Vaccine Preventable diseases

Public Hearing

February 28, 2019

Good morning, my name is Dr. Toni Bark and I am a licensed MD in the state of Illinois. I am trained in pediatrics and rehabilitative medicine and I ran an emergency room, a pediatric emergency room in the inner city, During that time, I witnessed several children, after being in the vaccine clinic coming to the emergency room in status epilepticus with asthma, even respiratory arrest. That was a while ago. Since that time, there has been an emerging field called epigenetics, which is the field of looking at the link between genetics and environmental toxins affecting people individually. Vaccines are not safe and effective for everyone. This cannot be one-sized fits all, not everyone has the same risk factors. But in the last 20-30 years we have elucidated some things that are known as risk factors and they are called Single Nucleotide Polymorphic Variants. These interface with things like drugs and vaccines very differently for different people. This is not a one in a million type of issue. There can be maybe up to 10-15% of people that are quite susceptible to different vaccines. These are a minority, a susceptible minority, who are being left out in the rain without an umbrella. So, while it sounds good and well that vaccines are safe and effective, just so you understand, that they are legally classified as unavoidably unsafe and the manufacturers are not liable. This is a liability free product that is being mandated on children who have epigenetic susceptibility to injury. And the injuries are serious, including death and chronic encephalopathies. While there has only been two deaths from measles in this country since 2003, there has been at least 400 some odd children who have died from the vaccine. According to Gregory Poland, who is a vaccinologist at Mayo Clinic, he has written an article called the Paradox of Measles, which states, that you cannot eradicate a virus like measles with a live viral vaccine. You also will see that the majority of outbreaks, while it is different in this community because you have a tight community of unvaccinated people where this measles outbreak is happening, but the majority of measles cases around the country are actually in the vaccinated. So, this is a complex picture, it is not one sided, there is a lot of grey areas, it is very complex. The left panel would have you believe that it is not complex, that vaccines are safe and effective and the vaccine prevents measles and that if everyone was vaccinated there would not be measles and that is not true. The largest outbreak New York City has ever seen was just a few years ago and it was started by a 22-year-old recent recipient of an MMR booster. And 35-40 people who had all been vaccinated got a vaccine strain measles. In Corpus Christi 1983 there were over 400 students who had all been vaccinated, 98% vaccination rates, 97% of which had antibodies, memory antibodies and they still got measles. This is not a clear black and white picture. And if you eliminate exemptions, we all know how difficult medical exemptions are because the requirements for medical exemption as laggings about 30 years behind the science of the epigenetic risk factors. If you eliminate the exemptions you are basically making a large minority of people susceptible to very serious risks including death.

Thank you

State of Washington

February 28, 19

Report of Toni Lynn Bark MD, MHEM, LEED, AP

Re Vaccination(s) that have been proposed for Johnny Golucky (DOB 1st January 2018)

Introduction to Report

1. I am a Medical Doctor holding an MD, MHEM, LEED, AP, Medical Director of the Center for Disease Prevention and Reversal in Evanston, Illinois, practicing preventative medicine.

- **Qualifications and expertise**

2. I practice as an independent physician and have no conflicts of interest. Although I have co-produced a documentary and appear in others which highlight conflicts of interest in vaccine policies, I have received zero pay for my work and receive no monies directly or indirectly from the sale or distribution of the films.

3. I have provided expert testimony in relation to vaccination in numerous family law cases in several countries, and for the National Vaccine Injury Compensation Program.

4. My expertise in vaccination and the vaccine-targeted infectious diseases arise initially from my formal medical training, and subsequently from:

   a. my experience in Pediatric Emergency, including *inter alia*, attending to an unexpectedly high number of patients who had been vaccinated earlier the same day and were suffering serious reactions, and

   b. my private medical practice for over 24 years, in which a significant proportion of patients I have found to have been suffering chronic disorders, such as autoimmune and neurological damage, with a strong temporal link to vaccination.

