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Submission to the Senate Community Affairs Legislation Committee

Re: Social Services Legislation Amendment (No Jab, No Pay) Bill 2015

Summary

The Social Services Legislation Amendment (No Jab, No Pay) Bill 2015 introduces a 2015 Budget measure that from 1 January 2016 children of all ages (i.e. up to 19 years)¹ must be fully vaccinated in accordance with the standard vaccination schedule, or catch up vaccination schedule, to access child care benefit, child care rebate or the family tax benefit Part A supplement.²

According to the current 'standard vaccination schedule', **children aged from birth to 15 years will have at least 43 doses of vaccines via combined vaccines and revaccinations**.³ This does not include the dubious annual flu vaccinations we are all being pressured to have.⁴

New vaccine products are added to the schedule without consultation with the community. With the No Jab, No Pay Bill we are now being set up to be compliant to every lucrative vaccine product in the international vaccine industry's pipeline. Vaccines are the booming new market for pharmaceutical companies⁵, it appears the floodgates opened in the 1980s when the United States protected vaccine manufacturers from liability.⁶ We have no idea of the long term cumulative consequences of this ever-increasing vaccine load.

Citizens are entitled to demand the right to give their 'informed consent' before administration of these vaccine products to themselves and their children. Citizens are also entitled to question what level of disease risk justifies mass vaccination. These rights are being denied by the No Jab, No Pay Bill.

The No Jab, No Pay Bill will make vaccination compulsory to access financial inducements – this is at odds with the obligation for 'legally valid consent' before vaccination see for example Section 2.1.3 of The Australian Immunisation Handbook⁷ which acknowledges:

"In general, a parent or legal guardian of a child has the authority to consent to vaccination of that child..." and states "For consent to be legally valid, the following elements must be present:"

- 1. It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of being vaccinated.
- 2. It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
- 3. It must cover the specific procedure that is to be performed.
- 4. It can only be given after the potential risks and benefits of the relevant vaccine, risks of not having it and any alternative options have been explained to the individual.
- (My emphasis.)

As the Australian Federal Government's vaccination schedule will be effectively compulsory to obtain financial benefits, I suggest this contravenes point 2 above re legally valid consent before vaccination, i.e. "it must be given voluntarily in the absence of undue pressure, coercion or manipulation."

How can a person give 'legally valid consent' to a medical intervention, i.e. vaccination, when they are being 'pressured, coerced and manipulated' into having this intervention with a financial inducement, and are not being allowed to properly consider "the potential risks and benefits of the relevant vaccine, risks of not having it and any alternative options", as outlined in point 4 above?

In reference to the Statement of Compatibility with Human Rights attached to the No Jab, No Pay Bill⁸, I argue that this Bill is in conflict with human rights. As well as denying the right to informed consent before the medical intervention of vaccination without "undue pressure, coercion or manipulation"⁹, this Bill will also result in compulsory <u>over</u>-vaccination of children with vaccine products and revaccinations of questionable value, for example:

the arbitrary <u>second</u> dose of live measles, mumps and rubella (MMR) vaccine (GSK Priorix), which is being forced upon children despite the fact the manufacturer (GlaxoSmithKline) indicates most seronegative individuals will be immune after the <u>first</u> dose (which can be verified via antibody titre testing, i.e. a blood test). I question whether the strong resistance I have received to my arguments about the second dose of live GSK Priorix MMR vaccine is about protecting the market for the MMRV vaccine (GSK Priorix-Tetra) which is the second dose of MMR vaccine now given to 18 month olds, known as the MMRV, i.e. including varicella (chickenpox). (See Section 1 below for more detail); and

2. Gardasil human papillomavirus (HPV) vaccine (3 x doses), a vaccine product which was originally rejected by the Pharmaceutical Benefits Advisory Committee (PBAC), a decision that was overturned in dubious circumstances after interference by then Coalition Prime Minister John Howard in the run-up to the 2007 election. In July 2012 then Labor Federal Health Minister Tanya Plibersek oversaw implementation of Gardasil vaccination for boys with enthusiastic public support from the co-inventor of the technology enabling the HPV vaccines, Ian Frazer. In his official message of support for the funding of the national HPV vaccine program for boys, Professor Frazer failed to declare his conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in the developed world. (See Section 2 below for more detail.)

It is wrong that children will be compelled to have these questionable medical interventions to access taxpayer funded financial inducements.

There are also question marks over other vaccine products, for example repeated revaccination with the apparently defective acellular pertussis (whooping cough) vaccine which may actually be causing new strains of the disease to develop¹⁰, and spreading the disease via vaccinated individuals¹¹. The problems with this vaccine raise important questions about "what is immunity"? I am undertaking enquiries re pertussis vaccination and will make submissions on the repeated use of this problematic vaccine product in due course. (It is also interesting to consider if the recently published research which indicates some vaccines might support the evolution of more virulent viruses¹² may also have implications for non-viral vaccines such as pertussis.)

As well as questions about **"What is immunity?"**, I suggest **we should also be considering if an over-use of vaccine products may have long-term repercussions similar to the over-use of antibiotics and the rise of superbugs?**¹³ Are there any independent academics in the area of infectious diseases capable of considering this possibility? We also need to be wary of the extensive experimentation that is being undertaken with viruses and bacteria etc, without effective ethical oversight. The controversial research into making H5N1 more transmissible, funded by the US National Institutes of Health, is a prime example, see my letters on this subject dated <u>31 January 2012</u>, <u>17 December 2012</u> and <u>22 October 2014</u>.

I am also pursuing The Cochrane Collaboration and *The Lancet Infectious Diseases Journal* in regards to a systematic review of the safety of aluminium-adjuvanted vaccines, published in 2004¹⁴. 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 the defective diphtheria, tetanus and pertussis vaccines, and multiple doses of HPV vaccines**, amongst others. The meningococcal B vaccine is the latest to be promoted, **despite the fact this vaccine product has been rejected** <u>*three times*</u> by the Pharmaceutical Benefits Advisory Committee (PBAC)¹⁵. Members of the powerful 'vaccination clique' in Australia continue to agitate for the **Gardasil HPV vaccine was eventually forced onto the vaccination schedule, see Section 2 below.** My letters to the Cochrane Collaboration provide more background re my challenge to the poor quality review prepared by members of the Cochrane Vaccines Field, see letters dated <u>8 July 2014</u>, <u>17 July 2014</u> and <u>16 December 2014</u>, and my letter to the Editor of *The Lancet Infectious Diseases* dated <u>11 August 2014</u>. I am pursuing this matter further.

I also question the use of the word 'immunisation' in the No Jab, No Pay Bill documentation and other government documentation, e.g. the National **Immunisation** Program Schedule, which should be titled the National **Vaccination** Program Schedule, and The Australian **Immunisation** Handbook which should be titled The Australian **Vaccination** Handbook. The words 'immunisation' and 'vaccination' are often used interchangeably, even by so-called experts¹⁷ but this is incorrect usage. These words have different meanings¹⁸ and vaccination does not always result in immunisation. It is important to note that immunisation after vaccination is seldom verified. It is alarming that a Bill which may result in a compulsory medical intervention, i.e. vaccination, displays such a level of ignorance of correct terminology.

It must also be recognised that there is a serious lack of transparency and accountability for vaccination policy and practice in Australia.

Academics involved in vaccination policy seldom publicly declare their potential conflicts of interest, e.g. their associations with vaccine manufacturers. I have been campaigning for transparency in this area since 2011, but only recently has brief conflict of interest information for members of the Australian Technical Advisory Group on Immunisation (ATAGI) become publicly accessible, after I wrote to former Prime Minister Tony Abbott on the topic.¹⁹ Conflict of interest information for members of other groups influencing vaccination policy is still not being publicly disclosed, i.e. the TGA's Advisory Committee on the Safety of Vaccines (ACSOV), the Pharmaceutical Benefits Advisory Committee, the TGA's Australian Influenza Vaccine Committee, and the

Australian Academy of Science's Working Group and Oversight Committee for the Australian Federal Government funded publication **The Science of Immunisation: Questions and Answers**.

Secrecy also surrounds the cost of taxpayer funded vaccine products. I have sought information re costs from the Department of Health only to be told it is 'commercial in confidence'.²⁰ Why is this information kept from the public?

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. (See Section 3 below for more detail.)

Health Minister Sussan Ley has also announced a "\$26m booster to Immunise Australia...which will include incentive payments to GPs and other immunisation providers to identify children in their practice overdue for vaccinations and catch them up."²¹ (My emphasis.)

Doctors are now the frontline sales force for vaccine products. Doctors have a conflict of interest in this matter in that they receive financial inducements to persuade parents to have vaccinations for their children. I suggest there are serious ethical problems here in regards to their obligation to obtain 'valid consent' before vaccination, as outlined in The Australian Immunisation Handbook²², particularly if they are **over**-vaccinating their patients/clients with questionable vaccine products, which would violate the AMA's Code of Ethics, e.g. "Consider first the well-being of your patient" and "Make sure you do not exploit your patient for any reason"²³. A doctor's duty is to serve their patient/client, not to impose medical interventions without question.

