FDA Halts HPV Vaccine Roll-Out – SaneVax News Release

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SaneVax Asks the FDA: Gardasil® What is Wrong With This Picture?

Medical consumers worldwide applaud the recent FDA decision not to expand the use of Gardasil to women over the age of 26. Now they want to know when the FDA will admit the original approval may have been a mistake.

FOR IMMEDIATE RELEASE

PRLog (Press Release) – *Apr 12, 2011* – Last week, the FDA refused to approve Merck's application for expanded use of Gardasil® in women over the age of 26. According to a recent article 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."

The SaneVax team respectfully suggests that if this is the case for women between the ages of 27 and 45, it may also be true for young women between the ages of 9 and 26 for whom Gardasil® was originally approved as a potential cervical cancer preventive. It may also be true for the male population for whom Gardasil® recently received expanded approval by the FDA as a potential preventive for anal cancer.

The efficacy analysis submitted by Merck to obtain FDA approval for the use of Gardasil® in the male population in November 2010 contains the following pivotal results [note-AIN2/3 are high-grade neoplastic lesions, AIN3 is higher than AIN2 – both are potentially precancerous]:

Table 2 – Efficiency against HPV 6/11/16/18-related AIN in the MSM FAS Population:
AIN2 or worse 18/275 (Gar); 39/276 (placebo) Efficiency= 54% (95%CI; 18, 75)
AIN3 10/275 (Gar); 19/276 (placebo) Efficiency= 46.8% (95%CI; -20, 80)
Table 4 – Efficiency against any HPV type-related AIN in MSM FAS Population:
AIN2+ 44/275 (Gar); 59/276 (placebo) Efficiency= 24% (95%CI, -14, 50)

Please note the 'efficiency' ratings when the CI (confidence interval) is taken into consideration. The levels range from a potential low of minus (-) 20% to a potential high of 80%. One has to wonder what the FDA was thinking when they approved a 'vaccine' with such a broad range of 'efficacy' potential, particularly when there was an indication that it may actually increase the possibility of developing potentially AIN3 pre-cancerous lesions.

Since Gardasil® is not recommended to be used in conjunction with HPV genotype monitoring, the data for HPV 6, 11, 16, 18-related AIN means nothing to average medical consumers, or their physician. Without adequate genotyping no one knows which sexually active man or woman may benefit from the vaccine, or which HPV genotype is causing the lesions developing after vaccination.

Merck also included results on efficacy in regard to AIN1. AIN1 lesions are totally reversible, therefore, pose no threat to anyone. They can be caused by numerous "non-carcinogenic" HPV genotypes.

According to Dr. Garner, lead clinical monitor in the Gardasil® AIN trials, speaking to VRBPAC members at the FDA review hearing,

" …unlike cervical cancers, not all anal cancers are associated with HPV. So HPV cannot be said to be, quote/unquote, necessary and sufficient for the development of anal cancer."

During the same meeting, Dr. Vicki DeBold, the consumer representative member of the VRBPAC expressed many concerns, one of which was,

"One of the reasons that I'm not comfortable is due to some of the data that's on slide 23 that the FDA presented where we see much higher levels of immunogenicity in the younger age groups, and I can't help but to wonder if some of this reactivity that we're seeing here might also have a relationship to some of the safety issues that have been raised not only by the last public speaker but the enormous number of reports that are coming into not only the National Vaccine Information Center but VAERS.

I am not reassured by the safety data that have been presented, partly because they're using a reactive placebo, an aluminum-based placebo, rather than something that is nonreactive. I think that it makes it very difficult, if not totally impossible, to understand what is truly going on."

The SaneVax Team wants to know: How can the results of studies conducted on MSM (males who have sex with males) of specific ages be used to determine potential outcomes when using Gardasil® in other men, or women for the possible prevention of anal cancer.

There are substantial hormonal differences between pre-pubescent males and young adult males, as there are substantial differences between males and females. A one-size-fits-all 'vaccine' just does not make sense unless studied for safety and efficacy in all target populations.

According to the National Cancer Institute, "Vaccines are medicines that boost the immune system's natural ability to protect the body against 'foreign invaders,' mainly infectious agents that may cause disease."

HPV (human papillomavirus) is a foreign invader. Cancer cells are not. Cancer cells are host human cells that have mutated to allow uncontrolled growth, hence the tumors. Scientists are trying to make patient's cancer cells to be recognized as foreign invaders by the host immune system to create therapeutic vaccines to treat cancers with little success. A preventive vaccine against cancer is incomprehensible.

HPV vaccines were never designed to attack the cancer cells; they were designed to produce a greater immune response to 'foreign invasion' by human papillomavirus. The hope is that by eliminating the virus, cancer rates will be reduced. No one will know whether this will actually happen for at least 15 to 20 years. However, based on the post-vaccination reports, many Gardasil-vaccinated women have continued to develop cervical cancer and precancerous lesions.

The SaneVax Team wants to know: Why is Gardasil® approved by the FDA as a cervical cancer preventive when there is no clinical evidence that reducing some self-reversing lesions is indeed associated with reduction of cervical cancer rates?

The SaneVax Team wants to know: Have any of the ingredients in this vaccine, which is being promoted as protection against various types of cancer thought to be caused by HPV, been approved for use under the Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act?

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 SaneVax Team and medical consumers around the world demand scientific proof that Gardasil® is safe, effective and necessary.

[Note from SaneVax: Three members of the VRBPAC officially retired the day before the hearing to decide whether they would recommend extended use of Gardasil® for men and boys. These three members were Dr. Jack Stapleton, VRBPAC chairman, Dr. Jose Romero and Dr. Pablo Sanchez. Drs. Romero and Sanchez attended the Gardasil portion of the meeting, but since they were retired, one can presume they did not vote on the ultimate outcome. That left only six members of what was originally a twelve member committee in attendance. To make up for the shortage of voting personnel, the FDA appointed nine 'temporary voting members.' One of these nine, Dr. Theodore Tsai, was an industry representative – the second industry representative in attendance. According to the FDA charter for VRBPAC, industry representatives are not allowed to vote. Even so, at least one of the industry reps in attendance was listed as a voting member. There is apparently no public record of who voted and who did not.]

Sources:
1. Visit http://sanevax.org/news-blog/2011/04/sanevax-asks-the-fd … for complete article with links to all sources.
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