Allegations of Scientific Misconduct by GACVS/WHO/CDC Representatives et al

An open-letter of complaint to the Director-General of the World Health Organization, Dr. Margaret Chan chanm@who.int

Cc: The Ministry of Health, Labour and Welfare, Japan, www-admin@nhlw.go.jp
Minister of Health, Labour and Welfare, Japan, shiozaki@y-shiozaki.or.jp
Thomas Frieden, Director CDC, tomfrieden@cdc.gov
Vice-Chancellor, Professor Stuart McCutcheon, The University of Auckland, s.mccutcheon@auckland,ac.nz

From: Sin Hang Lee, MD shlee01@snet.net

Date: January 14, 2016

Dear Dr. Chan:

As a medical doctor and scientist, I write to present grave concerns regarding the conduct of certain members of the Global Advisory Committee on Vaccine Safety (GACVS), the World Health Organization, the CDC and other scientific/health professionals during the time shortly before the public hearing on HPV Vaccine Safety which was held in Tokyo, Japan on February 26, 2014. I have come into possession of documentation which leads me to believe multiple individuals and organizations deliberately set out to mislead Japanese authorities regarding the safety of the human papillomavirus (HPV) vaccines, Gardasil® and Cervarix®, which were being promoted at that time.

I am sure you are well aware of the controversy currently surrounding these vaccines on a global level. I am also sure you are aware of the fact that public confidence in national and international health authorities is at an all time low throughout the world.

Should the information in this letter prove to be accurate, nothing short of an immediate independent investigation resulting in appropriate disciplinary actions for those involved will be able to restore the public trust. Therefore, I implore you to act quickly and decisively regarding this critical public health issue.

FOI Request and Significant Related Communications

A series of emails recently uncovered via a Freedom of Information request submitted in New Zealand revealed evidence that Dr. Robert Pless, the chairperson of the Global Advisory Committee on Vaccine Safety (GACVS), Dr. Nabae Koji of the Ministry of Health of Japan, Dr. Melinda Wharton of the CDC, Dr. Helen Petousis-Harris of Auckland University, New Zealand, and others (including WHO officials) may have been actively involved in a scheme to deliberately mislead the Japanese Expert Inquiry on human papillomavirus (HPV) vaccine safety before, during and after the February 26, 2014 public hearing in Tokyo. I believe the information supplied by this group led directly to the issuance of the GAVCS statement on the continued safety of HPV vaccination on March 12, 2014 which contains the following paragraph:

"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. While the GACVS has not formally reviewed this work, both the finding of DNA fragments in the HPV vaccine and their postulated relationship to clinical symptoms, have been reviewed by panels of experts. First, the presence of HPV DNA fragments has been addressed by vaccine regulatory authorities who have clearly outlined it as an expected finding given the manufacturing process, and not a safety concern [15]. Second, 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]. The paper described 2 fatal cases of sudden death in young women following HPV vaccine, one after 10 days and one after 6 months, with no autopsy findings to support death as result of cerebral vasculitis or an inflammatory syndrome. Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]: given the extremely small quantities of residual HPV DNA in the vaccine, and no evidence of inflammation on autopsy, ascribing a diagnosis of cerebral vasculitis and suggesting it may have caused death is unfounded." (the references 13-17 quoted were those listed in the GACVS Statement)

I believe this paragraph to be deceitful based on the following analysis:

The first sentence, "*Several papers have also been published pertaining to the finding of HPV L1 gene DNA fragments in clinical specimens following HPV vaccination [13, 14]"* was apparently constructed for dissembling and designed to mislead. The study in reference 13 [Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceut Reg Affairs 2012, S12:001] was about HPV L1 VLPs. The authors of reference 13 never mentioned HPV L1 gene DNA fragments at all. Dr. Pless knew the difference between HPV L1 VLPs and HPV L1 gene DNA fragments because in his February 18, 2014 email addressed to Dr. Helen Petousis-Harris and the others involved in this scheme, Dr. Pless specifically asked Dr. Petousis-Harris to address her "*statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects*." (see copy of February 18, 2014 email attached- It was not about HPV L1 VLPs). One cannot help but conclude that Dr. Pless intentionally put these two unrelated articles together and claimed that both articles studied HPV L1 gene DNA fragments in order to mislead the non-scientific readers and vaccination policy makers.

