01 October 2011
Dr. Eric Abadie, Chairman of CHMP

Dear Dr. Abadie:

Thank you for your letter of 22 September 2011, in which you informed consumers of the Committee for Medicinal Products for Human Use (CHMP) position regarding the findings of recombinant HPV DNA in the vaccine Gardasil®.

This is the first time a government regulatory agency, or a representative of the pharmaceutical industry has officially stated, "***The presence of recombinant DNA fragments does not represent a case of contamination and is not considered to be a risk to vaccine recipients. All medicinal products manufactured using recombinant technology may contain small fragments of residual DNA.***"

The statement above is astonishing because a thorough search of all the product information sheets available to medical consumers about the specifications of Gardasil® failed to find such a statement in those documents.

It is well known that all recombinant DNA fragments you made reference to, which are being used in the manufacturing of Gardasil®, consist of a segment of HPV DNA encoding the L1 capsid protein initially isolated from the HPV virus itself; subsequently cloned into plasmid pGAL110 for transformation of the yeast spheroplasts. According to the US patents [1, 2] granted to Merck & Co., expression systems for this genetically modified gene are not limited to yeast cells, but also include mammalian cells.

When these types of recombinant DNA are attached to aluminium adjuvant and injected intramuscularly into a human host, the resulting antigen may function as a DNA vaccine and should therefore be classified as such for regulatory purposes.

You also stated: ***"Furthermore, the amount of these residual substances is minimized [sic] by robust manufacturing processes."*** As you should appreciate, the term "minimized" is arbitrary and non-actionable. To what level is it minimized? There has to be a point of reference and that reference needs to demonstrate that the level of minimization has been tested robustly, peer reviewed and considered of no risk to any recipient including those with any form of immune suppressed system.

It is clear that your statement implies two things: 1) that residual substances are undesirable and therefore potentially harmful at a certain level; and 2) that the substances found in this vaccine are below that level. Given this, how can you on the one hand say minimized and ignore any issues and yet also imply that residual substances are "undesirable" and one assumes therefore have the potential to cause harm? Clearly these statements are at considerable odds.

Given that there is no safe level for residual substances indicated in the regulatory filings, can you please

provide both what the EMA determined is the level considered "safe" and the actual level measured in the final product post manufacturing? We assume that you must have these as otherwise there can be no basis for the EMA not to investigate the contamination of Gardasil® with viral DNA further.

Do you realize, Dr Abadie, your letter has in fact approved for the first time a DNA vaccine for human use on behalf of the EMA? Do you and the CHMP have the authority to make such an unprecedented decision now – to approve the world's first human DNA vaccine for prevention of any disease without a full disclosure?

Dr Abadie, this is a very serious matter, not just a language game. Many parents are heart-broken after having lost their perfectly healthy daughters or are still trying to cope with the hardship of caring for their disabled daughters. Their suffering is quite likely a consequence of intramuscular injections of this undisclosed DNA vaccine.

Had they been adequately informed that the vaccine contains recombinant DNA fragments, as you believe without a doubt, they might not have agreed to let their daughters receive the Gardasil® injections in the first place.

Many informed consumers know recombinant DNA is a potential biohazard[3], especially when injected intramuscularly with aluminium adjuvant, a recognized factor in triggering autoimmune-based inflammatory disorders.[4] Rheumatoid arthritis, including juvenile rheumatoid arthritis, occurred 3 times more frequently in the Gardasil®-vaccinated subjects than in the placebo group during clinical trials.[5] Complexes of anti-DNA antibodies with microbial or self DNA may play a role in the activation of B cells by Toll-like receptors and surface IgM rheumatoid factor.[6, 7] The immunotoxic reactions may be further augmented by the aluminum adjuvant in the vaccine.[4]

Your simple dismissal of a child developing acute onset juvenile rheumatoid arthritis immediately after 3 Gardasil® injections as "coinciding with vaccination" is arbitrary and capricious.

There have been at least 7 reports published in peer-reviewed journals documenting a poorly understood group of inflammatory neurodegenerative brain disorders in young girls receiving Gardasil®, probably related to autoimmune-based acute disseminated encephalomyelitis.[8-14] The findings of recombinant HPV DNA adsorbed to amorphous aluminium hydroxyphosphate adjuvant in an intramuscular injectable vaccine may provide a scientific basis for further investigation into the pathogenesis of this and other debilitating disorders, or even as a cause of unexplained deaths for some of the victims after Gardasil® vaccination.

SANE Vax Inc., on behalf of informed consumers, requests you and the CHMP reconsider your hasty decision to dismiss the potential adverse health impacts of recombinant DNA in an injectable protein-based vaccine. Recombinant DNA molecules have long been recognized as potential biohazards by some of the pioneer scientists who discovered this technology.[3] Recombinant DNA administered intramuscularly may enter mammalian cells and replicate in the form of plasmids under certain conditions.[15, 16] Chromosomal integration of foreign DNA may occur through poorly understood mechanisms[17, 18] with uncertain consequences.[19] Retention of residual recombinant DNA in protein-based vaccines has been a concern in the industry since induction of cancer is a single-cell phenomenon, and a single functional unit of foreign DNA integrated into the host cell genome might serve to induce cell transformation as a single event or part of a series of multifactorial events.[20]

The health authorities should institute a program to follow the cancer incidence rate among the young girls who have been inadvertently injected with a Gardasil® vaccine contaminated with "***recombinant DNA fragments"*** adsorbed to amorphous aluminum hydroxyphosphate adjuvant, in particular the incidence of lymphoma and leukemia in the next 20 years.

