

**From:** Robert Pless [<mailto:rpless2@gmail.com>]

**Sent:** Tuesday, 18 February 2014 6:20 a.m.

**To:** Helen Petousis-Harris

**Cc:** Robert Pless ([Robert.Pless@phac-aspc.gc.ca](mailto:Robert.Pless@phac-aspc.gc.ca)); "難波江 功二(nabae-koji)"; ZUBER, Patrick Louis F.; Wharton, Melinda (CDC/OID/NCIRD)

**Subject:** URGENT: Regarding the posted commentary on the coronial inquiry expert witness testimony

Dear Dr. Petousis-Harris,

I am writing you with an urgent request outlined below, having read the Immunization Advisory Centre's Commentary on coronial inquiry expert witness testimony that was prepared in response to allegations by Chris Shaw and Sing Hang Lee. I am a current member of the WHO Global Advisory Committee on Vaccine Safety and am writing in part on behalf of Dr. Koji Nabae of the Japanese Ministry of Health, for assistance. The GACVS has been looking at this issue from the global perspective and have released several statements over the last two years to address concerns around aluminum and autoimmune disease.

As you may be aware, there have been ongoing concerns in Japan regarding the HPV vaccine, where cases of chronic pain and complex regional pain syndrome allegedly linked to the vaccine have led to a partial suspension of their national vaccination program and there has been a great deal of public interest. An expert advisory group has met several times but have not reached a conclusion about the restart of the program. A meeting has recently been organized in Tokyo for February 26th, where Dr. Lee will present his findings. It is likely that Dr. Shaw's co-investigator, Lucija Tomljenovic will be present as well. There will be a second presentation on Macrophagic Myofasciitis and the HPV vaccine, a stretch of the MMF story first related to the hepatitis B vaccine.

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.

While we appreciate the short notice, the meeting and even the date were very recently confirmed. That said, the ideal would be someone who would be available to travel to the meeting in Japan and address the issue as it arises in

person. Please let me know if I can clarify anything by phone, and indeed if this is at all possible and who could be contacted and provided with further details.

Best regards,  
Rob

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Robert Pless, MD, MSc  
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Ottawa, Ontario K1A 0K9  
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**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 11<sup>th</sup> 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.

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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?

A phone call would probably be useful. It is a little after 9am in NZ.

Kind regards.

Helen

Helen Petousis-Harris. PhD, MRSNZ  
Senior Lecturer, General Practice and Primary Health Care  
Director of Immunisation Research and Vaccinology  
Immunisation Advisory Centre  
University of Auckland  
DDI +64 9 923 2078 Fax 9 3737030 Mob [REDACTED]  
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Private Bag 92019, Victoria St West, Auckland 1142, New Zealand

**From:** 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>  
**Sent:** Tuesday, 18 February 2014 3:29 p.m.  
**To:** Helen Petousis-Harris  
**Subject:** RE: URGENT: Regarding the posted commentary on the coronial inquiry expert witness testimony

Dear Helen,

It was so nice talking to you and thank you so much for agreeing on joining our meeting. It is indeed very helpful.

Just quickly, **I understand you are unable to travel to Japan in such a short notice next week.**

**Is this correct!? We are happy to invite you (we will cover the travel cost) in case you happen to be able to travel!!**

Grateful for your response at your earliest opportunity.

Warm regards,

Koji Nabae  
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](mailto:nabae-koji@mhlw.go.jp)

**From:** 難波江 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 hearing 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](mailto: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](mailto:jbeytout@chu-clermontferrand.fr); Wharton, Melinda (CDC/OID/NCIRD); Koji Nabae ([k-nabae-@nifty.com](mailto: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

**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 smoothly).

Thank you so much for your help.

I look forward to meeting and talking to you later.

Warm regards,

Koji Nabae

**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!  
I 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

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**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.

I will script what I say to these slides and ensure I am within the five minutes. There are really only six slides I will speak to.

We can test the technology again later today. I will use my laptop. We tested the microphone and camera today and it is all working.

Kind regards  
Helen

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**From:** 難波江 功二(nabae-koji) [<mailto:nabae-koji@mhlw.go.jp>]

**Sent:** Tuesday, 25 February 2014 4:00 a.m.

**To:** Helen Petousis-Harris

**Subject:** Doc and Video Conf

Dear Helen,

I hope this finds you well. And thank you so much for your excellent support. It has been extremely helpful for us.

We would be truly grateful if you could send us your presentation no later than 12pm (noon) 25th Feb NZ time so that we can send it to a printing center to be distributed during the meeting.

Further, we wish do a testing for the video conference machine as early as 2pm (NZ time) tomorrow.

We look forward to talking to you again soon.

Warm regards,

Koji Nabae

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**From:** 難波江 功二(nabae-koji) <nabae-koji@mhlw.go.jp>  
**Sent:** Thursday, 27 February 2014 3:31 a.m.  
**To:** Robert Pless; SAHINOVIC, Isabelle; Robert Pless; mew2@cdc.gov; Helen Petousis-Harris; ZUBER, Patrick Louis F.; jbeytout@chu-clermontferrand.fr; LAMBACH, Philipp  
**Cc:** 阿部 圭史(abe-keishi); 難波江 功二(nabae-koji)  
**Subject:** HPV mtgs in Japan  
**Attachments:** Dr Helen Petousis-Harris.pdf; Prof Jean Beytout.pdf; Summary of 25 Feb Symposium.pdf

Dear colleagues,

The two meetings on HPV vaccine in Japan today went very well.

I wish to express our sincere appreciation to all of you, particularly Prof Beytout who came all the way to Japan (in economy class!) and made an excellent and very convincing presentation (attached file) and Helen, despite the technical difficulty, generated a straightforward and punchy argument (attached file).

The media has already picked up the events. The tone is very neutral and some reports that these arguments were dismissed for lack of scientific evidence.

[http://www.tv-tokyo.co.jp/mv/mplus/news/post\\_61006](http://www.tv-tokyo.co.jp/mv/mplus/news/post_61006)  
<http://www3.nhk.or.jp/news/html/20140226/k10015558551000.html>

And I thank colleagues in WHO GACVS (Philipp, Patrick, Isabelle, Rob and Melinda) for your enormous support and encouragement. We really hope that our committee would come to a conclusion in a month or two and we can move forward with our immunization program.

I will send you a summary of the meeting today once ready. In the meantime, I attach an internal report of the symposium that took place yesterday (not for wider circulation, please keep it only among GACVS members).

Millions of thanks again and I look forward to talking to you soon.

Warmest regards,

Koji