

A jab too far?

The case for a review of vaccination policy.

(Submission on **Public Health and Wellbeing Amendment (No Jab, No Play) Bill 2015**)

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“.....in spite of the widespread agreement that vaccines are largely safe and serious adverse complications are extremely rare, a close scrutiny of the scientific literature does not support this view.”

– Professor Chris Shaw/Dr Lucija Tomijanovic, (senior post doctoral researchers in vaccine safety, University of British Columbia).

Background:

1. Australian citizens are currently being subjected to policy measures aimed at increasing adherence to a vaccination schedule that is at odds with what is considered best practice in a number of other Western nations. This paper is of necessity brief but its intention is to present an overview of a range of areas which taken as a whole present a strong case for policy change. This is set against proposed legislation in the state of Victoria that will deny childcare to children who do not conform to the current schedule.

2. Dozens of academic papers and media articles have been reviewed and inputs received from immunologists, geneticists, epidemiologists, and various other medical professionals, as well as government officials, journalists, risk minimization experts and ethicists globally and locally. A large amount of supporting information can be supplied if required.

Overview:

3. This paper will look at how the medical evidence base has been almost completely compromised by pharmaceutical marketing concerns; how the selective release of data skews results, and how this is used to mislead policy makers, the medical community and the general public.

4. It will look at evidence that some vaccine products and ingredients are implicated in neurological harm, autoimmune dysfunction, and other negative health outcomes.
5. It will present a case that the Australian model of regulation and monitoring is far from adequate, and issues of liability have been largely overlooked. Correct risk minimization processes have been inverted, and a lack of transparency has been identified in key areas.
6. It will also look at the media bias surrounding this issue, and the techniques used by pharmaceutical marketing and its allies to suppress independent journalism and science. It will touch upon the appalling record of pharmaceutical companies which includes many instances of fraud, bribery, intimidation and deliberate negligence.
7. This paper is not intended to be in any way definitive, but it is meant to give a brief overview of the case for policy change, and an urgent review of how pharmaceutical interests operate in this country.

Contamination of the medical evidence base:

8. In 2002 the editor of the Lancet, Dr Richard Horton, claimed that around 90% of clinical guidelines are being written by people with financial links to pharmaceutical companies. Since then it has been revealed that articles in medical journals are being 'ghost written' by pharmaceutical employees, and that data is being routinely withheld.

"Horton declared, "**Much of the scientific literature, perhaps half, may simply be untrue.** Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, **science has taken a turn towards darkness.**" (1)

9. The work of Dr Peter Doshi and the independent Cochrane Collaboration should give us pause for thought.

"The current system..... is one in which the meager details of clinical trials published in medical journals, often by authors with financial ties to the companies whose drugs they are writing about, **is insufficient to the point of being misleading**".(2)

10. The industry has not been slow to respond.

"The pharmaceutical industry has "mobilised" an army of patient groups to lobby against plans to force companies to publish secret documents on drugs trials.

Drug companies publish only a fraction of their results and keep much of the information to themselves, but regulators want to ban the practice. If companies published all of their clinical trials data, independent scientists could re analyse their results and check companies' claims about the safety and efficacy of drugs." (3)

11. The much vaunted medical evidence base is in a bad state of disrepair. As Dr Marcia Angell, a former editor for the New England Journal of Medicine states,

"It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine. "(4)

Adverse events following vaccination:

12. Vaccine manufacturers acknowledge a range of adverse reactions in their product disclosure information, and there are over forty acknowledged vaccine induced adverse events. (5) There is no doubt that vaccines can cause harm, and even death, in some instances. So regardless of what anyone may make of individual research papers the fact is that there is agreement that vaccination is never entirely safe. There can be risks involved. And efficacy rates vary.