Dr. Abadie, did you or the CHMP rule ***"the presence of recombinant DNA fragments does not represent a case of contamination….."*** during the original licensing process? If so, please publish that record so at least medical consumers can be informed of your ruling.

In a US patent granted to Merck [21], the patented purification process for HPV vaccine production is to remove the "***contaminating biomolecules, including DNA, lipids and proteins are removed from the lysate."*** Thus, the vaccine manufacturer always considered DNA in the yeast lysate to be a contaminant which must be removed from the vaccine for product safety and so did the US FDA. In fact, as early as 1985, the US FDA issued explicit guidelines for the **production and testing of new drugs and biologicals produced by recombinant DNA technology.** Specifically, the FDA stated that, "*although recombinant DNA products may be demonstrated to be 99% pure by physicochemical characterization,* ***special attention should be directed toward the removal of certain contaminants*** *which may be present in small amounts. The purification process should be designed to* ***specifically eliminate detectable*** *viruses, microbial and* ***nucleic acid contamination*** *and undesirable antigenic materials*."[22]

In its application to the FDA, Merck represented that the vaccine ***"contains no viral DNA."***[23] This categorical declaration of absence of viral DNA in the vaccine absolved Merck's obligation to perform safety studies on the ***small fragments of residual DNA***. Now you claim, "***All medicinal products manufactured using recombinant technology may contain small fragments of residual DNA."*** So you knew all along that the vaccine Gardasil® may contain these residual HPV DNA molecules which the manufacturer recognizes as contaminant, and yet accepted the claim of "no viral DNA" in the final product when the vaccine was approved for marketing?

In the minds of most consumers, the statement "no viral DNA" eliminated any need for further enquiry as to whether the vaccines contained small fragments of residual HPV DNA, particularly since it is not listed in the product specifications at all.

Now, the public discovers Gardasil® does contain the contaminant and raises concerns. You simply dismiss the findings as no surprise to you. As an expert in the pharmaceutical industry, you further affirm that, "***All medicinal products manufactured using recombinant technology may contain small fragments of residual DNA."*** You seemed to make this matter-of-fact statement without any surprise. Can we conclude, therefore, that Cervarix has similar fragments of foreign DNA contaminants?

If you knew vaccines being injected into our children contain residual recombinant DNA without disclosing this to medical consumers, you and the CHMP may have violated the patient's right to informed consent.

Gardasil® is different from all other childhood vaccines made for the purpose of preventing contagious diseases, which may pose an impending health hazard to the interacting children in a community. No other vaccines are developed for prevention of a disease which may or may not occur 30 years down the road after vaccination.

Gardasil® is marketed as a vaccine for the women from age 9 to 26 primarily targeting children age 9 to 12 to reduce their risk of cervical cancer in the distant future. Based on the Testimony on Cervical Cancer by Nancy C. Lee, M.D. of the CDC before the U.S. Congressional Committee on Commerce, Subcommittee on Health and Environment March 16, 1999, patients developed cervical cancer at an average age of 54 in the United States. The death rate among African American women was 6.7 per 100,000 and that for whites less than half, namely < 3.3 per 100,000. For cervical cancer prevention, "***the main focus should remain screening women who are not receiving regular screening, as they account for the majority of cervical cancer cases.***" [24]

Even before 1999 cervical cancer death was almost entirely preventable by good gynecological care in developed countries. Mass HPV vaccination is just an added cost to society providing little benefit because women are required to continue their regular Pap cytology screening regardless of vaccination status.

If parents of the Gardasil® victims had been fully informed of all the high risks and low benefits of Gardasil®, including the presence of recombinant DNA in the vaccine which may cause autoimmune-based disorders, immediate death, or permanent disabilities at age 12, they might have been able to make an informed decision. They could have made an informed choice as to whether it was better for their children to risk immediate negative outcomes with a vaccine or to better teach their children about an already proven safe and effective method of controlling cervical cancer, namely regular screening and good gynecological care.

Dr Abadie, given the opportunity to make a truly informed choice many of these heart-broken parents would never have consented to risk their precious daughter's future on a vaccine when a safe and proven effective method of controlling cervical cancer is already available. Worst case scenario, their daughters would have had another 40 years of life without the harmful Gardasil® side effects they are experiencing. By failing to disclose what you knew about the presence of recombinant HPV DNA in Gardasil®, you have deprived parents of a critical piece of information they needed before they gave consent to vaccinate their daughters.

These parents trusted the information provided by the FDA, the EMA and other government agencies worldwide that **HPV vaccines did not contain any viral DNA.** Since, you appear to have been aware of the contaminants in Gardasil® and consider them perfectly normal, you and other authorities around the world have deceived the public by not disclosing all pertinent facts as you became aware of them. You have admitted to the presence of rDNA in Gardasil® but appear not to have even taken steps to demand scientific studies to determine how serious this contamination could be. Your complacency and lack of concern regarding public health and safety is extremely disturbing and will be noted by the general public. This is a violation of the public trust and an issue that will not go away.

On behalf of millions of medical consumers around the world, the SANE Vax team respectfully requests you and the CHMP reconsider your position.

Yours sincerely,
Norma Erickson, President
SANE Vax Inc.

Signed on behalf of the SANE Vax Inc. Board of Directors:
Freda Birrell, Secretary
Janny Stokvis, VP of Research
Rosemary Mathis, VP of Victim Support
Leslie Carol Botha, VP of Public Relations

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