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Meningococcal B vaccination / conflicts of interest in vaccination policy

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For the attention of: Mr Steven Marshall Premier of South Australia

Mr Marshall, since the recent State election, you have been under pressure to implement a meningococcal B vaccination program in South Australia, i.e. **Demand for Steven Marshall to fund meningococcal B strain vaccinations program**, as reported in *The Advertiser* newspaper, 20 March 2018.

Heart-rending stories about rare cases of meningococcal B are reported in the media, for example the recent case of Jordan Braddock of Mount Gambier who sadly died after meningococcal B infection. Troy Bell, the Member of Parliament for Mount Gambier says he hopes "to get all South Australian children immunised against the dangerous B strain rather than waiting for the jab to get on the national program".[1] Tony Pasin, the Federal Member of Parliament for Barker, has taken it upon himself to meet with the vaccine's manufacturer, GlaxoSmithKline, and to push for the Bexsero meningococcal B vaccine to be fast-tracked onto the taxpayer-funded National Immunisation Program Schedule.[2]

However, meningococcal B is a rare disease and mass vaccination is not justifiable. The vested interests behind the media promotion of meningococcal B cases must be examined, particularly as the meningococcal B vaccine is being hailed as a 'magic bullet' to prevent this disease, a claim that is open to question.

Mr Marshall, so far the Bexsero meningococcal B vaccine has been *rejected three times* by the Pharmaceutical Benefits Advisory Committee due to *multiple uncertainties in relation to the clinical effectiveness against the disease and other reasons*.[3] Given the multiple uncertainties about the Bexsero meningococcal B vaccine product, I question why the Therapeutic Goods Administration allowed this vaccine product to be registered in the first place? The TGA is funded by industry - is this an example of product evaluation failure by the conflicted regulator of vaccine products?

Despite the PBAC's multiple rejections of the Bexsero vaccine, vaccine industry lobbyists continue to press for this questionable vaccine product to be added to the schedule, there are serious conflicts of interest impacting on vaccination policy.

In Australia it appears vested interests are trying to undermine the PBAC's evaluation process by lobbying the States to implement mass meningococcal B vaccination programs, e.g. in South Australia.

Mr Marshall, I suggest you think carefully before implementing a novel vaccine program for a very rare disease, this is a serious matter that should not be a knee-jerk response to industry and media lobbying, particularly as this vaccine product is likely to be mandated if it gets onto the National Immunisation Program Schedule.

Is this about public health, or about developing lucrative vaccine product markets for companies such as GlaxoSmithKline? Industry website FiercePharma reports that vaccines are a 'financial bright spot' for GlaxoSmithKline, with its 'star' Bexsero meningococcal B vaccine product having 'stellar sales'. GSK is building a US\$175 million plant in Germany so it can expand production of the meningococcal B vaccine.[4]

Another FiercePharma report indicates GlaxoSmithKline is the vaccine industry leader with US\$7.1 billion of vaccines sales in 2017, with sales for its meningitis vaccines (i.e. including Bexsero) growing 27% to US\$1.24 billion.[5]

GlaxoSmithKline is developing a lucrative global market for its Bexsero meningococcal B vaccine, and it seems obliging governments are being persuaded to spend millions of taxpayers' dollars on this questionable vaccine product for a rare disease, with Australia being at the forefront of this GSK campaign.

A Sydney Morning Herald investigation into the health industry, published in 2010, revealed pharmaceutical companies are buying political access and influence through lobbying[6] - has GlaxoSmithKline 'bought' the South Australian government?

In South Australia the media has been used to fear-monger about meningococcal B to promote GlaxoSmithKline's Bexsero vaccine trial involving 60,000 SA high school students, a vaccine trial that was supported by the former

Labor government. In December 2016, *The Advertiser* reported "It is hoped the findings will provide a strong push to get the vaccine on the taxpayer-funded National Immunisation Program."[7]

It seems this vaccine trial is biased from the outset. It is alarming that a member of the Federal Government's Australian Technical Advisory Group on Immunisation (ATAGI), A/Professor Helen Marshall, is the lead researcher on this GlaxoSmithKline-sponsored vaccine product trial, a serious conflict of interest. While beating up the risks of meningococcal B in South Australia, A/Professor Marshall admits that meningococcal B is an 'uncommon infection'[8], and yet promotes widespread mass vaccination of students with this still experimental vaccine product.

Do the students involved in this trial, and their parents, fully understand that the still experimental Bexsero vaccine was rejected three times by the PBAC, and that they are guinea pigs for this vaccine product for a rare disease? Have they been sufficiently informed about the uncertainties of this product to properly give their 'informed consent' to participate in this industry-funded trial?

An advertisement currently being broadcast on television in South Australia coaxes students to continue their participation in this vaccine trial, saying "Help protect yourself, while also protecting your family and friends".

[9] I suggest this advertisement is misleading as the long-term consequences of meningococcal B vaccination are unknown, which is the point of this unfortunately biased trial...

