FDA approved Gardasil 9: Malfeasance or Stupidity?

By Norma Erickson

Malfeasance is when a public official violates the public trust by performing an act that is wrongful, legally unjustified, or contrary to law. Nonfeasance is the failure to act where there is a duty to act. Misfeasance is conduct that is lawful but inappropriate. Perhaps, when it comes to the recent approval of Gardasil 9 all of these apply.

10 December 2014: The FDA approved the use of a reportedly 'new and improved' version of Gardasil, which will be marketed as Gardasil 9. According to the FDA approval letter, this action was taken without consultation with VRBPAC (the Vaccines and Related Biological Products Advisory Committee) which is responsible for reviewing and evaluating data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products.

The FDA approval letter, signed by Marion Gruber, Director of Office of Vaccines Research and Review CBER, states the reason for bypassing the advice of VRBPAC writing:

> *"We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues which would have benefited from an advisory committee discussion."*

So, the Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER) committee took it upon themselves to decide there were "no concerns or controversial issues" regarding the approval of Gardasil 9?

This division of CBER decided there would be no benefit from "an advisory committee discussion"?

According to their own mission statement, the FDA is "responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."

The FDA, and all committees associated with the FDA, are public officials and therefore obliged to act in the public's best interest particularly when it comes to health and safety issues.

Is bypassing advisory committee discussions regarding Gardasil 9's potential safety and efficacy acting in the public's best interest, or is it malfeasance, nonfeasance and/or misfeasance?

Examine some Gardasil 9 facts

CBER decided there was no need for VRBPAC to review or evaluate any data concerning the safety, effectiveness, and appropriate use of Merck's proposed Gardasil 9 vaccine before making a decision to

approve the nine-valent HPV vaccine. This move is particularly disturbing when one considers the worldwide controversy surrounding Gardasil's safety, effectiveness and appropriate use.

The proposed Gardasil 9 package insert and the current Gardasil package insert are a good place to start a critical examination. The table below lists the ingredients of both Gardasil and Gardasil 9. All differences from one HPV vaccine package insert to the next are highlighted.

Gardasil	Ingredient	Gardasil 9
225 mcg	AAHS (aluminum adjuvant	500 mcg
9.56 mcg	Sodium Chloride	9.56 mcg
.78 mcg	L-Histidine	.78 mcg
50 mcg	Polysorbate 80	50 mcg
35 mcg	Sodium Borate	35 mcg
<7 mcg	Yeast Protein	<7 mcg
20 mcg	HPV 6 L1 protein	30 mcg
40 mcg	HPV 11 L1 protein	40 mcg
40 mcg	HPV 16 L1 protein	60 mcg
20 mcg	HPV 18 L1 protein	40 mcg
	HPV 31 L1 protein	20 mcg
	HPV 33 L1 protein	20 mcg
	HPV 45 L1 protein	20 mcg
	HPV 52 L1 protein	20 mcg
	HPV 58 L1 protein	20 mcg
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40 mcg	HPV 11 L1 protein	40 mcg
40 mcg	HPV 16 L1 protein	60 mcg
20 mcg	HPV 18 L1 protein	40 mcg
	HPV 31 L1 protein	20 mcg
	HPV 33 L1 protein	20 mcg
	HPV 45 L1 protein	20 mcg
	HPV 52 L1 protein	20 mcg
	HPV 58 L1 protein	20 mcg

Take a look at the first line in the chart to the left. Aluminum is a known neurotoxin. A quick search of *PubMed* for 'aluminum toxicity human' returns no less than 1652 peer-reviewed and published scientific papers on the subject. **Why did Merck more than double the amount of aluminum adjuvant in Gardasil 9?**

What long-term health consequences are associated with the injection of 1,500 mcg of aluminum over a period of less than a year via 3 doses of Gardasil 9?

Does this risk increase if Gardasil 9 is received at the same time as another vaccine containing an aluminum adjuvant? If so, how much?

Surely the members of CBER are aware there are potential health risks resulting from aluminum exposure. Did they discuss these risks before making a decision?

Why did Merck increase the amount of HPV L1 protein for 3 of the HPV types already contained in the first version of Gardasil and not for the 4th type? Why do the amounts of these increases vary so much from one HPV type to another?

Are there any potential health risks associated with increasing the total amount of antigen (HPV L1 protein) from 120 mcg in Gardasil to 240 mcg in Gardasil 9?

There seems to be no public record of the CBER meeting, so the general public – including medical professionals who will be expected to administer this new HPV vaccine to their patients may never know whether or not these subjects were even discussed.

Bombshells from the Gardasil 9 package insert

The potential risks discussed above pale in comparison to some of the bombs dropped in the rest of the Gardasil 9 package insert. Any medical professional who reads the entire package insert and still recommends the use of either Gardasil, or Gardasil 9 does not care about the health and well-being of their patients.

Bombshell #1 Serious Adverse Events

According to the FDA a serious adverse event must fit one of the following criteria: death, life-threatening, hospitalization, disability or permanent damage, congenital abnormality/birth defect, or the requirement to intervene to prevent permanent impairment.

