From: Sin Hang Lee [mailto:shlee01@snet.net]
Sent: 11 December 2015 08:47 AM
To: 'Sarah XXXX'; mherbst@cansa.org.za; info@cansa.org.za
Subject: Sin Hang Lee's response to Professor Herbst's opinionated letter to Ms XXXX

December 11, 2015

Dear Professor Herbst:

Based on your 06 December 2015 letter addressed to Ms XXXX on behalf of the Cancer Association of South Africa, you are obviously not a scientist, but are trying to dismiss a very important scientific issue which has affected the health of many teenagers worldwide. Since you are masquerading as a health specialist, acting as a spokesman in a cancer association and trying to discredit my scientific work on the finding of HPV L1 gene DNA in the vaccine Gardasil® while using your position to influence health policy decision making according to your agenda, your letter must not be allowed to pass without challenge.

The first exposure of your lack of understanding of the science involved in this matter is contained in your statement *"Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]. These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis."*

You quoted as reference #13 a paper published by "Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceut Reg Affairs 2012, S12:001". If you had understood what HPV L1 gene DNA fragments mean, you would not have made such an erroneous statement as you did because in their entire paper, Tomljenovic and Shaw never mentioned "HPV L1 gene DNA fragments" even once. These authors demonstrated HPV-16L1 VLPs, not DNA fragments in the blood vessel walls. You obviously do not understand the difference between HPV L1 VLPs and HPV L1 gene DNA fragments.

You quoted as reference #14 a paper published by "Lee, SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. Advances in Bioscience and Biotechnology, 2012, 3, 1214-1224". You are basically putting your words into the author's mouth because I know the author did not claim cerebral vasculitis in this case report.

In an attempt to boost your credibility, your also wrote *"….the case reports [13] of adverse events hypothesized to represent a causal association between the HPV L1 gene DNA fragments and death were flawed in both clinical and laboratory methodology [16]."* For reference 16, you cited a CISA Technical report from a U.S. CDC webpate: http://www.cdc.gov/vaccinesafety/Activities/cisa/technical_report.html

However, in this CDC technical report, the unnamed authors of the document only questioned the HPV-16L1 particles, never HPV L1 gene DNA fragments. Therefore, it further confirms the fact that you really do not understand these two important and distinct chemicals in the HPV vaccine at all. And there is a Disclaimer following this document, stating: The information and conclusions in this report are those of the work group participants addressing this issue and do not necessarily represent the official position of CDC. So you blindly misquoted a technical

report written by a team of ghost writers to dismiss a potential causal association between the HPV L1 gene DNA fragments and death.

You were unable to find a scientific publication published in a peer-reviewed journal to challenge the plausible mechanism leading to potential harm induced by residual HPV DNA left in the vaccine Gardasil®. So you had to use a blog written by a Dr Helen Petousis-Harris who knows even less than you do on this subject to support your opinion. In her blog (your reference #17), Dr Helen Petousis-Harris did not even cited a single publication of mine, and used some social media articles published on the Internet to attack me by character assassination. Although she had no personal experience on viral DNA research, she was brave enough to declare that the quantity of residual HPV DNA left in the vaccine Gardasil® has no health impacts on the vaccinees. It is unfortunate for the teenagers of this world to have people like you and Dr Helen Petousis-Harris to rely on selling your biased opinions without any scientific evidence of your own to influence health policy decision making. Neither of you has done any work to support your opinions. Neither of you knows what you are talking about. If you want to prove me wrong, please show me a report of the amount of HPV L1 gene DNA fragments (type 16, 11, 18 and 6) which are bound to the aluminum adjuvant, as found in the vaccine Gardasil® that has been shown to be of no short-term or long-term risk to humans.

Since you have quoted in your reference #12, a paper published by Slade BA, Leidel L, Vellozzi C, Woo EJ, Hua W, et al. Postlicensure safety surveillance for quadrivalent human papillomavirus recombinant vaccine. JAMA. 2009 Aug 19; 302(7):750-7. Let me point out to you that this CDC study shows that among 12,424 reported adverse events following Gardasil® vaccination from June 1, 2006 through December 31, 2008, there were 32 deaths with a mean age of 18 years old, who died 2 to 405 days after the last Gardasil® injection. Medical records and autopsy reports on 20 of the 32 deaths were available for review and confirmed there were 4 unexplained deaths and 6 cardiac-related deaths.

This same report also stated that syncope is the most common adverse reaction after Gardasil® injections and “The reporting rates per100 000 qHPV doses distributed were 8.2 for syncope;”

Syncope is defined as temporary loss of consciousness and posture, described as "fainting" or "passing out." It's usually related to temporary insufficient blood flow to the brain. It most often occurs when the blood pressure is too low (hypotension) and the heart doesn't pump a normal supply of oxygen to the brain.

In view of the high incidence of syncope developed among Gardasil® vaccinees, the FDA Prescribing Information for Gardasil® (qHPV) contains the following Warnings and Precautions:

“Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL®. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.”

So why do Gardasil® vaccinees have a higher rate of syncope as compared to other vaccinees? The ugly truth that you and those agencies you have quoted to support your biased opinions would not like to face may be in the HPV L1 gene DNA fragments when the viral DNA fragments combine with the aluminum adjuvants in the vaccines. To understand this, you really have to spend time to study the history on the science of aluminum adjuvants in vaccination.

