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An open letter to: 4 November 2015

Senator Paschal Mooney Seanad Éireann

Dear Senator Mooney

I recently viewed <u>your speech</u> about young girls and women in Ireland suffering adverse events after Gardasil human papillomavirus (HPV) vaccination.¹ It is heartening to see a politician speak out so passionately for those people who are enduring health problems after the implementation of this very questionable vaccine product.

I do not agree with your concession that HPV vaccination is "a benefit, it's shown as a benefit". As yet we do not have an independent and objective review of HPV vaccination's supposed benefits, it will be decades before we know the outcome of fast-tracked universal HPV vaccination.

In the meantime, international victim support groups such as SaneVax³ provide a record of young women who have suffered after HPV vaccination. Around the world negative stories about HPV vaccination continue to emerge, e.g. in Scotland⁴ ⁵, the United Kingdom⁶, Denmark⁻ ፆ, Colombiaց, Japan¹o, the United States¹¹, Canada¹², India¹³, New Zealand¹⁴ etc. When negative stories appear the medical/scientific establishment often intervenes to stifle discussion on the matter, as can be seen by the backlash against the *Toronto Star*'s report "A wonder drug's dark side", which was subsequently censored¹⁵, and attacks on US journalist and TV host Katie Couric, who presented personal stories from mothers who claim their daughters suffered serious harm after HPV vaccination (one girl died)¹⁶.

As you know Senator Mooney, in Ireland the R.E.G.R.E.T. support group has been set up by parents of Irish teenage girls who have developed serious health problems after Gardasil HPV vaccination. This group is trying to get help for their daughters and raise awareness of the safety issues surrounding HPV vaccination. The group feels the information provided by Ireland's health services (the HSE) is incomplete and biased, downplaying the safety issues while exaggerating the HPV vaccine's effectiveness. This group has had some attention in the Irish media, for example the articles "HPV vaccine support group concerned at side-effects" and "Concerns over cervical cancer vaccine in Ireland".

A member of R.E.G.R.E.T., nurse Fiona Kirby, claims her daughter suffered "horrendous adverse effects" after being vaccinated with the Gardasil HPV vaccine and now needs permanent care. **Ms Kirby has initiated legal action** against the use of the Gardasil HPV vaccine in Ireland, as reported in *The Irish Times* on 2 November 2015²⁰.

Senator Mooney, Australia was the first country to implement a funded national HPV vaccination program with Gardasil added to the National Immunisation Program from April 2007²¹. The implementation of HPV vaccination in Australia occurred in very dubious circumstances, with political interference in the approval process for this vaccine product.²² This provides an illuminating case study of the way politicians are manipulated into implementing taxpayer funded medical interventions of questionable value.

Subsequent to the fast-tracked implementation of HPV vaccination in Australia, in a domino effect, HPV vaccination has been rolled out around the world, with many millions of children being vaccinated with this still experimental vaccine product.

HPV vaccination of all adolescents is now set to become compulsory in Australia to access financial inducements, if the Australian Federal Government's controversial No Jab, No Pay Bill is passed by the Senate.²³ The No Jab, No Pay Bill contravenes the obligation for 'valid consent' before vaccination.²⁴ The Australian Federal Government is currently being challenged by many concerned citizens about the impact of this Bill on human rights.²⁵ ²⁶

HPV vaccination is seen as an Australian 'success story', with the co-inventor of the technology enabling the HPV vaccines, Ian Frazer, being named 'Australian of the Year' in 2006²⁷. At that time many people, including politicians, were swept away by the idea of what was then misleadingly described as a 'cervical cancer vaccine'²⁸. **The long-term uncertainties about the effectiveness and safety of this vaccine product were not properly considered by decision-makers.**

Gardasil HPV vaccination was originally rejected for addition to the Australian National Immunisation Program Schedule by the Pharmaceutical Benefits Advisory Committee (PBAC) in 2006²⁹, a decision that was overturned within 24 hours 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.³⁰ 31

In July 2012 then Labor Federal Health Minister Tanya Plibersek oversaw implementation of Gardasil vaccination for boys with enthusiastic public support from Ian Frazer.³² In his official message of support for the funding of the national HPV vaccine program for boys³³, Ian Frazer failed to declare his conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in the developed world.³⁴

The basis for mass vaccination with the Gardasil HPV vaccine to prevent cancers such as cervical cancer is highly questionable. I suggest Gardasil HPV vaccination should *not* be on the taxpayer funded schedule, and that the fast-tracked implementation of this still experimental vaccine product in 2006/2007 should be subject to an investigation.

A report evaluating HPV vaccination in Australia acknowledges that: "Australia has one of the lowest rates of incidence and mortality from cervical cancer in the world.³⁵ In 2008, there were 9 cases of cervical cancer per 100,000 women of all ages, and in 2007, the age-standardised mortality rate from cervical cancer was 2 deaths per 100,000.³⁶ These are the lowest rates observed to date. Cervical cancer in Australia now occurs predominantly in unscreened or under-screened women."³⁷

Gardasil Consumer Medicine Information approved by the Therapeutic Goods Administration (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.³⁸ (Cervical screening is scheduled to change to 5-yearly HPV testing from May 2017.³⁹) The implementation of HPV vaccination may give young women the false impression they are fully protected by this vaccine, which may lead to a fall in appropriate screening.