It is notable that the No Jab, No Pay Bill includes a financial impact statement, i.e. **"This Bill is expected to produce savings of \$508.3 million over the forward estimates."** As parents will be penalised if they refuse <u>any</u> of the 43 vaccine doses currently on the schedule, **this appears to me to be a cynical exercise in budget savings**.

Former Prime Minister Tony Abbott elevated vaccination policy to Prime Ministerial level with his personal **No Jab** – **No Play and No Pay for Child Care** announcement in April 2015.²⁴ It appears former Prime Minister Abbott responded to the Murdoch Media's crude 'No Jab, No Play' campaign, with *The Sunday Telegraph* gloating about the 'stunning victory' of its campaign.²⁵

It is astonishing that a Prime Minister would endorse a policy for government mandated vaccination in response to a tabloid newspaper campaign, without giving serious consideration to the complexity of the matter, including the lack of transparency and accountability for vaccination policy in Australia. At least the Fairfax Media provided an alternative view by publishing Michael Leunig's cartoons, e.g. <u>Fascist epiphany</u> and <u>Some mothers do 'ave 'em</u>, which reflect the concern some parents have about the plethora of lucrative vaccine products being pressed upon children.

I request the Senate Community Affairs Legislation Committee reject the deeply flawed No Jab, No Pay Bill. I also request the Senate Community Affairs Legislation Committee consider my full submission, including Sections 1, 2 and 3 below, and:

- provide legal and ethical opinion in regards to compulsory vaccination for financial inducements, and the conflict with The Australian Immunisation Handbook's criteria for 'valid consent' before vaccination.
- 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 must also be made public.
- take steps to ensure parents are offered the option of antibody titre testing (i.e. a blood test) to verify
 immunisation after the first dose of live MMR vaccine, (even if they have to pay for antibody titre testing
 themselves), and that parents not be compelled to have their children revaccinated with a second dose
 of live MMR vaccine if they are already immune after the first dose. I also request a review of
 compulsory varicella vaccination via the MMRV.
- initiate an urgent review of industry and politically motivated Gardasil HPV vaccination, which was fasttracked in dubious circumstances after its original rejection by the PBAC in 2006.

Challenging compulsory over-vaccination with the arbitrary second dose of live measles, mumps and rubella (MMR) vaccine

The National Immunisation Program Schedule stipulates that children have **two doses** of live measles, mumps and rubella (MMR) vaccine.²⁶ The first dose of live MMR vaccine (GSK Priorix) is scheduled around 12 months of age. The second dose was previously scheduled for around four years of age²⁷, but this has now been changed to 18 months of age²⁸, with this second dose of live MMR vaccine being combined with varicella (chickenpox) vaccine, i.e. the MMRV (GSK Priorix-Tetra) which was introduced in July 2013.

According to the manufacturer's data for the GSK Priorix MMR vaccine, **most seronegative individuals are likely to be immune after the first dose of live GSK Priorix MMR vaccine (98.4% for measles, 94.8% for mumps and 100% for rubella)**²⁹, but a second dose is given to cover the small amount of individuals who might not have responded to the first dose. As two doses are stipulated on the National Immunisation Program Schedule, **this means the majority of individuals are over-vaccinated with the second dose of live MMR vaccine**, if the vaccine is as effective after the first dose as claimed by the manufacturer, GlaxoSmithKline.

I argue parents should be given the option of antibody titre testing (i.e. a blood test) to verify immunisation after the first dose, rather than be compelled to have an arbitrary revaccination with a second dose of the live MMR vaccine. Cautious parents may prefer the option of antibody titre testing rather than an arbitrary second dose of live MMR vaccine.

There is a precedent for parents being informed of the option of antibody titre testing before their child being revaccinated with the second dose of live MMR vaccine.

In the state of New Jersey in the United States, the health department provides information on antibody titre testing. <u>The Antibody Titer Law³⁰ (Holly's Law</u>) allows parents to seek testing to determine a child's immunity to measles, mumps and rubella before receiving the second dose of MMR vaccine.

The law was enacted in response to the death of five year old Holly Marie Stavola who died of encephalopathy which she developed seven days after receiving her second dose of MMR vaccine.³¹ Holly's family campaigned for this law, wishing they had known about the option of the antibody titre test before Holly's arbitrary revaccination with the second dose of live MMR vaccine.

I suggest to not offer the option of antibody titre testing instead of the arbitrary second dose of live MMR vaccine contravenes the obligation for 'valid consent' before vaccination, as outlined in Section 2.1.3 of The Australian Immunisation Handbook.³² The Australian Immunisation Handbook acknowledges:

"In general, a parent or legal guardian of a child has the authority to consent to vaccination of that child..." and states "For consent to be legally valid, the following elements must be present:"

- 1. It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of being vaccinated.
- 2. It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
- 3. It must cover the specific procedure that is to be performed.
- 4. It can only be given after the potential risks and benefits of the relevant vaccine, risks of not having it and any alternative options have been explained to the individual. (My emphasis.)

Point 4 specifically states any 'alternative options' must be explained to the individual. I suggest in the case of the MMR second dose this is not happening in many cases, particularly for children, i.e. their parents are not being informed of the evidence-based option of antibody titre testing to check it they are already immune after the first dose, an option that some cautious parents might be willing to pay for themselves if necessary.

Parents of small children might be surprised to discover that vaccination 'best practice' for companion animals is now more advanced than that for children, with international vaccination guidelines for dogs re live vaccines recommending antibody titre testing rather than an arbitrary 'booster', i.e.

"the principles of 'evidence-based veterinary medicine' would dictate that testing for antibody status (for either pups or adult dogs) is a better practice than simply administering a vaccine booster on the basis that this should be 'safe and cost less'".³³

Over-vaccination with the live MMR and MMRV vaccine products needlessly puts children at risk of an adverse event after vaccination. For example, a TGA list of adverse events after vaccination with GSK Priorix MMR vaccine (often administered with other vaccine products), generated for the dates 1 July 2012 to 1 July 2015, indicates 729 adverse event reports were made in that period. (Death was reported as an outcome in three of these cases, although the individual cases of death were not identified.)

250 of these adverse event reports occurred in four year olds, and 99 reports in three year olds. As it is likely many of these children had already been vaccinated with GSK Priorix MMR vaccine at 12 months of age, and were likely already immune (if the GSK Priorix MMR vaccine is as effective as claimed by the manufacturer), they underwent revaccination for no benefit and incurred unnecessary harm.

Other age groups, including adults, also reported adverse events after vaccination with the GSK Priorix MMR vaccine. It is also questionable why the adults involved in these adverse events were subjected to the GSK Priorix MMR vaccination, as they may have already had natural immunity or prior vaccination, was this verified? These adults should also have been offered antibody titre testing to check if they were already immune before being subjected to GSK Priorix MMR vaccination.

The GSK Priorix-Tetra MMRV vaccine was added to the Australian Government's National Immunisation Program Schedule in July 2013 for vaccination of children at 18 months of age, after vaccination with the GSK Priorix MMR vaccine at 12 months of age. A TGA adverse event list generated for the dates 1 July 2013 to 1 July 2015 shows **305 reports of adverse events after vaccination with the GSK Priorix-Tetra MMRV vaccine. If the individuals** involved in these reports had already been vaccinated with the GSK Priorix MMR vaccine at 12 months of age, again it is likely they were already immune to measles, mumps and rubella, (if the GSK Priorix MMR vaccine is as effective as claimed by the manufacturer), and underwent revaccination with the MMR component of the vaccine for no benefit and subsequently incurred harm.

It should be recognised that adverse events after vaccination are likely to be under-reported. The TGA acknowledges that reporting of adverse events to the TGA is voluntary, and that there is under-reporting in Australia, and around the world.³⁴

In regards to the lack of safety information for the MMR vaccine, the Cochrane Collaboration's systematic review of MMR vaccination notes:

"The design and reporting of safety outcomes in MMR vaccine studies, both pre- and postmarketing, are largely inadequate."³⁵

I have previously raised the matter of over-vaccination with the GSK Priorix MMR vaccine with other parties including the National Health and Medical Research Council (NHMRC) (my letters dated <u>19 March 2014</u>, <u>12 April 2014</u>, and <u>15 April 2014</u>), and Professor Terry Nolan, then Chair of the Australian Technical Advisory Group on Immunisation (ATAGI) (<u>my email dated 11 March 2013</u>), and then Australian Federal Minister for Health, Tanya Plibersek (<u>my letter dated 28 June 2012</u>). Ms Plibersek's office refused to respond to my letter. I also raised the matter with Dr Steve Hambleton, then President of the Australian Medical Association (<u>my email dated 2 May 2014</u>), but I received no response.

The response I received from the NHMRC (letter dated 22 July 2014) was most unsatisfactory and failed to acknowledge the right of parents to access the evidence-based option of antibody titre testing to verify an immune response after the first dose of live MMR vaccine. Ironically, the letter from the NHMRC noted "**immunisation in Australia is not compulsory...**"³⁶ but this will be overturned by the No Jab, No Pay Bill which will make vaccination compulsory for children of all ages to access financial inducements.³⁷

The NHMRC referred me to a response I had previously received from Professor Nolan. In his letter dated 27 May 2013, Professor Nolan stated:

"With respect to your comments regarding the recommendation that individuals receive two doses of measlescontaining vaccine, it is important to note that while measles immunity induced by 1-dose vaccination provides long-term immunity in most recipients, approximately 5% of recipients fail to develop immunity after 1 dose. Following a second vaccine dose, approximately 99% of recipients will be immune to measles."

