

# Reluctance to vaccinate: Reasons and solutions

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## Abstract

**Introduction:** The World Health Organisation has declared vaccine hesitancy to be one of the 10 greatest threats to global health in 2019 and has produced materials to help understand and deal with the issues. The author contends that a lack of trust is the major reason for vaccine hesitancy.

**Trust:** Five issues relating to trust are identified and examples given. The analysis suggests that it is reasonable for an intelligent, well read, concerned person to respectfully ask questions about aspects of orthodox advice that he or she receives regarding vaccination, and to receive a respectful and informative (and truthful) response.

**The missing research:** The author contends that a recurring question voiced by many who have concerns about vaccination is, 'why has no substantial research been published in leading medical journals comparing chronic disease profiles of fully vaccinated and completely unvaccinated children'. Without such research it is not possible to make a comprehensive comparison between the full risks and benefits of vaccines.

For the first time, seven small studies comparing the chronic illness profiles of vaccinated and unvaccinated children are examined which show consistent results and emphasise the need for a substantive and objective examination of this question. It is shown that such research is both ethically and practically possible and could be done quickly at relatively little expense with the cooperation of federal and regional governments. An example from Australia is provided.

**Conclusion:** It is concluded that if this missing piece of research is undertaken and made freely available it would contribute to re-establishing trust in orthodox advice among many vaccine hesitators. Depending on the findings, governments may be required to re-examine parts of vaccine policy, and vaccine hesitators may need to re-evaluate their concerns. However, if parents were able to participate in an open and transparent conversation based on unbiased research it would strengthen confidence in orthodox authorities and help diffuse what has become an often bitter and unproductive attack on anyone who asks reasonable questions about the overall safety of vaccination.

## Introduction

The World Health Organisation (WHO) has declared vaccine hesitancy to be one of the 10 greatest threats to global health in 2019 [1].

WHO states that: "Vaccine hesitancy refers to delay in acceptance or refusal of vaccines despite availability of vaccination services. Vaccine hesitancy is complex and context specific varying across time, place and vaccines. It includes factors such as complacency, convenience and confidence". They have postulated some solutions, stating that "in most cases, interventions should be dialogue based and directly targeted to a specific under-vaccinated population group [2]".

In fact, vaccine hesitancy should also include people/parents who do not delay accepting vaccines but do so with a degree of unease or uncertainty. In an American study of parents in 2000, 19% indicated they had "concerns about vaccines" [3] In a similar survey in 2009 this number was 50% [4].

The WHO has produced materials to better understand and deal with vaccine hesitancy. They include:

- Report of the SAGE Working Group on Vaccine Hesitancy [5],
- Tailoring Immunization Programmes (TIP) [6], and
- Vaccine Hesitancy Survey Questions Related to SAGE Vaccine Hesitancy Matrix [7].

## Trust: The key reason

The above WHO analyses plus the considerable body of materials examining this issue make it clear that reasons behind vaccine hesitancy are complex [8]. The author has been working with vaccine hesitators and vaccine refusers since 1985 and has found that the key reason is a lack of trust (or in WHO terms, confidence). This can include:

1. Trust in the integrity of politicians who are lobbied by pharmaceutical companies;
2. Trust in the independence of government regulatory and research institutions
3. Trust in pharmaceutical companies whose principal goal is profits;
4. Trust in researchers and medical journals who may have conflicts of interest, and
5. Trust in doctors who may be under-educated in vaccinations, or who are afraid to voice concerns.

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The issue of trust has been identified by other researchers [9,10], as well as by the WHO in a booklet *Vaccination and Trust: How concerns arise and the role of communication in mitigating crises* [11].

### Examples of trust issues:

**1. Trust in the integrity of politicians who are lobbied by pharmaceutical companies:** One well quoted example of politicians receiving direct funding from Pharma is Dr Richard Pan, a Democrat who represents the 6th Senate District, located in Sacramento, California. Dr Pan was the prime sponsor of Bill SB277, which in 2015 eliminated the personal belief exemptions for vaccines. The law essentially mandated vaccines for children entering school.

