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Call for retraction of Jefferson et al's scientifically unsound review on aluminium and vaccine safety

Elizabeth Hart <elizmhart@gmail.com> Tue, Mar 20, 2018 at 11:21 PM
To: Tom Jefferson <jefferson.tom@gmail.com>
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For the attention of:
Dr Tom Jefferson,
previously of Cochrane Vaccines Field and Health Reviews Ltd, Rome, Italy

Dr Jefferson

I suggest your systematic review on aluminium and DTP vaccine safety, published in *The Lancet Infectious Diseases* in February 2004 [1]**, is scientifically unsound and is promoting an unsubstantiated notion that aluminium-adjuvanted vaccines are categorically safe.**

Your review is helping to facilitate a global *over*-vaccination epidemic with these lucrative vaccine products, with no apparent consideration of the cumulative long-term effects of these products. The proliferation of these vaccine products must be subjected to urgent scrutiny.

Your review was published as being associated with the Cochrane Vaccines Field [2], and the Cochrane 'brand' provides your review with a guarantee for quality [3] which is not justified in this instance.

Dr Jefferson, I request you take urgent action to retract your systematic review as it is impacting on vaccination policy, resulting in gross *over*-vaccination and vaccination injuries.

In your joint complaint with Cochrane Nordic to the European Medicines Agency relevant to the safety of HPV vaccines[4] **you now acknowledge aluminium adjuvants are potentially neurotoxic, but this matter is also pressing in regards to other aluminium-adjuvanted vaccines given to children**, e.g. the GlaxoSmithKline Engerix B hepatitis B vaccine given at birth, and the combined GlaxoSmithKline Infanrix Hexa injection for diphtheria, tetanus, whooping cough (pertussis), hepatitis B, polio, Hib (haemophilus influenzae type B) given to babies at two, four and six months of age, plus more aluminium adjuvanted vaccines at 18 months, 4 years and 10-15 years.

To provide you with a very small snapshot of reported adverse events after aluminium-adjuvanted diphtheria, tetanus and acellular pertussis containing vaccine products, **please see attached a document generated from the Australian Therapeutic Goods Administration (TGA) adverse events database, containing 2,184 reports (including one death) re the aluminium-adjuvanted GlaxoSmithKline Infanrix vaccine products administered to children at various ages. (**These vaccines are often given in conjunction with other vaccine products, e.g. the GlaxoSmithKline Priorix-Tetra measles, mumps, rubella and varicella (chickenpox) 'live' vaccine at 18 months.)

The attached TGA adverse event document is generated for the period 1 January 2016 to 15 December 2017, the latter being the latest date available for reports. From January 2016, vaccination of children is mandatory in Australia to access financial benefits (i.e. the No Jab, No Pay law), and more recently to access childcare and pre-school in some states. **In other words, parents are being coerced into having multiple vaccine products for their children (currently around 46 doses)**[5]**, without valid informed consent before each of these medical interventions. In many cases I suggest children are being grossly *over*-vaccinated with a plethora of vaccine products.**

The TGA acknowledges that adverse event reporting from health professionals and consumers is voluntary and that there is likely to be under-reporting.[6] I suggest under-reporting could be very significant in Australia where there is an aggressive coercive vaccination culture where doctors cannot be be trusted to acknowledge and report adverse events after vaccination, and where consumers are poorly informed about the procedure for making adverse event reports. When adverse event reports are submitted to the TGA, anecdotally I have heard there is little or nothing in the way of follow-up of these cases, i.e. investigating the long-term consequences. In other words there is inadequate post-marketing surveillance of vaccine products. The TGA is also conflicted in this matter as it is funded by the vaccine industry via fees and charges.[7]

In Australia, parents are now being coerced to have multiple doses of pertussis-containing aluminium-adjuvanted vaccine products for their children, i.e. at two months, four months, six months, 18 months, four years, and 10-15 years, plus in utero via the recommendation for pregnant women to have a dTpa for every pregnancy. ***Would you be willing to roll up your sleeve and have all these revaccinations Dr Jefferson?***

The more recently implemented Infanrix dTPa vaccination at 18 months was lobbied for by GlaxoSmithKline, and approved by the accommodating Pharmaceutical Benefits Advisory Committee[8] and added to the taxpayer funded schedule after the No Jab, No Pay law was implemented in January 2016. (As noted above, this additional dTPa dose at 18 months is given with the second dose of 'live' measles, mumps and rubella vaccine, e.g. the GlaxoSmithKline Priorix-Tetra MMR vaccine, which includes varicella (chickenpox), the first dose of 'live' MMR being given just six months earlier at 12 months, different to other countries which vaccinate with the second dose of MMR later, e.g. Denmark (four years) and England (three years four months) and with no varicella/chickenpox. International vaccination guidelines are surprisingly inconsistent, which raises questions about the evidence supporting individual vaccinations.)