In other words, **Professor Nolan acknowledges measles immunity induced by 1-dose vaccination provides long-term immunity in approximately 95% of recipients.** In fact, according to the GSK Priorix Product Information Leaflet, **antibodies against measles were detected in** <u>98.4%</u> of previously seronegative subjects³⁸, i.e. after the first dose, and I again argue that parents should not be compelled to have two doses of this vaccine for their children, and should be offered the option of antibody titre testing to verify an immune response after the first dose.

In his response to me Professor Nolan also proferred the excuse that two doses of live MMR vaccine are required because one component of the vaccine, i.e. the mumps component, might not be as effective as claimed by the manufacturer, i.e. Professor Nolan stated:

"Consideration must also be given to the immunogenicity conferred by other components of the vaccine – while clinical trials of mumps-containing vaccine also indicated 95% seroconversion after a single dose of MMR vaccine, **outbreak investigations and post-marketing studies have reported on(e) dose vaccine effectiveness to be between 60 and 90%**. Protection against mumps is greater in two-dose vaccine recipients, who have seroconversion rates up to 100%." (My emphasis.) (No references were provided by Professor Nolan to support this statement.)

In other words, Professor Nolan is saying the mumps component of the vaccine may not be fulfilling the manufacturer's claim of a 95% seroconversion rate after a single dose, and that this is a reason to revaccinate all individuals with a second dose of live MMR vaccine, i.e. including the measles and rubella components. While Professor Nolan indicates the mumps component of the MMR vaccine may not be achieving the level of effectiveness claimed by the manufacturer, he provides no indication that this vaccine failure is being investigated. It is also unclear whether this refers to Australian or international mumps outbreaks.

I suggest the manufacturer of the MMR vaccine used in Australia, i.e. GlaxoSmithKline, should be challenged if the vaccine is not achieving the level of effectiveness claimed for the mumps component of the vaccine.

In regards to a possible failure of the mumps component of the GSK Priorix MMR vaccine, it is also relevant to consider lawsuits currently underway in the US in regards to Merck's M-M-R II vaccine, **in which it is alleged Merck lied about the efficacy of its mumps vaccine**, **i.e. two whistleblowers**, former Merck virologists, say that Merck may have 'misstated' the vaccine's efficacy to the US Government.³⁹ Has a similar situation occurred in Australia?

In regards to the second dose which is now given, i.e. the MMRV vaccine, including varicella, The Australian Immunisation Handbook describes varicella as "usually a mild disease of childhood".⁴⁰ While the Handbook notes "complications occur in approximately 1% of cases"⁴¹, it is questionable whether mass vaccination with the varicella vaccine is justified, and whether parents should be compelled to have this vaccine for their children to access government financial benefits. It is notable that varicella vaccination is not universal. For example varicella vaccination is currently not part of the routine childhood vaccination schedule in the UK, where the NHS acknowledges: "Chickenpox is usually a mild illness, particularly in children. The condition is so common in childhood that 90% of adults who grow up in the UK are immune to the chickenpox virus because they have had it before."⁴²

I question whether varicella vaccination should be on the schedule, and raise the possibility of 'unintended consequences' with this vaccine, i.e. what the long-term effects of this vaccine might produce due to interference with natural progression of what has previously been regarded as a mild illness of childhood.

I also query whether the strong resistance I have received to my arguments about the second dose of live MMR(V) vaccine are about protecting the market for the GSK MMRV Priorix-Tetra vaccine. Incidentally, I have tried to find out the cost of this vaccine product, but have been thwarted in this endeavour because such information is deemed 'commercial in confidence', i.e. the cost of taxpayer funded vaccine products is kept secret from the public.⁴³

• I request the Senate Community Affairs Legislation Committee ensure parents are offered the option of antibody titre testing (i.e. a blood test) to verify immunisation after the first dose of live MMR vaccine, (even if they have to pay for antibody titre testing themselves), and that parents not be compelled to have their children revaccinated with a second dose of live MMR vaccine if they are already immune after the first dose. I also request a review of compulsory varicella vaccination via the MMRV.

2. Challenging compulsory over-vaccination with the Gardasil human papillomavirus (HPV) vaccine

The Gardasil human papillomavirus (HPV) vaccine (3 x doses) is listed on the schedule for all adolescents aged between 12 and 13 years⁴⁴, and will be compulsory to access financial benefits from 1 January 2016.⁴⁵

Gardasil human papillomavirus (HPV) vaccination was originally rejected by the Pharmaceutical Benefits Advisory Committee (PBAC) in 2006⁴⁶, a decision that was overturned in dubious circumstances after interference by then Coalition Prime Minister John Howard in the run-up to the 2007 federal election, when Gardasil vaccination was implemented for girls.⁴⁷

In July 2012 then Labor Federal Health Minister Tanya Plibersek oversaw implementation of Gardasil vaccination for boys with enthusiastic public support from the co-inventor of the technology enabling the HPV vaccines, Ian Frazer⁴⁸. In his official message of support for the funding of the national HPV vaccine program for boys⁴⁹, Professor Frazer failed to declare his conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in the developed world.⁵⁰

I suggest that Gardasil HPV vaccination should *not* be on the taxpayer funded schedule, and that the fast-tracked implementation of this vaccine product in 2006 should be subject to an investigation.

The basis for mass vaccination with the experimental Gardasil HPV vaccine is highly questionable, as the risk of cancer associated with the HPV virus is very low, as admitted by Professor Ian Frazer:

In an article on the Australian government and university and CSIRO-funded The Conversation website, titled **Catch** cancer? No thanks, I'd rather have a shot!, Professor Frazer states:

"Through sexual activity, most of us will get infected with the genital papillomaviruses that can cause cancer. Fortunately, most of us get rid of them between 12 months to five years later without even knowing we've had the infection. Even if the infection persists, only a few individuals accumulate enough genetic mistakes in the virus-infected cell for these to acquire the properties of cancer cells."⁵¹ (My emphasis.)

If only "a few individuals accumulate enough genetic mistakes in the virus-infected cell for these to acquire the properties of cancer cells", I question whether it is justifiable to compel children to have HPV vaccination.

A Cancer Australia Fact Sheet acknowledges that cervical cancer is uncommon, and that:

"since the introduction of the National Cervical Screening Program in 1991, the number of new cases of cervical cancer for women of all ages almost halved to 2005, and mortality also halved from 1991 to 2006".⁵²

The Australian National Cervical Screening Program (NCSP) website notes:

"Most people will have HPV at some time in their lives and never know it...Most HPV infections clear up by themselves without causing any problems. Infections can cause cervical abnormalities, which, if they persist, can lead to cervical cancer."

The NCSP website notes:

"It is important to remember that most women who have HPV clear the virus and do not go on to develop cervical cancer" and "For most women, their immune system will clear the virus, similar to getting rid of a common cold."⁵³

Gardasil Consumer Medicine Information approved by the TGA in Australia acknowledges Gardasil **will not protect** against all HPV types, and women will need to continue to follow their doctor or health care provider's instructions on regular Pap tests.⁵⁴ (Cervical screening is scheduled to change to 5-yearly HPV testing from May 2017.⁵⁵)

There is a welter of material in the often biased 'peer-reviewed' literature supporting HPV vaccination. **Much of this material is conflicted by industry funding and authors' associations with vaccine manufacturers.**⁵⁶ For example a review published in *The Lancet Infectious Diseases* includes this interpretation*:*

"Our results are promising for the long-term population-level effects of HPV vaccination programmes. However, continued monitoring is essential to identify any signals of potential waning efficacy or typereplacement."⁵⁷ (My emphasis.)

One of the authors of this review is Julia Brotherton who has been involved in the promotion of HPV vaccination since at least 2003, and who has links with industry, e.g. CSL and Merck.⁵⁸ Julia Brotherton is an author of **Planning for human papillomavirus vaccines in Australia: Report of a research group meeting**, published in June 2004.⁵⁹ This report was co-authored with Peter McIntyre, who is currently an ex-officio member of the Australian Technical Advisory Group on Immunisation (ATAGI).⁶⁰ The ATAGI Conflict of Interest document notes Professor McIntyre has been associated with grant funding from GSK, Pfizer, Novartis, Sanofi, bioCSL, Baxter, Merck, Janssen & Janssen (Crucell), NHMRC, ARC etc.⁶¹ Professor McIntyre is Director of the National Centre for Immunisation Research & Surveillance (NCIRS)⁶². Professor McIntyre was also on the Working Group for the publication **The Science of Immunisation: Questions and Answers** published by the Australian Academy of Science with funding from the Department of Health and Ageing.⁶³ Professor McIntyre was also involved in co-ordinating the **Evaluation of the National Human Papillomavirus Vaccination Program – Final Report**.⁶⁴ Professor McIntyre is part of the very powerful 'vaccination clique' in Australia.

It is concerning that people such as Julia Brotherton and Peter McIntyre, who have associations with 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.

