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The history of questionable fast-tracked global HPV vaccination

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Dr Jefferson and Professor Gøtzsche, further to my previous correspondence re HPV vaccination, including reference to unnaturally high antibody titres, lack of evidence for multiple doses, and fear-mongering re HPV.

It is pertinent to consider the history of globally fast-tracked HPV vaccination, consider this Australian perspective below.

Summary:

Australia was the first country to implement a funded national HPV vaccination program with Gardasil added to the National Immunisation Program from April 2007.[1]

The implementation of HPV vaccination in Australia occurred in very dubious circumstances, with political interference in the approval process for this vaccine product.[2] 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 multiple doses of the still experimental VLP HPV vaccine products.

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 2006. At that time many people, including politicians, were swept away by the idea of what was then misleadingly described as a 'cervical cancer vaccine'[3]. **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 2006[4], a decision that was overturned with 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.[5,6]

In July 2012 then Labor Federal Health Minister Tanya Plibersek oversaw implementation of Gardasil vaccination for boys with enthusiastic public support from Ian Frazer.[7] In his official message of support for the funding of the national HPV vaccine program for boys[8], 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.[9]

In an article promoting HPV vaccination at the time, Ian Frazer infers the implementation of HPV vaccination will unequivocally prevent death from cervical cancer.[10] **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".[11] 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 vaccination[12] and this will require independent and objective observation, which is not evident at the current time.**

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

Further background:

Gardasil HPV vaccination for girls was fast-tracked in Australia when Coalition politician 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" [13].

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...**"[14] (My emphasis.)

Despite the PBAC's considerable doubts about the Gardasil vaccine product, the PBAC's decision to reject the addition of Gardasil to the national vaccination schedule was hurriedly overturned, after political interference and other lobbying by vested interests.

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"[15]. Opposition Leader Kim Beazley urged Mr Howard to intervene so the PBAC would reverse its decision"[16]. "The Queensland deputy premier said "frankly the Health Minister Tony Abbott, in all conscience has to intervene"[17]. 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"[18]. **The group of 22 female senators also wrote to Mr Abbott, asking him to "intervene" on the PBAC's decision.**"[19] (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".[20] (My emphasis.)

After this intense lobbying, then Coalition Prime Minister John Howard intervened, overturning the PBAC's rejection of Gardasil, and delivering "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."[21]

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."**[22]

The Gardasil initiative has indeed taken funds which might have been more usefully expended against "different fatal diseases and miserable illnesses". For example, Gardasil vaccination of boys and girls in 2013/2014 cost A\$97 million[23], a very questionable expenditure, but a lucrative windfall for bioCSL, Professor Ian Frazer[24], and the University of Queensland[25]. These parties benefit from royalties from the sale of HPV vaccines in developed countries.

In regards to future revaccinations with this product, i.e. 'boosters', Julie Rowbotham also notes: **"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."**[26]

The concern about the need for 'booster' shots is an important consideration. Apart from the additional cost, the current example of the apparently defective acellular pertussis (whooping cough) vaccine, which may actually be causing new strains of the disease to develop[27], and spreading the disease via vaccinated individuals[28], and the inexplicable recommendations for repeated 'boosters' throughout life[29] with this defective vaccine, also raises the alarm about the future of still experimental VLP HPV vaccination.

Research which indicates some vaccines might support the evolution of more virulent viruses[30], and the reported early waning of maternal antibodies in infants born to measles-vaccinated mothers[31], also gives food for thought for those capable of thinking about the 'big picture' and the possibility of unintended consequences.

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 superbugs[32]. 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?

Marion Haas also 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"**. [33]

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."**[34]

Marion Haas et al provide further analysis in their paper **Drugs, sex, money and power: An HPV vaccine case study**. [35] 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"**.

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."**[36]

After the Australian Government's interference in this matter, other countries adopted HPV vaccination, resulting in billions of dollars' worth of sales for the makers of the HPV vaccines, i.e. Merck (Gardasil) and GlaxoSmithKline (Cervarix)[37], and royalties for entrepreneurial scientist Ian Frazer from sales of HPV vaccines in developed countries[38], and for CSL which receives royalties from sales of Gardasil[39].

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 addition of the Gardasil HPV vaccine to the Australian taxpayer funded national vaccination schedule is highly controversial and also raises questions about what level of disease risk justifies mass vaccination.

There must be an urgent review of industry and politically motivated HPV vaccination in Australia and elsewhere.

Dr Jefferson and Professor Gøtzsche, as I have demonstrated, the fast-tracked implementation of universal HPV vaccination is highly questionable. Citizens must be informed of the controversial historical background on this matter.

