# Gardasil a new vaccine

Gardasil has been approved by the FDA this June 29, 2006 as a vaccine for HPV (humanpapillomavirus) caused cervical cancer. Despite the approval, many people refuse its compulsory or required vaccination for women. Consideration whether it should or it should not be required for vaccination questions whether gardasil is really safe and effective, the length of time of the experimentation and the number of respondents as to concretize the pre-licensure trial, and if the price set by Merck and his company gives justice to the consumer.

According to National Vaccine Information Center (NVIC) president Barbara Loe Fisher, pre-licensure trials of gardasil have not been disclosed neither by the FDA nor Merck. They did not reveal the truth and made it appear that the whole procedure has been safety. Far from the knowledge of the consumers, gardasil contains aluminum adjuvant that has potential health risk. Merck neither the FDA revealed that the aluminum content of Gardasil is 225 mcg. Researches show the unfavorable effects of aluminum with respect to health (Redhead K. et al. 1992). It has been determined that aluminum adjuvant produces the high risk of aluminum to enter the brain. Other than that there were serious adverse reactions such as headache, gastroenteritis, arthritis, appendicitis etc. that also manifested to gardasil recipients during the clinical trials. Loe Fisher told that, “ Merck and the FDA have not been completely honest with the people,” which is the right impression.

Health-wise, it is still very doubtful for gardasil to be considered a complete vaccine. Though Merck promises that gardasil can prevent four strain of HPV, it only works to about 70 percent of humanpapillomavirus. Those who will be vaccinated by gardasil will just be protected to that 70 percent of HPV and remain unprotected to that 30 percent more. Gardasil will not work to patient

who already has HPV which implies that it can not be used as a treatment to the presence of HPV, too early to say that it is already a complete and effective vaccine.

Another is that the said immunization has been tested to women with ages ranging from 9-26 years old. We should not be ignorant that based on the current researches, according to experts (Main Cancer Registry, 2006), data shows that incident rates of HPV related cervical cancer is lower during the bracket ages lower than 30. Cervical cancer is at higher risk at the age of thirty above. The period by which the research has been conducted and the number of respondents used is not sufficient to conclude that the pre-licensure trial is a success. Higher risk of cervical cancer happened during forties and above then those ages should also be included.

Is the vaccine worth of its cost? (A course of three shots over six months will cost from $300 to $500.) Could you imagine the price that Merck has given to the said vaccine which could not be a reality to some countries that conducts mass vaccination especially to poor regions? Giving the vaccine right away is too hasty and setting the price is exaggerating too. The point is, there has been proven negative reactions during the experimental period and we do not want those people from non-stabilized economic regions just to pay for a wrong diagnosis or a medicine that is still under doubts.

Therefore it is a hasty and careless move to implement that Gardasil vaccination should be made a requirement. Safety and efficacy are our main concerns and it is still a way too early to conclude that gardasil vaccine be made compulsory. More research and analysis should be made in order to wholly drive to the conclusion that gardasil will really benefit human needs.

ANNOTATED BIBLIOGRAPHY (Con-side):

Merck & Co., Inc. 2006. Gardasil [Quadrivalent Human Papillomavirus Types 6, 11, 16, 18) Recombinant Vaccine] product insert. Table 6. The product content of Gardasil revealed later on after the test (through the product insert) that there is an aluminum adjuvant present on the vaccine.

Merck & Co., Inc. 2006. " Gardasil product insert: Serious Adverse Experiences." 2006. 06 June, 2006. Based on the recorded results of the pre-licensure trials, there are serious adverse effects that have been gathered to the recipients of gardasil during the experimentation. These data only proves the potential danger that gardasil has to human.

Redhead K. et al. 1992. Aluminum-adjuvanted vaccines transiently increase aluminum levels in murine brain tissue. Pharmacol. Toxico. 70, 278-280. Aluminum has an adverse long term effect both to human and to animals based on the data resulted from the conducted tests. It is therefore needed that its usage should be of precautionary measure or in avoidance since this may critically affect many normal health functions.

Maine Age-Specific Incidence Rates - Cervical Cancer, 1997-1998. 06 July, 06. The data shows the graph of the ages and the frequent incident of cases of cervical cancer to females based on the given bracket ages. The data shows that there is the higher incident of cervical cancer during the ages of thirty and above compared to ages 29 down.

Gardasil® HPV vaccine: Cancer cause or Cancer preventive? Updated June 9, 2006. 06 July, 06. A group that supports and guards the people to the potential harm that vaccine may incur to people thus presenting information and data how a particular vaccine could be potentially harmful to health. This reveals how Gardasil if not properly informed could make a person/s believe and trust on what the vaccine can do without making necessary analyses of

future problems.

“ Mercks Gardasil Vaccine Not Proven Safe For Little Girls”. 2006. 06 July, 2006. A group that critically analyzes the decisions made regarding vaccines. People without any scientific knowledge could be misinformed by the promise medicine and vaccine gives therefore to subjecting themselves in just taking medicine without knowing the danger. This team of experts presents data and factual information that will be helpful for people to make a correct judgment as to decide whether medicine or vaccine intake and usage is safe, economical, and effective. Their argument shows how gardasil could be potentially harmful to health and longer time to experimentation and studies should be first devoted before to conclude that the vaccine is effective and safe.

ANNOTATED BIBLIOGRAPHY (Pro-side):

U. S. Food and Drug Adminstration. Product Approval Information - Licensing Action GARDASIL® Questions and Answers. Updated: June 8, 2006. 06 July, 2006. < http://www. fda. gov/cber/products/hpvmer060806qa. htm> The analysis of the experimentation of Gardasil marked out that it can prevent 70 percent of cervical cancers. The research has been conducted by Merck & Company and they are striving to show the positive results that gardasil can produce based on the data. The vaccine is effective against HPV 16 and 18, those that are responsible for about 70 percent of cervical cancer and HPV 6 and 11 that cause 90 percent of genital warts. Information shows that gardasil work only to prevent some HPV related cervical cancer but not a way to treat it. This will no longer work during the incident of cervical cancer. Licensure was given which describes the safety and efficacy of its usage.