I suggest it is essential that any individuals undertaking systematic reviews of the literature, or other evaluations supporting the use of pharmaceutical products, e.g. HPV vaccine products Gardasil and Cervarix, demonstrate they have no conflicts of interest in the matter. It is important that we have a critical and objective review of often conflicted literature, which must also be open access, i.e. not behind journal paywalls.

Children and their parents are not being properly informed of the low risk of cancer associated with the HPV virus, and the possibility of waning efficacy or type-replacement with the use of HPV vaccines, and the implications this may have.

In regards to the possibility of type-replacement, in an article published in New Scientist in September 2011 Charlotte Haug questions:

"...what effect will the vaccine have on the other cancer-causing strains of HPV? Nature never leaves a void, so if HPV-16 and HPV-18 are suppressed by an effective vaccine, other strains of the virus will take their place. The question is, will these strains cause cervical cancer?"⁶⁵

Also refer to other articles by Charlotte Haug questioning HPV vaccination, i.e. Human Papillomavirus Vaccination – Reasons for Caution⁶⁶ and The Risks and Benefits of HPV Vaccination⁶⁷

It is my strong suspicion that in many instances 'legally valid consent' is not being properly obtained before HPV vaccination, and that children and their parents are unaware that they are being used as guinea pigs for this still experimental vaccine product. The long-term consequences of this vaccine product are unknown and yet this vaccine will be compulsory for all adolescents to access government financial benefits if the No Jab, No Pay Bill is passed.

A recent article in the UK media about girls suffering adverse experiences after HPV vaccination, includes negative comments about HPV vaccination from British epidemiologist Dr Tom Jefferson, a global authority on vaccine trial evidence associated with The Cochrane Collaboration.⁶⁸ In the article Dr Jefferson says:

"The HPV vaccine's benefits have been hyped and the harms hardly investigated...The reason for introducing vaccination against HPV was to prevent cancer...but there is no clinical evidence to prove it will do that. We have to tread a very careful line, weighing the potential benefits and harms that a vaccine may cause. With HPV, the harms have not been properly studied...It is extremely difficult to publish anything against HPV vaccination. Vaccines have become like a religion. They are not something you question. If you do, you are seen as being an anti-vaccine extremist. The authorities do not want to hear 'side-effect'".⁶⁹ (I suggest Dr Jefferson's comments are relevant to both the Gardasil and Cervarix HPV vaccines.)

The article notes Dr Jefferson is **"highly critical of the drug company funded clinical trial data that is used to justify the use of mass vaccination**" and adds that **"pharmaceutical companies may hide negative results deep in their trial data and hugely inflate the benefits**".⁷⁰ In other parts of the world negative stories about HPV vaccination continue to emerge, e.g. in Denmark⁷¹, Colombia⁷², Japan⁷³, the United States⁷⁴, Canada⁷⁵ and India⁷⁶.

In Australia, 3,386 adverse events after Gardasil HPV vaccination have been recorded in the TGA's adverse events database for the period 26 September 2006 to 15 July 2015. As noted previously, it should be remembered the TGA admits there is under-reporting of adverse events after vaccination in Australia, and around the world.⁷⁷

GP Dr Deirdre Little has reported three cases of premature ovarian insufficiency after Gardasil HPV vaccination. In her paper on this matter Dr Little notes:

"Enduring ovarian capacity and duration of function following vaccination is unresearched in preclinical studies, clinical and postlicensure studies. Postmarketing surveillance does not accurately represent diagnoses in adverse event notifications and can neither represent unnotified cases nor compare incident statistics with vaccine course administration rates. The potential significance of a case series of adolescents with idiopathic premature ovarian insufficiency following HPV vaccination presenting to a general practice warrants further research. Preservation of reproductive health is a primary concern in the recipient target group. Since this group includes all prepubertal and pubertal young women, demonstration of ongoing, uncompromised safety for the ovary is urgently required...⁷⁷⁸ (My emphasis.)

Gardasil HPV vaccination for girls was fast-tracked in Australia under very questionable circumstances when Tony Abbott was Federal Health Minister in 2006. **The Gardasil HPV vaccine was originally rejected by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) but this decision was overturned after interference by then Prime Minister John Howard.** According to an article by Matthew Stevens published in *The Australian* newspaper at the time it took just 24 hours for John Howard to deliver "**sparkling prime ministerial endorsement to Gardasil**" along with a clear direction to then Health Minister Tony Abbott, "**that the immunisation program should proceed.** And pronto."⁷⁹

Professor Marion Haas provides some commentary on the Australian Government's interference with the PBAC's initial rejection of Gardasil, noting Prime Minister Howard:

"intervened personally by announcing that the drug would be subsidised (i.e. listed) as soon as the manufacturer offered the right price. The PBAC subsequently convened a special meeting and recommended that Gardasil be listed on the PBS".⁸⁰

Professor Haas notes government reaction which results in reversal of PBAC decisions has:

"the potential to send signals to manufacturers and lobby groups that a decision made by the PBAC may be reversed if sufficient public and/or political pressure is able to be brought to bear on the PBAC...this may undermine the processes used by the PBAC to determine its recommendations and hence the perceived independence of the PBAC..."

Professor Haas et al provide further analysis in their paper **Drugs, sex, money and power: An HPV vaccine case** study.⁸² Also refer to a paper by Elizabeth Roughead et al **The Australian funding debate on quadrivalent HPV** vaccine: A case study for the national pharmaceutical policy.⁸³

After the Australian Government's interference in this matter, other countries adopted HPV vaccination⁸⁴, **resulting in billions of dollars' worth of sales for the makers of the HPV vaccines**, i.e. Merck (Gardasil) and GlaxoSmithKline (Cervarix)⁸⁵, and royalties for entrepreneurial scientist Ian Frazer from sales of HPV vaccines in developed countries⁸⁶, and for CSL which receives royalties from sales of Gardasil⁸⁷.

The addition of the Gardasil HPV vaccine to the Australian taxpayer funded national vaccination schedule is highly questionable and raises questions about what level of disease risk justifies mass vaccination. It is wrong that the Australian Federal Government will compel children to have this vaccine product to access government financial benefits.

• I request the Senate Community Affairs Legislation Committee initiate an urgent review of industry and politically motivated Gardasil HPV vaccination, which was fast-tracked in dubious circumstances after its original rejection by the PBAC in 2006.

3. Lack of transparency and accountability for vaccination policy and practice in Australia

The Australian Federal Government must 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 vaccine products which can result in the addition of new vaccine products to the national vaccination 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.⁸⁸

The powerful influence of these groups raises serious political and ethical questions about their impact on the bodily integrity of citizens, particularly 'pre-citizens', i.e. children.

As the decisions of these committees 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.

For example, a register providing the history of any relationships with the vaccine industry, e.g. detailing research grants, consultancies, honorariums, committee 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, 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 Australia Code for the Responsible Conduct of Research, in particular sections 4.9 "Disclose research support accurately" and 7. "Conflicts of interest.⁸⁹

For example, on 26 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 website⁹⁰, there was still no disclosure of information about potential conflicts of interest. I also raised this subject with Professor Terry Nolan, then Chair of ATAGI, but he failed to address the matter. **Only recently has (inadequate) conflict of interest information for members of ATAGI become publicly accessible⁹¹, after I wrote to former Prime Minister Tony Abbott on the topic in January 2015.⁹²**

Conflict of interest information for members of other groups influencing vaccination policy is still not being publicly disclosed.

For instance the Therapeutic Goods Administration (TGA)'s webpage for the Advisory Committee on the Safety of Vaccines (ACSOV) provides a list of members and affiliations⁹³, **but there is no clarity re potential conflicts of interest of these people.**

In fact, it is very surprising to discover that this advisory committee on the safety of vaccines is chaired by Dr 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. I suggest it is inappropriate to have a person involved with the appraisal of vaccine products for the national schedule also to be in a position to evaluate post-marketing safety issues as there is potential for a conflict of interest.

Another example of lack of transparency is the Pharmaceutical Benefits Advisory Committee (PBAC) webpage, which lists members of the PBAC and their affiliations⁹⁴, **but again provides no clarity re potential conflicts of interest of these people.**

Then there is the TGA's Australian Influenza Vaccine Committee (AVIC), which 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

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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 members and affiliations⁹⁵, **there is still no information re potential conflicts of interest.**

The Australian Academy of Science is also influential on vaccination policy. In December 2012 I asked Professor 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.⁹⁶ Despite promises that this matter would be addressed, as at 15 October 2015, **disclosure information is still not provided on the Academy's The Science of Immunisation: Questions and Answers webpage.**⁹⁷

These examples indicate there is a serious problem with a lack of disclosure of potential conflicts interest that needs to be addressed.

Inter-relationships between these groups should also be investigated. These groups combine to make a very powerful clique biased towards increasing the use of vaccine products. I am concerned that with the overuse of vaccine products we may be heading towards a potentially disastrous situation similar to the overuse of antibiotics, i.e. the rise of superbugs. I have seen little evidence of independent academics considering this possibility.

Secrecy also surrounds the cost of taxpayer funded vaccine products. I have sought information re costs from the Department of Health only to be told it is 'commercial in confidence'. Why is this information kept from the public?

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 the Senate Community Affairs Legislation Committee 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 must also be made public.

