

**Elizabeth Hart**  
Adelaide, South Australia  
[eliz.hart25@gmail.com](mailto:eliz.hart25@gmail.com)

11 August 2014

**For the attention of:**  
Mr John McConnell  
Editor, *The Lancet Infectious Diseases*

Mr McConnell

I write to you to challenge a systematic review prepared by members of the [Cochrane Vaccines Field](#)<sup>1</sup>, i.e. [Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence](#), published in *The Lancet Infectious Diseases* in February 2004 (*behind the paywall*).<sup>2</sup>

I have already forwarded letters on this matter to Professor Peter Gøtzsche, co-founder of The Cochrane Collaboration. Please see attached letters dated [8 July 2014](#) and [17 July 2014](#). My letters to The Cochrane Collaboration are also published on my website: <http://over-vaccination.net/cochrane-collaboration/>

**I request that *The Lancet Infectious Diseases* take urgent action to re-evaluate this review prepared by members of the Cochrane Vaccines Field.**

**In my opinion this so-called ‘systematic review’ should be retracted by *The Lancet Infectious Diseases*.**

**I suggest this review has facilitated poorly evidenced acceptance of the safety of aluminium-adjuvanted vaccines.** As a consequence, an increasing number of aluminium-adjuvanted vaccines are being added to vaccination schedules around the world e.g. multiple doses of diphtheria, tetanus and pertussis vaccines, and multiple doses of human papillomavirus (HPV) vaccine, amongst others. [The meningococcal B vaccine is the latest to be promoted.](#)<sup>3</sup> **The long-term cumulative effects of the ever-growing list of vaccine products are unknown.**

In their systematic review, authors Tom Jefferson, Melanie Rudin and Carlo Di Pietrantonj state: **“We found no evidence that aluminium salts in vaccines cause any serious or long-lasting adverse events.”** They also admit that: **“Overall, the methodological quality of included studies was low”**. Bizarrely, Jefferson et al conclude: **“Despite a lack of good-quality evidence we do not recommend that any further research on this topic is undertaken.”**<sup>4</sup>

**From my layperson’s perspective, Jefferson et al’s ‘systematic review’ is an example of ‘garbage in, garbage out’.**

Professor Christopher Exley of Keele University has raised this matter with your journal previously. In a letter published in *The Lancet Infectious Diseases* in June 2004<sup>5</sup> (*behind the paywall*) he noted:

*“I was surprised that the authors were able to conclude from their review that further research in this field was unnecessary. It would seem to me that this conclusion did not adequately reflect the findings of the limited resource base underpinning the review. **The authors criticised the quality of the data they had available to them and yet these data were still deemed sufficient to support such a strong conclusion. In addition, the authors made no reference to the fact that aluminium-based adjuvants contribute to the recipients systemic body burden of aluminium. We now know that aluminium in adjuvants is dissolved and transported throughout the body, including the brain<sup>6</sup> and we cannot discount the biological availability of this aluminium. It is a sobering thought that aluminium adjuvants have not had to pass any of the safety trials that would be expected of any drug or treatment. Their application is historical and this should not necessarily be equated with their safety. There is no consensus as to whether it is safe to introduce aluminium in prophylaxis or otherwise, and until the requisite research is carried out it is misleading to conclude that aluminium adjuvants are safe for all to use.**”* (My emphasis.)

Professor Exley followed up with another letter published in *The Lancet Infectious Diseases* in April 2006<sup>7</sup> (*behind the paywall*) in which he stated:

*“In 2004, I commented in *The Lancet Infectious Diseases* that **it was too early to conclude that aluminium adjuvants were safe for all to use.**<sup>8</sup> **This opinion has been strengthened by recent research highlighting delayed hypersensitivity to aluminium in children who have received aluminium-adsorbed vaccines.**<sup>9,10</sup> Contact allergy to aluminium has been known for some time<sup>11</sup>, although delayed hypersensitivity to aluminium is a recently recognised phenomenon of unknown aetiology. **The observation that the body retains a “memory” of previous exposure to aluminium (as an adjuvant) is intriguing and may***

**support research that reported the development of anti-aluminium monoclonal antibodies.**<sup>12</sup> Delayed hypersensitivity to aluminium raises a number of issues relating to the biological availability of this environmental toxin, perhaps not least of which, and pertinent to this moment in time, is the plan to improve the immunogenicity of (bird) flu vaccine by using aluminium-based adjuvants.<sup>13</sup> **It is my opinion that substantially increased use of aluminium-adsorbed vaccines should be put on hold until research has demonstrated their safety, if not to all then to most individuals.**” (My emphasis.)