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

References:

1. **"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.
2. 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, and Haas, Marion. **Government response to PBAC recommendations.** Health Policy Monitor, March 2007, and Marion Haas et al. **Drugs, sex, money and power: An HPV vaccine case study.** Health Policy 92 (2009) 288-295.
3. For example, the Australian of the Year website describes Ian Frazer as the inventor of the 'Cervical Cancer Vaccine'
4. Australian Government Funding of Gardasil® Archived Fact Sheets.
5. See for example Haas, Marion. **Government response to PBAC recommendations.** Health Policy Monitor, March 2007.
6. Significant events in human papillomavirus (HPV) vaccination practice in Australia. NCIRS Fact Sheet.
7. See for example **Schoolboys to get Gardasil vaccine.** Brisbane Times, 12 July 2012.
8. 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.
9. **"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**, Brisbane Times, 12 July 2012. 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 Ian Frazer's conflict of interest, i.e. that he receives royalties from the sale of HPV vaccines in developed countries.**

10. Ian Frazer. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012.

11. Madonna Kind. **Ian Frazer: The man who saved a million lives.**

12. **HPV vaccine effect: is the glass half full or half empty?** The Lancet. Vol. 377. June 18, 2011.

13. November 2006 PBAC Outcomes – 1st time decisions not to recommend.

14. 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.

15. 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.

16. **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.

17. 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.

18. 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.

19. 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.

20. 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.

21. **Howard rescues Gardasil from Abbott poison pill**. The Australian, 11 November 2006.

22. Julie Rowbotham. **Let's not get into valuing one type of patient over others**. Sydney Morning Herald. 14 November 2006.

23. The National HPV Vaccination Program is a school-based program provided under the National Immunisation Program (NIP). Vaccinations provided under the NIP are free for eligible cohorts. The current contract with bioCSL for supply of Gardasil for the National HPV Vaccination Program is for both the male and female programs for 2013 and 2014, at a total cost of \$97,678,540.96 (GST inclusive). Senate Community Affairs Committee. Answers to Estimates Questions on Notice. Health and Ageing Portfolio. Additional Estimates 13 & 15 February 2013. Question: E12-172

24. **"Ian Frazer as co-inventor of the technology enabling the HPV vaccines receives royalties from their sale in the developed world."** Disclosure statement on Ian Frazer's article **Catch cancer? No thanks, I'd rather have a shot!**. The Conversation, 10 July 2012.

25. "The Merck vaccine, Gardasil, was commercially released in 2006. Under the licensing arrangements, milestone and royalty payments from the sale of the Merck and GSK vaccines will be payable to UniQuest and will ultimately flow back to UQ (University of Queensland) and the researchers (Ian Frazer)." Group of Eight Australia. Module 4: Intellectual property and commercialisation. Case Study: Gardasil - an example of university licensing.

26. Julie Rowbotham. **Let's not get into valuing one type of patient over others**. Sydney Morning Herald. 14 November 2006.

27. 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**. 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 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, and **Sharp rise in cases of new strain of whooping cough**. UNSW Australia Newsroom, 21 March 2012. 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), and Anna M Acosta et al. **Tdap Vaccine Effectiveness in Adolescents During the 2012 Washington State Pertussis Epidemic**. Pediatrics April 2015, and Bart MJ et al. **Global population structure and evolution of Bordetella pertussis and their relationship with vaccination**. MBio. 2014 Apr 22;5(2), 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, 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.

28. 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, 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. 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, 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.

29. 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?"**

30. See **Some Vaccines Support Evolution of More-Virulent Viruses.** PennState Science, 27 July 2015, and **Leaky vaccine promote the transmission of more virulent virus.** Center for Infectious Disease Dynamics. Penn State. The study referred to in this article is: Andrew F. Read et al. **Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens.** PLOS Biology, July 27 2015.

31. **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). 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.

32. 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. 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. Also see **UPDATE 1 – Cameron enlists ex-Goldman economist in global superbug fight,** Reuters, 2 July 2014.

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

34. *Ibid.*

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

36. *Ibid.*

37. In FierceVaccines report on the Top 10 best selling vaccines of 2013, Gardasil was second with worldwide sales of \$2.167 billion. 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.

38. **Catch cancer? No thanks, I'd rather have a shot!** The Conversation, 10 July 2012. 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."*

39. **CSL ups profit guidance on Gardasil sales.** The Australian, 27 November 2012. Also see CSL Limited ASX Half-year Information 31 December 2014, and CSL takes the fight to the flu, 3 November 2014 - *"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..."*