Conclusion

 I request the Senate Community Affairs Legislation Committee reject the deeply flawed No Jab, No Pay Bill.

I also request the Senate Community Affairs Legislation Committee give careful consideration to the matters raised in my full submission, including Sections 1, 2 and 3 above, and:

- provide legal and ethical opinion in regards to compulsory vaccination for financial inducements, and the conflict with The Australian Immunisation Handbook's criteria for 'valid consent' before vaccination.
- 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 must also be made public.
- take steps to ensure parents are offered the option of antibody titre testing (i.e. a blood test) to verify immunisation after the first dose of live MMR vaccine, (even if they have to pay for antibody titre testing themselves), and that parents not be compelled to have their children revaccinated with a second dose of live MMR vaccine if they are already immune after the first dose. I also request a review of compulsory varicella vaccination via the MMRV.
- initiate an urgent review of industry and politically motivated Gardasil HPV vaccination, which was fast-tracked in dubious circumstances after its original rejection by the PBAC in 2006.

For information, I have previously forwarded letters questioning vaccination policy to former Prime Minister Tony Abbott. Current Prime Minister Malcolm Turnbull and other political representatives⁹⁸ have also received copies of these submissions, ie:

- Vaccination policy and practice in Australia lack of transparency and accountability (21 January 2015).
- Compulsory vaccination and legally valid consent (22 June 2015).
- Challenging compulsory vaccination with the Gardasil HPV vaccine (4 July 2015).
- Challenging compulsory revaccination with the second dose of live MMR vaccine (4 August 2015).
- <u>Questioning the secrecy surrounding the cost of taxpayer funded vaccine products</u> (10 August 2015).
- <u>Requesting a review of the burgeoning vaccination schedule, i.e. untainted by vaccine industry bias, with</u> reference to Michael Leunig's cartoon 'Fascist epiphany' (26 August 2015).

A record of my correspondence on vaccination is being maintained on my website: http://over-vaccination.net/

Sincerely

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

16 October 2015

References: (Links accessible as at 16 October 2015.)

¹ "From 1 January 2016 (subject to the passage of legislation): Parents who do not fully immunise their children (up to 19 years of age) will cease to be eligible for Child Care Benefit, Child Care Rebate and the Family Tax Benefit Part A end of year supplement (family assistance payments)..." (My emphasis.) UPDATE: No Jab No Pay – Immunisation Catch-Up Arrangements, Australian Government Department of Health:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/clinical-updates-and-news/\$File/Update-No-Jab-No-Pay-Immunisation-Catch-Up-Arrangements(D15-1126865).pdf

² Explanatory Memorandum – Social Services Legislation Amendment (No Jab, No Pay) Bill 2015:

http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/r5540_ems_78b7b14d-fa5d-469e-a038-

2840207a8f3e/upload_pdf/503827.pdf;fileType=application%2Fpdf

³ I calculate at least 43 doses of individual vaccines ie breaking down combination vaccines and including revaccinations on the general schedule for children aged from birth to 15 years ie:

- 4 x Hepatitis B
- 5 x Diphtheria
- 5 x Tetanus
- 5 x Acellular pertussis
- 4 x Haemophilus influenza type b
- 4 x Inactivated poliomyelitis
- 3 x Pneumococcal conjugate
- 2 x Rotavirus (possibly 3 doses, see note b on the schedule)
- 1 x Meningococcal C
- 2 x Measles
- 2 x Mumps
- 2 x Rubella
- 1 x Varicella (Chickenpox)
- 3 x Human papillomavirus

Total 43 doses of vaccines. Also consider many children are being vaccinated with annual flu vaccines too, and are being set up for annual flu vaccination for life - another profit centre for Big Pharma. Plus Aboriginal and Torres Strait Islanders and 'medically at risk groups' are recommended to get annual flu vaccines plus additional Pneumococcal conjugate (13vPCV) and Pneumococcal polysaccharide (23vPPV) vaccines.

Refer to the National Immunisation Program Schedule (From 20 April 2015):

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule

⁴ People in countries such as Australia and the US continue to be pressured to have annual flu vaccinations, even though reviews of flu vaccine studies challenge the supposed benefits of this questionable medical intervention.

The Cochrane Reviews "Vaccines for preventing influenza in healthy adults" and "Vaccines for preventing influenza in the elderly", and the systematic review and meta-analysis published in the Lancet "Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis" indicate the evidence supporting widespread flu vaccination is poor. In an article published in The Vancouver Sun (15 November 2012), Cochrane's Dr Tom Jefferson said: "For the past two decades, I have been involved in the writing and periodic updating of Cochrane reviews on influenza vaccines in children, healthy adults, the elderly, and

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healthcare workers who care for sick people. My group and I also carried out a review on 270 influenza vaccines studies on all types of populations published from the 1940s up to 2007 and found near universal poor methodological quality. We also found that pharma-funded studies were more likely to be published in the top journals and be more often quoted than their non pharma counterparts, but the quality and size of the studies were the same as the others. Their conclusions were not surprisingly far more optimistic on the vaccines' performance. Their publication in top journals was probably a result of the fatal attraction of pharma sponsorship for big journals and their publishers." (My emphasis.) ⁵ See for example **The top 5 vaccine makers by 2014 revenue**, FierceVaccines, 13 August 2015:

http://www.fiercevaccines.com/special-reports/top-5-vaccine-makers-2014-revenue and Expect vaccines market to swell to \$40B by 2020: Tufts CSDD, FierceVaccines, 16 July 2015: http://www.fiercevaccines.com/story/expect-vaccines-market-swell-40b-2020-tufts-csdd/2015-07-16 My webpage Over-vaccination - A Multi-Billion Dollar Market also provides some background: http://over-vaccination.net/over-vaccination-a-multi-billion-dollar-market/

⁶ The US National Vaccine Injury Compensation Program was established to protect vaccine manufacturers from direct liability: http://www.hrsa.gov/vaccinecompensation/index.html Also see Feds Vows to Publicize Vaccine Injury Help Program, The New York Times, 21 November 2014. This AP article is still available online via the UK Daily Mail:

http://www.dailymail.co.uk/wires/ap/article-2844694/Feds-vows-publicize-vaccine-injury-help-program.html

⁷ Section 2.1.3 Valid consent. The Australian Immunisation Handbook, 10th Edition: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10home~handbook10part2~handbook10-2-1

⁸ Explanatory Memorandum – Social Services Legislation Amendment (No Jab, No Pay) Bill 2015: http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/r5540_ems_78b7b14d-fa5d-469e-a038-

2840207a8f3e/upload_pdf/503827.pdf;fileType=application%2Fpdf
⁹ Section 2.1.3 Valid consent. The Australian Immunisation Handbook, 10th Edition:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-

home~handbook10part2~handbook10-2-1

¹⁰ In March 2012, The Conversation reported on a new strain of whooping cough that appears to be resistant to vaccination i.e. "A team led by scientists at The University of New South Wales believes the emerging strain of the Bordetella pertussis bacterium may be evading the effects of the widely-prescribed acellular vaccine (ACV) and increasing the incidence of the potentially fatal respiratory illness, according to a study published in The Journal of Infectious Diseases". See Vaccine-resistant whooping cough takes epidemic to new level: https://theconversation.com/vaccine-resistant-whooping-cough-takes-epidemic-to-new-

level-5959 In The Conversation article, Professor Lyn Gilbert, a Professor in Medicine and Infectious Diseases at the University of Sydney, said there was a range of ways scientists might tackle the new strain of whooping cough, including administering "more boosters of the current vaccine". The question is, how does increasing the numbers of 'boosters' of the current vaccine protect against the new strain? Also see my email enquiries on this matter to Professors Lyn Gilbert and Ruiting Ian

in December 2012: http://users.on.net/~peter.hart/Whooping cough enquiry.pdf which did not receive a response. Also see Octavia, S. et al. Newly Emerging Clones of Bordetella pertussis Carrying prn2 and ptxP3 Alleles Implicated in Australian Pertussis Epidemic in 2008-2010. JID 2012:205 (15 April). Brief Report:

http://jid.oxfordjournals.org/content/early/2012/03/14/infdis.jis178.full.pdf+html and Sharp rise in cases of new strain of whooping cough. UNSW Australia Newsroom, 21 March 2012: https://newsroom.unsw.edu.au/news/health/sharp-rise-casesnew-strain-whooping-cough

¹¹ See for example FDA study helps provide an understanding of rising rates of whooping cough and response to vaccination. FDA News Release, 27 November 2013:

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376937.htm and Jason M Warfel et al. Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model. PNAS, 22 October 2013: http://www.pnas.org/content/111/2/787.full.pdf

¹² See Some Vaccines Support Evolution of More-Virulent Viruses. PennState Science, 27 July 2015: http://science.psu.edu/news-and-events/2015-news/Read7-2015 and Leaky vaccine promote the transmission of more virulent virus. Center for Infectious Disease Dynamics. Penn State: http://www.cidd.psu.edu/research/synopses/leaky-vaccinespromote-the-transmission-of-more-virulent-virus The study referred to in this articles is: Andrew F. Read et al. Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens. PLOS Biology, July 27 2015: http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198

