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Dr Margaret Hamburg, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring
MD 20993-0002

Dear Dr Hamburg

Gardasil – HPV Vaccine

I first wrote to you on the 16th March 2009, and you very kindly replied to me the same day, concerning my daughter Megan Hild who died suddenly within a short period of time after having had her Gardasil shot. Megan had not been keeping very well after being vaccinated but had intended coming over to my home to help us with some painting work. She phoned to tell me she would be over after she had taken a shower. Sadly, she died in the shower and to this day I do not know the reason why she died as her autopsy report states “death unknown”. Megan was a very active and healthy young lady prior to Gardasil and I truly believe in my heart that she would be here today if she had not been vaccinated. Megan’s is not the only case where young women have died with no cause of death being known. Dr Hamburg, that is not normal where healthy and even athletic young women die for no apparent reason and yet the common link between them is the Gardasil vaccination. If it is not this vaccine then there has to be some serious virus or illness spreading around our young people one way or another and either killing them or leaving them seriously injured.

I am attaching two documents for you to see, one is called the “**Memorial Document**” and the second is called “**Gardasil Injuries**”. The stories posted here are just the tip of the iceberg. There are hundreds if not thousands more. Many families are not aware of the link between the vaccine and their daughter’s ensuing illness. Other girls may have suffered strokes and died while driving a car or falling in the bathroom like my daughter Megan Hild, or Lisa Ericzon’s daughter, Jessica Faye Ericzon. We may never know the final number of girls who have suffered adversely from this vaccine now ... or in the future ... or if their side effects may even affect their future health and/or fertility. Please note throughout these documents the number of girls who are experiencing serious menstrual problems, almost like the onset of the menopause.

You may, and probably will, be shocked to read these documents, these are true stories and very sad stories and these young girls and women were all alive or healthy before having the Gardasil vaccination. That point is factual but when you take a look at the symptoms that are being experienced by the young ladies, many of these are repeated over and over again, such as seizures, brain fog, paralysis, severe joint and muscle pain, exhaustion, muscle spasms, disruption of the menstrual cycle, as noted above. Where diagnoses have been established by medical practitioners and these include Amyotrophic Lateral Sclerosis (Motor Neurone Disease/ALS). As you know, MND usually strikes in late middle age (the late 50’s is average) or lately there has been an increased rise in young adults. It could be stated honestly that it will be extremely rare for a 13 year old girl to have this illness – Jenny’s story on the Memorial Document will tell you her story. Other such diagnoses include pancreatitis, gastrointestinal disorders, Lyme disease, hypothyroidism, peripheral neuropathy, Posterial Orthostatic Tachacardia Syndrome (POTS) and again it was only after the Gardasil vaccination that these young women became ill with various side effects and after a long period of time eventually were diagnosed with these conditions. It should also be recognized that in the case of some of these illnesses, the treatment given to contain or improve the effects being experienced does not always work which makes you wonder if there is a “copy cat” type of situation going on or if the symptoms being experienced are very similar to those of clinically recognized illnesses, such as Lyme disease. By that I refer to Gardasil type illnesses which are new and not recognized as such at the moment.

May I ask a question, when have you ever known cases where young, very active and extremely intelligent young ladies, like Samantha Hendrix, 1(c), who was regarded as a walking encyclopaedia and who is now reduced to failing examinations and cannot concentrate on her studies? Where has this once intelligent lady

gone and where have the other young women who have been afflicted in the same way gone? These bright, intellectual young women are in some dark space unable to be the people they once were. What has happened to them, their symptoms are identical and the common thread that exists between them is “Gardasil”? You wonder why we question this, we live with the result of a global tragedy which is occurring in every State in our country and you know the reality of all of this “No one seems to care”.

Also In the case of young Samantha, she had a serious history of illnesses prior to vaccination, have you ever discovered if Merck carried out research on impaired immune responsiveness to establish if young girls with a medical history would be well enough to have this vaccine? In the case of Cervarix, GlaxoSmithKline did not carry out this research prior to the commencement of the vaccination programme in the United Kingdom. This young girl had many health problems before being vaccinated but now she is far worse off and what the future holds for her we just do not know. Perhaps, if more care and attention had been given by the pharmaceutical company in all of this, if they had taken more time to carry out the research into all aspects of safety and just had given it a few more years, exactly the same advice that Dr Harper gave to the UK regarding Cervarix, then perhaps these young ladies would not be so ill and I would not be writing to you today to ask for your help. With respect to Cervarix, many of the same “Gardasil” illnesses are occurring in the United Kingdom also so there appears to be a common thread that exists between these two HPV vaccines.