5. I have been compelled to conduct extensive study of relevant published peer-reviewed medical literature partly by my above observations and medical public health obligations, and subsequently further by:

   a. my research for my Masters Degree in Medical Science and Medical Emergency Management, and

b. requests for expert testimony in the Federal Vaccine Compensation Program, Senate Health committees and staffers, and in Family Law matters in the United States, Canada, Australia and New Zealand. I have been accepted as an expert witness on the subject of vaccination in several family court matters in these countries, some of which matters have been heard in the past 12 months.

6. My fields of expertise include vaccine adversomics, which is a new, emerging research field,[i] and is the study of vaccine adverse reactions including their frequencies and mechanisms of causality, incorporating the use of immunogenomics (genetic influences on immune system responses) and systems biology approaches. The ultimate objective within this field of study is to determine, with sufficient accuracy and precision, the probability of a serious adverse effect by vaccination on any particular individual, and accordingly, when the probability for that individual does not exceed the benefit, avoid the relevant vaccination(s). Hence, this is the subject that is of most central to making the vaccination decision that is in any individual child's best interests.

   Vaccine adversomics is not yet covered in any formal medical training. Hence qualifying in such fields as immunology, epidemiology, pediatrics or genetics (or gaining membership of any associated societies) does not involve or require any study of risks of vaccines relative to their benefits, in relation to determining either population averages or any individual variations in susceptibilities. Formal medical education is supported by funding from the vaccine industry, which has no beneficial interest in sponsoring any field of study that might lead to a reduction in vaccine uptake.

7. The development of expertise in vaccine adversomics requires extensive study of relevant medical research. Some of that study I have demonstrated by way of the Notes and References in my report. It is augmented by my substantial clinical experience in this area, as stated in paragraph 4.b above.

8. The extensive study that I have conducted has necessarily covered publications that are relevant for determining:

   a. the strength of the link between vaccinations and serious disorders that I have encountered in my patients, and

   b. the relative benefits of the above countries' government-scheduled vaccinations for individuals with various health profiles, in particular:

i. the government-published rates of notifications, complications and sequelae from the respective vaccine-targeted infectious diseases in the United States, Canada, Australia and New Zealand, and

ii. the level of scientifically demonstrable effectiveness of the vaccines, and

c. the overall impact that the scheduled vaccines have had on the public health burden.

- **Subject of this Report**

9. I have been asked to provide my opinion concerning the potential impact of certain vaccinations upon Johnny Golucky ("Johnny"), born 1st January 2018 (aged 1 year) in consideration, *inter alia,* of his health and personal and family medical histories as an individual.

10. Johnny has not received any vaccinations.

11. I am informed that it has been proposed that Johnny be "caught up" with the following vaccinations:

- five diphtheria-tetanus-pertussis (DTaP) vaccine doses, four poliomyelitis vaccine doses, three hepatitis b vaccine doses, two varicella (chickenpox) vaccine doses and two combined measles-mumps-rubella vaccine doses.

12. What follows is a report containing a risk analysis of non-vaccination versus vaccination in relation to these diseases as applies to Johnny as an individual.

- **Notes and References to my Report – page 71 to end of report**

13. I reference a large volume of notes and source material in this report. These notes and references begin on page 71 of the report.

- **Process and Methodology**

14. In preparing this report, I have relied primarily on validated data at the national and international level for my statistics, augmented with extensive information contained in peer-reviewed medical and scientific literature.

Summary of Report Findings

15. Evidence available from multiple authoritative sources, including both government and medical research publications, all indicates that in the case of Johnny, the risk posed by

each of the proposed vaccinations cannot reasonably be demonstrated to be less than any risk arising from not receiving the vaccination.

The important reasons for this are that:

1. **Very low risks from the targeted infectious diseases**

   Government published data indicates that the rates of serious outcomes from the targeted diseases to even totally unvaccinated children, especially outcomes that are not otherwise avoidable, range from zero or negligible to minimal (as covered in paragraphs 33 to 83 on pages 10 to 24 of my report).

   These risks are slightly lower still for Johnny in the case of diphtheria, tetanus and pertussis to the extent that the single dose of diphtheria-tetanus-pertussis vaccination that he has already been given is reasonably effective.