13. There are a large amount of research papers discussing possible harm from vaccines and/or specific ingredients. The senior post doctoral researchers in vaccine safety at the University of British Columbia Professor Chris Shaw and Dr Lucija Tomijanovic have presented many papers on the deleterious effects of vaccine adjuvants. They have investigated the mechanisms of aluminium based adjuvants in paediatric populations and concluded that children have an immune system that is a work in progress, and is far more susceptible to harmful side effects. Their **'observations raise plausible concerns about the overall safety of current childhood vaccination programs.'** (6)

14. "Infants and young children should not be viewed as "small adults." Their unique physiology makes them much more vulnerable to noxious environmental insults in comparison with the adult population. **In spite of this, children are routinely exposed to much higher levels of Al vaccine adjuvants than adults, even though adequate safety data on these compounds are lacking.** That Al vaccine adjuvants can induce significant autoimmune conditions in humans can hardly be disputed, although still debatable is how common such side effects are. However, the existing data (or lack thereof) raise questions on whether the current vaccines aimed at pediatric populations can be accepted as having adequate safety profiles. Because infants and children represent those who may be most at risk for complications following vaccination, **a more rigorous evaluation of potential vaccine-related adverse health impacts in pediatric populations than what has been provided to date is urgently needed."** (6)

15. Tomijanovic states, **'Physicians should adopt a more rigorous evidence-based medicine approach,** in order to provide a balanced and objective evaluation of vaccine risks and benefits to their patients' (7)

16. They also concluded that **“.....in spite of the widespread agreement that vaccines are largely safe and serious adverse complications are extremely rare, a close scrutiny of the scientific literature does not support this view.”**(6)

17. Professor Yehuda Shoenfeld spoke in Australia in 2013. He has investigated how aluminum based adjuvants can trigger auto immune dysfunction if a genetic predisposition exists. There is widespread acceptance of his finding that **aluminium adjuvants can cause catastrophic auto immune dysfunction** (8). He has identified key genetic markers indicative of a predisposition towards adverse events, and yet little work seems to be being done identifying individuals who may be at risk.

18. Australia is currently experiencing what politician Bill Shorten described as an ‘epidemic’ of broad spectrum neurological dysfunctions, so if there is the slightest possibility that Professor Shaw, Shoenfeld et al are correct, we need to be looking at what other countries are doing in this regard. In 2014 France held an open enquiry into the issue of aluminium adjuvants. So far Australia has avoided looking at this issue, or conducting any transparent enquiry into the side effects of vaccination.

Issues of efficacy:

19. If you bought a new car and there was only a one in twelve chance that it would work properly, how would you feel? And what if there was a one in three chance that it was downright dangerous? Faced by these sorts of statistics, most consumers would be furious. And yet according to an article in the ‘Journal of Law, Medicine and Ethics’, entitled ‘Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs’ this may well be the state of affairs with pharmaceutical products.. The **“.....proportion of new products with clinical advantages seems to have moved from about 1 in 8 down to 1 in 12, while the proportion with serious harms has gone up from 1 in 5 towards 1 in 3**” (9)

20. Dr Tom Jefferson of the independent Cochrane Collaboration has undertaken comprehensive reviews of some vaccines. According to his findings the ‘flu vaccine for example showed **“no effect on specific outcomes:** laboratory-proven influenza, pneumonia, or deaths from pneumonia”. .In other words, the flu vaccine policy, ‘while eminently agreeable, is unsupported by evidence that has been systematically collected, critically evaluated, and properly synthesised.’ He is wary of the ‘trust us, we’re experts’ pose taken by many policy makers. He states that ‘in my opinion, **that response is only fit for underlings, not intelligent, responsible healthcare workers facing the pointy end of a syringe this season.** (10)

21. It is also worth pondering the words of immunologist Dr Tetyana Obukhanych, author of ‘Vaccine Illusion’

“I am very concerned that “immunologic memory” of adjuvant-containing vaccines is actually the basis of sensitization rather than the basis of immunity.

Furthermore, I am very concerned that “successful” prevention of childhood diseases by means of short-term protective effects of live attenuated viral vaccines during childhood has led to the loss of maternal ability to transfer immuno-protection to their young, thereby leaving infants vulnerable to those diseases, should the exposure occur.