In California alone pharmaceutical companies and their trade groups gave more than \$2 million to current members of the Legislature in 2013-2014. Nine of the top 20 recipients are either legislative leaders or serve on either the Assembly or Senate health committees. Senator Pan directly received more than \$95,000. The industry also donated more than \$500,000 to outside campaign spending groups that helped elect a number of current members in 2014. Leading pharmaceutical companies also spent nearly \$3 million more during the 2013-2014 legislative sessions lobbying the Legislature, the governor, the state pharmacists' board and other agencies, according to state filings.[12]

Nationally, donations to politicians by Pharma are tracked by the Centre for Responsive Politics and published on their website <https://www.opensecrets.org>. The top ten recipients for 2017-18 are shown in Table 1.

In addition, they showed that over \$280 million was spent in 2017-18 on lobbying for pharmaceuticals and health products. These are the declared amounts [14].

In Australia, a Guardian analysis estimated "About 72 separate pharmaceutical businesses engage paid lobbyists to influence government decisions and policy. They are represented by 29 separate lobbying firms, many of which have former ministerial or political advisers as staff [15]"

**2. Trust in the independence of government regulatory and research institutions:** A paper by Charles Seife MS, published in *JAMA* in April 2015 revealed huge ethical breaches found by the FDA when they inspected the sites of clinical drug trials between 2008 and 2013. In 57 published clinical trials inspected by the FDA during this period there was significant evidence of:

- Falsification or submission of false information [22 trials, 39%];
- Problems with adverse events reporting [14 trials, 25%];
- Protocol violations [42 trials, 74%];

**Table 1.** Top ten recipients, 2017-2018 [13]

Rank	Name, Party	Office	Amount
1	Walden, Greg (R-OR)	House	\$221,500
2	McCarthy, Kevin (R-CA)	House	\$215,650
3	Casey, Bob (D-PA)	Senate	\$201,368
4	Brady, Kevin (R-TX)	House	\$179,550
5	Heitkamp, Heidi (D-ND)	Senate	\$164,204
6	Lance, Leonard (R-NJ)	House	\$161,550
7	Donnelly, Joe (D-IN)	Senate	\$160,377
8	Hatch, Orrin G (R-UT)	Senate	\$157,189
9	Barrasso, John A (R-WY)	Senate	\$147,250
10	Tester, Jon (D-MT)	Senate	\$142,547

- Failure to protect the safety of patients and/or issues with oversight or informed consent [30 trials, 53%], and
- Inadequate or inaccurate record keeping [35 trials, 61%).

The paper notes that when these breaches occur, the FDA "has no systematic method of communicating these findings to the scientific community, leaving open the possibility that research misconduct detected by a government agency goes unremarked in the peer-reviewed literature." In fact, only 4% of the research found to have significant violations mentioned any such problems when the research was published. Seife notes: "No corrections, retractions, expressions of concern, or other comments acknowledging the key issues identified by the inspection were subsequently published [16]"

The Centres for Disease Control and Prevention (CDC), is the leading national public health institute of the United States. The CDC is a United States federal agency under the Department of Health and Human Services. It is tasked with protecting Americans against diseases. It has made the following five-point pledge to the American people: "1. Be a diligent steward of the funds entrusted to our agency; 2. Provide an environment for intellectual and personal growth and integrity; 3. Base all public health decisions on the highest quality scientific data that is derived openly and objectively; 4. Place the benefits to society above the benefits to our institution; 5. Treat all persons with dignity, honesty, and respect [17]"

A strong case can be made that the CDC have failed to honour every part of the pledge. However, for this paper the revelations by whistle blower and current CDC senior scientist in the vaccine safety division, Dr William Thompson, who revealed a culture of deceit and research fraud show that, at least, points 2, 3 and 4 have been breached. Full transcripts of conversations between Dr Thompson and Dr Hooker have been published [18], and Dr Thompson made a statement through his legal representatives stating that; "I regret that my coauthors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics*. The omitted data suggested that African American males who received the MMR vaccine before age 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data were collected, and I believe that the final study protocol was not followed [19]"

The so called "revolving door" between regulatory bodies and pharmaceutical companies in both the USA and Europe has been well documented [20-22].

**3. Trust in pharmaceutical companies whose principal goal is profits:** Trust in pharmaceutical companies is at its lowest ebb in the USA in 2018. "Trust has hit a new low for pharma in Edelman's annual Trust Barometer survey. The 13-point drop from 51% to 38% in the U.S. was the category's biggest plummet in the five years the public relations and marketing firm has been tracking sentiment [23]"

The most thorough review of the influence of PhRMA on every aspect of the orthodox health system in the USA, with direct application in other developed countries, was undertaken over five years by Fellows of the *Edmond J. Safra Center for Ethics* at Harvard University Law School. The Harvard analysis involved a symposium on **Institutional Corruption and Pharmaceutical Policy** published in the *Journal of Law, Medicine and Ethics*, Vol. 41, No. 3 (2013). All symposium articles are freely accessible through the *Edmond J. Safra Center for Ethics* website [24], or available through summaries [25,26].

