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An open letter to: 23 June 2016

Professor Chris Baggoley Chief Medical Officer Australian Government Department of Health

Professor Baggoley

RE: CONFLICTS OF INTEREST AND LACK OF TRANSPARENCY AND ACCOUNTABILITY FOR VACCINATION POLICY AND PRACTICE IN AUSTRALIA

In your role as the Australian Government's Chief Medical Officer and principal medical adviser to the Minister and the Department of Health, I request you take urgent action to address the lack of transparency and accountability for vaccination policy and practice in Australia, and the problem of potential conflicts of interest and lack of disclosure by people influencing vaccination policy.

Various committees and groups provide advice to the Australian Federal Government on vaccines which results in the addition of new vaccine products and revaccinations to the National Immunisation Program Schedule. **These groups of unelected individuals wield enormous power.** The members of these groups are part of a process that results in effectively mandating medical interventions (i.e. vaccinations) for healthy people. The decisions these people make affect not only children and adults in Australia, but can also impact internationally as the ripple effect of their decisions spreads around the world.¹

Securing approval for a vaccine product to be added to the taxpayer funded National Immunisation Program Schedule is the golden goose for vaccine manufacturers, providing an assured national market and also a domino effect when other countries follow suit and adopt the vaccine, creating a massive international market. Even better for the vaccine manufacturers when vaccines are made compulsory by accommodating governments such as the Australian Federal Government, i.e. via the No Jab, No Pay law enacted by the Coalition government in January 2016.

The powerful influence of vaccination committees and groups raises serious political and ethical questions about their impact on the bodily integrity of citizens, including 'pre-citizens', i.e. children. As the decisions of these committees and groups can result in the imposition of medical interventions for healthy people, and massive sales of lucrative vaccine products for pharmaceutical companies, it is vital that the process of adding vaccine products to the national vaccination schedule is open and transparent, and that any potential conflicts of interest of the members of these groups are accessible for public perusal.

At this time, publicly accessible information on potential conflicts of interest for members of vaccination committees and groups is severely lacking in Australia. I suggest this lack of transparency contravenes The Australian Code for the Responsible Conduct of Research, in particular sections 4.9 "Disclose research support accurately" and 7. "Conflicts of interest.²

For example, in November 2011, I asked then Federal Health Minister Nicola Roxon for details of membership of the Australian Technical Advisory Group on Immunisation (ATAGI), including their professional affiliations, and including any links with the pharmaceutical industry. While names of members of ATAGI and their affiliations were subsequently published on the Immunise Australia website, there was still no disclosure of information about potential conflicts of interest. In March 2013 I also raised this subject with Terry Nolan, then Chair of ATAGI, but he failed to address the matter. Only in recent times has (inadequate) conflict of interest information for members of ATAGI become publicly accessible³, after I wrote to former Prime Minister Tony Abbott on the topic in January 2015.⁴

Conflict of interest information for members of ATAGI remains woefully inadequate. For example, there is no indication of ex officio ATAGI member, and National Centre for Immunisation Research & Surveillance (NCIRS) Director, Peter McIntyre's involvement in the promotion of HPV vaccination, which was fast-tracked in Australia in 2006/2007⁵, and subsequently hastily implemented around the world.⁶ As detailed in a report co-authored by Peter McIntyre and Julia Brotherton, in December 2003 the NCIRS co-ordinated a meeting to promote HPV vaccination. As well as Peter McIntyre and Julia Brotherton, this meeting included key players such as Ian Frazer and Suzanne Garland, along with representatives of CSL Vaccines and GlaxoSmithKline. McIntyre and Brotherton's report on the meeting acknowledges: "We would like to thank CSL Pharmaceuticals and GlaxoSmithKline for their support in facilitating this meeting..." Peter McIntyre's participation in the development of the lucrative international HPV vaccines market should be recorded on the ATAGI webpage, his involvement with industry should be properly disclosed.

A paper published in 2015⁸ notes a potential conflict of interest for Peter McIntyre, indicating "P.M. is an investigator on a survey of HPV seroprevalence in Australia that is partly funded by bioCSL", but this funding by bioCSL is not currently recorded on the ATAGI conflict of interest document (see attached). Peter McIntyre was also involved in co-ordinating the Evaluation of the National Human Papillomavirus Vaccination Program – Final Report (published in 2014)⁹. It is concerning that people such as Peter McIntyre, who have associations with the vaccine industry, and who may also have an ideological and career interest in 'proving' the benefits of HPV vaccination, are also the ones evaluating the effectiveness of HPV vaccination.