It appears to me Jefferson et al’s systematic review was biased from the outset, and that the goal was to defend the use of aluminium adjuvants, i.e.: *“Assessment of the safety of aluminium in vaccines is important because replacement of aluminium compounds in currently licensed vaccines would necessitate the introduction of a completely new compound that would have to be investigated before licensing. No obvious candidates to replace aluminium are available, so withdrawal for safety reasons would severely affect the immunogenicity and protective effect of some currently licensed vaccines and threaten immunisation programmes worldwide.”*<sup>14</sup> (My emphasis.)

This Cochrane Vaccines Field review plays into the hands of vaccine manufacturers who are keen to develop a mass market for lucrative vaccine products. [A World Health Organisation presentation](#) acknowledges that vaccines are **“becoming an engine for the pharmaceutical industry”**, creating a global market with a **“spectacular growth rate”**, growing in value from US\$5 billion in 2000 to almost US\$24 billion in 2013, and projected to rise to US\$100 billion by 2025.<sup>15</sup>

Aggressive vaccine marketing by the pharmaceutical industry and conflicted industry-affiliated ‘experts’ is threatening citizens’ bodily autonomy. **It’s time there was an objective look at the burgeoning vaccine market and independent consideration of whether mass vaccination with all these lucrative vaccine products is justifiable.** The potential conflicts of interests of academics working in the areas of vaccine development and promotion, and the influence of these academics on government policy, needs to be examined.

**We need an investigation into the relationships between governments, the vaccine industry, and the industry’s handmaidens in the scientific/medical establishment, but who can we trust to do that?** The mainstream media has generally been completely useless on this matter, and incapable of providing critical analysis, merely supporting the status quo.<sup>16</sup>

Likewise medical journals appear to be stalwart promoters for the pharmaceutical industry, and are beset by their own financial conflicts of interest in selling the literature and advertising medical products. *The Lancet’s* editor, Richard Horton, has confessed that: **“Journals have devolved into information laundering operations for the pharmaceutical industry”**.<sup>17</sup> In his book **Deadly medicines and organised crime: How big pharma has corrupted healthcare**, The Cochrane Collaboration’s Peter Gøtzsche notes: **“Sadly, and although there are notable exceptions, our medical journals contribute substantially to the corruption of medical science.”**<sup>18</sup>

But of course even The Cochrane Collaboration is not above reproach. It is mystifying that an organisation which promises **“to promote evidence-informed health decision-making by producing high-quality, relevant, accessible systematic reviews and other synthesised research evidence”**<sup>19</sup> could give its name to a ‘systematic review’ of such poor quality as [Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence](#). Can the public rely on Cochrane?

Mr McConnell, I again request that ***The Lancet Infectious Diseases*** take urgent action to re-evaluate this review prepared by members of the Cochrane Vaccines Field.

**In my opinion this systematic review should be retracted by *The Lancet Infectious Diseases*.**

I request your urgent response on this matter.

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: Professor Richard Horton, Editor, *The Lancet*  
Professor Peter Gøtzsche, The Cochrane Collaboration

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 11 August 2014. It may be necessary to copy and paste long links into a web browser.)