"Their research shows that widespread practices in the medical and pharmaceutical industries can lead to doctors who are psychologically,

financially, or intellectually dependent on drug companies, a phenomenon which has resulted in insufficiently tested drugs, many of which cause harmful side effects.

Their research also reveals how top medical researchers can be financially tied to drug firms. For example, researchers have been found to conduct clinical trials on medications while simultaneously calling for their consumption and guaranteeing that insurance companies will pay for them. Doctors who take such misleading information at face value prescribe drugs that are often unnecessary, harmful to patients, or more costly than equivalent medications. Fellows uncovered how pharmaceutical marketing also distorts medical practice, and how drug firms are even funding social network websites for doctors in order to quietly track their opinions on issues that affect their bottom lines.

Drawing on insights from law, medicine, behavioral psychology, economics and finance, business, sociology, political science, and philosophy, the Fellows' research also shows how lawmakers and patient advocacy organizations can be dependent on money from drug companies, resulting in representation that serves the interests of big pharma rather than the public. The pharmaceutical industry's own mission and purposes are often undermined, the investigation concluded [27].

#### 4. Trust in researchers and medical journals who may have conflicts of interest

Three influential 'insiders', former editors of leading medical journals, have revealed the following.

**1. Dr. Marcia Angell**, former Executive Editor of the *New England Journal of Medicine* (1988-2000) and currently is a corresponding member of the faculty of Global Health and Social Medicine at Harvard Medical School and faculty associate in the Center for Bioethics.

Dr Angell wrote *Drug Companies and Doctors: A Story of Corruption* in which she outlined the inappropriate relationships between the pharmaceutical industry, the medical establishment and local and federal politicians. She tells us how the pharmaceutical industry has infiltrated every part of the medical system, buying access and the hearts and minds of our physicians.

She wrote "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* [28]."

**2. Dr. Richard Smith**, former editor and chief executive of the *BMJ Publishing Group* for 13 years and worked for *the British Medical Journal* for a total of 25 years.

Dr Smith left *BMJ* in 2004, and in 2006 published the book: *The Trouble with Medical Journals*. He wrote an editorial that appeared in *PLOS Medicine Journal* in 2005 - 'Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies' - in which he asserts: "The Problem: Less to Do with Advertising, More to Do with Sponsored Trials". He stated that "Peer review is a failure and, ironically, it's more faith-based than science-based. What passes as 'science' today is really a cult of pet opinions pushing an agenda [29]."

**3. Dr. Richard Horton**, Current Editor in Chief of *The Lancet Medical Journal*. In April of 2015, Dr. Horton published an editorial in *The Lancet Medical Journal* that corroborates the statements of his fellow editors regarding the trustworthiness of research published in

medical journals. This editorial offers a thoughtful perspective on what Dr. Horton refers to as "one of the most sensitive issues in science today: the idea that something has gone fundamentally wrong with one of our greatest human creations."

"The case against science is straightforward: 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."

"*Journals have devolved into information-laundering operations for the pharmaceutical industry* [30]."

Vaccine hesitators may distrust the motives of research and researchers funded by Pharma, as well as research methods which avoid the questions they want answered. Comparisons are made involving short-term vaccine effects and potential disease costs, but comparisons involving chronic consequences of vaccination in vaccinated and unvaccinated cohorts are avoided. The saying in statistics 'if you want the right answer then ask the wrong question' appears to be followed by many researchers. For example, the most recent study concluding no link between MMR vaccine and autism relied, as many other studies have done, on a comparison between two differently vaccinated groups of children rather than comparing a vaccinated cohort and a completely unvaccinated cohort [31].

**5. Trust in doctors who may be under-educated in vaccinations, or who are afraid to voice concerns:** There are assertions that doctors are taught very little about vaccines in medical school. There are differing claims by doctors posted on the internet, some saying medical students are well educated regarding vaccination [32], and some saying they are not [33]. Published research is lacking, but one paper suggests that education in vaccines is not comprehensive [34]. More research evaluating doctors' education regarding vaccination is needed.