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".⁴⁰

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. While the NCSP says: "Infections can cause cervical abnormalities, which, if they persist, can lead to cervical cancer" the NCSP 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."⁴¹

Even HPV vaccine entrepreneur lan Frazer admits the risk of cancer associated with HPV is very low, saying: "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." (My emphasis.) (Ian Frazer made this statement in his article promoting HPV vaccination, i.e. Catch cancer? No thanks, I'd rather have a shot!, published on the Australian government and university and CSIRO-funded The Conversation website in July 2012, 42 at the time Gardasil HPV vaccination was being introduced for boys in Australia⁴³.)

lan Frazer admits only "a few individuals accumulate enough genetic mistakes in the virus-infected cell for these to acquire the properties of cancer cells".

Given the admitted low risk associated with HPV and cancer, I question whether it is justifiable to compel children to have HPV vaccination.

In the same article Ian Frazer states cervical cancer "kills over 250,000 women world wide every year".⁴⁴ No evidence is provided by Ian Frazer to support this statement. In Australia an estimated 245 deaths were attributed to cancer of the cervix for the year 2014.⁴⁵ As stated previously, the risk of cervical cancer has been steadily decreasing in Australia since 1991⁴⁶. Between 1982 and 2014 cervical cancer was one of the cancers showing the greatest percentage-point decrease in incidence, from 14.2 to 7.0 per 100,000⁴⁷. In the same period, the age standardised mortality rate of cervical cancer decreased from 5.2 to 1.8 per 100,000.⁴⁸ Cervical cancer is listed as 19th on a list of the estimated 20 most common causes of death from cancers for females in 2010⁴⁹ and 2014⁵⁰.

In his promotional article for HPV vaccination, Ian Frazer says "we need to make sure it's used globally, **to prevent this second most common cause of cancer death in women**"⁵¹. (My emphasis.) Again, no evidence is provided by Ian Frazer to support his statement that cancer is the "**second most common cause of cancer death in women**". I question Ian Frazer's use of alarming statistics in his article **as it appears cervical cancer is 19**th **on the list of deaths from cancer** for women in Australia⁵².

Claims about the global prevalence of cervical cancer are being challenged. For example Allyson Pollock and colleagues examined a series of claims made by international health charity PATH about cervical cancer in India, among them that "in raw numbers, India has the largest burden of cancer of the cervix of any country worldwide".⁵³

Allyson Pollock explains: "The aim of our study was to look at whether data on cervical cancer in (India) justify the introduction of HPV vaccination...We found that current data on cervical cancer incidence do not support PATH's claim that India has a large burden of cervical cancer...Neither the epidemiological evidence nor current cancer surveillance systems justify the general roll out of an HPV vaccination programme in India or in the two states where PATH was conducting its research...It's important to compare the burden of cervical cancer in India to other major health concerns, such as primary care, malaria, maternal anaemia and malnutrition, and consider best use of financial resources...HPV vaccine which is among the most expensive vaccines on the market is not justified as a health care priority for India." (My emphasis.)

In his article promoting HPV vaccination, Ian Frazer also infers that the implementation of HPV vaccination will unequivocally prevent death from cervical cancer.⁵⁵ The public is being seduced by exaggerations of the effectiveness of HPV vaccination. For example Ian Frazer is credited as being "The man who saved a million lives".⁵⁶ In fact there is no evidence that Ian Frazer has saved any lives, it will take decades to know the outcome of universal fast-tracked HPV vaccination⁵⁷ and this will require independent and objective observation, which is not evident at the current time.

In the meantime, international victim support groups such as SaneVax⁵⁸ are now providing a record of young women who have suffered after HPV vaccination. Around the world negative stories about HPV vaccination continue to emerge, e.g. in Scotland⁵⁹ ⁶⁰, the United Kingdom⁶¹, Denmark⁶² ⁶³, Colombia⁶⁴, Japan⁶⁵, the United States⁶⁶, Canada⁶⁷, India⁶⁸, New Zealand⁶⁹, as well as Ireland⁷⁰ ⁷¹ ⁷² etc. (In Australia there is little or no media coverage of the worldwide controversy about HPV vaccination. The Murdoch Media has been running a campaign for compulsory vaccination in Australia in its tabloid newspapers, i.e. the 'No Jab, No Play' campaign.⁷³ This aggressive tabloid campaign for compulsory vaccination has now been adopted by the Australian Federal Government as vaccination policy with the No Jab, No Pay Bill⁷⁴.)

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 2015.⁷⁵

In regards to side effects/adverse events associated with medicines and vaccines, the TGA notes: "It is generally acknowledged that adverse event reports are under-reported around the world, with estimates that 90-95% of adverse events are not reported to regulators." So there may be many more people adversely affected after HPV vaccination than is currently recognised.

As you said in your recent speech Senator Mooney: "And there are many more out there, parents who probably think their daughter is unique, and yet they are part of this growing pattern."