The very worrying aspect of it all is that in most cases, after the young girls and women have been through the medical system and have had CT scans, MRI’s, various blood tests, x-rays and whatever else may be required, the results usually come back normal. Doctors recognize that something is going on but do not have a clue what it could be. So there is something very sinister in all of this that in this country, where our health care should be second to none, hundreds of young women cannot be diagnosed by the medical profession, their illnesses are genuine but yet there does not appear to be many doctors who can identify what is actually wrong. So now we have two such bizarre situations – cause of death unknown and serious illnesses being experienced by young women not being identified by the physicians they go to see.

In your position as Head of the FDA, have you ever come across a situation like this where it involves healthy young girls and women who just suddenly die, with no history of serious illnesses, or who become disabled, have repetitive seizures, lose the use of their legs, have no control over their bodies and our doctors appear not to even consider a link with the Gardasil vaccine? Why is it that many of these events occur within a very short time span after the Gardasil shot? Let me repeat the words of Dr Diane Harper when she was interviewed by the Australian team in the video identified at the top of the Gardasil Injuries Document 1(b) **“The majority of them (side effects) actually occur in what we call the biologically plausible time frame. Up till about 42 days is the time frame in which if there was something that was going to happen, it could be attributed potentially to the vaccine and that’s where these cases are happening.”** As you probably know, Dr Harper helped design and carry out the Phase II and Phase III safety and effectiveness studies to get Gardasil approved, and authored many of the published, scholarly papers about it. She has been a paid speaker and consultant to Merck. It is highly unusual for a researcher to publicly criticize a medicine or vaccine she helped to obtain approval for.

Perhaps, and this is only a suggestion, would you be willing to meet with Dr Harper to ask her what her concerns are relating to the Gardasil vaccine? I would also like to suggest at this venture if you would also be willing to meet some of the moms who have told their stories as this would give them hope that someone in a high position was actually caring for them and willing to listen. Something really serious has happened to their daughters and as the common link in all of the cases is Gardasil, then we felt you would be interested to hear their side of things. All of the cases mentioned can be checked by your Department direct to their physicians.

There are four issues that I believe you may care to consider in relation to Gardasil:

1. It is well reported that the Gardasil test trials showed side effects of placebo vs. vaccine. However, this is not really a true determination of side effects since the placebo in Merck’s study used aluminium as the adjuvant (rather than saline). Given this, one would not see significant differences between the two groups because both aluminium hydroxide and aluminium phosphate have, in the past, shown a causal relationship to multiple neurological issues. Perhaps, the side effects of BOTH groups should have been added together rather than shown as separate entities and if so perhaps the levels of adverse reactions might be a lot higher than Merck/VAERS report.
2. VAERS data suggests that both lots U and X of Gardasil are severely problematic, yet these lot numbers have yet to be recalled by Merck. There is speculation that something is perhaps amiss, eg extra yeast?
3. There is growing evidence that Gardasil may trigger existing Auto Immune Disease issues or worse latent ones such as a genetic predisposition to an AID, Lupus and Rheumatoid Arthritis etc. There is also speculation that there is a potential link between vitamin B deficiency, Gardasil and adverse reactions. If this link is proven, is it not cause for tests to be conducted on proposed recipients of Gardasil BEFORE it is administered?

The above points are the thoughts and research carried out by many of the parents whose children have been afflicted and they should be commended for caring enough to try and find out why their children have been harmed. They do more as “amateur scientists” attempting to discover the truth than those who should be investigating these issues and appear to be trying to hide the truth.

The Vaccine Adverse Event Reporting System (VAERS) is used by the CDC and FDA to detect and record possible side effects or adverse events following vaccination. The horrible realization is that VAERS is very limited and is often inaccurate. A large # of Gardasil mothers state that their children are not in VAERS because their doctors refuse to admit that Gardasil is causing the side effects. As a result, neither the parents nor the doctors have filed reports. According to Barbara Loe Fisher, Director of the National Vaccine Information Center between 1 to 10% of vaccine adverse reactions are only being reported to VAERS. This low percentile skews all of the statistics that have come in on deaths and injuries from Gardasil. By doing a simple query within the VAERS system, it is very easy to identify that the majority of side effects appear to be coming from 3 primary batches. By querying the HOT LOTS from VAERS and identifying the MERCK lots reported 10 times or more, a common theme appears with the lots ending in U, X, and F.