It is apparent in recent years that any doctor who publically questions the safety and/or effectiveness of vaccines will be pursued and possibly deregistered. This has happened in Australia, where doctors who supported-vaccine hesitant parents were investigated, and in some cases forced out of practice [35]. The well-publicised efforts involved in discrediting Dr Andrew Wakefield for suggesting a possible link between MMR vaccine and autism also serve as a dis-incentive to doctors with differing views [36,37].

It has been postulated that many vaccine hesitators incorrectly believe that they know more than doctors regarding vaccines, attributed to Dunning-Kruger effects which occur when individuals' lack of knowledge about a particular subject leads them to inaccurately gauge their expertise on that subject [38]. However, the authors failed to consider whether some doctors and politicians are also influenced by Dunning-Kruger effects when it comes to facts regarding vaccination.

However, it is clear that many vaccine hesitators are not convinced that doctors, regulators and politicians are fully informed regarding vaccine safety. They may or may not believe that they are better informed, but the end result is that they therefore mistrust advice they are given.

#### The missing research

The above analysis suggests that it is reasonable for an intelligent, well read, concerned person to respectfully ask questions about aspects of orthodox advice he or she receives regarding vaccination, and to receive a respectful and informative (and truthful) response.

Fahlquist noted “To communicate respectfully entails not treating vaccine sceptics as ill-informed or less educated, but instead taking the concerns of the vaccine hesitant, who potentially could change their minds, as a starting-point of a respectful discussion [39]”.

The author contends that a recurring question voiced by many who have concerns about vaccination is “Why has no substantial research been published in leading medical journals comparing chronic disease profiles of fully vaccinated and completely unvaccinated children?” Without such research it is not possible to make a comprehensive comparison between the risks and benefits of vaccines.

If this unresolved question was answered it would either show that vaccines do not cause an increase in chronic conditions or, that they do. If no causative link is found, then many hesitators would be reassured. If a link was found then the benefit: risk equation would need to be reassessed by health authorities and politicians in the light of comprehensive facts, not limited and selective information.

Some authors have suggested this research could not be ethically undertaken because it would prevent children from being protected by vaccines, but this suggestion is incorrect. [40,41] Retrospective research in the primary school cohort (where most children are aged between 6 and 12 years) would not cause any child to be unprotected as the decision whether to vaccinate or not was already made by their parents. An analysis published in 2016 of the ability to undertake this research in Australia identified around 60,000 children in the unvaccinated primary school cohort, as shown in Table 2.

It is probable that these figures have changed due to recent Federal and State legislation penalising parents who have not fully vaccinated their children; it is likely that the numbers of partially and completely unvaccinated children would have reduced, but there would remain tens of thousands of unvaccinated children in the primary school cohort. This is enough to allow a study with high power to be undertaken, without geographical, gender or economic confounders interfering [42]. It would be an inexpensive and quickly-completed project if supported by national and local governments.

If such a study was undertaken in several countries the results would prove to be invaluable in assessing the true long-term impact of vaccination.

The need for this research is supported by the consistent findings of seven small studies which have attempted such a comparison. The studies are:

- 1990's: The Odent study in the UK; [43-45]
- 2004: The Golden study in Australia; [46]

- 2006/7: The Generation Rescue (GR) study in USA: [47]
- 2007: The Nakajima et al. study in Australia; [48]
- 2012: The Bachmair/KiGGs comparison in Europe (figures regularly updated); [49]
- 2017: The Mawson et al. study in USA, [50] and
- 2017: The Morgensen et.al. study in Guinea-Bissau [51].

The findings of these studies are summarised in Table 3. The figures show whether the condition is more or less more likely to be found in vaccinated compared to completely unvaccinated children. They are generally odds ratios calculations. A result >1.0 shows the condition is more likely to occur in vaccinated children, and <1.0 is less likely to occur in vaccinated children. Figures in bold show where the results are statistically significant ( $p>95\%$ ). The Generation Rescue and Bachmair studies did not test for statistical significance.

Table 4 summarises this information by calculating (i) a simple average of results, (ii) a weighted average of results, and (iii) a simple average of statistically significant results for each condition. These figures are indicative only and are presented as a guide.

These small studies all suggest that there is need for more research. Whilst they are each insufficiently powered to allow a definitive conclusion to be drawn, they all arrive at similar conclusions – that there is a link between vaccination and an increased incidence of chronic diseases.