2. **Very high rates of adverse effects reported from vaccine clinical trials**

   There is a relatively very high frequency of adverse events reported from active surveillance by manufacturers by way of clinical trials. Reasonable estimations of the proportion that are causally related to the vaccinations indicate that adverse effects from vaccination, including serious adverse effects, occur at a far greater frequency than any adverse effects that might arise to Johnny as a result of not receiving the vaccination. (Frequencies of adverse events reported from vaccine clinical trial testing are covered in paragraphs 86 to 90, which start on pages 25 to 27 of my report.)

3. **The limitations in the clinical trials indicate higher true rates of adverse effects**

   The limitations in the clinical trials – in the monitoring period, numbers of subjects and health profiles of subjects, indicate that the true rate of serious adverse effects from vaccination is likely to be higher still than the frequencies published from clinical trials (covered in "*Limitations of clinical trial testing*" in paragraphs 91 to 99 starting on pages 31 to page 34 of my report).

4. **Very high rates of adverse effects evident from government surveillance**

   After the vaccines are released for public use, the results from passive, post-marketing surveillance, when combined with the government-estimated underreporting rates and government causality assessments also are that the rates of serious adverse effects of the vaccinations are significantly higher than the rates

of disease-associated serious adverse effects arising from non-vaccination (covered in paragraph 103 starting on pages 36 of my report).

In summary, the risks of serious adverse effects (SAEs), evident from passive, post-marketing surveillance alone, can be approximated as follows for the diphtheria, tetanus, pertussis, polio, chickenpox, measles, mumps and rubella vaccinations:

Vaccine	**DTaP**	**Polio**	**Hepatitis B**	**Hib**	**Pneumo-coccal**	**Chicken-pox**	**Measles-Mumps-Rubella**	**Tota**
***Increase,* due to non-vaccination, of disease-associated serious risk (SAE)** (unadjusted by immunity already gained								
Disease SAE over material period (a)**	**<1 in 400,000**	**<1 in 1 trillion**	**negative to <1 in 25,000**	**<<1 in 40,000**	**<<1 in 13,000**	**negative to <<1 in 55,000**	**negative to <1 in 400,000**	**<1 i 6,00**
Vaccine serious risk (SAE) 'certainly'/'probably' causally related, based on government surveillance/assessment								
Vaccine SAE (b)**	**>1 in 500**	**>1 in 1,500**	**>1 in 3,600**	**>1 in 6,700**	**>1 in 1,700**	**>1 in 1,500**	**>1 in 700**	**>1 i 175**
Comparison result: factor by which Vaccine SAE risk (b) greater than Disease-associated SAE risk (a)								
Vaccine SAE (b) ÷ Disease SAE (a)**	**> 800**	**> 670 million**	**>>>> 7 to infinite**	**>>>> 6**	**>>>> 7**	**>>>36 to infinite**	**>>> 560 to infinite**	**>>>**

An expanded version of the above table is included at the end of my report, along with relevant notes.

As indicated in the table, for an average vaccine-eligible unvaccinated adequately nourished child in the US receiving the vaccines proposed for Johnny as an individual, for DTaP, Polio, Hepatitis B, Hib, Pneumococcal, Chickenpox and Measles-Mumps-Rubella vaccination, the risks of a serious AE "certainly"/"probably" caused by vaccination (row marked "(b)") appears to outweigh any increased risk to Johnny of a serious disease-associated AE (row marked "(a)") arising from him not being vaccinated, by, respectively, factors estimable to be more than (">") 800, 670 million, 7, 6, 7, 36 and 560, and overall more than 35.

5 Johnny he him (object) him (possessive) 1 year being vaccinated

These factors are only quite conservatively estimated because they incorporate only the results derivable from frequencies of vaccination adverse event reports from passive surveillance and government assessments of reporting completeness and causality.

5. Relatively high rates of adverse effects evident from government surveillance

The United States' vaccine injury compensation rate, when viewed in the light of the artificial obstacles to the receipt of compensation, also indicates an overall significantly greater risk from the vaccinations than any risks arising from not receiving them (covered in paragraphs 104 to 109 starting on pages 38 to 39 of my report).