End Letter	# of Times Reported	% of Volume
U	3,088	63%
X	906	19%
F	881	18%
	4,875	100%

Numerous parents have contacted Merck with this information and asked for more detail to analyze the data further only to be told that they would have to go through Merck’s Legal Office which in turn doesn’t respond to the calls. Why do our consumer protection laws not protect our children if the product/vaccine is deemed faulty and why is the producer of the vaccine not required to provide the needed information? The drug companies are selling a product and the consumers should have specific rights as they would with other goods purchased. As of June 1, 2009, more than 25 million doses of Gardasil were distributed in the United States. An analysis needs to be performed to determine out of the 25M lots distributed, how many have actually been administered. The analysis should be broken down by batch so that the side effects are truly studied. If a problem is deemed batch specific, then the lots ending in U, X, and F need to be pulled from the market and a thorough investigation needs to be performed to determine the differences in these specific batches from other batches which are not posing problems if there are differences. Could the problems be arising from production issues at Merck? A closer look needs to be taken.

Many of the doctors who vaccinated these children were not familiar with VAERS and did not even know how to file a report. How can the #'s within VAERS be accurate if doctors don’t file the reports? Shouldn’t our doctors be required to fully understand the side effects of the vaccines that they are administering and VAERS has a database to record and track these side effects? Our doctors should be required to file all reports of side affects instead of simply brushing off the patients. If the doctors do not fully understand the side effects, they should not be giving the immunizations. It should be mandatory that the doctors fully understand vaccines and side effects and that they inform the parents UPFRONT of what could happen.

A rose by any other name is still called a rose. A virus by any other name is still called a virus; “a submicroscopic parasitic particle of a nucleic acid surrounded by protein that can only replicate within a host cell”¹. *and travels with that cell to destinations unknown or to where there is a host receptor.* Are they just sexually transmitted? A virus comes out to play when the condition of the body becomes prime to be its host – and that is due to a plethora of reasons: genetic, environmental, nutritional, and immunological. It is well known that viruses i.e.; herpes for example may lie dormant within the body for years until the right factors ensure its survival and it can replicate and thrive in an environment that has lost its hostility.

Why has it been unfeasible to consider that the Human Papillomavirus may also be transmitted in a non-sexual manner through other body fluids– similar to HIV/AIDS, or Adenoviruses, Herpes Simplex 1, Molluscum contagiosum, Cytomegalovirus to name a few. Viral cells are transported through fluids. “There is growing evidence” or “compelling evidence” that HPV infection is acquired through “non-sexual” routes, specifically mother/child transmission. In addition, there are multiple studies that cite HPV detection in virgins, infants/children and juveniles. Since laryngeal papillomatosis was shown to be caused by HPV, it became apparent that the virus may be transmitted by other routes as well. A virus called by any other name is still a virus and it will travel whatever route to find a host to ensure its survival.

The [American Social Health Association](#) (ASHA) cites that in a 1997 article in the American Journal of Medicine, about 74 percent of Americans or three out of four have been infected with genital HPV at some point in their lives. Only one in four Americans ages 15-49 has not had a genital HPV infection. Most often genital HPV produces no symptoms or illness, and so a person who has been infected may never know about it.

Further evidence of research proving that young children can be infected by the HPV virus can be found in this research paper, the [Journal of Medical Virology](#), where it not only proves that this does occur, it also proves that non-infected children who were examined previously, have become infected since their previous examination.

In the FDA's [VRBPAC Background Document](#), dated May 18, 2006, the government acknowledged the non-sexual transmission of HPV, reference page 13, 'Concerns regarding Primary Endpoint Analyses among Subgroups. In addition, they stated that the HPV Vaccine, Gardasil, may increase the risk of cervical cancer by 44.6% if women were vaccinated without being aware that they had the virus. It should also be noted that if a young person has the virus and is vaccinated, then she will not be protected and it will have been a complete waste of time in vaccinating her in the first place. The danger here is that if the FDA and the pharmaceutical company do not accept the research that has been carried out then young lives could be put at greater risk as stated above. An interesting point, what will you do when you find out that vaccinated girls or young women are found to be infected with the HPV virus at their next pap screening, or worse still that they have signs of cervical cancer? The responsibility for this will lie entirely with you. Perhaps, in the interests of safety this is an area that you should investigate sooner rather than later.