- <sup>1</sup> Cochrane Vaccines Field: "It is the intention of the Cochrane Vaccines Field to contribute to a greater global understanding of vaccine quality by facilitating the identification, assembling, analysis, synthesis, dissemination and updating of information on the effects of vaccines from single studies into reviews.": <http://vaccinesfield.cochrane.org/aims-and-activities>
- <sup>2</sup> Jefferson T, Rudin M, Di Pietrantonio 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>
- <sup>3</sup> The Joint Committee on Vaccination and Immunisation originally rejected the Bexsero Meningitis B Vaccine see for example: **Meningitis B vaccine rejected by UK – Joint Committee on Vaccination and Immunisation says there is not enough evidence to justify routine jabs with Bexsero**, The Guardian, 24 July 2013: <http://www.theguardian.com/society/2013/jul/24/meningitis-b-vaccine-rejected-uk>  
 This decision was subsequently overturned after a "**determined campaign by doctors, health charities, a public petition and a wave of letters to Health Secretary Jeremy Hunt**": **Babies to get jab on NHS against lethal meningitis B – A life-saving vaccine against deadly meningitis B will be introduced on the NHS for all babies from two months old in a dramatic U-turn announced yesterday**, Express, 22 March 2014: <http://www.express.co.uk/life-style/health/466236/Jeremy-Hunt-changes-NHS-baby-vaccine-policy-after-huge-letter-campaign> Also refer to the JCVI position statement on use of Bexsero meningococcal B vaccine in the UK, March 2014: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/294245/JCVI\\_Statement\\_on\\_MenB.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/294245/JCVI_Statement_on_MenB.pdf)
- <sup>4</sup> Jefferson T, Rudin M, Di Pietrantonio 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>
- <sup>5</sup> Exley C. Aluminium-containing DTP vaccines. *Lancet Infect Dis* 2004; 4: 324.
- <sup>6</sup> Flarend R. Absorption of aluminium from antiperspirants and vaccine adjuvants. In: Exley C. ed. Aluminium and Alzheimer's disease. The science that describes the link. Amsterdam: Elsevier, 2001: 75-96.
- <sup>7</sup> Exley C. Aluminium-adsorbed vaccines. *Lancet Infect Dis*. 2006; 6: 189.
- <sup>8</sup> Exley C. Aluminium-containing DTP vaccines. *Lancet Infect Dis* 2004; 4: 324.
- <sup>9</sup> Bergfors E, Trollfors B, Inerot A. Unexpectedly high incidence of persistent itching nodules and delayed hypersensitivity to aluminium in children after the use of adsorbed vaccines from a single manufacturer. *Vaccine* 2003; 22: 64-69
- <sup>10</sup> Bergfors E, Björkelund C, Trollfors B. Nineteen cases of persistent pruritic nodules and contact allergy to aluminium after injection of commonly used aluminium-adsorbed vaccines. *Eur J Pediatr* 2004; 164: 691-97.
- <sup>11</sup> Bohler-Sommeregger K, Lindemayr H. Contact sensitivity to aluminium. *Contact Dermatitis* 1986; 15: 278-81.
- <sup>12</sup> Levy R, Shohat L, Solomon B. Specificity of an anti-aluminium monoclonal antibody toward free and protein-bound aluminium. *J Inorg Biochem* 1998; 69: 159-63.
- <sup>13</sup> Wadman M. Race is on for flu vaccine. *Nature* 2005; 438: 23.
- <sup>14</sup> Jefferson T, Rudin M, Di Pietrantonio 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>
- <sup>15</sup> Miloud Kaddar, Senior Adviser, Health Economist, WHO, IVB, Geneva. **Gobal Vaccine Market Features and Trends:** [http://who.int/influenza\\_vaccines\\_plan/resources/session\\_10\\_kaddar.pdf](http://who.int/influenza_vaccines_plan/resources/session_10_kaddar.pdf) (Powerpoint slides 5 and 6.)
- <sup>16</sup> For example in Australia debate on vaccination has been polarised between avidly 'pro' and 'anti' forces. The media in Australia is generally supportive of the avidly 'pro' vaccination camp and appears to be incapable of providing objective analysis on the worth of individual vaccine products. Also refer to my letter to Professor Warwick Anderson, CEO of the National Health and Medical Research Council, which includes reference to News Corp Australia's extraordinarily crude pro-vaccination campaign: [http://users.on.net/~peter.hart/Letter\\_to\\_Warwick\\_Anderson\\_NHMRC\\_re\\_MMR\\_vaccination.pdf](http://users.on.net/~peter.hart/Letter_to_Warwick_Anderson_NHMRC_re_MMR_vaccination.pdf)
- <sup>17</sup> Horton R. The dawn of McScience. *New York Rev Books*. 2004; 51: 7-9. (As noted in Peter Gøtzsche's book below.)
- <sup>18</sup> Gøtzsche PC. *Deadly Medicines and Organised Crime: How big pharma has corrupted healthcare*. London: Radcliffe Publishing Ltd, 2013. See Chapter 6, Conflicts of interest at medical journals.
- <sup>19</sup> The Cochrane Collaboration – About us: <http://www.cochrane.org/about-us>