The second sentence, *"These papers claimed an association with clinical events of an inflammatory nature, including cerebral vasculitis"* is not true because the author in reference 14 (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) never claimed clinical events of an inflammatory nature, including cerebral vasculitis. Dr. Pless in fact mis-states the author's words in this document apparently to create a target to attack.

When the facts don't fit – simply change them?

The purpose of Dr. Pless intentionally combining two unrelated studies and two unrelated chemicals shows up in the following sentence: "*the finding of DNA fragments in the HPV vaccine and their postulated relationship to clinical symptoms, have been reviewed by panels of experts".* Who were these panels of experts? Dr. Pless presented none of their names.

The sentence *"Second, 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],"* is a blatant misrepresentation of the facts. The authors quoted in Reference #13 never presented any data on HPV L1 gene DNA fragments. Reference #16 never reviewed the potential harm of HPV L1 gene DNA fragments in the HPV vaccines when injected into humans.

A plea for help – and anyone will do?

The fact that Dr. Pless could not find any scientific reviews on the HPV L1 gene DNA fragments in HPV vaccines was illustrated in the email he sent to Dr. Helen Petousis-Harris on February 18, 2014 with the following plea for help:

> *"We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. The GACVS has not yet had a chance to delve into the DNA question."*

The FDA declaration confirming HPV DNA fragments in Gardasil® as an expected finding (Ref. 15), but providing no safety data on these HPV DNA fragments after being injected into animals or humans, obviously does not represent a review by panels of experts because it does not refer to any animal or human experimental data on *"aluminum binding to DNA fragments and subsequent effects,"* which was supposed to be Dr. Pless' major concern.

It is worth noting Dr. Helen Petousis-Harris demonstrated to Dr. Pless that she had experience using similar tactics in her *February 18, 2014* email which stated:

> *"To the best of my knowledge the rebuttal on our website is the only attempt to address this particular issue which Shaw and Lee presented at a coronal enquiry here. Placing the rebuttal in the public domain was the only means of providing the information to the crown representatives involved in that process at the 11th hour."*

Apparently under pressure to issue a statement within a week or two after the public hearing, Dr. Pless needed to find a panel of experts to declare the safety of aluminum bound to DNA fragments after injection into humans. The only publication remotely related to the subject he could use was Reference #16, a Clinical Immunization Safety Assessment (CISA) Network Technical Report titled "Review of a

published report of cerebral vasculitis after vaccination with the Human Papillomavirus (HPV) Vaccine" dated November 9, 2012.

However, in this CDC technical report, the unnamed author(s) of the document only questioned the data on HPV-16 L1 particles, never HPV L1 gene DNA fragments because the Lee paper reporting the finding of HPV L1 gene DNA fragments (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) was not published until December 27, 2012, one and a half months after the CISA Network Technical Report was issued.

For the record, the quoted CISA report (Reference #16) began with the following paragraph:

> *"Recently there was discussion on a federally-sponsored vaccine safety listserv of a report in the literature of cerebral vasculitis after vaccination with the Human Papillomavirus Vaccine (HPV) (*Tomljenovic L, Shaw CA. Death after Quadrivalent Human Papillomavirus (HPV) Vaccination: Causal or Coincidental? Pharmaceutical Regulatory Affairs: Open Access 2012,S12:001*). To address questions about the findings and conclusions reported in this manuscript, CDC convened a CDC-Clinical Immunization Safety Assessment (CISA) working group. Researchers from Vanderbilt Medical Center, Johns Hopkins University, Columbia University, Duke Clinical Research Institute (Duke University), CDC and FDA participated in the call."*

Lack of Peer-Review Credibility

According to: http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/publications.html, this is the ONLY Technical Report issued in the last 12 years of records that has never been published in peer- reviewed journals. The Disclaimer at the end of this report states:

> *"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."*

In other words, the CDC's "Technical Report" (Ref #16 of the GACVS Statement) was written by unnamed ghost writer(s) based on phone conversations.

