SANEVax – Our Daughters Should Not Be Experiments for The Drug Industry

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SANEVax News Release

Parents of Daughters & Women Injured from Gardasil React to FDA Decision

Why are medical consumers the medical experiments? Safety and efficacy studies should be conducted for all intended age intended before market release.

On April 7, 2011 the media broke the news about the U.S. FDA's ruling against Merck's supplemental biologics license application (sBLA) for an indication to use GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] in women ages 27-45. This was Merck's 4th request to expand Gardasil use to an older population of women.

According to a report in MedPage Today,

'The decision was based on a trial in 3,253 women ages 27 to 45. Although the vaccine appeared to prevent persistent HPV infection, no significant benefit was found for more important outcomes such as high-grade neoplastic lesions or cervical cancer when all participants were included irrespective of baseline HPV status.'

Within days the news of the FDA's decision traveled across the country and across the world. SANE Vax Inc. asked parents whose daughters have been injured by the vaccine as well as victims themselves to comment on the decision.

Instead of protecting her life, it took her life.

I am thankful that the FDA did not give Merck a license to provide Gardasil for women over the age of 26 to 45 years. That is only one small step when in my opinion the FDA has made many

errors with this program of vaccination. My 14 year old daughter died after having her second shot of Gardasil. She was in perfect health until she received this vaccination. We were told that we had to be responsible parents and that it was important that she have this vaccine. *Instead of protecting her life, it took her life.* The FDA still dares to suggest that this program is safe and effective and the benefits outweigh the risks. That is not true in my case or in the cases of all those who have lost their daughters, and even their sons, to this vaccine; and not forgetting the many thousands who have also been injured. There can never be a benefit when there is the death of a child.

Linda Morin, Quebec, Canada

With over 20,000 adverse injuries reported and around 100 deaths,
why is nothing being done to pull the vaccine from the market?

I am very disappointed in the FDA and CDC in general regarding Gardasil and the monitoring of adverse reactions. The FDA recently rejected Merck's 4th request to expand Gardasil use to women 26 years and older. I think this was a very good decision on their part, but the fact that they have left the vaccine on the market for females 25 and below is appalling. My 12 year old daughter was disabled by the Gardasil vaccine and missed almost an entire year of school. 2 ½ years later, she still suffers from the adverse effects of the vaccine. With over 20,000 adverse injuries reported and around 100 deaths, why is nothing being done to pull the vaccine from the market?

I have personally seen the damage the vaccine can do to a young, healthy girl. I feel it is justified to not allow the vaccine to be

marketed for older women. I personally would never consider this vaccine for my 18 year old son or for myself as one who falls in the older age bracket. I wish I had known of the adverse effects and Gardasil prior to my daughter's vaccine injury.

I would like the FDA to explain how Gardasil is acceptable in younger women when they say it has not been demonstrated to prevent HPV-related CIN 2/3 or worse in women older than 26 years of age. What is the difference? How can it be accepted as safe in the younger group but not in the older group?

Rosemary Mathis, North Carolina

U.S. FDA has rejected the use of Gardasil in women between 27-45 years old.

The problem in Spain is that the vaccine is recommended for women older than 26.

How can it be effective for women in one country and not the other?

All our suffering cannot be paid with all the money they are losing. Money is just money; they will earn or lose it. However our daughters will never recover the years they have lost suffering the side effects of a vaccine that has been on the market without enough evidence of its efficacy. The governments around the world should do something to prevent these things from ever happening again.

Health Authorities around the world should inform parents about the risks of this vaccine, so that parents can make an informed decision about their daughter´s health. I wish I had known all the dangers this vaccine had before vaccinating my daughter – but the only information I received was (1) the vaccine protects women from getting cervical cancer – **not**

true- and (2) the vaccine may only produce local effects such as pain or swelling on the site of the injection – **not true either.**
When my daughter was in hospital we wrote a press release to the International Scientist Community asking for help and the answer we received from Spanish Health Authorities was that the only two cases of seizures in Spain and Europe were the Valencian girls; one is my daughter. We felt hopeless when we learned all the incidents of seizures reported to VAERS before February 2009 when my daughter received her second shot. Now the FDA has rejected the use of Gardasil in women between 27-45 years old. The problem we have in Spain is that the vaccine is recommended for women older than 26. How can it be effective for women in one country and not the other? I do not understand how these things can happen in the world.