¹³ In regards to the overuse of antibiotics see for example: **PM's plan on antibiotics not urgent enough, report says**, BBC News Health, 7 July 2014: http://www.bbc.com/news/health-28165152 This is a topic to watch very carefully, particularly in regards to vested interests, as apparently the solution to the overuse of antibiotics is...more antibiotics, e.g. "What this demands, according to academic and industry experts, is a new business model that rewards drug firms for developing new antibiotics even *if they are rarely used.*" How to fix a broken market in antibiotics, Reuters, 6 July 2014: <u>http://in.reuters.com/article/2014/07/06/uk-health-antibiotics-idINKBN0FB0AE20140706</u> Also see UPDATE 1 – Cameron enlists

ex-Goldman economist in global superbug fight, Reuters, 2 July 2014: http://www.reuters.com/article/2014/07/02/healthantibiotics-idUSL6N0PD25O20140702

¹⁴ 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 See Recommendations made by the PBAC July 2015 - Subsequent decisions not to recommend. In relation to the GSK Multicomponent Meningococcal Group B Vaccine (4CMENB) the PBAC made this statement: "The PBAC rejected the resubmission requesting listing of the 4CMenB vaccine on the NIP Schedule for the prevention of meningococcal B disease in infants and adolescents. The basis of the rejection was that the re-submission did not address multiple uncertainties in relation to the clinical effectiveness of the vaccine against the disease when delivered in a vaccination program, that the use of optimistic assumptions about the extent and duration of effect and herd immunity as raised by the PBAC in previous consideration of this vaccine were not addressed, and the unacceptably high and uncertain ICER, presented in the re-submission." Other statements about this vaccine were also made in the PBAC July 2015 document, refer to this link:

http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2015-07/web-outcomes-july-2015-subsequentdecision-not-to-recommend.pdf

¹⁶ See Meningococcal B vax rejection a bad move: expert: Medical Observer, 24 August 2015:

http://www.medicalobserver.com.au/medical-news/meningococcal-b-vax-rejection-a-bad-move-

expert?mkt_tok=3RkMMJWWfF9wsRoivqvMZKXonjHpfsX%2B7OoqX6C2IMI%2F0ER3fOvrPUfGjI4FTstrI%2BSLDwEYGJIv6SgF SLHMMbNn0LgLXhg%3D

¹⁷ For example the Australian Technical Advisory Group on Immunisation should be more correctly titled the Australian Technical Advisory Group on Vaccination. Also consider the incorrect use of the word immunisation in an article by Professor Raina MacIntyre, <u>Want to boost vaccination? Don't punish parents, build their trust</u>, and another by Associate Professor Kristine Macartney, <u>Forget 'no jab, no pay' schemes, there are better ways to boost vaccination</u>, both published on The Conversation website.

¹⁸ This dictionary definition provides some clarity: **Q**: *What is the difference between vaccination and immunisation?* **A**: Vaccination is when a vaccine is administered to you (usually by injection). Immunisation is what happens in your body after you have the vaccination. The vaccine stimulates your immune system so that it can recognise the disease and protect you from future infection (i.e. you become immune to the infection). 'Vaccination' and 'immunisation' are often used interchangeably but their meanings are not exactly the same. Ref: <u>http://www.nps.org.au/medicines/immune-system/vaccines-and-immunisation/for-individuals/questions-and-answers-about-vaccines/difference-between-vaccination-and-immunisation</u>

¹⁹ See my letter to Prime Minister Tony Abbott questioning vaccination policy in Australia (21 January 2015), requesting he urgently address the problem of potential conflicts of interest and lack of disclosure by members of groups influencing vaccination policy in Australia: <u>http://users.on.net/~peter.hart/Letter to Tony Abbott PM re vax policy.pdf</u> For a summary of my letter to Prime Minister Abbott on this matter, including the response from the Immunisation Branch of the Department of Health with reference to the Australian Technical Advisory Group on Immunisation (ATAGI), see this webpage: <u>http://over-</u>

vaccination.net/letters-challenging-over-vaccination/letter-to-australian-prime-minister-re-vaccination-policy-in-australia/ ²⁰ I have also written to (former) Prime Minister Abbott questioning the secrecy surrounding the cost of taxpayer funded vaccine products, my letter can be accessed via this link: <u>https://drive.google.com/file/d/0B9ZVuVqOGTd5QINHZIJ6c1ZuLTA/view</u> ²¹ Minister for Health Sussan Ley's announcement **\$26m booster to Immunise Australia**:

http://www.health.gov.au/internet/ministers/publishing.nsf/Content/B13A5C4233686A99CA257E2E0013E611/\$File/SL044.pdf ²² Section 2.1.3 Valid consent. The Australian Immunisation Handbook, 10th Edition:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10home~handbook10part2~handbook10-2-1

²³ AMA Code of Ethics – 2004. Editorially revised 2006: <u>https://ama.com.au/position-statement/ama-code-ethics-2004-editorially-revised-2006</u>

²⁴ Former Prime Minister Tony Abbott's No Jab – No Play and No Pay for Child Care announcement was previously accessible via this link but appears to have been removed: <u>https://www.pm.gov.au/media/2015-04-12/no-jab-no-play-and-no-pay-child-care-0</u>

0 ²⁵ See Anti-vaccination parents face \$15,000 welfare hit under 'No Jab' reforms, The Sunday Telegraph, 13 April 2015: <u>http://www.dailytelegraph.com.au/news/nsw/anti-vaccination-parents-face-15000-welfare-hit-under-no-jab-reforms/story-fnpn118l-1227300073570</u>

²⁶ National Immunisation Program Schedule (from 20 April 2015):

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule ²⁷ Refer to **Significant events in measles, mumps and rubella vaccination practice in Australia**, National Centre for Immunisation Research & Surveillance: <u>http://www.ncirs.edu.au/immunisation/history/Measles-mumps-rubella-history-December-</u> 2013.pdf

<u>2013.pdf</u>
 ²⁸ Refer to Significant events in varicella vaccination practice in Australia, National Centre for Immunisation Research & Surveillance: http://www.ncirs.edu.au/immunisation/history/Varicella-history-December-2013.pdf

²⁹ According to the GSK Priorix Product Information Leaflet, in "*a more recent study comparing the formulation of PRIORIX* (albumin-free) with the previous formulation containing albumin, **antibodies against measles, mumps and rubella were detected in 98.4, 94.8 and 100% of previously seronegative subjects** (*n*=191)". The leaflet also contains similarly high seroconversion rates from earlier studies. The GSK Priorix Product Information Leaflet notes that: "**Seroconversion has been shown to equate with protection against each of the measles, mumps and rubella viruses."** Despite the fact it appears **one dose** of PRIORIX MMR live vaccine is likely to provide protection for most previously seronegative subjects, the GSK Priorix Product Information Leaflet indicates **two doses** are to be given, i.e. "*The Australian NH&MRC Immunisation Handbook recommendations for MMR vaccinations are as follows: MMR vaccine is recommended for all children at 12 months of age and again at 4-6 years of age unless there is a genuine contraindication."* So it appears the NHMRC is behind the two dose 'recommendation'. GSK Priorix Product Information Leaflet as accessed on the TGA website:

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-

<u>3&d=2015042916114622412&d=2015052816114622412</u> (Note: The second dose of live MMR vaccine is described as a 'booster' in the GSK Priorix Leaflet - I suggest this term is misleading as a 'booster' is not required if the individual is already immune after the first dose.)

³⁰ Antibody Titer Law – Information for Parents. (Holly's Law) (NJSA 26:2N-8-11), passed on January 14, 2004, concerns vaccination of children with the Measles, Mumps, Rubella (MMR) vaccine. The law allows parents to seek testing to determine a child's immunity to measles, mumps, and rubella, before receiving the second dose of the vaccine. This brochure has been prepared by the New Jersey Department of Health and Senior Services to assist parents in making the decisions related to the MMR vaccine and the test: http://www.state.nj.us/health/cd/documents/antibody_titer_law.pdf

³¹ HopeFromHolly. Providing NJ Physicians and Parents With More Knowledge about Childhood Vaccines: <u>http://hopefromholly.com/blog/our-purpose/</u> ³² Section 2.1.3 Valid consent. The Australian Immunisation Handbook, 10th Edition: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10home~handbook10part2~handbook10-2-1
 ³³ See page 7 under "Serological Testing to Determine the Duration of Immunity (DOI)" in Day, M.J., Horzinek, M.C., Schultz, R.D. World Small Animal Veterinary Association's (WSAVA) Guidelines for the Vaccination of Dogs and Cats. Journal of Small Animal Practice. Vol. 51. June 2010: http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf
 ³⁴ "Adverse event 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." About the DAEN – Reporting levels: http://www.tga.gov.au/about-daen-medicines#.UyglSfmSz-t
 ³⁵ Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. Vaccines for measles, mumps and rubella in children. The Cochrane Library, published online 15 Feb 2012: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004407.pub3/abstract
 ³⁶ The letter from the NHMRC stated: "...With regard to the issues you raised about the informed consent process for participation in the immunisation program, the information provided to parents is based on the most available evidence reflected

in the immunisation handbook. As you are aware, immunisation in Australia is not compulsory and provisions exist to enable parents to apply for an exemption to immunisation requirements in order to retain their eligibility for the Family Tax Benefit Part A Supplement..." (My emphasis.) The NHMRC letter was dated 22 July 2014, and signed by Samantha Robertson, Executive Director, Research Translation Group.