Again, it is alarming that a member of the Federal Government's Australian Technical Advisory Group on Immunisation, A/Professor Helen Marshall, is leading this industry-funded vaccine trial. According to the ATAGI conflict of interest document (see attached), A/Professor Marshall is an investigator on clinical trials associated with funding from GlaxoSmithKline, Merck, Novartis, Pfizer and Sanofi. She also presents at conferences sponsored by vaccine companies.

Another ATAGI member, A/Professor Jodie McVernon, who was interviewed on Dr Norman Swan's ABC Health Report discussing meningococcal B and W[10], is also an investigator on clinical trials funded by GlaxoSmithKline, bioCSL, Novartis and Pfizer, and is funded to attend workshops and symposiums sponsored by vaccine companies. (These conflicts of interest were not disclosed when A/Professor McVernon was interviewed on Norman Swan's ABC Health Report. It is notable that in the interview with Dr Swan, A/Professor McVernon admitted meningococcal "is still a very, very rare disease", and that meningococcal B has been "...slowly declining over time, for reasons we don't understand", i.e. before the implementation of meningococcal B vaccination.)

The former Chairperson of ATAGI, Professor Terry Nolan, also promotes the GSK Bexsero meningococcal B vaccine product[11], and along with A/Professor Helen Marshall and A/Professor Jodie McVernon, has been involved with meningococcal B vaccine studies sponsored by the vaccine industry[12].

Another avid promoter of the GSK Bexsero meningococcal B vaccine product is Professor Robert Booy, who is Head of Clinical Research at the National Centre for Immunisation Research & Surveillance, a government-funded body which is influential on vaccination policy. Professor Booy's Clinical Research Group undertakes studies supported by vaccine manufacturers. (The recently retired director of the NCIRS, Professor Peter McIntyre, was also an ex officio member of the Federal Government's Australian Technical Advisory Group on Immunisation, and was also involved in industry-funded vaccine clinical trials - see the ATAGI conflict of interest document attached for some incomplete information in this regard.)

Professor Booy has lobbied for the Bexsero meningococcal B vaccine to be added to the taxpayer-funded national schedule, e.g. as reported in *Medical Observer* in August 2015 [13] and in the ABC News in November 2017[14]. Professor Booy is also the Medical Advisor for Meningococcal Australia, an organisation funded by GSK Australia and Pfizer Australia[15], which has campaigned for the Bexsero meningococcal B vaccine to be added to the taxpayer funded schedule[16].

Professor Booy is also a Board member and Chair of the Scientific Advisory Committee of the Immunisation Coalition, a vaccination lobby group which is sponsored and supported by GlaxoSmithKline, Pfizer, Sanofi Pasteur, Roche, Seqirus, Astra Zeneka, Mylan, and Bupa.[17]

Professor Booy's association with the industry-sponsored Immunisation Coalition (formerly Influenza Specialist Group) was not disclosed in the *Medical Observer* article nor the ABC News report promoting the Bexsero meningococcal B vaccine, and is currently not disclosed on the Meningococcal Australia website, nor does it appear to be disclosed on the National Centre for Immunisation Research & Surveillance website. While Professor Booy and other academics are keen to flourish their academic affiliations, they are often reluctant to clearly disclose their associations with the vaccine industry.

It is wrong that members of groups and organisations influencing vaccination policy are also involved in industry-sponsored vaccine promotion and vaccine clinical trials, this is a serious conflict of interest. The government should have independent specialists in infectious diseases to objectively consider the implementation of vaccination programs, not conflicted academics associated with the vaccine industry.

Note also that information on membership of ATAGI and conflicts of interest was previously shrouded in secrecy, and only came to light when citizens such as myself persisted in challenging then Federal Health Minister Nicola Roxon, and then Prime Minister Tony Abbott, for this information, see for example my letter to Tony Abbott dated 21 January 2015: http://users.on.net/~peter.hart/Letter_to_Tony_Abbott_PM_re_vax_policy.pdf

Similarly, the Immunisation Coalition/Influenza Specialist Group was reluctant to disclose the names of its members, this was only revealed after my persistent enquiries to the CEO, Kim Sampson.

Via industry-associated academics such as Helen Marshall, Robert Booy, Jodie McVernon, Peter McIntyre and Terry Nolan, the vaccine industry is influencing government vaccination policy, including government-mandated vaccination, e.g the Federal Government's No Jab, No Pay law, and No Jab, No Play laws being implemented by some States.

Conflicts of interest are impacting on government-mandated vaccination policy, a serious matter in our liberal democracy where there must be transparency and accountability for vaccination policy.

Mr Marshall, the current Australian vaccination schedule for children is burgeoning with at least 46 doses of vaccines now being imposed on children via combination vaccine products and revaccinations. I suggest children are being grossly **over**-vaccinated with this plethora of lucrative vaccine products.