6. The U.S. IOM has found that many serious risks are not disproven

There are also serious limitations to post-release evaluations of vaccine safety, and U.S. Institute of Medicine has found that the testing conducted to date in relation to many reported serious post-vaccination adverse events, including common ones, have not been scientifically disproven them to be caused by vaccinations (covered in paragraphs 110 to 118 on pages 40 to 45 of my report).

7. Further medical research indicates strong likelihood of further serious risks

Medical research into the effects of directly and repeatedly injecting the various vaccine ingredients provides substantial explanation for the adverse events that are observed after vaccination and also evidence that there are risks of additional serious adverse conditions, which are at the very least biologically plausible, and are not incorporated in the results of clinical trials. Many are common and most notably include autism, which Johnny has evidently developed only after being vaccinated (covered in paragraphs 119 to 175 on pages 46 to 60 of this report).

8. Properly controlled comparison studies indicate risks higher from vaccinations

Properly controlled comparison studies conducted to date of serious adverse effects rates from vaccination versus non-vaccination find higher risks from vaccination than non-vaccination (covered in paragraphs 176 to 177 on pages 60 to 62 of this report).

9. Johnny's own health profile shows higher risk still for him as individual

The characteristics of Johnny's individual health profile and medical history (covered in paragraph 181 on pages 63 to 64 and paragraph 173 on page 58 of this report) are recognisable signals, based upon published medical research, that Johnny has a substantially increased susceptibility to adverse effects of vaccinations.

- **Summary of report conclusion and recommendation**

16. The precautionary principle of medical ethics obliges me to not recommend any vaccination unless its benefits can confidently be shown to outweigh its risks. Based upon that principle alone, but especially after additionally incorporating the substantial evidence herein that the risks of each of the vaccinations significantly outweigh the benefits for Johnny, I am strongly obliged by my professional code of conduct to recommend against all of the proposed vaccinations.

    Taking into account the rate of incidence in the population of the targeted diseases, and harm therefrom, the demonstrated level of effectiveness of the vaccinations in protecting against harm, and the evident risks – proven and plausible, from vaccination, the evidence indicates any potential benefit achievable from any of the vaccinations, even if not achievable by other means, is far too low, where present at all, to consider to be worth tolerating the evident risk from any of the vaccinations in Johnny's case.

    In Johnny's case there is an especially evident high risk that vaccinations will exacerbate existing conditions from which he already suffers, and there is also a significant risk that they would result in him suffering additional type(s) of serious condition(s).

17. In the alternative, that is, in the event that the court nevertheless permits any vaccinations(s), I include at the end of my report a set of recommendations in relation to the scheduling and management of any such vaccinations, so as to minimise the risk of detriment to Johnny's health as a result of any such permitted vaccination(s).

- **End of Introduction to Report -**

Comparison of benefit versus risk of proposed vaccinations

If Johnny is *not* VACCINATED - risks from non-vaccination…

- **Vaccination benefits otherwise attainable - risk-free measures for disease prevention**

18. As a medical doctor I am ethically obliged to follow the precautionary principle when making judgments and recommendations in relation to any medical procedure or medication that carries accepted risks and/or unproven but biologically plausible risks.

19. Pursuant to the precautionary principle, any risk of harm to either child must be avoided wherever possible. Therefore, in relation to the benefit that is the purpose of this procedure, it is important to first consider all reasonably practical method(s) by which that benefit may be obtained *without* incurring *any* risk.

20. Therefore I begin this analysis with an examination of risk-free measures for obtaining the benefit of protecting Johnny from any sequelae from infectious diseases.

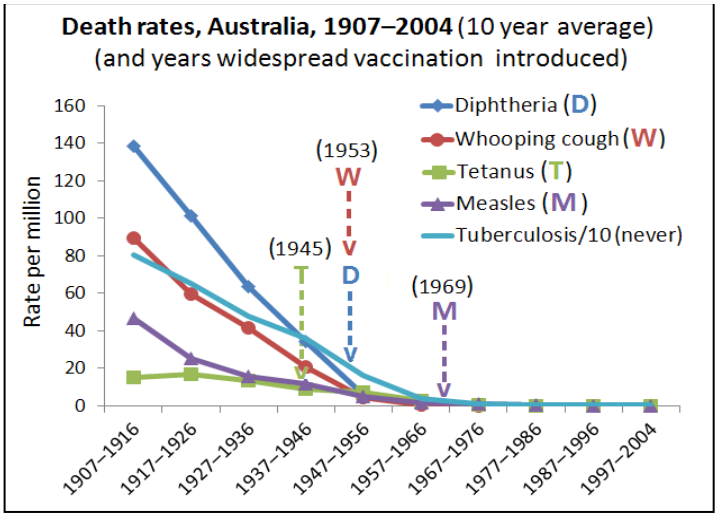
21. It is only where there is, or reasonably may be, a benefit of vaccination that is not achievable by such other risk-free method(s) that the procedure can then be considered.