Apparently Dr. Pless had no choice but to misbrand two unrelated articles and two unrelated chemicals in the vaccine Gardasil® so that he could use the CISA Network Technical Report on HPV-16 L1 particles to support his declaration on safety of HPV L1 gene DNA fragments after injection into humans. But first, he had to make policy makers believe "HPV-16 L1 particles" were synonymous to "HPV L1 gene DNA fragments" in chemistry. Once that was done, he apparently thought he could use the opinion on HPV-16 L1 particles to uphold the safety of HPV L1 gene DNA fragments bound to aluminum adjuvant.

Unable to find a scientific report published in a peer reviewed journal on this issue of concern, Dr. Pless had to knowingly misquote the CISA report on HPV-16 L1 particles as evidence to support Dr. Helen Petousis-Harris' blog published in the social media as he wrote in the GACVS statement:

"Thus the hypotheses raised in these papers are not supported by what is understood about the residual DNA fragments left over following vaccine production [17]".

Acknowledgement of Residual HPV DNA in Gardasil®

Dr. Helen Petousis-Harris, the author of Ref. 17, was the only writer brave enough to publicly claim "*extremely small quantities of residual HPV DNA in the vaccine*" to be harmless without any supportive data.

Who is Dr. Helen Petousis-Harris? Her qualification was disclosed in Dr. Pless' email dated February 18, 2014 as he wrote:

"A meeting has recently been organized in Tokyo for February 26th, where Dr. Lee will present his findings…

…We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. The GACVS has not yet had a chance to delve into the DNA question."

Accepting the assignment, Dr. Helen Petousis-Harris wrote back immediately on February 18, 2014 as follows:

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz] Sent: Tuesday, February 18, 2014 5:19 AM To: 'Robert Pless' Cc: Robert Pless (Robert.Pless@phac-aspc.gc.ca); 難波江 功二(nabae-koji); ZUBER, Patrick Louis F.; Wharton, Melinda (CDC/OID/NCIRD) Subject: RE: URGENT: Regarding the posted commentary on the coronial inquiry expert witness testimony

Dear Rob Oh dear! I am so saddened to hear how extensive the impact of Lee, Shaw and Tomljenovic's activities has become. I will certainly do anything I can to assist. To the best of my knowledge the rebuttal on our website is the only attempt to address this particular issue which Shaw and Lee presented at a coronal enquiry here. Placing the rebuttal in the public domain was the only means of providing the information to the crown representatives involved in that process at the 11th hour. Prof David Gorsky has written prolifically on some of the experiments in his science blog over the past few years so I assume he has also given the material some thought.

I do not know if I am expert on this but certainly have some experience in considering aluminium in vaccines and its role in inflammatory responses and local AEFI as part

> *of my PhD some years ago. I assume you are referring to the VLP tightly bound to the adjuvant and the Shaw and Tomljenovic 'hypothesis' that it somehow finds its way to the brain carried by macrophage?"*

Lack of Qualification/Credibility of Expert Witness Dr. Helen Petousis-Harris

Based on the above correspondence, Dr. Helen Petousis-Harris had no clue what Dr. Pless wanted her to address at the February 26, 2014 public hearing. She mistakenly assumed she was being asked to comment on "the VLP tightly bound to the adjuvant." She did not even know that VLP is a protein, and cannot be tightly bound to the aluminum adjuvant as the DNA molecules can.