GP Deirdre Little has reported three cases of premature ovarian insufficiency after Gardasil HPV vaccination. In her paper on this matter Deirdre Little notes: "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..." 78

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.** 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 type-replacement." (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.⁸¹ Julia Brotherton is an author of **Planning for human papillomavirus vaccines in Australia: Report of a research group meeting**, published in June 2004.⁸² In the acknowledgements of this report it is noted: "We would like to thank CSL Pharmaceuticals and GlaxoSmithKline for their support in facilitating this meeting..." This report was co-authored with Peter McIntyre, who is currently an ex-officio member of the Australian Technical Advisory Group on Immunisation (ATAGI).⁸³ The ATAGI Conflict of Interest document notes Peter McIntyre has been associated with grant funding from GSK, Pfizer, Novartis, Sanofi, bioCSL, Baxter, Merck, Janssen & Janssen (Crucell), NHMRC, ARC etc.⁸⁴ Peter McIntyre is Director of the National Centre for Immunisation Research & Surveillance (NCIRS)⁸⁵. Peter 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.⁸⁶ Peter McIntyre was also involved in co-ordinating the Evaluation of the National Human Papillomavirus Vaccination Program – Final Report.⁸⁷ Peter 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. Personally I have no confidence in their objectivity on this matter. I've also become very cynical about the often industry-associated 'peerreviewed literature'. Even The Lancet's editor, Richard Horton, has confessed that: "Journals have devolved into information laundering operations for the pharmaceutical industry." 88

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.

A recent article in the UK media about girls suffering adverse experiences after HPV vaccination, includes negative comments about HPV vaccination from British epidemiologist Tom Jefferson, a global authority on vaccine trial evidence associated with The Cochrane Collaboration. In the article Tom 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 antivaccine extremist. The authorities do not want to hear 'side-effect'". (I suggest Tom Jefferson's comments are relevant to both the Gardasil and Cervarix HPV vaccines.)

The article notes Tom 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". 91

In regards to the possibility of type/strain-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?" 92

Also refer to other articles by Charlotte Haug questioning HPV vaccination, i.e. **Human Papillomavirus Vaccination** – **Reasons for Caution**⁹³ and **The Risks and Benefits of HPV Vaccination**⁹⁴

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 they are being used as guinea pigs for this still experimental vaccine product. 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/strain-replacement with the use of HPV vaccines, and the implications this may have. The long-term consequences of this vaccine product are unknown and yet this vaccine will be compulsory for all adolescents in Australia to access government financial benefits if the No Jab, No Pay Bill is passed.

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) "on the basis of uncertainty about duration of effect and unfavourable cost effectiveness" A media release issued by Tony Abbott's office at the time states: "(PBAC) has not recommended the human papillomavirus vaccine (HPV), marketed by CSL as GARDASIL® for listing on the National Immunisation Program at this time....PBAC has advised that there was a lack of information in CSL's application on how long the vaccine remains effective, whether a booster would be needed and if so, how to determine the right target group for the follow up. The PBAC was also not provided with enough information on the long term effects of the vaccine on the incidence of cervical cancer. The PBAC also found that it is not cost effective for taxpayers at this time to fund GARDASIL® on the National Immunisation Program at the price proposed by CSL..." (My emphasis.)

In their paper The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy, Elizabeth Roughead et al note: "Within the first 24h of the decision (to not recommend Gardasil) becoming public it was condemned by the leader of the opposition, the opposition health spokesperson, 22 women senators of both parties and the Queensland government. All called on the government to intervene. "Federal opposition health spokeswoman Julia Gillard said a Labor government would overturn a decision" PRAC would reverse its decision" The Queensland deputy premier said "frankly the Health Minister Tony Abbott, in all conscience has to intervene" In what would appear to be an unprecedented move, the Queensland government published a full-page advertisement in the Sunday Mail, which was "an open letter to Mr Howard seeking a commitment to include the vaccine in the National Immunisation Scheme as soon as possible 100. The group of 22 female senators also wrote to Mr Abbott, asking him to "intervene" on the PBAC's decision." (My emphasis.)

Roughead et al also note **"Experts, who were not necessarily independent, also disputed the PBAC decision.** Dr Gerry Wain, who was usually cited as Westmead Hospital gynaecology director or NSW cervical screening program scientific director, **but rarely acknowledged as the chair of CSL's Gardasil® advisory board,** said "They clearly don't value the lives and health of Australian women, especially young, poor women who can't afford to buy it but need it most". ¹⁰² (My emphasis.)

Commenting on the 22 female senators who interfered and helped overturn the PBAC's approval processes in regards to Gardasil HPV vaccination, Julie Rowbotham, the Sydney Morning Herald's Medical Editor at the time, said: "The senators want Gardasil hurried onto a national program on the grounds that you can't put a price on someone's life. But if they succeed in bending the cost-effectiveness rules, they will effectively be setting the lives of women who develop cervical cancer above those of people who happen to be afflicted by different fatal diseases and miserable illnesses. That is offensive." 103

Rowbotham also noted: "The advisory committee's concern that booster shots may be needed in future is not a trivial quibble. Duration of protection is a critical issue when the aim is to achieve lasting human papillomavirus immunity and it is central in determining a reasonable price for the vaccine now." 104

The concern about the need for 'booster' shots is an important consideration. The current example of the apparently defective acellular pertussis (whooping cough) vaccine, which may actually be causing new strains of the disease to develop¹⁰⁵, and spreading the disease via vaccinated individuals¹⁰⁶, and the inexplicable recommendations for repeated 'boosters' throughout life¹⁰⁷ with this defective vaccine, also raises the alarm about the future of still experimental HPV vaccination. The recently published research which indicates some vaccines might support the evolution of more virulent viruses¹⁰⁸, and the reported early waning of maternal antibodies in infants born to measles-vaccinated mothers¹⁰⁹ also give food for thought for those capable of thinking about the 'big picture'.