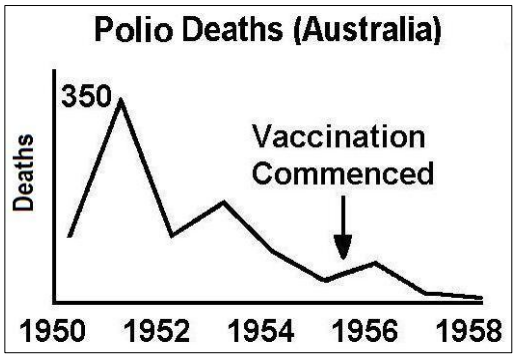
22. There is a clear historical record of dramatic achievement over the past century with respect to overcoming the former scourge of clinical infectious diseases in developed countries, including the United States. Therefore it is instructive to look at the historical record to establish factors key to that achievement, in particular the level of contribution made by significant advances in risk-free public health measures such as improved nutrition, as opposed to vaccines.

23. A hundred years ago, tuberculosis was more important than the diseases presently targeted, with a death rate more 5 to 50 times higher than the concurrent rates for presently vaccine-targeted diseases such as diphtheria, pertussis, tetanus, measles and (especially) polio. Typhoid deaths were also more common and scarlet fever and dysentery also caused many deaths. These diseases have essentially disappeared from developed countries along with presently targeted diseases, without vaccination or widespread vaccination.

24. 90-99% of the decline in the importance of vaccine-targeted diseases in developed countries also occurred prior to vaccination, or any other significant medical interventions such as antibiotics.

25. For example, the following graphs of death rates in Australia during the 20th century of some targeted and non-targeted diseases illustrate this pattern of decline.





By 1950, in Australia, whooping cough (WC) and measles were already considered to be no longer important enough to be notifiable.[ii] In 1956, similarly, it was declared that "*as causes of infant mortality in Australia all the infective diseases have been overcome*".[iii]

This death rate decline trend has been very similar in other developed countries, including the United States.

26. Governments, WHO and published scientific research around the world instruct on many factors credited with the past[iv] and continuing protection[v] against clinical infectious diseases: improved nutrition, sanitation and fitness, breastfeeding, reduced family size, less overcrowding and general health.

27. In particular in relation to nutrition, Vitamin A has been found to halve measles risks,[vi] and Vitamin C of sufficient dosage to be effective for overcoming a large variety of infections, including pertussis and other lung infections.[vii] Directly addressing thus the body's nutritional needs at the time is importantly a risk-free measure, unlike vaccination which is well acknowledged to carry risks.

28. For specific diseases, governments have specifically listed (cited below) additional factors that (a) cause higher risk, showing that the disease risk to most children is lower than the population average, and that have reduced risk,[viii] knowledge of which is very instructive for indicating what accessible measures will be effective for minimizing any risk for any child in the future.

29. Disease management measures are also undertaken by medical staff, because the quality of disease management also makes a difference to the risk of an adverse outcome. Hence, on the very rare occasions that harm has arisen from any of the targeted infectious diseases, it may have been avoidable by more informed or competent

management by the medical staff involved. Large doses of Vitamin C are not normally administered in hospitals unless requested by the family.

Risk comparison of non-vaccination versus vaccination, primarily for a "vaccine-eligible" child aged 1 year in the United States

30. For the purpose of this report I will assume that, in the case of each proposed vaccination, there is a potential benefit to from vaccination that is not achievable by such other risk-free method(s).