According to the Gardasil 9 package insert, the following percentage of serious adverse events were collected during follow-up (up to 48 months):

SERIOUS ADVERSE EVENTS

Number receiving shot	Type of vaccine	Percentage Serious AE's	Number of Serious AE's
13,236	Gardasil 9	2.3%	305
7,378	Gardasil	2.5%	185

For the first time, Merck has disclosed what may indeed be close to the true rate of serious adverse events people are suffering after the use of Gardasil and will probably continue to suffer if they consent to using Gardasil 9. The only difference would be that the rates may be higher when used in the general population because certain at-risk groups are excluded from clinical trial participation but not from vaccination programs.

2.3-2.5% doesn't sound that bad until you compare apples to apples. Cervical cancer rates are always quoted as # per 100,000. Given the above information, for every 100,000 people using Gardasil 9 there would be 2,300 serious adverse events. The cervical cancer diagnosis rate in the United States is 7.9/100,000.

What health official in their right mind is willing to anticipate 2,300 serious adverse events to try and prevent 7.9 cases of cervical cancer?

Keep in mind that the cost of vaccinating 100,000 people is around $30 million ($100 per injection, 3 injections). This doesn't even begin to address the cost of treating 2,300 serious adverse events, the emotional, physical and financial expense to families and the cost to society via the lost productivity of the injured.

Bombshell #2 Systemic Autoimmune Disorders

An autoimmune disorder occurs when the body's immune system attacks and destroys healthy body tissue by mistake. There are more than 80 types of autoimmune disorders. Many of the people diagnosed as suffering systemic autoimmune disorders after HPV vaccines were first mis-diagnosed

with conversion disorder or psychosomatic illnesses. Below are the rates of "new medical conditions potentially indicative of autoimmune disorders" experienced during Merck's Gardasil 9 clinical trials.

SYSTEMIC AUTOIMMUNE DISORDERS

Number receiving shot	Type of vaccine	Autoimmune Disorders	Number
13,234	Gardasil 9	2.4%	321
7,378	Gardasil	3.3%	240

So, in addition to the serious adverse events, you now have an additional 2,400 people who may be left with systemic autoimmune disorders. How can any health official possibly think Gardasil 9 is worth this kind of risk?

Bombshell #3 Pregnancy Outcomes

According to the Gardasil 9 package insert, 1,028 women who were injected with Gardasil 9 became pregnant during the course of the clinical trials along with 991 women who had been injected with Gardasil. Overall, 14.1% of the Gardasil 9 women suffered adverse outcomes while 17.0% of the Gardasil women suffered the same fate. A total of 313 women either lost their babies to spontaneous abortion or late fetal death or gave birth to children with congenital anomalies.

This population was further broken down into those who became pregnant within 30 days of an injection and those who became pregnant more than 30 days post-injection. The charts are below.

OUTCOME WHEN INJECTED WITHIN 30 DAYS OF PREGNANCY ONSET

Number of pregnancies	Type of vaccine	% abortion/stillborn	Lost Babies
62	Gardasil 9	27.4%	17
55	Gardasil	12.7%	7

OUTCOME WHEN INJECTED MORE THAN 30 DAYS BEFORE PREGNANCY ONSET

Number of pregnancies	Type of vaccine	% abortion/stillborn	Lost Babies
960	Gardasil 9	10.9%	105
933	Gardasil	14.6%	136

Note: The numbers from these two charts do not add up to the total number Merck stated in the first paragraph. That is because in the 'more than 30 days' group there were also 20 cases of congenital anomalies after Gardasil 9 and 21 cases after Gardasil.

Merck stated in the package insert, **"The proportions of adverse outcomes observed were consistent with pregnancy outcomes observed in the general population."**

Unless they are talking about some country other than the United States, **THIS IS NOT TRUE**.

According to the CDC's latest publication on fetal mortality, the rate of spontaneous abortions and fetal deaths in the United States is 6.05/1,000 pregnancies or 0.605% – hardly 10.9%, much less 27.4%, and certainly not 'consistent with outcomes observed in the general population' of the United States.

Do CBER officials not even go to the trouble of verifying the 'facts' presented by vaccine manufacturers when they are 'evaluating data concerning the safety, effectiveness, and appropriate use' of vaccines?

Whether these actions, or lack of proper actions are a result of malfeasance, laziness, or just plain stupidity does not matter at this point. It is obvious to the most casual observer the FDA either cannot or will not properly handle their responsibility to protect and preserve the public's health and safety. They have violated the public trust.

There is absolutely no excuse for exposing young women and men to this level of risk for a vaccine that provides nothing other than promises of results far down the road.

The FDA needs to be removed from the responsibility of 'assuring the safety, efficacy and security' of vaccines. It is quite obvious they are not up to the task. They are most certainly not acting in the best interests of the public.

Medical consumers – do not consent to the administration of Gardasil 9 unless you and your medical provider have read and discussed the entire package insert together. The choice is yours, make it an informed one.