I am also very concerned that vaccination campaigns work by disrupting disease transmission, which reduces the chances of exposure, rather than by establishing a population’s immunity. By doing so, **vaccination campaigns wipe out population’s immunity to childhood diseases rather than help to maintain it.** If in prior decades there was naturally established herd immunity to childhood diseases among the adult population, then I am afraid that vaccination campaigns have ensured that it is long gone.

All of this is a direct outcome of the “desired” vaccination effects, the impact of which hasn’t been carefully thought through in advance of introducing mass vaccination. **We thought that vaccines work just like natural immunity. Well, apparently they don’t and we are now reaping the consequences of that.”** (11)

Correlative studies:

22 Correlative studies cannot be considered definitive, but in conjunction with other research they often indicate areas that require further examination. There has so far not been an exhaustive and independent study comparing more general health outcomes between vaccinated and non vaccinated children. Can we definitively say we are not trading one health issue for another?

23. A report in ‘Human and Experimental Toxicology’ stated:

"Our findings show **a positive correlation** between the **number of vaccine doses** administered and the **percentage of hospitalisations and deaths**"? (12)

24. And, "the US childhood vaccination schedule has 26 doses for infants aged less than 1 year, the most in the world, yet 33 nations have better Infant Mortality Rates.....**Nations that require more vaccine doses tend to have higher infant mortality rates**"(13)

25. A Spanish research team concluded that, “vaccines containing adjuvants may be associated with an **increased risk of autoimmune/inflammatory adverse events** following immunization”(14)

Regulation and monitoring:

26. In a submission to parliament Dr Martin Whitely, senior advocate for the Western Australian Health Consumers Council stated:

“When licensing drugs for marketing Australia’s Therapeutic Goods Administration (TGA) relies on research funded and controlled by pharmaceutical companies. Too often pharmaceutical companies ‘**cherry pick**’ favorable evidence and hide or ‘**spin**’ unfavorable evidence to support their commercial interests.” (4)

27. Most vaccination proponents will argue that serious adverse reactions are rare, but a big problem is that we do not have accurate, agreed upon figures. During the height of the flu vaccine adverse reactions in 2010 Peter Collignon, a professor of infectious diseases from the Australian National University, was interviewed by ABC news. He felt **the number of adverse reactions was probably under estimated**, given that authorities don’t have a congruent and approachable system to monitor peoples’ reactions. He believed that an effective surveillance system should monitor a sample group of thousands for one or two weeks before a new vaccine is rolled out for the entire population. "We need a better system than voluntary notification to the TGA (Therapeutic Goods Administration) that there's a problem," he said. "Because whenever you do that you really underestimate how much of a problem there is. (15)

28. Dr. Whitely has argued that there needs to be mandatory reporting of adverse events. (4) Without agreed upon figures for adverse events an accurate risk analysis cannot be undertaken, and we are unable to state whether the current schedule of vaccinations is in fact safe, or creating more negative health outcomes than it is intended to prevent.

Tactics used by pharmaceutical companies to silence dissent:

29. “Pharmaceutical companies are master manipulators.....”, Dr Whitely has stated. “They pull the wool over the eyes of drug safety regulators everywhere”. (4) They use a range of tactics which can include:

- a.** Controlling the medical evidence base via influencing clinical trial guidelines; ‘ghost writing’ articles for journals; selectively releasing data, and selectively marketing trial results.
- b.** Utilizing ‘Key Opinion Leaders’ who often have undue influence upon policy – a problem the independent Cochrane Collaboration refers to as ‘Eminence Based Medicine’.(10)
- c.** Maintaining a barrage of websites and blogs that purport to support ‘science’, but embed their marketing objectives.
- d.** Embedding their marketing in established news and information websites.
- e.** Undertaking virulent campaigns to discredit researchers who question their products. Terms such as ‘junk science’, ‘questionable’, ‘not evidence based’, and many more are routinely used in attempts to discredit researchers who threaten their profit margins.
- f.** Maintaining a small army of internet trolls to present the interests of pharmaceutical companies in online discussion forums, the comments sections of articles, and any other area where they can present their views.