31. I am then obliged to determine if I can be satisfied that, for Johnny, it can be demonstrated with confidence that that benefit outweighs its risks, because unless and until I can be so satisfied, the precautionary principle obliges me to take the default position of favoring maintenance of the *status quo* - non-interference, and hence to not recommend the procedure for that individual.

32. I begin with an analysis on the following pages 10 thru 24 of the level of benefit, unattainable by other means in the United States, of each vaccination, i.e. the unavoidable increase in risks arising from non-vaccination to a "vaccine-eligible" child aged 1 year with Johnny's socioeconomic status.

- **Parameter values used in calculating risk of serious outcomes from non-vaccination**

  ➢ **Period of risk exposure**

33. In this analysis I treat the next 14 years as the relevant period for calculation of the increased risks arising from non-vaccination as explained under those respective headings), because that is the time that it will take for Johnny, presently 1 year of age, to reach 15 years of age, at which age:

  (i) Johnny may be old and mature enough to be able to make an informed decision himself, and

  (ii) after 14 years the risks associated with the vaccine-targeted diseases will not be the same, especially in the case of any to which Johnny develops natural immunity between now and then, and/or

  (iii) any protectiveness of vaccines given now may have significantly waned by 14 years' time, and/or

(iv) the risks from any vaccines given then may not be the same as the risks from the same vaccines if given now.

Also, the government provides disease notification figures totalled by age groups, and at 15 years of age, a child moves into a new age group (15-19 year olds), across which group the disease notification rates are less relevant to the decision to be made in these proceedings.

➢ **Vaccination coverage**

34. The exact vaccination coverages are unknown but the figures that I use are reasonable approximations based upon U.S. government records.[9]

➢ **Vaccination effectiveness**

35. The effectiveness of any vaccination for protecting against harm from the targeted infection(s) has not been scientifically demonstrated but an assumption is widely relied upon that vaccine-induced antibodies provide protection. The figures that I use in these calculations are also generously based upon that assumption, even though severe disease and even death have occurred in fully vaccinated patients with high antibody titres.[11] I have, however, partially taken into account the waning of vaccine-induced serum antibody levels over time, leading me in some cases to use lower figures than the initial seroconversion rates for estimates of average vaccination effectiveness over the period that I use for the risk calculation (in most cases, 14 years).

- **Diphtheria and Tetanus**

36. **Notification rate in US:** There have been no cases of diphtheria in US children in the 1-14 year age group since 1994. With an average birth cohort of 4 million children, the approximate annual chance today of a child in the US contracting diphtheria is **less than 1 in 1.3 billion**.[ix]

In 2007-2015 there were 15 cases of tetanus in 1 to 14 year old children in the US. With a vaccination coverage of about 93% and assuming an average vaccination effectiveness over 14 years to be 90%, the notification rate of tetanus in totally unvaccinated children totaled over 14 years and hence applicable to Johnny, is approximately **1 in 400,000**.[9]

37. **Death rate in US:** There are zero deaths from these diseases in children.[9]

38. **Transmission from another person is also impossible or almost impossible**, of tetanus or diphtheria respectively:

- tetanus is not at all contagious, which shows that herd immunity from those vaccinated cannot be what protects unvaccinated children; and
- diphtheria is not very contagious - prolonged contact is usually required, such as sleeping in the same room as a case.[x,8]

39. **Summary for Diphtheria and Tetanus:**

- Disease risk for Johnny - of contraction and especially of a serious outcome or death, from diphtheria or tetanus is effectively zero to negligible.

- **Pertussis**

40. **Notification rate of pertussis in US:** The pertussis rate in children 1-14 years of age in 2007-2015 averaged **1 in 4,563** annually, totaling less than **1 in 300** over 14 years.[9]

41. **Death rate from pertussis in US:** The risk for Johnny of death from pertussis is zero to negligible. Virtually all deaths are in infants under 6 weeks, a very small proportion a little older (almost always found to be fully vaccinated for their ages), and some in the very elderly. Deaths are not occurring in Johnny's age group.

42. **Pertussis vaccines are not claimed or evidenced to prevent transmission, infection or risk of adverse outcomes:**
The pertussis vaccine manufacturers' only claim for their vaccines is that some studies have indicated that they reduce the duration of an uninterrupted period of coughing. Coughing is not a complication or sequela but arises, only temporarily, from the body's own defences that it mounts to prevent any long-term harm.