If this finding was confirmed by a substantial study then it does not mean that vaccination is not beneficial, but it would mean that the benefit: risk equation would need to be reassessed by taking into account chronic as well as acute consequences of vaccination. This may mean that the vaccine schedule be reduced to include only potentially devastating diseases and/or more rigorous safety testing be mandated. It may mean that vaccine manufacturers be held more to account and be required to better compensate victims rather than be indemnified from prosecution by governments. And so on. The consequences would depend on the findings.

## Conclusion

Truth is the basis of trust. If a person finds that another person or institution has been untruthful, whether intentionally or not, they lose trust in the other person or institution.

If vaccines are indeed as safe as governments claim then an appropriately designed, well powered, properly matched, comparative

**Table 2.** Vaccination compliance with classification of parents and estimated number of children aged 6-11 years by category in Australia (2016)

% of children	Vaccination status	Classification of parents	% of children	Est. # children aged 6-11 yrs
92%	Fully vaccinated	<b>Active acceptors</b> Strongly believe in benefits and seek to use vaccines	30%	540,000
		<b>Passive acceptors</b> Comply with recommendations without strong belief in benefits	50%	900,000
		<b>Hesitators</b> Uncertain whether to use, delay or refuse vaccines	12%	216,000
4%	Partially vaccinated	<b>Refusers</b> Make a conscious decision not to (continue to) vaccinate	3.5%	63,000
		<b>Hesitators</b> Uncertain whether to use, delay or refuse vaccines	0.5%	9,000
4%	Completely Unvaccinated	<b>Hesitators</b> Uncertain whether to use, delay or refuse vaccines	1.5%	27,000
		Don't know/Don't care/ Other, e.g. health issues	0.5%	9,000
<b>Estimated number of Australian children in 6-11-year cohort</b>				<b>1,800,000</b>

**Table 3.** Likelihood of condition in vaccinated compared to unvaccinated children

Condition	Odent (446)	Golden (605)			Gen. Res. (boys) (9,175)	Nakajima (8,443)	Bachmair Vs KiGGS (23,845)	Mawson (666)	Morgensen (1,057)
		Hom. Imm. Only (72)	General health Only (51)	No Immuni-sation (150)					
Asthma	5.43	15.2	3.9	2.7	2.3	1.33	1.9		
Eczema	1.28	7.4	7.8	2.6	-	1.5	1.8	2.9	
Ear/Hearing	1.89	2.2	2.5	3.8	-		1.6	3.8	
Allergies	-	4.9	3.4	2.5	-	1.4	2.1	3.9	
Behaviour (general)	-	1.5	2.1	1.0	-		-	3.7	
ADHD	-	-	-	-	3.2		4.0	4.2	
Autism	-	-	-	-	1.6		-	4.2	
Epilepsy	-	-	-	-	-		9.0		
Hayfever	-	-	-	-	-		3.6	30.1	
Sinusitis	-	-	-	-	-		13.3		
All/other conditions	1.44	2.7	9.4	2.1	2.6		-	2.4	
Learning disabilities								5.2	
Death (DTP)									5.0

**Table 4.** Indicative increase in the condition in vaccinated compared to unvaccinated children

Condition	Simple Average	Weighted Average	Simple Average of Statistically Significant Figures
Asthma	4.7	2.4	6.2
Eczema	3.6	2.4	4.4
Ear/Hearing	2.6	1.7	3.2
Allergies	3.0	2.0	12.7
Behaviour (general)	2.1	3.0	3.7
ADHD	3.8	3.8	4.2
Autism	2.9	1.8	4.2
Epilepsy	9.0	9.0	-
Hayfever	16.9	4.3	30.1
Sinusitis	13.3	13.3	-
All/other conditions	3.4	2.3	2.4
Learning Disabilities	5.2	5.2	5.2

analysis of the incidence of chronic conditions in vaccinated and completely unvaccinated cohorts will show that. Vaccine hesitators will have one less concern to deal with and should have more confidence in orthodox advice regarding vaccination.

If the research shows that vaccines are less safe than claimed, then responsible governments will need to change some aspects of their vaccination policies.

Either way, there will be some improvement in trust between vaccine hesitant parents and health authorities.

If this research is not undertaken then many vaccine hesitant parents will continue to question and will continue to mistrust official answers as to why something so easy to do, and so obviously needed, remains undone and their vaccine hesitancy will also continue.

## Authorship

Isaac Golden is the sole author.

## Competing interest

The author has researched and used homoeoprophylaxis since 1985.

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