- g.** Mobilizing patient and consumer groups to represent their interests.
- h.** Manipulating a compliant media, which is at times compromised by conflicts of interest, especially at an executive level where a cross pollination occurs with pharmaceutical interests occurs.(16) They also exploit the quick turnaround in the media which can mitigate against in depth research.
- i.** Lobbying policy makers and opinion leaders.
- j.** Selective use of statistics. For example global statistics on disease mortality are often used to panic policy makers in Western nations. Issues with nutrition, hygiene and so forth in some ‘third world’ nations may play a significant role in mortality figures for diseases which have low mortality in robust individuals in Western nations.
- k.** An ‘all of nothing’ approach that lumps all vaccine /disease combinations together, and leverages the most extreme disease threats to compel compliance with a vaccine based approach to those with low mortality. The ‘pro/anti’ dualism is also used to sideline and discredit anyone who presents critical research of a particular product.

30. Aside from pharmaceutical marketing there is a more complex and less easily understood phenomenon involving groups and individuals that present themselves as being pro ‘science’ or more specifically pro vaccination. They often take it upon themselves to run campaigns against individuals or groups that they perceive as being critical of vaccination. Their tactics can be crude but effective, and at times of questionable legality. They can include:

- a.** Cyber bullying and threats.
- b.** Disinformation campaigns including misrepresenting research.
- c.** Making spurious complaints to academic institutions and professional bodies.
- d.** Disseminating fictitious personal information designed to cause embarrassment or a loss of credibility.
- e.** Using seemingly authoritative or popular websites to launch attacks designed to hystericise consumers, and ostracize critics. In some instances the wording can be considered ‘hate speech’ and adds to an atmosphere of fear surrounding this issue.

27. One of the world’s most awarded journalists Sharyl Atkisson describes this as the ‘astro turf’ movement. She has researched the tactics used by pharmaceutical concerns and their allies to silence the very many researchers from eminent Universities who are critical of their products.

“....if the propagandists are to be believed, each of the researchers is an incompetent crank, quack, nut or fraud (and, of course, “anti-vaccine” for daring to dabble in research that..... leads to vaccine safety issues). The scientists and their research are “controversial,” simply

because the propagandists declare them to be.....“Weak,” “too small,” “haphazard,” “not replicated,” “junk science,” “flawed,” “unrelated,” declare the propagandists, without exception. Just as attackers spent years challenging any study that linked tobacco to lung cancer.

They know that **reporters who don't do their homework** will conduct an Internet search, run across the blogs with science-y sounding names, and **uncritically accept their word as if it's fact** and prevailing thought.” (17)

31. Pharmaceutical marketing leverages off a kind of religious fervor that surrounds this issue. Dr Jefferson has said that ‘**vaccines have become like a religion**... something you don't question. If you do, you are seen as being an anti-vaccine extremist. The authorities do not want to hear ‘side-effect’(18)

The appalling record of ‘Big Pharma’:

32. Pharmaceutical companies have a terrible record of corporate crimes.

"A recent study from US Public Citizen found that, since 1991, there have been **239 legal settlements, totaling \$30.2 billion** in federal and state penalties, levied against US pharmaceutical companies. **There's a real laundry list of crimes, but defrauding the government, hiding drug safety information, and hawking drugs for purposes beyond which they are approved** are the main ones. Drug companies have pledged to change, signed ‘corporate integrity agreements’ and indicated that they want to move on, promising a better future. We can be hopeful, but we also have to be realistic. Paying huge fines for illegal activity is one thing, but will they be still playing the eminence game? Will they continue to fund their own experts and do research that goes through a selective reporting of ‘the evidence’? Sadly, that's probably going to be the case so you must immunise yourself: keep asking questions and questioning answers." (10)

33. Recently Forbes magazine concluded that the pharmaceutical industry is ‘**addicted to fraud**’, whilst **Merck is being sued by its own scientists over a raft of frauds relating to its MMR vaccine**. (20) The list of alleged frauds is far-ranging including failing to disclose a reduced efficacy, using ‘improper testing techniques’, manipulation of testing methodologies, falsifying test data, with holding data, and forgery of compliance documents. This kind of behavior has become entirely common in the pharmaceutical industry.

