 'savvy disease education,' and building 'a market out of thin air.'

Indeed, Merck took home a "fistful" of top television ad honors at the 2008 10th Annual Pharmaceutical Advertising and Marketing Excellence Awards (PhAME) gala event at the Guggenheim Museum in New York City.

"When I think about Gardasil<sup>®</sup>, the entire approach is to make sure we get as many appropriate people vaccinated as possible," said David Schechter, executive director, Merck vaccines and infectious disease. "We looked at innovative and creative approaches to get to the consumers, and have them take action and talk to their healthcare professionals."

***I could be one less.  
One less statistic One less  
I want to be one less woman who will battle cervical cancer.  
One less***

France has now banned advertisements claiming HPV vaccines prevent cervical cancer  
The UK Advertising Standards Authority has banned Cervarix 'armed for life' advertisements stating they are misleading and untrue.



**One More Girl Unveils  
Truth behind HPV Vaccine Travesty  
Documentary Hailed as  
Social/Political Statement on  
Marketing of Global Medical Experiments**

This provocative film documents the stories of the numerous girls adversely affected by the HPV vaccines – giving these young women and their families a chance to speak out – share their dismay and sense of betrayal for simply believing the pharmaceutical and medical industries were protecting them when marketing HPV vaccines for the prevention of cervical cancer. Filled with stories of anguish, loss of innocence, guilt on the part of mothers who encouraged their daughters to get the vaccine – and financial devastation as families use

their hard-earned savings to find a cure for their daughter's illness, leaving no viewer untouched.

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