The vaccine manufacturers do not claim that their pertussis vaccines:

- reduce infection or transmission of pertussis, and it is well acknowledged that they do not.[xi] That explains why almost all pertussis cases, in some outbreaks even 100%, occur in the vaccinated.[xii] In October 2015, a very large Australian study (covering 64,364 live-births) was published which found that: *"vaccinating parents with dTpa during the four weeks following delivery did not reduce pertussis diagnoses in infants*."[xiii] This confirmed the same finding of 2012, which resulted in most Australian states ending free pertussis vaccination for parents.[xiv]

Observer bias has been found to lead to an exaggerated perception of vaccine effectiveness.[xv]

There is voluminous evidence that vaccination may result in "*silent reservoirs*"[xvi] of "*readily transmitted*" infection,[xvii] increasing, instead of decreasing, the risk of transmission[xviii] and also *increasing susceptibility to the disease*, due in part to a phenomenon called "Original Antigenic Sin".[xix]

- reduce cough severity, total duration of any intermittent cough, or risk of longer term adverse outcome(s) and scientific research has not found that they do reduce the risk of harm or death, for example, Chuk et al (2008).[12(6)]
- that vaccine-induced antibodies persist for long period. The antibodies have been found to wane substantially within only a few years, one study finding an almost 50% decline within one year.[xx]

43. **Benefits to Johnny if they contract pertussis during childhood:**

- **Long term protection from pertussis risks**: Pertussis is safest during childhood. Natural infection in the unvaccinated is thought to provide natural immunity lasting several decades or lifelong,[xxi] providing protection during the higher risk older years.

44. **Summary for Pertussis:**

- The disease risk to Johnny of sequelae or death from not receiving doses of pertussis vaccination during his childhood is effectively zero to, at most, negligible
- Vaccination may increase their susceptibility to pertussis.
- There are significant benefits for the long term of developing natural immunity to the disease before reaching adulthood, and the chance developing long term natural immunity is reduced with each dose that Johnny receives of pertussis vaccine.

- **Poliomyelitis (polio)**

45. **Notification rate in US:**

The hypothesis of a existent risk arising from the possibility of importation of polio from overseas can no longer be reasonably sustained because:

- the US has been certified polio-free since 1979, which means that there has been no reported cases since then that have originated in the country nor any transmission.[9]

Last year (2017) in the entire world population of 7.5 billion people, only 16 cases of polio were reported in any countries (which were Afghanistan, Pakistan and Nigeria), and

- since 1979, over 10 billion unvaccinated person years have transpired amongst US citizens, plus billions of travellers have entered the US from other countries, all without leading to any transmission of polio in the entire country.[9] A few cases have been imported, but no transmission resulted.

Governments state that various factors other than local vaccination are preventing the disease in the developed world, including the 99.99% decrease in polio globally since 1988 and "adequate treatment of sewerage and provision of safe drinking water and foods".[8]

46. **Risk of paralysis:** Even if local transmission of polio were to occur and the resultant case was vaccine-preventable:
    - there is only a 1 in 1000 chance that the polio infection would cause paralysis[8] and
    - even if paralysis developed, almost all cases of the paralysis are temporary, and
    - even if paralysis developed and did not self-resolve within a few days, researched treatment is available that would most likely enable recovery to occur,[xxii] and
    - in Johnny's case, if there is still any risk to an unvaccinated child but the vaccine is reasonably effective, then he already enjoys protection from the vaccine dose that he has already been given.

47. **Risk of death from polio*:*** Zero to negligible, based upon the above.

48. **Summary for Polio:**

    Johnny's chance of polio contraction, and especially sequelae or death, is now zero to negligible.

- **Hepatitis B (HBV) (chronic)**

49. **Notification rate in US:** The US Government cites the main burden of hepatitis B disease (HBV) to be chronic infection. There were an annual average of 112 reports of chronic HBV in the US in the 1 to 14 year old age group in 2014-2015[xxiii] – an annual rate of 1 in 500,000.