There is much that is unknown about the long-term effects of vaccination, hence we should exercise caution in implementing new vaccine products for diseases which pose little serious risk for the majority of the population, and which take away health funding from other more effective health strategies. (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 superbugs¹¹⁰. Are there any *independent and objective* academics in the area of infectious diseases capable of considering this possibility, or are all the academics in this area too busy carrying out clinical trials of vaccine products for vaccine manufacturers?)

After the PBAC's initial rejection of Gardasil, and subsequent lobbying by advocates for the vaccine, including senators and other politicians, and vested interests, it took just 24 hours for then Prime Minister John Howard to intervene and 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." 111

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".¹¹²

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."113

Marion Haas et al provide further analysis in their paper **Drugs, sex, money and power: An HPV vaccine case study**. Their analysis of HPV vaccination implementation in seven industrialised countries, including Australia, shows that these countries "approved the vaccine and established related immunization programs exceptionally quickly even though there still exist many uncertainties as to the vaccine's long-term effectiveness, cost-effectiveness and safety" and that "some countries even bypassed established decision-making processes". Haas et al also note the voice of special interest groups was prominent in all countries, "drawing on societal values and fears of the public". 114

Haas et al warn: "It is important that decision-makers adhere to transparent and robust guidelines in making funding decisions in the future to avoid capture by vested interests and potentially negative effects on access and equity." (My emphasis.)

After the Australian Government's interference in this matter, other countries adopted HPV vaccination¹¹⁶, resulting in billions of dollars' worth of sales for the makers of the HPV vaccines, i.e. Merck (Gardasil) and GlaxoSmithKline (Cervarix)¹¹⁷, and royalties for entrepreneurial scientist lan Frazer from sales of HPV vaccines in developed countries¹¹⁸, and for CSL which receives royalties from sales of Gardasil¹¹⁹.

I suggest former Prime Minister John Howard made a very big blunder when he submitted to the lobbying of senators, other politicians and vested interests, and overturned the PBAC's initial rejection of the Gardasil HPV vaccine in 2006. The questionable fast-tracking of still experimental Gardasil HPV vaccination in Australia and around the world is a very illuminating case study of the way politicians are manipulated into implementing taxpayer funded medical interventions of questionable value. This is particularly alarming when such questionable medical interventions are being made compulsory via the Australian Federal Government's No Jab, No Pay Bill.

The addition of the Gardasil HPV vaccine to the Australian taxpayer funded national vaccination schedule is highly controversial 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. In my submission to the Senate review committee re the No Jab, No Pay Bill, I have requested an urgent review of industry and politically motivated Gardasil HPV vaccination in Australia.¹²⁰

Senator Mooney, as I have demonstrated, the fast-tracked implementation of universal HPV vaccination is highly questionable. Citizens in Ireland need to be informed of the controversial historical background on this matter.

Yours sincerely

Elizabeth Hart

http://over-vaccination.net/

<u>Postscript</u>: On the subject of questionable vaccine implementation, it appears the Bexsero meningococcal B vaccine is shaping up to be the next Gardasil. Despite the fact the vaccine for this rare disease¹²¹ has been rejected <u>three</u> times by the Pharmaceutical Benefits Advisory Committee (PBAC) ¹²², members of the powerful vaccination clique' in Australia continue to agitate for this vaccine to be added to the schedule.¹²³ The Bexsero meningococcal B vaccine, which is now owned by GlaxoSmithKline¹²⁴, has been forced onto the NHS vaccination schedule in the UK recently after a similar process of initial rejection by the Joint Committee on Vaccination and Immunisation, and subsequent publicity and strong lobbying of MPs to overrule the decision.¹²⁵)

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- ³ SaneVax: http://sanevax.org/
- ⁴ See MSPs To Consider Safety Of HPV Vaccine. Heart 100-103, 27 October, 2015:

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⁵ Freda Birrell's presentation to the Scottish Petitions Committee on the subject of HPV vaccination safety is accessible on the SaneVax website: http://sanevax.org/hpv-vaccines-freda-birrell-addresses-petitions-committee/

⁶ Thousands of teenage girls report feeling seriously ill after routine school cancer vaccination. The Independent, 15 July 2015: http://www.independent.co.uk/life-style/health-and-families/thousands-of-teenage-girls-report-feeling-seriously-ill-after-routine-school-cancer-vaccination-10286876.html and 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: 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

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¹⁰ Side effects in young girls take Gardasil out from Japanese market. The Tokyo Times: http://www.tokyotimes.com/side-effects-in-young-girls-take-gardasil-out-from-japanese-market/

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¹² 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: http://www.thestar.com/news/2015/02/20/a-note-from-the-publisher.html
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14 See Gardasil Awareness NZ: http://www.ga-nz.com/#!victims/cl15

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²² See 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:

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²⁴ 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~handbook10-part2~handbook10-2-1

²⁵ Submissions are being published on the Australian Government website:

http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/No_Jab_No_Pay/Submissions_Due to the large volume of submissions received it appears all submissions will not be published on this website. This raises problems in regards to transparency and accountability. At this stage it is not clear what criteria is being used to discount submissions from individuals.