It is now well-known within academia that there are problems with the acellular pertussis vaccine, with the admission that ***"the startling global resurgence of pertussis, or whooping cough, in recent years can largely be attributed to the immunological failures of acellular vaccines..."***[9]

It is unaccountable that children, pregnant women and others continue to be pressed to have multiple revaccinations with the failing acellular pertussis aluminium-adjuvanted multivalent vaccine products, this is a haphazard experiment being carried out in the community, without adequate informed consent.

Dr Jefferson, I suggest your scientifically unsound review has helped facilitate the careless attitude to pushing multiple revaccinations with the questionable pertussis containing aluminium-adjuvanted vaccine products, your review is impacting on coercive vaccination policy.

For example, **your review is cited in material promoting the safety of aluminium-adjuvanted vaccines published by the Australian National Centre for Immunisation Research & Surveillance (NCIRS).**

The NCIRS is an influential organisation in Australia which claims to provide ***"independent expert advice on all aspects of vaccine preventable diseases and social and other issues related to immunisation to inform policy and planning for immunisation services in Australia"***[10]. The Director of the NCIRS, Peter McIntyre, is also an ex officio member of the Australian Technical Advisory Group on Immunisation[11] which makes recommendations re vaccine products for the Australian taxpayer funded vaccination schedule. **Peter McIntyre is very influential on vaccination policy and is associated with the vaccine industry via his participation in vaccine clinical trials[12] and his involvement with the vaccine industry sponsored bi-ennial PHAA Immunisation Conference.** [13] The NCIRS/Peter McIntyre were also instrumental in getting aluminium-adjuvanted HPV vaccination off the ground in Australia, see the report of a meeting held in December 2003: **"Planning for human papillomavirus vaccines in Australia - Report of a research group meeting"**, which was supported by CSL Pharmaceuticals and GlaxoSmithKline.[14]

The NCIRS Head of Clinical Research, Robert Booy, is also involved with the vaccine industry, and is a Board Director of the vaccine industry funded Immunisation Coalition, and also Chair of its Scientific Advisory Committee[15]**, conflicts of interest that do not appear to be disclosed on the NCIRS website. The Immunisation Coalition's sponsors include GlaxoSmithKline, Seqirus Australia, Sanofi Pasteur, Pfizer, Roche Australia, Astra Zeneka, Mylan and Bupa Australia.** Google is also an in-kind sponsor.[16] (A long list of medical organisations is also associated with the Immunisation Coalition, including the Australian Medical Association.)

Dr Jefferson, a FactSheet on Vaccine Components published by the vaccine industry associated NCIRS cites your review, saying ***"...a recent review of all the available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) found that there was no evidence that aluminium salts in vaccines cause any serious or long-term adverse events..."***[17] (See copy attached.)

Other papers and articles defending the use of aluminium adjuvants in vaccines also cite your review to make similar statements, see for example O'Hagan and Rappuoli [18], Eldred and Dean et al [19], Nolan and Richmond et al [20].

An article titled **"Aluminium in Vaccines Poses No Harm"**, published on the industry funded WebMD website in January 2004 to promote your review published in *The Lancet Infectious Diseases*, states ***"After scouring through all the available medical data, researchers in Rome say there is no evidence that aluminium - contained***

within the combined diphtheria, tetanus and pertussis vaccine commonly known as DTP and routinely given to children - poses any serious or long-term side effects".[21] This article includes comments from avid vaccine promoter Paul Offit, who describes your review as ***"a very thorough, thoughtful review of the subject"***, which leads me to wonder if he or others actually read beyond the abstract of your review...?

Dr Jefferson, in this WebMD article you are reported as saying ***"Scare stories on aluminium-containing vaccines are not supported by evidence".***

Yet in your review, you and your fellow authors, Melanie Rudin and Carlo Di Pietrantonj, acknowledge there was a lack of good quality evidence, admitting that:

> ***"Overall, the methodological quality of included studies was low. Few reports gave details of the randomisation process, allocation concealment, reasons for withdrawals, or strategies to deal with them in analysis. Inconsistencies in reporting, lack of clarity on numerators and denominators, variability of outcome definitions, and lack of outcome definitions led to much loss of data."***

And despite the lack of good quality evidence you recommended that no further research on the safety of aluminium salts be undertaken - what possessed you and your colleagues to make this unsubstantiated recommendation?