Evidently, her only qualification was she had written a social media blog much like Professor David Gorski, a well-known online character assassin masquerading as a science defender whom she also recommended to the group saying:

> *"Prof David Gorsky has written prolifically on some of the experiments in his science blog over the past few years so I assume he has also given the material some thought."*

I find it incredible that the WHO GACVS had to depend on online science blog writings as evidence to dismiss the potential risk of HPV DNA fragments in Gardasil®. As evidenced in the email above, on February 18, 2014, Dr. Pless knew very well that the CISA Network Technical Report dated November 2012 did not address the presence of HPV L1 gene DNA fragments in the vaccine Gardasil® because he wrote to Dr. Helen Petousis-Harris:

> *"…We are seeking your advice on someone who may be able to address the more detailed questions around HPV DNA - specifically the hypotheses you have address in your statement regarding the alleged role of aluminum binding to DNA fragments and subsequent effects. While the issue of whether the fragments constitute "contamination" has been dealt with, your statement was the only one to address the more obscure alleged consequences of the presence of those fragments. …"*

So, as of February 18, 2014 Dr. Pless and those whose names are listed on his email knew Dr. Helen Petousis-Harris and Professor David Gorski were the only two writers who had addressed the issue of HPV L1 gene DNA fragments in the HPV vaccine, but in social media blogs only, and not in peer-reviewed scientific journals. Dr. Pless needed to find someone to put a veneer of science over these online blogs. He found Dr. Helen Petousis-Harris for that.

Government Counter-Actions to Evidence of Harmful Effects of HPV Vaccination

The following emails showed the actions taken by the bureaucrats of the Ministry of Health, Labour and Welfare of Japan, the chair of the public hearing session, Dr. Pless and Dr. Melinda Wharton of the CDC to counter the plausible consequences of the presence of the HPV DNA fragments in the Gardasil® vaccines.

From: 鞆波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Friday, 21 February 2014 11:05 p.m.
To: Robert Pless; Helen Petousis-Harris; ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr; Wharton, Melinda (CDC/OID/NCIRD); Koji Nabae (k-nabae-@nifty.com); 阿部 圭史(abe-keishi); Robert Pless
Subject: RE: (FYI) HPV vaccine international sympo on 25 Feb in Tokyo
Attachments: GACVS Statement HPV Feb 2014 discussion draft.docx; Annotated Agenda 26 Feb 2014.docx; Participants List.docx

Dear Rob,

Thank you so much for the excellent work you and your colleagues have done.
It sounds very strong. It is indeed very helpful.

I made minor comments on the attached file.

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For the conference call today, there will be 4 participants from Japan.

Koji Nabae (Ministry of Health, Labour and Welfare (MHLW)) Keishi Abe (MHLW) Ichiro Kurane (Chair of the public hearing session, Deputy Director General of National Institute of Infectious Diseases(NIID)) Dr Hiroshi Yoshikura (Former DG of NIID)

In case you wish to discuss GACVS statement only among GACVS members, please let me know so that we will join you later.

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Attached please find the draft annotated agenda and participant list of the public heating meeting.

I look forward to talking to you soon.

Warm regards,

Koji
Deputy Director
Division of Tuberculosis and Infectious Disease Control Ministry of Health, Labour & Welfare Government of Japan-
Tel: [redacted]
Fax: +81-3-3581-6251
email: nabae-koji@mhlw.go.jp

-----Original Message-----
From: Robert Pless [mailto:rpless2@gmail.com]
Sent: Friday, February 21, 2014 4:19 PM
To: Helen Petousis-Harris; 難波江 功二(nabae-koji); ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr; Wharton, Melinda (CDC/OID/NCIRD); Koji Nabae (k-nabae-@nifty.com); 阿部 圭史(abe-keishi); Robert Pless
Subject: Re: (FYI) HPV vaccine international sympo on 25 Feb in Tokyo

Dear all,

Attached please find a draft GACVS statement for review. We can discuss it tomorrow (actually in a few hours) and then it would go through vetting by the committee if the feeling remains that it should be posted in advance of the events of next week.