- ²⁶ I have made a submission challenging the No Jab, No Pay Bill. At this time my submission has not been published on the Australian Government website. I have published my submission on the internet and it can be accessed via this link: http://bit.ly/1GdTXAt and also on my website: http://over-vaccination.net/
- ²⁷ Ian Frazer Australian of the Year 2006: http://www.australianoftheyear.org.au/honour-roll/?view=fullView&recipientID=109
- ²⁸ For example, the Australian of the Year website describes Ian Frazer as the inventor of the 'Cervical Cancer Vaccine': http://www.australianoftheyear.org.au/honour-roll/?view=fullView&recipientID=109
- ²⁹ Australian Government Funding of Gardasil® Archived Fact Sheets: http://archive.is/pm19
- ³⁰ See for example Haas, Marion. **Government response to PBAC recommendations**. Health Policy Monitor, March 2007: http://hpm.org/en/Surveys/CHERE Australia/09/Government_response_to_PBAC_recommendations.html which I discuss further in this submission.
- ³¹ Significant events in human papillomavirus (HPV) vaccination practice in Australia. NCIRS Fact Sheet: http://www.ncirs.edu.au/assets/provider_resources/history/Human-papillomavirus-history-July-2015.pdf

³² See for example **Schoolboys to get Gardasil vaccine**. Brisbane Times, 12 July 2012:

http://www.brisbanetimes.com.au/queensland/schoolboys-to-get-gardasil-vaccine-20120712-21xgg.html

- ³³ 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 Ian 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.
- ³⁴ "lan 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 lan 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: 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 lan Frazer's conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in developed countries.
- ³⁵ International Agency for Research on Cancer. CANCERMondial. 2012. (Accessed 11 July 2012). As quoted in 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
- ³⁶ Australian Institute of Health and Welfare (AIHW). Cervical screening in Australia 2009-2010. Cancer series no. 67. Cat. no. CAN 63. Canberra: AIHW; 2012. As quoted in 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
 37 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
- ³⁸ "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: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-CMI-05715-3
- ³⁹ 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

- ⁴⁰ Cervical cancer. Australian Government Cancer Australia: http://canceraustralia.gov.au/affected-cancer/cancer-types/gynaecological-cancers/cervical-cancer
- ⁴¹ 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
- ⁴² Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012:

https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568

- ⁴³ Schoolboys to get Gardsasil vaccine. Brisbane Times, 12 July 2012: http://www.brisbanetimes.com.au/queensland/schoolboys-to-get-gardasil-vaccine-20120712-21xgg.html
- ⁴⁴ Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012:

https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568

- ⁴⁵ See page xiii, Estimated mortality from cancer in 2014. Cancer in Australia: An overview 2014: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550202
- ⁴⁶ See Cervical cancer. Australian Government Cancer Australia: <a href="http://canceraustralia.gov.au/affected-cancer/cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecological-cancers/cervical-cancer-types/gynaecologi
- ⁴⁷ See page 20, Cancer in Australia: An overview 2014: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550202
- ⁴⁸ See page 52, Cancer in Australia: An overview 2014: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550202
- ⁴⁹ See page xi, Mortality from cancer in 2010. Cancer in Australia: An overview 2012. Australian Institute of Health and Welfare: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129542353
- ⁵⁰ See page xiii, Estimated mortality from cancer in 2014. Cancer in Australia: An overview 2014: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550202
- ⁵¹ Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012: https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568
- ⁵² See page xi, Mortality from cancer in 2010. Cancer in Australia: An overview 2012. Australian Institute of Health and Welfare: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129542353 and page xiii, Estimated mortality from cancer in 2014. Cancer in Australia: An overview 2014: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550202
- ⁵³ Controversial vaccine trial should never have been run in India, researchers say. Queen Mary University of London media release, 21 June 2012: http://www.qmul.ac.uk/media/news/items/smd/77823.html
 ⁵⁴ Ibid.

