

# Dr. Sin Hang Lee Challenges Medical and Scientific Community - SaneVax, Inc.

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By Norma Erickson



Dr. Sin Hang Lee

In an unprecedented move, pathologist/clinical microbiologist, Dr. Sin Hang Lee has decided to invite the international community of scientists and medical professionals to peer-review and/or discuss his latest research “Toll-like receptor 9 agonist in HPV vaccine Gardasil 9” in an open public forum.

According to Dr. Lee, during 2011/12, when he tried to publish papers describing HPV DNA fragments he had discovered in Gardasil 4, his first paper was rejected by three medical journal editors despite the fact that the manufacturer had assured health authorities worldwide no such fragments were in the final product.

The first of his papers regarding this subject was favorably peer-reviewed by three scientists who recommended publication. However, upon subsequent review by a journal editor publication was inexplicably denied.

Both papers were subsequently published in non-medical journals which deal with ‘pure science’ thereby limiting access to most medical professionals.

Dr. Lee also states that after submission of his latest research to “Vaccines” the editor-in-chief sent his paper out requesting a peer review. However, the editor’s subordinates refused to process the manuscript even though the journal claims to be “***an international, peer-reviewed open access journal focused on laboratory and clinical vaccine research, utilization and immunization.***”

Dr. Lee believes this unusual response illustrates a top-level concerted effort by vaccine stakeholders to suppress any information which could potentially impact the published safety profile of HPV vaccines.

Dr. Lee decided to release the paper to an open forum because:

- - He believes medical professionals need access to all information which might impact their analysis of the safety profile of HPV vaccines so they can help their patients make intelligent choices regarding cancer prevention options.
  - He believes the only way for medical consumers to make intelligent choices is to be informed of known potential risks as well as the promised benefits of any medical intervention, including HPV vaccines.
  - He believes the process of discovering mechanisms of action associated with serious adverse events after HPV vaccinations will be expedited if the medical/scientific community is aware of any new research in that arena.
  - He believes that discovering the mechanisms of action as quickly as possible will enable researchers to better define biological plausibility and causation, thereby allowing medical professionals to help those most susceptible to serious reactions avoid unnecessary risks.
  - He believes open discussion and honest debate may help restore the public’s faith in science.

Therefore, in the interest of public health and safety, Dr. Lee cordially invites any medical/scientific professional interested in the benefit/risk profile of HPV vaccines to review and/or discuss his latest research via the comment section below. He has kindly agreed to answer any scientific questions regarding the following paper.

## **Toll-like receptor 9 agonist in HPV vaccine Gardasil 9**

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### **Abstract:**

Gardasil9 is a recombinant human papillomavirus (HPV) 9-valent vaccine, containing purified major capsid L1 protein of HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 re-assembled into virus-like particles (VLPs) as the active ingredient. Since the antigens are purified recombinant proteins, Gardasil9 needs a potent adjuvant to enhance the initiation of the immune response through activation of innate immunity of the host to generate high and sustained levels of antibodies for maintaining efficacy of vaccination. Historically, the aluminum salt, amorphous aluminum hydroxyphosphate sulfate or AAHS which is listed as the adjuvant for Gardasil9, was known to require a Toll-like receptor agonist, such as phospholipids, to work in combination to achieve its potent adjuvant effects in the recombinant hepatitis B vaccine, Recombivax HB®. However, there are no phospholipids in the purified HPV L1 proteins or in the Gardasil9 formulation. Since the Food and Drug Administration has informed the public that Gardasil4 does contain recombinant HPV L1-specific DNA fragments, these HPV DNA fragments may serve as Toll-like receptor 9 agonist in Gardasil9 vaccination. The author has tested 5 samples of Gardasil9 from 4 manufacturing lots by PCR amplification with a set of degenerate primers followed by heminested PCR or by another 5 sets of non-degenerate nested PCR primers in an attempt to detect

all 9 vaccine-relevant HPV type-specific L1 gene DNAs bound to AAHS in the vaccine. Sanger sequencing of the PCR products confirmed the presence of HPV 18, 11, 16 and 6 L1 gene DNA bound to insoluble AAHS nanoparticles, but unevenly distributed even within one vaccine sample. In addition, these genotype-specific HPV DNA fragments were at least partially in non-B conformations. Since no L1 gene DNA of HPV 31, 33, 45, 52, and 58 was amplified by the commonly used degenerate PCR primers, the results suggest that these latter 5 type-specific HPV DNAs may all be in non-B conformations or have been removed as contaminants by a special purification protocol. Further research is warranted to standardize the HPV DNA fragments in Gardasil which are known to be potent Toll-like receptor 9 agonist.

Keywords: Gardasil 9; Gardasil; HPV vaccine; HPV DNA; non-B conformations; topological conformational change; Toll-like receptor 9 agonist; AAHS; amorphous aluminum hydroxyphosphate sulfate; DNA sequencing

[View entire paper here.](#)