Aluminum salts have been used as adjuvants in vaccination empirically to boost immune responses of the host to the protein antigens for many decades. However, the mechanism of the adjuvant effects of aluminum salts has only been recently investigated at the molecular level. It is now generally agreed in the scientific community that aluminum salts used as adjuvants are toxic and always damage the cells of the host at the site of injection, causing a localized inflammation at the vaccination site. This initial cell damage by the aluminum salt is an essential and necessary step to initiate its adjuvant effects because the free host DNA molecules released from the aluminum salt-damaged host cells act as mediators to trigger augmented immune responses of the host [1, 2]. The free DNA molecules of the dying host cells, also referred to as damage-associated molecular patterns (DAMPs) [3] bind the aluminum salt adjuvant at the site of injection, and the resulting DNA/aluminum complexes are phagocytized by the antigen-presenting cells (APCs) and macrophages. It was known as early as 2003, that when bound to aluminum salts as nanoparticles, free DNA molecules undergo dramatic conformational changes and can be introduced into mammalian cells as a means of gene transfection [4]. In vaccination with aluminum adjuvants, the transfected host DNA activates the pathways that would increase their ability to interact productively with antigen-specific CD4 T cells to boost host immune responses [1, 2]. In plain language, free DNA derived from the dying host cells is needed to be carried by aluminum adjuvants into the APCs or macrophages to function as mediators for boosting immune responses in vaccination.

However, the presence of recombinant HPV L1-specific DNA fragments in the vaccine Gardasil® has disrupted this expected normal immunity response platform in vaccination. The HPV DNA molecules, being of a viral origin, are “non-self” microbial products, also referred to as pathogen-associated molecular patterns (PAMPs). The human body’s defense system can distinguish the PAMPs from the DAMPs in order to mount an appropriate immune response to either the presence of a pathogen or a tissue damage [3].

The amorphous aluminum hydroxyphosphate sulfate (AAHS) nanoparticles which are expected to bind the free host DNA at the site of vaccine injection can also bind the fragments of HPV L1 gene DNA present in the vaccine Gardasil® [5] through a ligand exchange process between the phosphate groups of the DNA molecule and the hydroxyl groups on the aluminum adjuvant surface, similar to a reaction between phospholipids and AAHS in the recombinant hepatitis B vaccine [6]. In other words, Gardasil® has been furnished with a set of ready-made instant DNA immune “mediators” already in the adjuvant, in the form of a viral DNA/aluminum chemical compound, specifically an HPV L1 gene DNA/AAHS complex. The downstream events after transfection into the human macrophages of these viral DNA fragments which are rarely found in the human genome [7] are quite different from those after the DNA of the dying host cells is introduced into the macrophages. Despite similarities between DNA molecules, mammalian cells have the remarkable ability to distinguish viral DNA from their own DNA. The human macrophages are able to recognize the HPV L1 gene DNA as a 'stranger' and a 'danger' signal, and in response produce many antiviral immune molecules, collectively referred to as type I interferons and pro-inflammatory cytokines [8-10].

Massive systemic production of these type I interferons and pro-inflammatory cytokines induces an antiviral state and protects the host, but it also can contribute to endotoxin lethality and autoimmune diseases [9]. Many of these cytokines are myocardial depressants. The two cytokines that show the greatest cardiovascular effects in animals and humans are tumor necrosis factor (TNF)-α and IL-1β [11]. Administration of recombinant TNF-α in animal models is known to cause hemodynamic changes and even death [11].

Injection of Gardasil® into animals has been shown to induce unusually early strong innate immune responses with quick releases of a variety of cytokines from the macrophages [12]. Injection of HPV DNA/AAHS complexes into the host is also known to induce a strong immune reaction and a strong CD8 T cell response [13]. Based on experiments with other viral DNA molecules, the recombinant HPV L1 gene DNA fragments transfected into human macrophages would also be recognized as “stranger” and “danger” signal, and invariably activate the macrophages to release numerous antiviral cytokines. Many of these cytokines, including TNF-α and IL-1β, are recognized myocardial depressants [14-18]. Hypotensive shock induced by TNF-α has been well documented among animals [19, 20] and humans [21, 22].

This brief review of literature shows that there is a known molecular mechanism to explain why syncope occurs more often in people injected with Gardasil® than with other vaccines, and why certain predisposed vaccinees may suffer a sudden unexpected death as the result of Gardasil® vaccination. You and those who blindly dismiss the potential toxicity of aluminum adjuvant and in particular the toxicity of the newly created HPV L1 gene DNA/AAHS compound for marketing an HPV vaccine should be held responsible for intentionally ignoring the scientific evidence at the expense of public interest.

It is of interest that you mentioned that in June 2013, the GACVS reviewed the concerns arising in Japan in regard to reports described as CRPS in a few cases, and other chronic pain conditions following HPV vaccine. But you apparently purposely avoided mentioning the facts that the Japanese government has suspended its HPV vaccine recommendation since 2014 and that a December 10, 2014 Symposium held by the Japan Medical Association and the Japanese Association of Medical Sciences concluded that HPV vaccines should be promoted only after issues regarding vaccine safety are settled.

In summary, to protect the health of the young children there is an urgent need for open debate of the risks versus benefits of HPV vaccination being recommended or forced onto the 12-year old school girls and boys. A simple declaration of vaccine safety made by some armchair professor like you does not serve the interest of the public.

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