- ⁵⁵ Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012:
- https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568
- ⁵⁶ Madonna Kind. Ian Frazer: The man who saved a million lives: http://www.uqp.uq.edu.au/book.aspx/1265/lan%20Frazer-%20The%20man%20who%20saved%20a%20million%20lives
- ⁵⁷ HPV vaccine effect: is the glass half full or half empty? The Lancet. Vol. 377. June 18, 2011.
- 58 SaneVax: http://sanevax.org/
- ⁵⁹ See MSPs To Consider Safety Of HPV Vaccine. Heart 100-103, 27 October, 2015:
- http://www.heart.co.uk/scotland/news/local/msps-to-consider-safety-of-hpv-vaccine/#CETcKJdCvhFCHYka.97 and Campaigners: Schoolgirls should stop being given HPV vaccine until side effects are investigated. Evening Times, 28 October 2015: http://www.eveningtimes.co.uk/news/13899052.Campaigners Schoolgirls should stop being given HPV vaccine until side effects are investigated/?ref=arc and Schoolgirls should stop being given HPV vaccine until investigation into side effects, campaigner says. The Herald Scotland, 28 October 2015:
- http://www.heraldscotland.com/news/13899196.Schoolgirls_should_stop_being_given_HPV_vaccine_until_investigation_into_side_effects__campaigner_says/?ref=mr&lp=11
- ⁶⁰ Freda Birrell's presentation to the Scottish Petitions Committee on the subject of HPV vaccination safety is accessible on the SaneVax website: http://sanevax.org/hpv-vaccines-freda-birrell-addresses-petitions-committee/
- ⁶¹ Thousands of teenage girls report feeling seriously ill after routine school cancer vaccination. The Independent, 15 July 2015: http://www.independent.co.uk/life-style/health-and-families/thousands-of-teenage-girls-report-feeling-seriously-ill-after-routine-school-cancer-vaccination-10286876.html and 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: 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
- ⁶² See **Danish HPV centres flooded by ill girls**. Online Post, 1 September 2015: http://cphpost.dk/news/danish-hpv-centres-flooded-by-ill-girls.html and **Danish health authorities looking into HPV vaccines**. Online Post, 13 July 2015: http://cphpost.dk/news/danish-health-authorities-looking-into-hpv-vaccines.html
- ⁶³ A Danish program accessible on Youtube reports stories of girls suffering after HPV vaccination: https://www.youtube.com/watch?v=GO2i-r39hok
- ⁶⁴ **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/
- ⁶⁵ Side effects in young girls take Gardasil out from Japanese market. The Tokyo Times: http://www.tokyotimes.com/side-effects-in-young-girls-take-gardasil-out-from-japanese-market/
- ⁶⁶ 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
- ⁶⁷ 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: http://www.thestar.com/news/2015/02/20/a-note-from-the-publisher.html
 ⁶⁸ **Indian MPs criticize HPV vaccination project for ethical violations**. BMJ 2013;347:f5492:
 http://www.bmj.com/content/347/bmj.f5492
- 69 See Gardasil Awareness NZ: http://www.ga-nz.com/#!victims/cl15
- ⁷⁰ The REGRET group (Reactions and Effects of Gardasil Resulting in Extreme Trauma) is a support group set up by parents of Irish teenage girls who have become ill after Gardasil HPV vaccination: http://www.regret.ie/
- ⁷¹ Court told of 'horrendous adverse effects' of HPV vaccine. Fiona Kirby claims her daughter needs permanent care after receiving Gardasil. The Irish Times, 2 November 2015: http://www.irishtesaminer.com/ireland/mother-gardasil-disabled-my-child-362753.html
 November 2015: http://www.irishexaminer.com/ireland/mother-gardasil-disabled-my-child-362753.html
- ⁷² HPV vaccine support group concerned at side-effects. The Irish Times, 22 May 2015:
- http://www.irishtimes.com/news/health/hpv-vaccine-support-group-concerned-at-side-effects-1.2221556 and CASE STUDIES: Concerns over cervical cancer vaccine in Ireland. Irish Examiner, 16 July 2015: http://www.irishexaminer.com/ireland/case-studies-concerns-over-cervical-cancer-vaccine-in-ireland-342740.html
- ⁷³ See for example Anti-vaccination parents face \$15,000 welfare hit under 'No Jab' reforms. The Sunday Telegraph, 13 April 2015: http://www.dailytelegraph.com.au/news/nsw/anti-vaccination-parents-face-15000-welfare-hit-under-no-jab-reforms/story-fnpn118l-1227300073570 In this article reporter Samantha Maiden gloats about the stunning victory of "our No Jab, No Play' campaign". It is astonishing that former Prime Minister Tony Abbott responded to the Murdoch Media's crude 'No Jab, No Play' campaign, endorsing policy for government mandated vaccination without giving serious consideration to the complexity of the matter, including the lack of transparency and accountability for vaccination policy in Australia.
- ⁷⁴ The Social Services Legislation Amendment (No Jab, No Pay) Bill introduces a 2015 Budget measure that from 1 January 2016 children of all ages (i.e. up to 19 years)⁷⁴ 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. See 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
- ⁷⁵ The TGA's Database of Adverse Event Notifications (DAEN) is accessible via this link: https://www.tga.gov.au/database-adverse-event-notifications-daen
- ⁷⁶ Hazell L, Shakir SAW. <u>Under-reporting of adverse drug reactions: A systematic review Drug Saf 2006:29(5);385-396</u> as quoted on the TGA's webpage: **New web service helps consumer reporting of 'side effects'**: https://www.tga.gov.au/media-release/new-web-service-helps-consumer-reporting-side-effects
- ⁷⁷ Presentation by Senator Paschal Mooney, accessible on Youtube: https://www.youtube.com/watch?v=dmD_kG72Tik HPV vaccine October 8, 2015 Paschal Mooney.

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: http://hic.sagepub.com/content/2/4/2324709614556129

⁷⁹ 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. Answering human papillomavirus vaccine concerns; a matter of science and time. Infectious Agents and Cancer 2013, 8:22 I forwarded a letter challenging this review to the editors of the journal, including noting that the authors did not list their membership of a pro-vaccine lobby group (SAVN) as a 'competing interest'. Industry-funded studies are referred to in Hawkes et al's review, 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.

⁸⁰ 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.

⁸¹ As noted in this HPV Today Conflict of Interest Statement: http://www.hpvtoday.com/revista2829/20-conflict-of-interest.html
⁸² 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

83 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

84 Australian Technical Advisory Group on Immunisation – Conflict of Interest document: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/FC7BB2DC63225F8ACA257D770012DBF7/\$File/2015-ATAGI-conflict-interest.pdf Note that this information has only recently become publicly accessible. Publicly accessible information on potential conflicts of interest for members of vaccination committees and groups is severely lacking in Australia. In regards to the Australian Technical Advisory Group on Immunisation (ATAGI), on 26 November 2011 I asked then Federal Health Minister Nicola Roxon for details of membership of ATAGI, including their professional affiliations, and including any links with the pharmaceutical industry. While names of members of ATAGI and their affiliations were subsequently published on the Immunise Australia website, there was still no disclosure of information about potential conflicts of interest. I also raised this subject with 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 accessible, after I wrote to former Prime Minister Tony Abbott on the topic in January 2015, see this webpage for background: <a href="http://over-vaccination.net/letters-challenging-over-vaccination-policy-in-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-re-vaccination-policy-in-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-australia/letter-to-aus

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

⁸⁶ The Science of Immunisation: Questions and Answers: https://www.science.org.au/sites/default/files/user-content/documents/immunisation-lr.pdf

⁸⁷ 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

⁸⁸ As quoted in Richard Smith's essay Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies, PLOS Medicine 2005.