I propose the following topics for discussion on our call:

1. Introductions
2. Current situation in Japan with respect to the signal 3. Origins of the 2 meetings being held next week and potential outcomes 4. Planned and likely topics that may arise by the speakers (MMF, HPV DNA, ...other) 5. Responses during the meeting on the 26th (invited experts, Ministry, Expert advisory group) 6. Format and timing of responses outside the meetings (GACVS statement, follow up statements?) 7. Other interventions?
8. Other issues

Please feel free to add/alter
Looking forward to getting together on the phone, Rob

Based on the emails copied above, Dr Pless and those listed in these emails already drafted a GACVS statement before the public hearing. However, after having discussed to his boss, Dr. Nabae Koji wrote to the group on February 23, 2014 the following email:

From: 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Sunday, 23 February 2014 6:01 p.m.
To: SAHINOVIC, Isabelle; rpless2@gmail.com; Robert.Pless@phac-aspc.gc.ca; Helen Petousis-Harris; mew2@cdc.gov; ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr
Cc: 阿部 圭史(abe-keishi); 難波江 功二(nabae-koji)
Subject: HPV vaccine conf call Follow-up

Dear all,

Thank you so much for your time and commitment. The conference call was very useful for us.

I talked to my boss and we agree that it is better not to have WHO GACVS presence during the public hearing session [redacted] and there is no need to hurry for a statement. We are hoping the statement to come out a week or two weeks later so that our expert committee can refer to it when they finalize the report in March (or a bit later) (if things go smoothely).

Thank you so much for your help.

I look forward to meeting and talking to you later.

Warm regards,

Koji Nabae

In plain language, it appears that Dr. Nabae was instructing the WHO GACVS not to present any information formally in order to avoid cross-examination and scrutiny at the February 26, 2014 Public Hearing. Information provided after the public inquiry would provide a means for decision makers to be duly influenced by informal and cherry-picked 'expert' opinions.

I believe this maneuver was orchestrated by the Chairperson of the WHO GACVS and others as nothing more than a very cunning means of avoiding having to supply scientific evidence to decision makers. Actions like this corrupt the entire concept of science-based medicine.

Dr. Helen Petousis-Harris was finally selected as spokesperson for the February 26, 2014 Tokyo public hearing. But according to the emails uncovered, Dr. Petousis-Harris' Powerpoint slides had to be reviewed by the group before presentation at the public hearing to ensure she put forth the proper message.

I found it astonishing to read the February 25, 2014 email sent by Dr.Nabae Koji to Dr. Helen Petousis-Harris, their designated spokesperson. Dr. Nabae was concerned about Dr. Helen Petousis-Harris' Powerpoint slide which stated *"immune activation on uptake of HPV vaccine does not include an increase in inflammatory factors (incl TNF) even in vaccinees with large injection site reactions at time of local inflammation"* because such claim contradicted the data presented by another expert at their previous meeting which in fact confirmed that cytokines following vaccines increased particularly at injection site after Cervarix® compared to other vaccines (including tumor necrosis factor- TNF).

It is of interest to note that Dr. Nabae Koji also deleted some questionable "*Japanese Wildcard*" data from Dr. Helen Petousis-Harris' Powerpoint slides to be presented at the February 26, 2014 public hearing because he, Dr. Nabae, could not "*explain it well*".

GACVS Suppresses Vital Information and Manipulates Data to Support Claim of Vaccine Safety in the Face of Valid Contradictory Evidence

I find this to be yet another blatant example of suppression of information this group found to be potentially contradictory to and/or not totally compatible with their pre-determined GACVS "party line" statement on continued safety of HPV vaccination. Dr. Pless and the WHO officials seemed to have simply written a script for Dr. Helen Petousis-Harris to regurgitate at the public hearing and then proceeded to put forth the same presentation as an independent research reference to support their pre-determined GACVS statement. What an insult to the intelligence of the citizens of the world!

The Powerpoint slides Dr. Helen Petousis-Harris presented at the public hearing claimed Dr Lee's case report had no controls to prove that unvaccinated New Zealand teenage girls do not have HPV DNA in non-B conformations in their blood, therefore the findings are not scientifically valid. She said, "*There are no controls used (unvaccinated). This is a vital part of the scientific process*." [original emphasis.]