Peter McIntyre also led the scientific committee for the 14th PHAA National Immunisation Conference¹⁰ held in 2014, which was sponsored by bioCSL, GlaxoSmithKline, Novartis, Sanofi Pasteur, and Pfizer.¹¹ Again, Peter McIntyre's association with the vaccine/pharmaceutical industry via this conference is not listed as a conflict of interest on the ATAGI website. What other potential conflicts of interest remain undisclosed by Peter McIntyre on the ATAGI website?

There is also little or no trace of former members of ATAGI on the ATAGI website. For example, Terry Nolan was previously Chair of ATAGI, but there is currently no record of his tenure on the ATAGI website, nor his conflicts of interest, e.g. his involvement with the CSL sponsored children's monovalent 2009 influenza A(H1N1) vaccine trial. In regards to Terry Nolan's association with CSL, this was publicised after CSL's Fluvax vaccine caused febrile convulsions in children at nine times the expected rate. One parent was reported to be "flabbergasted to discover some of the federal Department of Health and Ageing's top immunisation advisers have links with the drug company that created the vaccine that landed her kids in hospital." Mother Sharron Coppin said "You'd think there'd be something to say that's a conflict of interest."

Another former member of ATAGI, Peter Richmond, was also involved with CSL's Fluvax vaccine¹⁵; and associated with scientific advisory groups for NCIRS, the industry-funded Influenza Specialist Group, GlaxoSmithKline, Pfizer and Baxter; and involved in research funded by Baxter, CSL, GlaxoSmithKline, Medimmune, Merck, Pfizer, Sanofi and Novartis¹⁶. Again, there is no record of Peter Richmond's previous membership of ATAGI, nor his conflicts of interest/associations with the vaccine/pharmaceutical industry, currently on the ATAGI website.

It appears ATAGI was a very obliging conduit for the vaccine industry under Terry Nolan's chairmanship. In November 2005, in an article titled **We'll be fast: new vax boss**, *Australian Doctor* reports "The new head of the Federal Government's revised vaccine advisory group, Professor Terry Nolan, will prioritise timely responses to new vaccines and industry developments". Certainly the Gardasil HPV vaccine product was approved and implemented very quickly in 2006/2007.

It is crucial that ATAGI members' current and historical involvement with the vaccine/pharmaceutical industry and promotion of vaccine products be recorded on the ATAGI website.

A register providing the history of any relationships with the vaccine/pharmaceutical industry, **including research** grants, consultancies, honorariums, committee/advisory board memberships, plus any shareholdings in vaccine companies, royalties received, directorships etc, must be publicly accessible. If a member indicates they have no potential conflicts of interest, this must be clearly recorded.

At this time no information re previous membership of ATAGI is available on the ATAGI website. Information re current and historical membership of working groups associated with ATAGI, and potential conflicts of interest of the members of these working groups, is also not available on the ATAGI website. Minutes/bulletins of ATAGI meetings do not list the names of ATAGI members. These are serious omissions. An openly accessible current and historical detailed record of people making decisions re vaccine products is essential to provide transparency and accountability for vaccination policy and practice.

ATAGI is now chaired by Ross Andrews, with other members being Christopher Blyth, Allen Cheng, Nigel Crawford, Michelle Giles, Madeline Hall, Noel Hayman, David Isaacs, Helen Marshall, Jodie McVernon, Debra Petrys, Nicholas Silberstein, and ex-officio members Masha Somi, Sonya Bennett, Ting Lu, Peter McIntyre and Karen Peterson.¹⁷ As can be seen from the attached conflict of interest document, many members of ATAGI are associated with the pharmaceutical industry via funding from GlaxoSmithKline, Merck, bioCSL, Pfizer, Novartis, Sanofi and others.

Conflict of interest information for members of other groups and organisations influencing vaccination policy is still not being publicly disclosed, i.e.:

• The National Centre for Immunisation Research & Surveillance (NCIRS), of which ex-officio ATAGI member Peter McIntyre is Director, notes "The Policy and Surveillance sections of NCIRS do not accept any

funding from pharmaceutical companies or other for-profit industry sources."¹⁸ NCIRS also notes: "NCIRS has a policy governing the interactions of staff members with the pharmaceutical industry."¹⁹ This is not clear – do NCIRS staff interact with the pharmaceutical industry? From recently accessible conflict of information for members of ATAGI, we know for example that Peter McIntyre has been associated with grant funding from GSK, Pfizer and Merck, plus other undisclosed associations with industry as I have listed above. I suggest any current and historical pharmaceutical associations, and any other potential conflicts of interest, should be disclosed for NCIRS staff members, e.g. the Executive, i.e. Peter McIntyre, Robert Booy, Kristine Macartney, Leon Heron, Aditi Dey, Nicholas Wood, Clayton Chiu and Frank Beard²⁰, and also for members of the NCIRS Scientific Advisory Committee, e.g. Cheryl Jones, Heath Kelly, Ross Andrews, Deanna Eldridge, Elizabeth Elliott, Mike Gold, John Kaldor, Stephen Lambert, John Litt, Ben Marais, Alison Marcus, Helen Marshall, Jodie McVernon, Terry Nolan, Peter Richmond, Lyndal Trevena. (Peter McIntyre, Robert Booy, and Kristine Macartney are also on the Scientific Advisory Committee)²¹; and for members of the NCIRS Advisory Board²².

- The Therapeutic Goods Administration (TGA)'s webpage for the Advisory Committee on the Safety of Vaccines (ACSOV) provides a list of members and affiliations²³, but there is no clarity re potential conflicts of interest of these people, i.e. Emily Banks, Karen Booth, Hazel Clothier, Kristine Macartney and Nicole Pratt. There is also no record of previous members of ACSOV, and meeting statements also fail to record details of members at meetings, resulting in a lack of historical transparency and accountability for this committee on the safety of vaccines. I personally retained a copy of the previous membership of ACSOV, which was chaired by Nicole Gilroy, who during the period 2005 to 2014 was also a member of ATAGI, including roles of Chair of the HPV Working Party, Chair of the HPV Implementation Working Group and Co-Chair of the Australian Immunisation Handbook Working Group (none of which information is currently recorded on the ATAGI or ACSOV webpages). It is inappropriate to have a person involved with the appraisal of vaccine products for the National Immunisation Program Schedule also to be in a position to evaluate post-marketing safety issues as there is an obvious conflict of interest.
- The Pharmaceutical Benefits Advisory Committee (PBAC) webpage lists members of the PBAC and their affiliations²⁴, but again provides no clarity re potential conflicts of interest of these people. There is also no record of previous members of the PBAC, and PBAC outcomes documents also fail to record details of members making decisions on vaccine products, again resulting in a lack of historical transparency and accountability for this committee which approves vaccine products for the National Immunisation Program Schedule. The PBS website describes the PBAC as "an independent expert body appointed by the Australian Government...Its primary role is to recommend new medicines for listing on the PBS".²⁵ I would like to see evidence of these experts' 'independence' but scant information is provided for current members Andrew Wilson, Terry Campbell, Catherine Cole, Jonathan Craig, Christopher Etherton-Beer, Peter Grimison, Jenny Gunton, Elizabeth Marles, Geoff McColl, David Newby, Andrew Roberts, Rashmi Sharma, Thomas Snelling, Rosalie Viney, Robyn Ward and Jo Watson.
- The TGA's Australian Influenza Vaccine Committee (AIVC) recommends influenza viruses to be used in the composition of influenza vaccines. Previously there were no details of membership of this committee provided on the AVIC webpage on the TGA website, let alone disclosure of potential conflicts of interest. In March 2014 I requested that the TGA provide publicly accessible information about the membership of this committee on the TGA website. While there is now a list of what are described as "independent voting' members" (i.e. Alan Hampson, Robert Booy, Helen Marshall and Greg Tannock) and their affiliations²⁶, there is still no information re potential conflicts of interest. I question whether the people listed as members of the TGA's AIVC are demonstrably 'independent'. For example Alan Hampson discloses he is currently Chairman of the Influenza Specialist Group, but doesn't disclose that this organisation is funded by the vaccine industry e.g. bioCSL, GlaxoSmithKline, Pfizer, Roche and Sanofi Pasteur²⁷, and that it is a Special Interest Group of the Immunisation Coalition.²⁹ of which he is also Chair. Robert Booy fails to disclose his role as a Director of the Immunisation Coalition.²⁹ Helen Marshall fails to disclose that she is a member of ATAGI, and also fails to disclose her association with GlaxoSmithKline, Merck, Novartis, Pfizer and Sanofi via clinical trials, as noted in the ATAGI conflict of nterest document, see attached.
- The Australian Academy of Science is also influential on vaccination policy. In December 2012 I asked Suzanne Cory, then President of the Australian Academy of Science, for public access to disclosure statements for members of the Working Group and Oversight Committee for *The Science of Immunisation: Questions and Answers* publication, which was funded by the Australian Federal Government's Department of Health and Ageing. Members of these groups are Ian Gust, Gus Nossal, Fiona Stanley, Robert Williamson, Tony Basten, Francis Carbone, Ian Frazer, Patrick Holt, Julie Leask, Peter McIntyre, Terry Nolan and Judith Whitworth, and they were all copied on most of my correspondence on this matter. Despite promises that this matter would be addressed, as at 22 June 2016, disclosure information is still not provided on the Academy's *The Science of Immunisation: Questions and Answers* webpage.