89 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

⁹⁰ 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: 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
⁹¹ Ibid

⁹² 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 $\underline{\text{http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2006-11/1st-time-decisions} \\$

⁹⁶ Australian Government Department of Health Ageing. Media release Tony Abbott MHR: **PBAC advice on GARDASIL**. Canberra. Australian Government Department of Health and Ageing; 2006 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

⁹⁷ AAP. Fed: Howard is hiding behind experts on cancer drug: Gillard. Sydney: Australian Associated Press, 2006 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

⁹⁸ Packham B. PM backflip on cancer vaccine. Herald Sun Melbourne, 2006:2 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

⁹⁹ AAP. Qld dep premier says fed govt Gardasil decision 'is ridiculous'. Sydney: Australian Associated Press; 2006 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

¹⁰⁰ Passmore D. PM urged to end Gardasil 'confusion'. Sunday Mail. Brisbane, 2006: 33 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

101 AAP. Gardasil vaccine won't be available before 2008 – Abbott. Sydney: Australian Associated Press; 2006 as quoted in 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912
 102 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: http://www.sciencedirect.com/science/article/pii/S0168851008000912

103 Julie Rowbotham. **Let's not get into valuing one type of patient over others**. Sydney Morning Herald. 14 November 2006: http://www.smh.com.au/news/opinion/lets-not-value-one-patient-over-others/2006/11/13/1163266478499.html?page=fullpage#contentSwap1
104 Ibid.

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, 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 Lyn Gilbert and Ruiting lan in December 2012: http://users.con.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 pro2 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-cases-new-strain-whooping-cough Also see Safarchi A et al. Pertactin negative Bordetella pertussis demonstrates higher fitness

under vaccine selection pressure in a mixed infection model. Vaccine. 2015 Oct 2. pii: S0264-410X(15)01340-7 (Epub ahead of print): http://www.ncbi.nlm.nih.gov/pubmed/26432908 and Anna M Acosta et al. Tdap Vaccine Effectiveness in Adolescents During the 2012 Washington State Pertussis Epidemic. Pediatrics April 2015:

http://pediatrics.aappublications.org/content/early/2015/04/28/peds.2014-

000000000000&nfstatusdescription=ERROR%3a+No+local+token and Bart MJ et al. Global population structure and evolution of Bordetella pertussis and their relationship with vaccination. MBio. 2014 Apr 22;5(2):

http://www.ncbi.nlm.nih.gov/pubmed/24757216 and Octavia S et al. Insight into evolution of Bordetella pertussis from comparative genomic analysis: evidence of vaccine-driven selection. Mol Biol Evol. 2011 Jan;28(1):707-15. Epub 2010 Sep 10: http://www.ncbi.nlm.nih.gov/pubmed/20833694 and Lam C et al. Selection of emergence of pertussis toxin promoter ptxP3 allele in the evolution of Bordetella pertussis. Infect Genet Evol. 2012 Mar;12(2):492-5. Epub 2012 Jan 24: http://www.ncbi.nlm.nih.gov/pubmed/22293463

¹⁰⁶ 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 Also see Martin SW et al Pertactin-negative Bordetella pertussis strains: evidence for a possible selective advantage. Clin Infect Dis. 2015 Jan 15;60(2):2223-7. Epub 2014 Oct 9: http://www.ncbi.nlm.nih.gov/pubmed/25301209 and Stacey W Martin et al. Pertactin-Negative Bordetella pertussis Strains: Evidence for a Possible Selective Advantage. Clin Infect Dis. (2015) 60 (2): 223-227. First published online: October 9, 2014: http://cid.oxfordjournals.org/content/60/2/223.long

⁹³ Charlotte J Haug. **Human Papillomavirus Vaccination – Reasons for Caution**. Editorial. The New England Journal of Medicine 359;8, August 21, 2008.

⁹⁴ Charlotte Haug. The Risks and Benefits of HPV Vaccination. JAMA, August 19, 2009 – Vol 302, No. 7.

⁹⁵ November 2006 PBAC Outcomes – 1st time decisions not to recommend:

107 In Australia children are having five vaccinations with the combination diphtheria, tetanus and acellular pertussis vaccine, i.e. primary vaccination at 2 months, 4 months and 6 months, then so-called 'boosters' at 4 years, and between 10-15 years, plus the PBAC has recently 'recommended' another 'booster' at 18 months, so this makes six vaccinations with the diphtheria, tetanus and acellular vaccine for children. And it doesn't stop there as, in an attempt to protect newborns from whooping cough, (which may cause death in babies in rare cases), pregnant women, household contacts of infants, and healthcare workers are also being urged to be revaccinated again and again with the diphtheria, tetanus and acellular pertussis vaccine, in other words lifelong revaccination. What is the point of imposing more and more so-called 'boosters' with an apparently defective vaccine which may actually be causing new strains of the disease to develop, and spreading the disease via vaccinated individuals. What sort of 'science' is this? The so-called 'vaccination experts' seem to be making this up as they go along, and using the population as guinea pigs. Certainly these repeated revaccinations must be a very lucrative profit centre for vaccine manufacturers, can we look forward to this occurring with other vaccine products too? The problems with the acellular pertussis vaccine raise important questions about "what is immunity?", "what is a vaccine preventable disease?", and "what level of disease risk justifies mass vaccination?"