Only a year or so earlier, in an interview with the medical correspondent of *The Telegraph* in 2002 titled **"Vaccines expert warns studies are useless"**[22], you reportedly warned that ***"Most safety studies on childhood vaccines have not been conducted thoroughly enough to tell whether the jabs cause side effects"*** and that ***"There is some good research, but it is overwhelmed by the bad. The public has been let down because the proper studies have not been done"***. The article noted you were especially concerned because future vaccination programs were likely to involve giving children ***"five, six, even seven vaccines all at once"***, and this is exactly what happens now, e.g. the GlaxoSmithKline Infanrix Hexa vaccine product containing diphtheria, tetanus, whooping cough (pertussis), hepatitis B, polio and Hib (haemophilus influenzae type b) is given along with the Pfizer pneumococcal Prevenar 13 vaccine to babies at two, four and six months, and the GlaxoSmithKline Rotarix rotavirus vaccine is also given at two and four months.

Just a year or so after your frank interview in *The Telegraph*, how could you backflip so dramatically and recommend against research into aluminium salts and vaccine safety when you knew that the data backing aluminium-adjuvanted DTP vaccines, and vaccine products in general, was so poor? Your recommendation, coming from a Cochrane Vaccines Field author, is likely to have hindered further research into aluminium and vaccine safety.

It is incredible that the peer reviewers at *The Lancet Infectious Diseases* did not challenge you on the poor quality of the data you reviewed, data on which it was inappropriate to categorically conclude there was ***"no evidence that aluminium salts in vaccines cause any serious or long-lasting adverse events"***. **Your poorly evidenced review should not have been published by *The Lancet Infectious Diseases* and this damaging review must be retracted as a matter of urgency.**

Dr Jefferson, in the attached document I have provided you with evidence of adverse events reported after aluminium-adjuvanted vaccination, specifically the GlaxoSmithKline Infanrix vaccine products. Who knows what longer term repercussions may be initiated by these adverse events? This is likely to be just a tiny fraction of adverse events experienced globally since your scientifically unsound review on aluminium and DTP vaccine safety was published in *The Lancet Infectious Diseases* in 2004.

Your review has given a poorly evidenced opinion on the safety of aluminium-adjuvanted vaccine products, and this has had ramifications for supporting repeated revaccinations with failing pertussis containing multivalent vaccine products, **and the implementation of new vaccine products, e.g. giving the green light to the global fast-tracking of the novel VLP HPV Merck/bioCSL Gardasil and GlaxoSmithKline Cervarix vaccine products, and the GlaxoSmithKline Bexsero meningococcal B vaccine product.**

Dr Jefferson, I suggest you have an ethical responsibility to redress this matter, and I again request you take urgent steps to have your scientifically unsound review on aluminium and DTP vaccine safety retracted in order to initiate an urgent review of the alarming amount of aluminium-adjuvanted vaccines and revaccinations being added to international vaccination schedules.

You must also contact parties citing your review to alert them that this poorly evidenced review should not be used to promote the safety of aluminium-adjuvanted vaccine products, e.g. see authors of references listed below at 18, 19 and 20.

Citizens must be warned about the unreliability of published literature in regards to the safety of vaccine products, this is a serious matter of public interest.

Sincerely
Elizabeth Hart

https://over-vaccination.net/

References:

1. Jefferson TO, Rudin M, Di Pietrantonj C. Adverse events following immunization with aluminium containing DTP vaccines systematic review of the evidence. Lancet Infect Dis 2004; 4: 8490.
2. The review paper published in *The Lancet Infectious Diseases* clearly states on the first page that all the authors are at Cochrane Vaccines Field in Italy.
3. Cochrane boasts: ***"Our work is recognized as representing an international gold standard for high quality, trusted information"***. About us, Cochrane, as downloaded from Cochrane website on 20 March 2018.
4. Complaint to the European Medicines Agency (EMA) over maladministration at the EMA, 26 May 2016.
5. Australian National Immunisation Program Schedule.
6. ***"Adverse events reports from consumers and health professionals to the TGA are voluntary, so there is under-reporting by these groups of adverse events related to therapeutic goods in Australia. This is the same around the world."*** TGA website - About the DAEN - medicines.
7. See the TGA website re fees and payments.
8. PBAC Positive recommendations, November 2014.
9. See for example **Resurgence of Whooping Cough May Owe to Vaccine's Inability to Prevent Infections** which states ***"The startling global resurgence of pertussis, or whooping cough, in recent years can largely be attributed to the immunological failures of acellular vaccines"***. A/Professor Christopher Gill says ***"This disease is back because we didn't really understand how our immune defenses against whooping cough worked, and did not understand how the vaccines needed to work to prevent it. Instead we layered assumptions upon assumptions, and now find ourselves in the uncomfortable position of admitting that we...made some crucial errors. This is definitely not where we thought we'd be in 2017."*** Boston University School of Public Health, 21 September 2017. It is mind-boggling that children are being repeatedly revaccinated with obviously problematic acellular pertussis vaccines via aluminium-adjuvanted multivalent vaccine products, and adults are also often pressed to have pertussis/whooping cough revaccination. Also see my email to (then) Chief Medical Officer Chris Baggoley re Australian Federal Government mandated pertussis revaccination: https://elizabethhart.files.wordpress.com/2016/05/re-australian-federal-government-mandated-pertussis-revaccination.pdf and my letter to Prime Minister Malcolm Turnbull re coercive over-vaccination of children and the flawed No Jab, No Pay law: https://elizabethhart.files.wordpress.com/2015/06/letter-to-pm-malcolm-turnbull-re-vaccination-policy-in-australia.pdf
10. NCIRS website home page.
11. ATAGI Membership includes Peter McIntyre as an ex-officio member as at January 2017.
12. ATAGI conflict of interest information for Peter McIntyre includes ***"Investigator on a number of clinical trials and observational studies related to vaccines. Untied grants and in kind support for laboratory assays provided via employer (Sydney Children's Hospitals Network) since 2010 from GSK, Pfizer and Merck"***.
13. For example, Peter McIntyre was the leader of the scientific committee of the 14th PHAA Immunisation Conference. This conference was sponsored by bioCSL, GSK, Pfizer Australia, Sanofi Pasteur and Novartis Vaccines, see A Roaring Success - 14th PHAA Immunisation Conference. Intouch, newsletter of the Public Health Association of Australia Inc. Vol 31 No 6, July 2014, and Media Alert - Experts Gather in Melbourne to Stop Spread of Preventable Diseases. Public Health Association of Australia. Re conference Tuesday 17 - Thursday 19 June 2014.
14. Julia ML Brotherton, Peter B McIntyre. Planning for human papillomavirus vaccines in Australia: Report of a research group meeting. Communicable Diseases Intelligence, Volume 28 Issue Number 2, June 2004. CSL Pharmaceutical and GlaxoSmithKline were thanked for their support in facilitating the meeting.
15. See 'About us' on the Immunisation Coalition website under 'Board of Directors' and 'Committees of the Immunisation Coalition'.
16. See 'About us' on the Immunisation Coalition website under 'Funding'.
17. NCIRS FactSheet Vaccine components, May 2013 (Content last updated February 2008).
18. A paper by Derek T. O'Hagan and Rino Rappuoli titled The safety of vaccines, published in *Drug Discovery Today* in 2004, states: ***"A recent meta-analysis of the available safety data on alum could find no evidence of any serious long-lasting adverse effects."*** (This paper is behind the paywall.)
19. A paper by Barbara E Eldred and Angela J Dean et al titled Vaccine components and constituents: responding to consumer concerns, published in the *Medical Journal of Australia* in 2006, states: ***"A systematic review of controlled safety studies reported that vaccines containing aluminium produce more erythema and induration than other vaccines in young children (up to 18 months of age), and greater local pain in older children (10-18 years). No association was found between aluminium and more serious or long-term adverse effects."*** (This paper is openly accessible on the MJA website.)
20. A paper by Terry Nolan and Peter C Richmond et al titled Safety and immunogenicity of a prototype adjuvanted inactivated split-virus influenza A (H5N1) vaccine in infants and children, published in *Vaccine* in 2008, states: ***"There is extensive and prolonged global experience of the safe use of aluminium adjuvanted vaccines in infants and children."*** (Jefferson et al's review is referenced to support Nolan and Richmond et al's statement.) (This paper is behind the paywall.)
21. Aluminium in Vaccines Poses No Harm. By Sid Kirchheimer, WebMD, 29 January 2004.
22. Vaccines expert warns studies are useless. By Lorraine Fraser, Medical Correspondent. The Telegraph, 27 October 2002.

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2 attachments

TGA daen-report-20180320 - GSK Infanrix - report date earliest first.pdf
806K

vaccine-components-fact-sheet NCIRS.pdf
107K