Dr. Helen Petousis-Harris evidently does not understand the difference between a case report and a clinical trial; nor does she seem to know how hard it is for pathologists to find any HPV DNA in blood samples of patients, even those known to have HPV infections, let alone HPV DNA in non-B conformations. This shows how little, if any, experience she has in laboratory medicine.

I find Dr Petousis-Harris blog[1] which was quoted as Ref. 17 by Dr Pless in the GACVS statement in support of the declaration of HPV vaccination safety, to be more concerned with character assassination than in disputing the science of HPV L1 gene DNA fragments in Gardasil® or in postmortem materials.

The very important email exchange between Dr. Nabae and Dr. Helen Petousis-Harris on February 25, 2014, one day before the Tokyo public hearing, is copied in this correspondence so you can judge for yourself whether these people manipulated the scientific data and process in order to mislead the Japanese Expert Inquiry, and vaccination policy makers worldwide.

First, please note Dr. Dr. Nabae's concern about Dr. Helen Petousis-Harris' claim of no cytokine increases in HPV vaccinees, as expressed in the email dated February 25, 2014 shown below, which was apparently written after he had an opportunity to review her proposed powerpoint presentation.

[1] http://www.nzdoctor.co.nz/media/2003295/response_to_theories_by_lee_and_shaw_final_180912.pdf

From: 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>
Sent: Tuesday, 25 February 2014 1:56 p.m.
To: Helen Petousis-Harris
Subject: RE: Doc and Video Conf
Attachments: NZ Public hearing session on HPV safety.pptx

Fantastic!! Very strong and convincing. Many many thanks!
It think there is no need for further explanation since your slides tell all the story.

One thing I came up to my mind,

- In addition, the immune activation on uptake of HPV vaccine does not include an increase in inflammatory factors (incl TNF) even in vaccinees with large injection site reactions at time of local inflammation.

In our previous meeting, one expert presented his studies on mice,
http://www.mhlw.go.jp/file/05-Shingikai-10601000-Daijinkanboukouseikagakuka-Kouseikagakuka/0000033876.pdf

In page 21 and 22, cytokines following vaccines increased particularly at injection site after Cervarix compared by other vaccines (incl TNF) but not in serum. I am just concerned that this finding may contradict with your statement.

I also deleted Japanese Wildcard (since I cannot explain it well!!) and found one typo in page 2.

Grateful for your confirmation!!

Best regards,

Koji

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 8:03 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

Dear Koji

Phew!

Here you are.

I have put some credentials on the first slide, please adjust to what you think would be most useful
Also, I have used the Japanese translation for the word Wildcard (according to Google) but if this doesn't work please remove it from Slide 3.

Later in the morning apparently after a video conference Dr. Helen Petoussis Harris replied, asserting her scientific authority to comment as follows:

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 10:02 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

Great!

Actually that is my own work, We have conducted a clinical trial using Gardasil vaccine. We specifically examined the reactogenicity of the vaccine and associations with 27 cytokines inlc TNF and IL1, all the main players. There was no elevation of any cytokine associated with reactogencity. I have it on a list to publish and it had been peer reviewed in a PhD thesis which is available in the University Library and the data is available for scrutiny.

So Dr. Helen Petousis-Harris used her PhD thesis[2] as authoritative research to support her theory of "*No elevation of any cytokine associated with reactogenicity*"?

In fact, her PhD thesis has not been published in a peer-reviewed scientific journal because not only the experimental design and methodology used were highly questionable, as demonstrated in over 500 pages of Official Information documents and emails, but also in section 8.2 on limitations of this thesis, where Dr. Petousis-Harris states:

> "Timing and lack of baseline cytokine measures: Only a single blood sample was taken. The absence of a baseline measure precludes any within-individual changes. It cannot be determined if there were any changes in cytokine levels as a result of the administration of the vaccine or if these were base-line levels. In addition, blood samples were taken on day two, the day following vaccine administration, as it was thought local reactions would peak on this day. Injection site reactogenicity is not reported in a way that clarifies the peak time of reactions therefore this was an educated guess. Reactions actually peaked on the day of vaccination. It is possible that any elevations in cytokine levels may have waned by day two. Also, as many cytokines have localised activity it is possible that increased activity is not captured systemically. The fact that atopic score was associated with a range of cytokines supported that the assays were conducted successfully."