Alicia Capilla, Spain

Why me? I was 25 & 4 months when I received the first vaccine and became injured.
Why is my genetic make up – or whatever it was that lead to this reaction -
so different than if I was 8 months older?

I was given the first dose of Gardasil by my GP in Australia in May 2008. I advised him that I had recently separated from my husband (in March 2008), and was convinced of his infidelity. As such, I requested a pap smear and full women's wellness test, which to my knowledge, included blood samples to be taken for STI's. The first dose of Gardasil had been administered prior to receiving the results which were negative. My GP was also aware that my immune system was severely lowered due not only to my separation, but moving house and changing employment.

Exactly two weeks after receiving the vaccine, I fell and snapped a bone in my foot. Once I was off crutches, I went to the GP as recommended to receive my second shot. I advised them that my walking was a bit funny due to getting off crutches. No warning was given, I was administered the shot, and not required to wait the mandatory waiting time. I was allowed to leave and drive. A few weeks later, everything started to deteriorate. This led to paralysis and my cerebellum to shut down. Prior to this, I was fit and healthy and had no health concerns. My question is: Why me? I was 25 & 4 months when I received the first vaccine. Why is my genetic make up – or whatever it was that lead to this reaction – so different than if I was 8 months older? It does not make sense. If there is something in an individual's genetic make up, should they not receive some sort of screening or testing prior to being vaccinated? We need to fill out pages of information to give blood (i.e. specimen coming out of our bodies), but this is not the same for something that goes into our body's, and may stay there for a lifetime. Furthermore, it may change our lives forever. I struggle every single day to accomplish seemingly simple every day tasks, and there is no saying that this will change. And I am one of the lucky ones.

We are guinea pigs. We place our lives in the hands of those who we believe are there to protect our health, and that sense of trust seems to be overwritten by money. Furthermore, not only was I a victim of Gardasil, the treatment to save my life – which is supplied by CSL Laboratories – was ultimately purchased by my parents to save my life as CSL would not donate it.

Kristin Clulow, Australia

What the heck is the difference in approving it for those who are one year younger!

As a parent dealing with a 20 year old daughter badly damaged by Gardasil I can say whilst it is pleasing to see that the FDA has not approved Gardasil for women over 26, I guess the question that everyone would now be asking is, what the heck is the difference in approving it for those one year younger!

Stephen Tunley, Australia

SANE Vax Inc., believes that if Gardasil has not been demonstrated to prevent CIN 2/3 or worse in older women the same applies for women younger than 26 years of age. Clinical trials used an endpoint insufficient to clearly demonstrate efficacy in this arena. Therefore, we believe that Gardasil needs to be taken off the market until an independent study on the vaccine's safety and efficacy is conducted.

- The SaneVax Team and medical consumers around the world demand scientific proof that Gardasil® is safe, effective and necessary for the approved age groups.
- The SaneVax Team and medical consumers around the world, once again request the FDA rescind their approval of Gardasil® until studies are conducted with appropriate endpoints.

The FDA has opened the door of doubt confirming our worst fears; Gardasil is a potentially dangerous vaccine fast-tracked into the medical consumer market without adequate testing. Medical consumers should never become medical experiments for the profit of the pharmaceutical industry or the government. SANE Vax, Inc. will continue our global campaign

on behalf of the parents whose daughters and sons have been injured or who have died post-vaccination, until the vaccine is taken off the market.
http://www.prlog.org/11443952-parents-of-daughters-women-injured-from-gardasil-react-to-fda-decision.html

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