Issues with risk minimization:

34. Correct risk minimization approaches are often inverted, with consumers and independent researchers expected to definitively prove harm, rather than the onus being on the product provider to firmly establish safety. The ‘Precautionary Principle’ – ‘if in doubt leave it out’ – has been largely bypassed, and the terms of reference inverted.

35. Pharmaceutical companies have positioned themselves so that policy makers often feel constricted in holding them to the same levels of risk minimization as other industries, due to the perception that they may forego important research, or cease delivering other effective products if their operations are subjected to greater scrutiny and bureaucracy.

36. Negative effects of pharmaceutical products are often diffused in the wider community, and not always easy to quantify due to inadequate reportage and monitoring. Unlike an airline disaster which has a very immediate consequence, the negative effects of a particular pharmaceutical product may be less discernable, especially if the effects are more long term.

37. Most people would agree that if a disease usually has a very low mortality rate, any vaccine intended to prevent it must be unequivocally safe and effective. Proper risk assessments are made difficult by the lack of robust monitoring of adverse events; the suppression of independent science, the withholding of clinical data, and myriad other issues mentioned in this paper.

38. No scientific research has been conducted comparing vaccinated with unvaccinated populations, in terms of overall, long term health outcomes.

Call for reform and greater transparency:

39. The dealings of the pharmaceutical industry in Australia appear to be largely exempt from Freedom of Information requests, and there is a lack of transparency surrounding possible Conflict of Interest situations on advisory bodies. Dr Whitely has also called for mandatory reporting of serious adverse events, and break out boxes on products warning of possible serious side effects. (4)

40. So far calls to bring the industry in line with the expectations of other industries have been largely ignored.

Issues with the application of ‘informed consent’:

41. The principle of ‘informed consent’ requires that patients be informed of all risks and benefits associated with any medical procedure, and that a decision be made free from coercion. In an environment where pharmaceutical marketing, the media, and various ‘attack ‘ groups hystericise the general population and vilify critics and independent researchers, the notion of ‘informed consent’ has become problematic. Consumers clearly feel pressurized.

42. Linking the decision to vaccinate to the provision of childcare available to everyone else, further complicates this. It can be argued that such policy enters a grey area in terms of informed consent.

43. Vaccination providers also seem reluctant to provide consumers with information on possible adverse effects. Many maintain the narrative that vaccines are ‘safe and effective’ in all

instances, despite package inserts clearly outlining possible adverse effects. An audit of how vaccination providers approach 'informed consent' is urgently needed.

Unresolved liability issues:

44. As the parents of Saba Button - who was permanently injured by a flu shot - found there is a lack of clarity when it comes to liability. (15) Australia is one of only three Western nations that does not have a vaccine injury compensation scheme despite the World Health Organisation arguing it is an 'ethical necessity'. In the case of an injury there is no clear indication of who takes responsibility.

45. If the parents of a vaccine injured child feel their decision to vaccinate was prompted by government policy, does the government take responsibility if their child is injured as a result? It would appear not. Pharmaceutical companies and vaccination providers also seem to avoid liability. This question requires immediate clarification. Currently there is a policy void surrounding issues of liability and compensation.