There are emerging problems with vaccines, e.g. the pertussis/whooping cough vaccine, with acknowledgement from academia that "the startling global resurgence of pertussis, or whooping cough, in recent years can largely be attributed to the immunological failures of acellular vaccines..."[18]

It is important to consider if the implementation of a vaccine may result in unforeseen deleterious consquences, e.g. the emergence of new strains of disease, as Dr Norman Swan suggested on the ABC Health Report in regards to meningococcal, i.e. "Has immunisation caused the problem, in a sense? In other words, that there is an ecological niche, if you like, for meningococcal infection. You get rid of C because of immunisation, then B emerges, then C and W and Y, because there's just an empty space for it to inhabit, a bit like sparrows..."[19]

The current over-use of vaccine products can be compared to the over-use of antibiotics, and also the over-use of other medical products such as opioids and anti-depressants. We desperately need objective and independent specialists to consider the 'big picture' on the over-use of medical products, rather than academics conflicted by their associations with industry.

Mr Marshall, in regards to including the GSK Bexsero meningococcal B vaccination on the national schedule you have said "We will certainly encourage Greg Hunt to make sure those vaccines are available free of charge to children in SA under the age of two...If that isn't forthcoming we will commit to making sure that the vaccine is available in SA".[20] Mr Marshall, on what do you base your commitment to "making sure the vaccine is available in SA"?

Mr Marshall, in light of the 'multiple uncertainties' about meningococcal B vaccination, and the conflicts of interest surrounding the promotion of the GlaxoSmithKline Bexsero meningococcal B vaccine product, I again ask you to very carefully consider the South Australian Government's position on this matter.

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

This email is being forwarded to Professor Andrew Wilson, Chair, PBAC; Mr Greg Hunt, Federal Health Minister; Stephen Wade, SA Minister for Health and Wellbeing; Mr Tony Pasin, Member for Barker; Mr Troy Bell, Member for Mount Gambier; and will also be publicly circulated to other parties.

References:

- 1. Meningococcal B victim Jordan Braddock's family mount online awareness campaign. The Advertiser, 25 March 2018.
- 2. Vaccine push. The Border Watch (tbw.newsgroup), 29 March 2018.
- 3. See for example Recommendations made by the PBAC July 2015 Subsequent decisions not to recommend.
- 4. GSK starts \$175M plant to boost production of vaccine star Bexsero. FiercePharma, 22 March 2017.
- 5. GlaxoSmithKline tops its peers with \$7.16B in 2017 vaccine sales. FiercePharma, 13 February 2018.
- 6. The other drug war the politics of big business. The Sydney Morning Herald, 27 February 2010.
- 7. Free meningococcal B-strain vaccine for 60,000 SA high school students under study into immunisation effect. The Advertiser, 13 December 2016.
- 8. Statements made in video included with the online article Meningococcal B victim Jordan Braddock's family mount online awareness campaign. The Advertiser, 25 March 2018.
- 9. B Part of IT | TVC 30 secs, video currently accessible on Youtube.
- 10. The segment titled 'Deadly meningococcal W concerns' included discussion on meningococcal B. ABC Health Report, 30 January 2017.
- 11. Meningococcal B vaccine: why aren't we using it more? MJA Insight, 6 November 2017.

- 12. See for example: Perrett KP et al. Immune responses to a recombinant, four-component, meningococcal serogroup B vaccine (4CMenB) in adolescents: a phase III, randomized, multicentre, lot-to-lot consistency study. Vaccine. 2015 Sep 22;33(39):5217-24; Terry Nolan et al. Vaccination with a multicomponent meningococcal B vaccine in prevention of disease in adolescents and young adults. Vaccine 33 (2015) 4437-4445; Terry Nolan et al. Persistence of Bactericidal Activity at 4 Years After 2 Primary Doses of a Recombinant, 4-Component, Meningococcal Serogroup B Vaccine (4CMenB) and Response to a Booster Dose in Adolescents and Young Adults. S322 OFID 2017:4 (Suppl 1) Poster Abstracts.
- 13. Meningococcal B vax rejection a bad move: expert. Medical Observer, 24 August, 2015.
- 14. Pressure grows to add meningococcal B strain to immunisation schedule, cases of disease rising. ABC News, 8 November 2017. In this article Professor Booy refers to the 'effectiveness' of the UK rollout of meningococcal B vaccination to justify implementation of the product in Australia. I await independent and objective evaluation of the Bexsero vaccine product in the UK. It is notable that Professor Booy failed to point out this vaccine product was also originally rejected in the UK, a decision that was overturned after intensive lobbying by vested interests, and when a person involved with the development of the Bexsero vaccine product, Professor Andrew Pollard, became Chair of the committee approving vaccine products, i.e. the UK Joint Committee on Vaccination and Immunisation, i.e. another example of conflicts of interest.
- 15. In December 2016 I emailed Professor Booy to ask if he or Meningococcal Australia received funding/support from the vaccine industry, but he did not respond. Subsequent to my email, the Meningococcal Australia 'About' page was updated to acknowledge receiving funding from GSK Australia and Pfizer Australia.
- 16. Subsidising meningococcal B vaccine deemed too costly for the federal budget. ABC News, 4 November 2016.
- 17. Immunisation Coalition 'About us', as downloaded 3 April 2018.
- 18. 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.
- 19. The segment titled 'Deadly meningococcal W concerns' included discussion on meningococcal B. ABC Health Report, 30 January 2017.
- 20. Demand for Steven Marshall to fund meningococcal B strain vaccinations program. The Advertiser, 20 March 2018.