108 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-vaccines-promote-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

109 Recent research (2013) which indicates mass vaccination with the MMR may be shortening the duration of protection of babies by maternal antibodies against measles is alarming. A study undertaken by Sandra Waaijenborg et al indicates infants born to measles-vaccinated mothers are likely to have lower levels of maternal antibodies at birth, and a shorter period of protection than infants of mothers who acquired measles naturally, i.e. babies of vaccinated mothers may be vulnerable to measles at an earlier age than those of mothers who have natural immunity. This is a startling discovery which has serious implications for vaccine use. See Sandra Waaijenborg et al. Waning of Maternal Antibodies Against Measles, Mumps, Rubella, and Varicella in Communities With Contrasting Vaccination Coverage. JID 2013:208 (1 July):

http://jid.oxfordjournals.org/content/early/2013/04/29/infdis.jit143.long Also see: Hayley A. Gans and Yvonne A. Maldonado. Loss of Passively Acquired Maternal Antibodies in Highly Vaccinated Populations: An Emerging Need to Define the Ontogeny of Infant Immune Responses. Editorial Commentary. JID Advance Access published 8 May 2013: http://jid.oxfordjournals.org/content/early/2013/04/29/infdis.jit144.full

110 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:

http://in.reuters.com/article/2014/07/06/uk-health-antibiotics-idINKBN0FB0AE20140706 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/health-antibiotics-idUSL6N0PD25O20140702

111 Howard rescues Gardasil from Abbott poison pill. The Australian, 11 November 2006:

http://www.theaustralian.com.au/archive/business/howard-rescues-gardasil-from-abbott-poison-pill/story-e6frg9lx-1111112503504

112 Haas, Marion. **Government response to PBAC recommendations. Health Policy Monitor**, March 2007:

http://hpm.org/en/Surveys/CHERE - Australia/09/Government response to PBAC recommendations.html

113 Ihid

Marion Haas et al. Drugs, sex, money and power: An HPV vaccine case study. Health Policy 92 (2009) 288-295:
 http://www.ncbi.nlm.nih.gov/pubmed/19505744
 Ibid.

"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

117 In FierceVaccines report on the Top 10 best selling vaccines of 2013, Gardasil was second with worldwide sales of \$2.167 billion: http://www.fiercevaccines.com/story/top-10-best-selling-vaccines-2013/2014-05-29 FierceVaccines report on the 20 Top-selling Vaccines – H1 2012 states that H1 2012 sales for Gardasil (Merck) were \$608 million, and sales for Cervarix (GlaxoSmithKline) were \$285 million: http://www.fiercevaccines.com/special-report/20-top-selling-vaccines/2012-09-25

118 Catch cancer? No thanks, I'd rather have a shot! The Conversation, 10 July 2012: https://theconversation.com/catch-cancer-no-thanks-id-rather-have-a-shot-7568 The disclosure statement on this article by lan Frazer states: "Ian Frazer as co-inventor of the technology enabling the HPV vaccines receives royalties from their sale in the developed world."

119 CSL ups profit guidance on Gardasil sales. The Australian, 27 November 2012. Also see CSL Limited ASX Half-year Information 31 December 2014: http://www.asx.com.au/asxpdf/20150211/pdf/42wjd3tg1ckr2w.pdf and CSL takes the fight to the flu, 3 November 2014: http://www.stocksinvalue.com.au/csl-takes-fight-flu/ "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..."

¹²⁰ I have published my submission on the internet and it can be accessed via this link: http://bit.ly/1GdTXAt and also on my website: http://over-vaccination.net/

¹²¹ "Invasive meningococcal B disease (IMD) is a rare disease caused by the bacterium *Neisseria meningitidis*." PBS Public Summary Document – Multicomponent Meningococcal Group B Vaccine, 0.5mL, injection, prefilled syringe, Bexsero® - November 2013: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-11/meningococcal-vaccine

¹²² 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 re-

submission 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-subsequent-decision-not-to-recommend.pdf

123 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%2B7OoqX6C2lMl%2F0ER3fOvrPUfGjl4FTstrl%2BSLDwEYGJlv6SgFSLHMMbNn0LqLXhq%3D

124 This FierceVaccines article give some background on Bexsero: **GSK finally seals U.K. Bexsero deal for £20 per dose**, 30 March 2015: http://www.fiercevaccines.com/story/gsk-finally-seals-uk-bexsero-deal-20-dose/2015-03-30

125 Natasha Crowcroft et al providing an interesting summary of the Bexsero meningococcal b vaccine's addition to the NHS schedule – see **Do we need a new approach to making vaccine recommendations?** BMJ 2015;350:h308 doi: 10.1136/bmj.h308 (Published 30 January 2015): http://www.bmj.com/content/350/bmj.h308 and David Isaacs and Jodie McVernon **Introducing a new group B meningococcus vaccine**. BMJ2014;348:g2415doi:10.1136/bmj.g2415(Published 2 April 2014): http://www.bmj.com/content/348/bmj.g2415