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For the attention of: 17 July 2014
Professor Peter Gøtzsche
Co-founder of The Cochrane Collaboration and Director of The Nordic Cochrane Centre

Professor Gøtzsche

RE: Vaccine safety and aluminium adjuvants

Thank you for your response[1] to my letter dated 8 July 2014 which challenges a systematic review prepared by the Cochrane Vaccines Field i.e. **Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence**.[2]

In your response you encourage me to "submit a criticism" on this important matter to The Cochrane Collaboration.

As noted in my previous letter, the systematic review in question was prepared by members of the Cochrane Vaccines Field, i.e. Tom Jefferson, Melanie Rudin and Carlo Di Pietrantonj, and was published in *The Lancet Infectious Diseases* in 2004 (behind the paywall). The review is listed in the bibliography on the Cochrane Vaccines Field website, but is not accessible online on The Cochrane Collaboration website, so I am unable to make an online comment.

Professor Gøtzsche, as you have encouraged me to make a submission, can you please clarify how I should do this?

For your information, I originally contacted Dr Jefferson directly about this matter in March 2013. (I had previously contacted Dr Jefferson on other vaccine-related matters. He is also formally copied on my submissions re controversial 'gain-of-function' research[3] in the influenza industry, see my letter to the NSABB Jan 2012 and my submission to the US CDC/HHS Dec 2012.)

Please see below the contents of my email forwarded to Dr Jefferson on 24 March 2013 in regards to his systematic review of adverse events after immunisation with aluminium-containing DTP vaccines. (Given my previous correspondence with Dr Jefferson, the tone is informal. I have added some references in the endnotes):

> Tom
>
> I'm reading your review: "Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence" (The Lancet Infectious Diseases. Vol. 4 2004.)
>
> The summary of your review concludes: "Despite a lack of good-quality evidence ***we do not recommend that any further research on this topic is undertaken***." (My emphasis.)
>
> Your review notes: "The results of our review should be interpreted within the limited quantity and quality of available evidence. Within these limits, we found no evidence that aluminium salts cause any serious or long-lasting adverse events..."
>
> So, you admit the quantity and quality of the evidence in your review was limited, but you still say that "***we do not recommend that any further research on this topic is undertaken***".
>
> ***Why would you say that?***
>
> I suggest you did not have enough information to say "we do not recommend that any further research on this topic is undertaken." ***Your review just plays into the hands of vaccine manufacturers like GlaxoSmithKline and Merck etc who are pushing repeat revaccinations with aluminium adjuvanted vaccines of questionable value.***
>
> Vaccines with aluminium adjuvants such as DTaP (repeat 'boosters' being recommended for all ages) and HPV x 3 shots for children, etc are now being pushed on the population. ***Who knows what the cumulative effect of this repeated vaccination with these vaccines might be? Have there been any long-term studies? I would suspect no...***
>
> My investigation into companion animal vaccines has led me to be very concerned about vaccines with an aluminium adjuvant. Do I have masses of material in the "peer-reviewed literature" to back me up? No, and neither have I had the time to do a full-blown literature search, what with spending so much of my time investigating questionable MMR 'boosters', HPV, flu, pertussis vaccination, etc, because of all the ***misinformation*** spread by the 'scientific' establishment... Who would fund such research anyway?
>
> **Experts in veterinary medicine have been calling for a decrease of live and inactivated vaccination of companion animals because of the risk of adverse reaction to vaccines.**[4] I'm becoming more concerned about the non-infectious/inactivated vaccines with aluminium adjuvants, (e.g. bordetella bronchiseptica with aluminium) that are given to many dogs every year, ***and now humans are being pressed to have regular revaccinations with aluminium adjuvanted vaccines (e.g. DTaP and HPV).***

For information, **see attached** a presentation by Michael J Day[5], from a World Small Animal Veterinary Association Congress (2004) in which he says:

> "We now recognize that vaccines (particularly multicomponent, modified live products) appear to be able to trigger a range of immune-mediated and autoimmune diseases. For example, much attention has recently focused on vaccines as an initiator of immune-mediated haemolytic anaemia in the dog. The mechanism by which this effect occurs is not well investigated. In theory, three separate components of the vaccine might be involved. ***Many vaccines contain adjuvant (particularly alum), the function of which is, in part, to non-specifically activate the immune system. It is theoretically possible that this activation might include autoreactive lymphocytes, and as alum is very effective at stimulating antibody responses, the activation of B cells and their particular helper T cells (Th2 cells) might readily arise...."*** (My emphasis.)
> Ref: 29th World Congress of the World Small Animal Veterinary Association October 6-9 2004, Rhodes, Greece.
> Michael Day is an author of the WSAVA Guidelines for Dogs and Cats,
> 2010: http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf

Also, here's a quote from a DVM roundtable of vaccine experts, (December 1988)[6], which included Ron Schultz, Jonas Salk, Ian Tizard and others during which Ian Tizard said:

> "And yet, the use of poorly understood adjuvants has a long and distinguished history in vaccinology. We've been using alum since the 1920s ***and are still not sure how it works***. It's also fair to say that we've been very conservative in our use of adjuvants. To the best of my knowledge, alum is still the only adjuvant used in human vaccines..." (My emphasis.)

In 2013, **do we yet know how alum works in vaccines?**

It is interesting to note that pregnant women are currently being urged to have DTaP revaccinations because of the resurgence of pertussis. However, it has been reported that the pertussis circulating is a new strain, ***so what is the point of revaccinating with the existing vaccine?*** Also, I don't buy this idea of a vaccine that 'wanes'. ***Either a vaccine immunises for life or forget it, we have been conned big time with these annual flu vaccinations and repeat DTaPs etc.***

On the topic of pregnant women and the DTaP, it is interesting to note that vaccination guidelines for dogs say:

> "*Should a pregnant dog be vaccinated?* ***Vaccination with MLV (attenuated) and/or killed (inactivated) vaccines during pregnancy should be avoided, if possible, to avoid potential injury to the fetus.*** There are exceptions, especially in shelters, where vaccination would be advised if the pregnant dog has never been vaccinated and there is risk of exposure to a highly pathogenic virus (e.g., CDV, CPV-2). (My emphasis.)
> Reference: 2011 AAHA Canine Vaccination
> Guidelines: http://www.aahanet.org/PublicDocuments/CanineVaccineGuidelines.pdf

Are pregnant women being properly informed about pertussis, about the 'new strain', and about questionable vaccines that wane? Have the possible long-term deleterious effects of vaccination of pregnant women with aluminium adjuvanted vaccines been properly researched? ***I suspect not...***

Tom, I suggest your Cochrane Review of aluminium-containing DTP vaccines is a bit of a worry in that it may have created a poorly evidenced acceptance of the safety of aluminium-adjuvanted vaccines.

Cochrane Reviews don't always get it right, as we know from Hayashi / Tamiflu...[7]

I would appreciate your response on this matter.

Regards
Elizabeth

Dr Jefferson responded to my email saying: ***"Very simple: it is not a Cochrane review"***.[8] Obviously this brief reply was an inadequate response to the serious matters I had raised. I was also bemused by his statement that the systematic review prepared by the Cochrane Vaccines Field was ***"not a Cochrane review"***. The review as published in *The Lancet Infectious Diseases* clearly identifies the authors as members of the Cochrane Vaccines Field, so surely The Cochrane Collaboration has a responsibility to be accountable for the recommendations of this review?

Professor Gøtzsche, as you have encouraged me to "submit a criticism" on this important matter, I would appreciate your advice as to how I can successfully make a submission to The Cochrane Collaboration.

I look forward to your response.

Sincerely
Elizabeth Hart
http://over-vaccination.net/

***Please note, in addition to the cc list below, this letter will be circulated to other parties, and has also been published on my website.**