The reasons some parents don't vaccinate their children:

46. Parents may choose to not vaccinate their children, delay vaccination, or adopt a reduced schedule. There may be many reasons for this including but not limited to:

- a.** Previous experience of an adverse reaction. If a child does exhibit an adverse reaction, few could argue that parents would want to expose their child to further adverse reactions.
- b.** Migrants may wish to adhere to the schedules of their countries of origin. There are many examples of western nations that have a much smaller schedule than Australia, but have an excellent record of controlling infectious disease, with little evidence of the widespread neurological disorders affecting Australian children.
- c.** Misgivings based upon independent science.
- d.** Misgivings based upon the information provided in package inserts.
- e.** Strongly held religious and ethical positions. These may include issues with the use of animal cell lines, aborted fetal cells, animal testing and so forth. They may also include more generalized objections.
- f.** Belief in less substantiated theories.
- g.** Mistrust of government.

47. In short there may be a wide variety of reasons why people make this choice. Some choices may be well considered and based upon research. Some may be quite different. There is no single set of reasons, although research suggests that those who question vaccination tend to be highly educated. A policy that has an element of coercion will almost certainly foster greater opposition in people who have made a considered decision.

Divisions in the medical community:

48. In many Western nations about half of medical professionals including doctors and nurses refuse routine vaccinations. A Canadian Nurses' Union representative stated that this was because they had seen how many adverse reactions can occur. National Nurses United (Canada) president Karen Higgins said, "nurses, joined by many physician organizations and researchers, **reject the notion that vaccination is a fail-safe solution there are health reasons why some elect not to be vaccinated.** Some vaccine products have been withdrawn, as when Bell's palsy developed for many recipients. It has just been reported that 800 European children contracted narcolepsy, an incurable sleep disorder, after receiving the swine flu vaccine."(20)

49. The notion that vaccination has the unilateral support of medical professionals is false.

Unintended consequences:

50. If the intention of the legislation is to increase vaccination rates, then it should be noted that the perception of coercive measures has led to a flourishing of contrarian activism. Consumers are wary of coercive measures, and perhaps with some reason given the poor record of pharmaceutical companies. Many will question what other measures may be next. Coercive measures will most likely foster greater resistance from those who have made a considered decision, and may also cause those who are generally pro vaccination but reserve the right to choose the schedule they feel most appropriate to adopt a contrarian position.

51. The community has been divided by extremist positions, enabled by media campaigns and 'attack' groups. A balanced assessment of policy is now very nearly impossible. An environment of fear and intimidation now exists. This is not an appropriate atmosphere for balanced and considered policy.

52. The denialism associated with adverse reactions to vaccination, and vaccination products and ingredients which have caused harm, is leading to a trust deficit with consumers, which could negatively impact the provision of health services.

Conclusion:

53. Vaccination policy in Australia seems to be largely driven by pharmaceutical interests that leverage media campaigns to achieve their objectives. There has been little interest in

acknowledging the contamination of the medical evidence base by pharmaceutical companies, and little impetus for reforming how pharmaceutical products are regulated, or more stringently monitoring adverse events.

54. Australian policy makers appear to have a ‘she’ll be right’ attitude to issues of liability, and independent research on the negative aspects of some vaccination products and ingredients. Correct risk minimization approaches have been overlooked, and a default position of ostracizing and vilifying critics has been assumed in some instances.

55. A balanced discussion on vaccination is now very difficult due to the extreme positions taken by elements of the media and ‘attack’ groups. An environment of fear and intimidation now defines the issue, mitigating against best overall health outcomes.

56. In approaching issues of national health no procedure, product, or individual should be considered a ‘sacred cow’. Independent scrutiny of all medical products and procedures should be the norm, and policy makers, media, regulators and consumers need to be properly insulated from pharmaceutical interests.

57. Australia is in urgent need of a comprehensive review of its vaccination policies. The government should be focused on this as a priority before it moves to impel the uptake of yet more pharmaceutical products.

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The Health Policy Initiative is an informal collaboration of health care providers, academics and other interested parties who advocate a move from a medical system that treats disease, to one that prevents it. HPI upholds the principle of informed consent in all instances.

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