³⁷ No Jab – No Play and No Pay for Child Care. Prime Minister's Media Release, 12 April 2015:

https://www.pm.gov.au/media/2015-04-12/no-jab-no-play-and-no-pay-child-care-0

³⁸ GSK Priorix Product Information Leaflet as accessed on the TGA website:

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-

<u>3&d=2015042916114622412&d=2015052816114622412</u> (Note: The second dose of live MMR vaccine is described as a 'booster' in the GSK Priorix Leaflet. I suggest this term is misleading as a 'booster' is not required if the individual is already immune after the first dose.)

³⁹ See for example these reports from FierceVaccines: Lawsuits claiming Merck lied about mumps vaccine efficacy headed to trial, 9 September 2014: http://www.fiercevaccines.com/story/lawsuits-claiming-merck-lied-about-mumps-vaccine-efficacy-headed-trial/2014-09-09 and Whistleblowers accuse Merck of withholding info on mumps vaccine, 11 June 2015: http://www.fiercevaccines.com/story/lawsuits-claiming-merck-lied-about-mumps-vaccine-efficacy-headed-trial/2014-09-09 and Whistleblowers accuse Merck of withholding info on mumps vaccine, 11 June 2015: http://www.fiercevaccines.com/story/whistleblowers-accuse-merck-withholding-info-mumps-vaccine/2015-06-11
 ⁴⁰ 4.22 Varicella. The Australian Immunisation Handbook:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-

home~handbook10part4~handbook10-4-22

⁴¹ Ibid.

⁴² Why aren't children in the UK vaccinated against chickenpox? NHS Choices webpage:

http://www.nhs.uk/chq/Pages/1032.aspx?CategoryID=62&SubCategoryID=63 Also see Chickenpox. NHS Choices webpage: http://www.nhs.uk/conditions/chickenpox/Pages/Introduction.aspx

⁴³ I have written to (former) Prime Minister Abbott questioning the secrecy surrounding the cost of taxpayer funded vaccine products, my letter can be accessed via this link: <u>https://drive.google.com/file/d/0B9ZVuVqOGTd5QINHZIJ6c1ZuLTA/view</u>
 ⁴⁴ Refer to the National Immunisation Program Schedule (From 20 April 2015) – see Footnote d:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/national-immunisation-program-schedule ⁴⁵ "From 1 January 2016 (subject to the passage of legislation): Parents who do not fully immunise their children (up to 19 years of age) will cease to be eligible for Child Care Benefit, Child Care Rebate and the Family Tax Benefit Part A end of year supplement (family assistance payments)..." (My emphasis.) UPDATE: No Jab No Pay – Immunisation Catch-Up Arrangements, Australian Government Department of Health:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/clinical-updates-and-news/\$File/Update-No-Jab-No-Pay-Immunisation-Catch-Up-Arrangements(D15-1126865).pdf

⁴⁶ Australian Government Funding of Gardasil® Archived Fact Sheets: <u>http://archive.is/pm19</u>

⁴⁷ See for example Haas, Marion. **Government response to PBAC recommendations**. Health Policy Monitor, March 2007: <u>http://hpm.org/en/Surveys/CHERE_-_Australia/09/Government_response_to_PBAC_recommendations.html</u> which I discuss further in this submission.

⁴⁸ See for example **Schoolboys to get Gardasil vaccine**, Brisbanetimes, 12 July 2012:

http://www.brisbanetimes.com.au/queensland/schoolboys-to-get-gardasil-vaccine-20120712-21xqg.html This article notes "The Queensland scientist who created the cervical cancer vaccine has hailed the decision to fund immunization for boys". The article does not disclose Professor Frazer's conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in developed countries.

⁴⁹ Message of Support from Professor Ian Frazer AC (creator of the HPV Vaccine) Funding of national HPV vaccine program for boys. 12 July 2012. This letter does not acknowledge Professor Frazer's conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in developed countries. This letter was published on the Department of Health and Ageing website, but I have not been able to access it online recently. I have a hard copy.

⁵⁰ "Ian Frazer as co-inventor of the technology enabling the HPV vaccines receives royalties from their sale in the developed world." This information was included in a disclosure statement on Ian Frazer's article **Catch cancer? I'd rather have a shot!**, published on research sector and government funded website The Conversation, 10 July 2012. I suspect that this disclosure was not made in mainstream news articles at the time, see for example: **Schoolboys to get Gardasil vaccine**, Brisbanetimes, 12 July 2012: <u>http://www.brisbanetimes.com.au/queensland/schoolboys-to-get-gardasil-vaccine-20120712-21xqg.html</u> This article notes "The Queensland scientist who created the cervical cancer vaccine has hailed the decision to fund immunization for boys". **The article does not disclose Professor Frazer's conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in developed countries.**

⁵¹ Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012: <u>https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568</u> ⁵² Cervical cancer. Australian Government Cancer Australia: <u>http://canceraustralia.gov.au/affected-cancer/cancer-types/gynaecological-cancers/cervical-cancer</u>

⁵⁴ "There are more than 100 HPV types, GARDASIL will not protect against all types." and "Continue to follow your doctor or health care provider's instructions on regular Pap test." GARDASIL® [Quadrivalent HPV (Types 6, 11, 16, 18) Recombinant Vaccine] Consumer Medicine Information: <u>https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-CMI-05715-3</u>

⁵⁵ Cervical screening is scheduled to change in May 2017 when *"The renewed National Cervical Screening Program will invite women aged 25 to 74 years, both HPV vaccinated and unvaccinated, to undertake an HPV test every 5 years."* http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/future-changes-cervical

⁵⁶ For example a review of HPV vaccination by members of a 'pro-vaccine' lobby group, SAVN, fails to consider the possible bias of industry associated studies included in the review. See David Hawkes, Candice E Lea, Matthew J Berryman. <u>Answering</u> <u>human papillomavirus vaccine concerns; a matter of science and time</u>. Infectious Agents and Cancer 2013, 8:22 I forwarded <u>a</u> <u>letter challenging this review</u> to the editors of the journal, including noting that the authors did not list their membership of a provaccine lobby group (SAVN) as a 'competing interest'. Industry-funded studies are referred to in <u>Hawkes et al's review</u>, see for example Ref. 2: Future II Study Group 2007 was "designed, managed, and analysed by Merck...". Ref. 3: Harper DM et al 2004 was "conceived jointly by GlaxoSmithKline Biologicals and consultants, some of whom also served as investigators. GlaxoSmithKline Biologicals funded and coordinated this study." Ref. 4: Villa LL et al 2006 "The studies were designed by the sponsor (Merck and Co, Inc) in collaboration with clinical site investigators. The sponsor collected the data, monitored the conduct of the study, performed the statistical analysis and coordinated the writing of the manuscript with all authors." Etc, etc... There are also other conflicts in regards to U.S. government-owned HPV vaccine patents, see Ref. 5: Herrero R et al 2011 "D.R. Lowy and J.T. Schiller are named inventors on U.S. government-owned HPV vaccine patents that are licensed to GSK and Merck, and so are entitled to limited royalties as specified by federal law." In short there are many potential conflicts of interest to consider in the studies 'reviewed' by Hawkes et al, including authors' associations with vaccine manufacturers via employment, research funding, consulting fees, advisory board memberships, honorariums etc.

⁵⁷ Melanie Drolet et al. Population-level impact and herd effects following human papillomavirus vaccination programmes: a systematic review and meta-analysis. The Lancet Infectious Diseases. Vol. 15, No. 5, p565-580, May 2015: http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2814%2971073-4/fulltext It is notable that this systematic review and meta-analysis is behind the paywall of The Lancet Infectious Diseases, i.e. it can be purchased for \$31.50 USD. I suggest it is highly problematic that papers which promote the use of vaccine products are not open access, i.e. easily accessible for public perusal. There's also commentary in The Lancet Infectious Diseases on this review: "Greatest effect of HPV vaccination from school-based programmes". Again, it's behind the paywall.... For interested citizens who do not have the privilege of institutional access, this will mean a time-consuming visit to a university library to try and access the paper there, or another \$31.50 USD for the coffers of The Lancet Infectious Diseases. One of the authors of this review is Julia Brotherton. This person has been involved in the promotion of HPV vaccination in Australia for some years, at least since 2003. See for example: Planning for human papillomavirus vaccines in Australia. Report of a research group meeting. CDI Vol 28 No. 2 2004. In the acknowledgements of this report published in 2004 it is noted: "We would like to thank CSL Pharmaceuticals and GlaxoSmithKline for their support in facilitating this meeting ... "Julia Brotherton, and the other author of the report, Peter McIntyre, currently an ex officio member of the Australian Technical Advisory Group on Immunisation, are part of the 'vaccination clique' in Australia, and have been associated with CSL and GSK for some time. It really concerns me that people such as Julia Brotherton, who have associations with 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. Personally, I have no confidence in their objectivity on this matter. I've also become very cynical about the often industry-associated 'peer-reviewed literature'. Even The Lancet's editor, Richard Horton, has confessed that: "Journals have devolved into information laundering operations for the pharmaceutical industry." (As quoted in Richard Smith's essay Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies, PLOS Medicine 17 May 2005.)