- The Influenza Specialist Group / Immunisation Coalition is an industry funded organisation with an alarming amount of influence on vaccination policy. As I have outlined above in this letter, members of this group are or have been in positions directly influential on vaccination policy, i.e. Alan Hampson, Robert Booy and Peter Richmond. Professor Baggoley, as I mentioned in my email to you dated 3 June 2016, another member of this vaccine industry funded organisation, Raina MacIntyre, also sits on the Influenza and Pneumococcal Working Parties for ATAGI. I have seen the current membership list of the Immunisation Coalition, and I suspect there are others who may also be influencing vaccination policy. Professor Baggoley, it is also notable that you spoke at the ISG's Annual Scientific Meeting in 2016.³¹ It is interesting to consider the cosy relationships between industry, academia and government and the impact this is having on the implementation of coercive vaccination policy in Australia.
- The Public Health Association of Australia is another organisation which is influential on vaccination policy, particularly via its industry-funded National Immunisation Conferences. Professor Baggoley, it is notable that you spoke at the 14th and 15th PHAA National Immunisation Conferences, again demonstrating the cosy relationships between industry, academia and government. As I noted previously in this letter, NCIRS Director and ATAGI ex officio member Peter McIntyre fails to disclose his involvement with the 14th PHAA National Immunisation Conference in his ATAGI conflict of interest statement. The current Chair of ATAGI, Ross Andrews, was a member of the organising committee for the 13th PHAA National Immunisation Conference held in 2012³², but he also fails to record this in the ATAGI conflict of interest document. Peter McIntyre and Ross Andrews are listed on the program for the 15th PHAA National Immunisation Conference, held on 7-9 June this year, along with their ATAGI colleagues Christopher Blyth, Nigel Crawford, Madeline Hall and Helen Marshall. It remains to be seen if these people disclose their involvement with this industry-sponsored conference in the ATAGI conflict of interest document.

Professor Baggoley, these examples indicate there is a serious problem with a lack of disclosure of potential conflicts interest, and a lack of transparency and accountability for vaccination policy that must be addressed. It is important to be able to evaluate the so-called 'independence' and objectivity of the people in these groups who are involved in promoting an ever-increasing amount of vaccine products.

As can be seen in the information provided in this letter, various people are members of multiple groups influencing vaccination policy. The full extent of inter-relationships between these groups is unknown as the current membership of working parties associated with ATAGI, and historical membership of all the vaccination committees and groups influential on vaccination policy, is not currently publicly accessible.

It is likely these groups are being dominated by an industry-associated clique of academics promoting an avidly 'pro-vaccine' ideology which is leading to the implementation of an excessive number of vaccine products and revaccinations. The over-use of vaccine products may prove to be problematic in future. For example we may be heading towards a potentially disastrous situation similar to the over-use of antibiotics and the rise of superbugs. I have seen little evidence of independent academics considering the 'big picture' possibilities in this regard.

Professor Baggoley, vaccination is an important ethical and political issue. We are on a slippery slope when potentially conflicted advisers to the Australian Federal Government on vaccine policy dictate lucrative medical interventions for healthy people, i.e. vaccinations, without adequate transparency of the process and consultation with the community. It is shocking that these unelected individuals are wielding so much power over our lives, i.e. implementing compulsory vaccination of healthy people without any consultation with the community.

I request you take urgent action to ensure the transparency and accountability of the Australian Federal Government's vaccination bureaucracy, and initiate an objective and independent review of the burgeoning national vaccination schedule, untainted by vaccine industry bias. The cost of taxpayer funded vaccine products, which is currently secret, must also be made public, citizens have a right to access this information.

I request your early response on matters raised in this letter.