In Dr Helen Petousis-Harris' own words, "*as many cytokines have localised activity it is possible that increased activity is not captured systemically.*" Nevertheless, Dr. Helen Petousis-Harris managed to satisfy Dr. Nabae that she only measured the cytokines in the serum and found no increase of cytokines after HPV vaccination and her data did not really contradict the findings presented by their

[2] https://researchspace.auckland.ac.nz/handle/2292/10600

expert which confirmed increases in cytokines at the site of HPV vaccine injection. So both Dr. Nabae and Dr. Petousis-Harris decided to use "no increase in serum" as evidence for "*No elevation of any cytokine associated with reactogenicity*" as illustrated in the following email exchange.

From: Helen Petousis-Harris [mailto:h.petousis-harris@auckland.ac.nz]
Sent: Tuesday, February 25, 2014 10:11 AM
To: 難波江 功二(nabae-koji)
Subject: RE: Doc and Video Conf

...yes, this was measured in human serum the day after vaccination – when the innate immune response and macrophages are at their busiest.

From: 難波江 功二(nabae-koji) [mailto:nabae-koji@mhlw.go.jp]
Sent: Tuesday, 25 February 2014 2:06 p.m.
To: Helen Petousis-Harris
Subject: RE: Doc and Video Conf

Great!! I understand this is in human serum. We will set the slides as I sent in my previous mail (change red color to black in page 2). Thanks!!

1

Koji

In my opinion these emails clearly demonstrate that ***this group of WHO officials and government employees charged with the responsibility to advise the expert committee of the Japanese government on HPV vaccination safety knew before the February 26, 2014 Tokyo public hearing that one of their own experts showed scientific evidence that HPV vaccination does increase cytokines, including tumor necrosis factor (TNF), particularly at the injection site compared to other vaccines. Yet, they chose to suppress this information at the public hearing.*** Of course, this piece of scientific data which was known to all members of the group, including Dr Robert Pless, the chairperson of GACVS, is also missing from the GACVS Statement on the continued safety of HPV vaccination issued on March 12, 2014.

So why does HPV vaccination increase the level of cytokines, including TNF, at the site of injection compared to other vaccines?

The answer is: HPV vaccines contain HPV L1 gene DNA fragments, the viral DNA fragments, bound to aluminum adjuvants in the vaccines. To understand this, the members of the GACVS should keep up with the recent research and scientific publications on aluminum adjuvants. A brief summary on this subject with 22 key peer-reviewed references is presented as follows.

Use of Aluminum Adjuvant

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 shows that there is a known molecular mechanism to explain why serious adverse reactions occur more often in people injected with HPV vaccines than with other vaccines, and why certain predisposed vaccinees may suffer a sudden unexpected death as the result of Gardasil® vaccination.

It is my opinion that Dr Pless, those whose names appeared in the emails attached to this complaint, and all who blindly dismiss the potential toxicity of the newly created HPV L1 gene DNA/AAHS compound in order to continue to promote HPV vaccinations should be held accountable for their actions. There is no excuse for intentionally ignoring the scientific evidence. There is no excuse for misleading global vaccination policy makers at the expense of public interest.

It is my contention these people have not only violated the Terms of Reference of the WHO Global Advisory Committee on Vaccine Safety (GACVS); they have violated the public trust. Immediate, independent and thorough investigations into their actions with appropriate disciplinary action is the only option available that might restore the public's confidence in worldwide health authorities.

Thank you for your attention to this matter.

Sincerely,

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Attachments:
GACVS Terms of Reference
GACVS Statement on the continued safety of HPV vaccination on March 12, 2014
WHO GACVS emails from February 18, 2014 to February 27, 2014 in chronologic order
Original FOIA -Attachment obtained in New Zealand

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