As mothers and grandmothers, aunts and sisters we are also concerned about the health of the First Family's daughters, 11-year-old Malia and 8-year-old Sasha Obama. They are within a year of being eligible to receive the Gardasil vaccine. Out of respect for President Obama and his wife, Michelle, we feel that it is only fair for them to be aware of the adverse reactions and suffering of other girls in their daughter's age group after receiving the HPV vaccine. We hope that this paper will be brought to their attention and that they will start researching the facts about Gardasil prior to inoculating their daughters.

Many points have been covered in this letter, the main purpose for this is my concern for the safety of our school children and young women who are being vaccinated with this HPV vaccine. We never wish to hear again that these deaths and illnesses occurred through "natural means", if that was the case then why are so many of the symptoms so similar, why have intelligent young ladies lost the ability to learn and why have there been deaths with no cause of death known. Someone has to take responsibility to initiate an immediate investigation into why these deaths and illnesses occurred – to neglect to do this is tantamount to not caring what happens to our young, beautiful and previously healthy young American daughters and I do not think you can afford to take that risk with two lovely young girls at present living in the White House. Rest assured, this correspondence will be seen by the President and the First Lady and at that point it will be up to them to decide which road they intend to travel. However, I do believe they will wish to hear and see all of the facts for themselves, from you Dr Hamburg, from the pharmaceutical company, from the doctors and most importantly from the mothers whose children have either died or have been left handicapped in one way or another. That at least would be the beginning of an investigation into these mystery illnesses which are prevalent in our country at the present time and to start by asking a serious question, "Why are these adverse events occurring in every country where the HPV vaccine is administered, be it Gardasil or Cervarix, the results are the same? That is a good starting point.

Yours sincerely

Karen Maynor
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Copied by email and by postal services to:

President Obama
First Lady Michelle Obama
Vice-President Joe Biden
Dr Jill Biden
Robert Gibbs, White House Press Secretary

Secretary of State Hillary Clinton
Secretary of State Kathleen Sebelius
Governor Arnold Schwarzenegger
First Lady Maria Shriver

Governor Charlie Crist (FL)
Senator Bill Nelson
Mayor Allen Green
Suzanne Kosmos

Governor Bobby Jindal (LA)
Senator Mary Landrieu
Senator David Vitter
Congressman Steve Scalise
Mayor Bob Zabbia
Attorney General James D Caldwell

Governor Deval Patrick (MA)
Office of the Lt. Governor
Senator John Kerry
Congressman Jim McGovern
Mayor Nancy Stevens
Attorney General Martha Coakley

Governor Jay Nixon (MO)
Senator Claire McCaskill
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Mayor Darwin Hindman
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Attorney General Chris Koster

Governor Beverly Purdue (NC)
Senator Richard Burr
Senator Kay Hogan
Congressman David Price
Congressman Virginia Foxx
Mayor George Church
Mayor Harold Weinbrecht, Jr
Attorney General Roy Cooper

Maryland and NY US elected representatives have also received this documentation
This letter and documents has also been copied to other State representatives by moms whose stories are not included in these documents

Copied by email and postal services also to:

Vaccines and Related Biological Products Advisory Committee

Dr J M Sharfstein, Deputy Commissioner, FDA

Governor Bill Richardson (NM)
Senator Jeff Bingaman
Senator Tom Udall
Congressman Martin Heinrich
Attorney General Gary King
Mayor Martin J Chavez
Mayor Ronnie Torres

Governor Ted Strickland (OH)
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Governor Edward G Rendell (PA)
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Governor Mark Sanford (SC)
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Senator Shane R Martin
Senator Harvey S Peeler, Jr
Mayor William Barnett, III
Attorney General Henry McMaster

Governor Rick Perry (TX)
Senator John Cornyn
Senator Kay Bailey Hutchinson
Congressman Sam Johnson
Office of the Attorney General

Governor Tim Kaine (VA)
Congressman Frank Wolfe
Senator Jim Webb
Senator Mark Warner

Governor Chris Gregoire (WA)
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