cc: Dr Tom Jefferson, Cochrane Vaccines Field
Mr Mark Wilson, CEO, The Cochrane Collaboration
Professor Paul Glasziou, Bond University
Professor Chris Del Mar, Bond University
Mr Ray Moynihan, Bond University
A/Professor Peter Doshi, University of Maryland
Dr Fiona Godlee, British Medical Journal
Professor Peter Collignon, Australian National University
Professor Christopher Exley, Keele University
Professor Chris Shaw, University of British Columbia
Dr Lucija Tomljenovic, University of British Columbia
Professor Warwick Anderson, NHMRC
Professor Ian Olver, NHMRC Australian Health Ethics Committee
Professor Ian Frazer, University of Queensland
A/Professor Ruiting Lan, University of New South Wales
Professor Lyn Gilbert, University of Sydney
Dr Linjie Zhang, Federal University of Rio Grande
Professor Ronald Schultz, Vaccination Guidelines Group, World Small Animal Veterinary Association
Professor Michael Day, Vaccination Guidelines Group, World Small Animal Veterinary Association
Professor Brian Martin, University of Wollongong
Ms Bea Mies, Independent Vaccine Investigator
Ms Monika Peichl, Independent Vaccine Investigator

References: (All links accessible as at 17 July 2014. It may be necessary to copy and paste long links into a web browser.)

[1] Email from Professor Peter Gøtzsche, 9 July 2014.

[2] Jefferson T, Rudin M, Di Pietrantoni C. Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence. Lancet Infect Dis. 2004 Feb; 4(2):84-90: http://www.ncbi.nlm.nih.gov/pubmed/14871632 This review is also listed in the Cochrane Vaccines Field Bibliography: http://vaccinesfield.cochrane.org/bibliography-2003

[3] A recent editorial in Nature provides an update on this controversial research: Biosafety in the balance. 25June 2014 (corrected 4 July 2014): http://www.nature.com/news/biosafety-in-the-balance-1.15447

[4] For example the World Small Animal Veterinary Association Guidelines for the Vaccination of Dogs and Cats state ***"we should aim to reduce the 'vaccine load' on individual animals in order to minimize the potential for adverse reactions to vaccine products"***. The Vaccination Guidelines Group also acknowledges that **"there is gross under-reporting of vaccine-associated adverse events which impedes knowledge of the ongoing safety of these products"** Day MJ, Horzinek MC and Schultz RD. Journal of Small Animal Practice. Vol. 51. June 2010: http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf Also refer to the WSAVA Vaccination Guidelines webpage: http://www.wsava.org/guidelines/vaccination-guidelines

[5] Day MJ. Infectious Triggers of Immune-Mediated Disease. 29th World Congress of the World Small Animal Veterinary Association. October 6-9 2004, Rhodes Greece: http://www.vin.com/proceedings/Proceedings.plx?CID=WSAVA2004&Category=&PID=8599&O=Generic

[6] Safety, efficacy heart of vaccine use; experts discuss pros, cons. DVM roundtable. DVM December 1988.

[7] Tom Jefferson. Hayashi's Problem: Dr Keiji Hayashi's question re Cochrane's Tamiflu/Oseltamivir review: *"We have some questions on the conclusion in your Oseltamivir review especially about the prevention of complication. You described that "Oseltamivir 150 mg daily prevented lower respiratory tract complications (OR 0.32, 95% CI 0.18 to 0.57)." (in abstract). However, we have found that this conclusion is based on the other review (Kaiser2003) and not on your own data analysis. The authors of the review were four employees of F. Hoffman-La Roche Ltd, one paid consultant to F. Hoffman-La Roche Ltd and Kaiser. We cannot find any raw data about this conclusion from your review. Kaiser's review included 10 RCTs; two RCTs (Nicholson 2000 and Treanor 2003) were published as articles in the peer-reviewed medical journal (JAMA and Lancet), but other 8 RCTs were proceedings of congress (5 RCTs), abstracts of the congress (one RCT) and meeting (one RCT) and data on file, Hoffmann-La Roche, Inc, Nutley, NJ (one RCT). The lower respiratory tract complication rates of these articles were summarized on table: there was no significant difference between Oseltamivir and placebo, and their Odds Ratio's (ORs) were 1.81. But ORs of other 8 RCTs were 4.37. We strongly suppose that the reviewer's conclusion about the complications was mainly determined by these 8 RCTs, we should appraise the 8 trials rigidly. Without this process it's difficult to conclude that oseltamivir can prevent lower respiratory tract complications."* (Powerpoint slide 12): http://chmg.cochrane.org/sites/chmg.cochrane.org/files/uploads/Jefferson_Hayashi's%20problem.pdf

[8] Email from Tom Jefferson, 24 March 2013.