⁵⁸ As noted in this HPV Today Conflict of Interest Statement: <u>http://www.hpvtoday.com/revista2829/20-conflict-of-interest.html</u>
 ⁵⁹ Julia 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:

http://www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-2004-cdi2802-htm-cdi2802p.htm

⁶⁰ Peter McIntyre is an Ex-officio member of the Australian Technical Advisory Group on Immunisation (ATAGI):

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/atagi

⁶¹ Australian Technical Group on Immunisation – Conflict of Interest document:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/FC7BB2DC63225F8ACA257D770012DBF7/\$File/2 015-ATAGI-conflict-interest.pdf

⁶² Peter McIntyre is Director of the National Centre for Immunisation Research & Surveillance: <u>http://www.ncirs.edu.au/about-us/our-staff/executive/</u>

⁶³ The Science of Immunisation: Questions and Answers: <u>https://www.science.org.au/sites/default/files/user-</u> content/documents/immunisation-Ir.pdf

⁶⁴ NCIRS Evaluation of the National Human Papillomavirus Vaccination Program. Final Report. 28 August 2014: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/evaluation-of-NHPVP

⁶⁵ Charlotte Haug. We need to talk about HPV vaccination – seriously. New Scientist, 16 September 2011:

https://www.newscientist.com/article/dn20928-we-need-to-talk-about-hpv-vaccination--seriously/?full=true#.VWATevmqqko 66 Charlotte J Haug. Human Papillomavirus Vaccination – Reasons for Caution. Editorial. The New England Journal of Medicine 359;8, August 21, 2008.

⁶⁷ Charlotte Haug. The Risks and Benefits of HPV Vaccination. JAMA, August 19, 2009 – Vol 302, No. 7.

⁵³ About the human papillomavirus. National Cervical Screening Program. Australian Government Department of Health: http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/about-the-human-papillomavirus

⁶⁸ Cochrane's 'About us' webpage notes: *"Who are we? We are a global independent network of researchers, professionals, patients, carers, and people interested in health. Cochrane contributors from more than 130 countries work together to produce credible, accessible health information that is free from commercial sponsorship and other conflicts of interest. Many of our contributors are world leaders in their fields – medicine, health policy, research methodology, or consumer advocacy – and our groups are situated in some of the world's most respected academic and medical institutions...Our work is recognized as representing an international gold standard for high quality, trusted information." http://www.cochrane.org/about-us*

⁶⁹ Just how safe is the cervical cancer jab? More and more families say their daughters suffered devastating side-effects from the HPV vaccine and experts are worried too. UK Daily Mail, 2/3 June 2015: <u>http://www.dailymail.co.uk/health/article-3106372/Just-safe-cervical-cancer-jab-families-say-daughters-suffered-devastating-effects-HPV-vaccine-experts-worried-too.html</u> ⁷⁰ *Ihid*.

⁷¹ A Danish program accessible on Youtube reports stories of girls suffering after HPV vaccination:

https://www.youtube.com/watch?v=GO2i-r39hok

⁷² Hundreds of teenage girls in Colombia struck by mystery illness. Global News, 27 August 2014:

http://globalnews.ca/news/1530883/hundreds-of-teenage-girls-in-colombia-struck-by-mystery-illness/

⁷³ Side effects in young girls take Gardasil out from Japanese market. The Tokyo Times: <u>http://www.tokyotimes.com/side-effects-in-young-girls-take-gardasil-out-from-japanese-market/</u>

⁷⁴ Was the HPV Vaccine Responsible for One Girl's Death? Footage from a show with Katie Couric accessible on Youtube: https://www.youtube.com/watch?v=LNoLeu01w3Y

⁷⁵ A story titled **A wonder drug's dark side** was taken down from the Toronto Star website after pressure from the medical establishment, as detailed in this note from the publisher: <u>http://www.thestar.com/news/2015/02/20/a-note-from-the-publisher.html</u>
⁷⁶ Indian MPs criticize HPV vaccination project for ethical violations. BMJ 2013;347:f5492: http://www.bmj.com/content/347/bmj.f5492

⁷⁷ "Adverse event 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." About the DAEN – Reporting levels: http://www.tga.gov.au/about-daen-medicines#.UvglSfmSz-t

⁷⁸ Deirdre Therese Little and Harvey Rodrick Grenville Ward. Adolescent Premature Ovarian Insufficiency Following Human Papillomavirus Vaccination: A Case Series Seen in General Practice. Journal of Investigative Medicine High Impact Case Reports. 2014 2: <u>http://hic.sagepub.com/content/2/4/2324709614556129</u>

⁷⁹ Howard rescues Gardasil from Abbott poison pill. The Australian, 11 November 2006: <u>http://www.theaustralian.com.au/archive/business/howard-rescues-gardasil-from-abbott-poison-pill/story-e6frg9lx-111112503504</u>

⁸⁰ Haas, Marion. **Government response to PBAC recommendations. Health Policy Monitor**, March 2007: <u>http://hpm.org/en/Surveys/CHERE - Australia/09/Government response to PBAC recommendations.html</u>

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⁸² Marion Haas et al. Drugs, sex, money and power: An HPV vaccine case study. Health Policy 92 (2009) 288-295.

⁸³ Elizabeth Ellen Roughead et al. The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy. Health Policy 88 (2008) 250-257

⁸⁴ "Australia was the first country to implement a fully funded National HPV Vaccination Program which commenced from April 2007." NCIRS Evaluation of the National Human Papillomavirus Vaccination Program. Final Report. 28 August 2014: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/evaluation-of-NHPVP

⁸⁵ In FierceVaccines report on the Top 10 best selling vaccines of 2013, Gardasil was second with worldwide sales of \$2.167 billion: <u>http://www.fiercevaccines.com/story/top-10-best-selling-vaccines-2013/2014-05-29</u> FierceVaccines report on the 20 Topselling Vaccines – H1 2012 states that H1 2012 sales for Gardasil (Merck) were \$608 million, and sales for Cervarix

(GlaxoSmithKline) were \$285 million: <u>http://www.fiercevaccines.com/special-report/20-top-selling-vaccines/2012-09-25</u> ⁸⁶ Catch cancer? No thanks, I'd rather have a shot! The Conversation, 10 July 2012: <u>https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568</u> The disclosure statement on this article by Ian Frazer states: *"Ian Frazer as co-inventor of the technology enabling the HPV vaccines receives royalties from their sale in the developed world,"*

⁸⁷ CSL ups profit guidance on Gardasil sales. The Australian, 27 November 2012. Also see CSL Limited ASX Half-year Information 31 December 2014: <u>http://www.asx.com.au/asxpdf/20150211/pdf/42wjd3tg1ckr2w.pdf</u> and CSL takes the fight to the flu, 3 November 2014: <u>http://www.stocksinvalue.com.au/csl-takes-fight-flu/</u> *"CSL IP revenue (2% revenue) generated revenues of \$US100 million, up 8% on the pcp (cct). The increase was driven by royalty contributions from human papillomavirus vaccine intellectual property..."*

⁸⁸ For example Australia has been a leader in implementing HPV vaccination for boys and girls. HPV vaccination is now being implemented around the world. See Section 2 of this letter re my challenge to HPV vaccination.

⁸⁹ 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: <u>https://www.nhmrc.gov.au/guidelines/publications/r39</u>
 ⁹⁰ Australian Technical Advisory Group on Immunisation (ATAGI):

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/advisory-bodies

⁹¹ Australian Technical Group on Immunisation – Conflict of Interest document:

http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/FC7BB2DC63225F8ACA257D770012DBF7/\$File/2 015-ATAGI-conflict-interest.pdf

⁹² 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: <u>http://over-vaccination.net/letters-challenging-over-vaccination/letter-to-australian-prime-minister-re-vaccination-policy-in-australia/</u>

⁹³ Advisory Committee on the Safety of Vaccines (ACSOV): <u>https://www.tga.gov.au/committee/advisory-committee-safety-vaccines-acsov</u>

⁹⁴ Pharmaceutical Benefits Advisory Committee (PBAC): <u>http://www.pbs.gov.au/info/industry/listing/participants/pbac</u>

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⁹⁵ Australian Influenza Vaccine Committee (AIVC): <u>https://www.tga.gov.au/committee/australian-influenza-vaccine-committee-aivc</u>
 ⁹⁶ A record of my correspondence with The Australian Academy of Science is accessible on my website: <u>http://over-vaccination/australian-academy-of-science/</u>

vaccination.net/letters-challenging-over-vaccination/australian-academy-of-science/ ⁹⁷ Australian Academy of Science – The Science of immunisation: <u>https://www.science.org.au/immunisation</u>

⁹⁸ I have also forwarded correspondence on this matter to other political representatives, i.e. Scott Morrison (former Minister for Social Services), George Brandis (Attorney General), Sussan Ley (Minister for Health), Bill Shorten (Leader of the Opposition), Mark Dreyfus (Shadow Attorney General), Jenny Macklin (Shadow Minister for Families and Payments), Catherine King (Shadow Minister for Health), Kate Ellis (Shadow Minister for Early Childhood), and Richard Di Natale (Leader, Australian Greens).