Sincerely

Elizabeth Hart

https://over-vaccination.net/

cc: Dr Tony Hobbs, Principal Medical Adviser, Department of Health – Strategic Policy & Innovation Professor Peter McIntyre, Director, National Centre for Immunisation Research & Surveillance Professor Ross Andrews, Chair, Australian Technical Advisory Group on Immunisation Professor Andrew Wilson, Chair, Pharmaceutical Benefits Advisory Committee

References:

¹ For example Australia fast-tracked HPV vaccination for girls and boys. HPV vaccination is now being hastily implemented around the world.

² Australian Code for the Responsible Conduct of Research. Jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. 2007.

³ Australian Technical Group on Immunisation – Conflict of Interest document, currently accessible on the ATAGI webpage on the Immunise Australia website.

⁴ A summary of my letter to former Prime Minister Tony Abbott, and the response I received from the Immunisation Branch of the Health Department, is available on my website: http://over-vaccination.net/letters-challenging-over-vaccination/letter-to-australian-<u>prime-minister-re-vaccination-policy-in-australia/</u>
⁵ Fact Sheet: Australian Government funding of Gardasil. (Updated 28 November 2006). Australian Government Department of

Health and Ageing.

⁶ A FiercePharma article reporting on Merck's 2012 vaccine revenue notes Merck's "shining star is easily human papillomavirus vaccine Gardasil" and notes "Merck partnered with the GAVI Alliance to bring the HPV vaccine to the developing world". Merck – 2012 Vaccine revenue: \$5.27 billion, by Alison Bryant, undated.

⁷ Julie ML Brotherton, Peter B McIntyre. Planning for human papillomavirus vaccines in Australia: Report of a research group meeting, Communicable Diseases Intelligence, Vol. 28, No. 2, June 2004.

⁸ Megan A Smith, Bette Liu, Peter McIntyre et al. Fall in Genital Warts Diagnoses in the General and Indigenous Australian Population Following Implementation of a National Human Papillomavirus Vaccination Program: Analysis of Routinely Collected National Hospital Data. JID 2015:211 (1 January).

⁹ NCIRS Evaluation of the National Human Papillomavirus Vaccination Program, Final Report. 28 August 2014.

¹⁰ As noted in A Roaring Success – 14th PHAA Immunisation Conference. Intouch – newsletter of the Public Health Association of Australia. Vol. 31 No 6, July 2014.

¹¹ As recorded in the 14th PHAA Immunisation Conference program.

¹² Terry Nolan et al. Immunogenicity of a Monovalent 2009 Influenza A(H1N1) Vaccine in Infants and Children. JAMA, January 6, 2010 - Vol. 303. No. 1.

¹³ A flu jab too close for comfort. The Australian, 29 September 2010.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Conflicts of interest disclosed in Peter Richmond's presentation: HealthED Immunisation Update: Recent Changes to National Immunisation Program for Children, copy downloaded from the internet.

¹⁷ Australian Technical Advisory Group on Immunisation membership. As accessed on the ATAGI Immunisation Australia webpage on 22 June 2016.

¹⁸ National Centre for Immunisation Research & Surveillance – Funding and Governance. As accessed on the NCIRS website on 22 June 2016.

¹⁹ Ibid.

²⁰ National Centre for Immunisation Research & Surveillance – Executive. As accessed on the NCIRS website on 22 June 2016.

²¹ National Centre for Immunisation Research & Surveillance – Scientific Advisory Committee. As accessed on the NCIRS website on 22 June 2016.

²² National Centre for Immunisation Research & Surveillance – Advisory Board. As accessed on the NCIRS website on 22 June 2016.

²³ Advisory Committee on the Safety of Vaccines (ACSOV). As accessed on the TGA ACSOV webpage on 22 June 2016.

²⁴ Pharmaceutical Benefits Advisory Committee (PBAC). As accessed on the PBAC webpage on 22 June 2016.

²⁵ Ibid.

²⁶ Australian Influenza Vaccine Committee (AIVC). As accessed on the TGA AIVC webpage on 22 June 2016.

²⁷ ISG Sponsorship & Support. As accessed on the ISG website on 22 June 2016.

²⁸ ISG Membership. As accessed on the ISG website on 22 June 2016.

²⁹ Ibid.

³⁰ A record of my correspondence with The Australian Academy of Science is accessible on my website: http://overvaccination.net/letters-challenging-over-vaccination/australian-academy-of-science/

³¹ ISG Annual Scientific Meeting 2016. As accessed on the ISG website on 22 June 2016.

³² As noted in Ross Andrews' bio on the Menzies School of Health Research website. As accessed on 22 June 2016.