    Based upon the assumptions of the seroprotection (SPP) rate being a reliable indicator of immunity against *chronic* infection and of a linear waning rate, and the measured rate of

decline of SPP averaging 1.36% (of the initial level) per year, then the average effectiveness of the hepatitis B vaccine over 14 years is about 86%.

The true number of hepatitis b cases may have been much less than 1 in 500,000 because a case can be reported more than once.[23] However, assuming that to be the true annual rate, and combining that with the vaccination coverage of 93% (approx.), and the estimated average vaccine effectiveness of 86%, the average annual risk of chronic HBV infection in an unvaccinated child could be estimated to be less than **1 in 140,000**,[xxiv] totaling about **1 in 10,000** over 14 years.

50. **Risk of cited complications or sequelae:** The cited risk of chronic HBV infection is that 15% to 40% of chronic cases can eventually lead to the development of cirrhosis of the liver and/or hepatocellular carcinoma. The total average risk for such a serious development over 14 years for an unvaccinated child can hence be estimated to be about **1 in 70,000** to **1 in 25,000**.

51. **Adverse effect of hepatitis b vaccination on hepatitis-related risk:** The risk of hepatitis b is higher for children in higher risk categories which include amongst many others that do not apply to Johnny, being immunocompromised and on immunosuppressive therapies. However, these conditions alone do not cause a substantial increase in risk because they do not lead to an increased risk of exposure to the virus.

52. Furthermore, although the purpose of hepatitis b vaccination is to protect the liver, experiments with mice have found hepatitis b vaccination to damage the liver and its function by changing the expression of 144 genes associated with liver function, induction of "loss of mitochondrial integrity, apoptosis induction, and cell death".[xxv] (See paragraphs 126 to 129 herein.)

    Similarly, in humans, abnormal liver function has been reported after vaccination. The frequency cited on the product insert is 0.1%-1% and a study of U.S. children less than 6 years old in 1993 and 1994 found that hepatitis B vaccination doubled the risk of liver problems.[25]

    Hepatitis B vaccination has also been evidenced to be positively associated with prevalent arthritis, incident acute ear infections and incident pharyngitis/nasopharyngitis.[xxvi]

53. **Summary for chronic Hepatitis B:**

- The average infection chance for an average child between the age of 1 and 14 (inclusive) is less than ("<") 1 in 10,000
- The average infection chance for an average child between the age of 1 and 14 of cirrhosis of the liver and/or hepatocellular carcinoma is less than ("<") 1 in 25,000
- Vaccination is evidenced to increase risk of harm to the liver (benefit evidenced to be negative).

- **Haemophilus Influenzae type b (Hib)**

54. Hib vaccination is not administered to children who have reached 5 years of age (except in exceptional circumstances that do not apply here), so the period of relevance for determining the risk of non-vaccination of Johnny ends at that time.

55. **Notification rate in US:** The average rate of Hib in children between 1 and 4 years of age (inclusive) in 2007-2015 was about **1 in 1,500,000 per year** (101 cases total).

    If we assume a vaccine effectiveness of 96% and average coverage of 93%, the annual average incidence rate in unvaccinated children in that age group has been about **1 in 160,000** over 2007-2015.[9] The total of that average rate over those 4 years of vaccine eligibility and recommendation is **1 in 40,000**.

56. **Death rate for children in US:** It was estimated in 1987 that approximately 4% of all Hib cases (including in adults) were fatal.[xxvii] Combining this estimate with the 1 in 40,000 average chance of Hib notification over the age range of 1 and 4 years, results in a total risk of death in that period of **1 in 1 million**. However, for children this is an over estimate because the case fatality rate is less in children than in adults.

57. **Vaccination effectiveness questionable:** The vaccination status among reported cases has sometimes been found to be similar to or higher than the vaccination rate in the broader community,[12,35] which calls into question the vaccine's effectiveness when the well documented phenomenon of doctor reporting bias is taken into account.[15]

    It has also been observed in medical research that Hib vaccination, similar to pertussis vaccination, may increase susceptibility to infection with non-targeted, more virulent strains, and may select for increased virulence.[76] Hence, the overall protective effectiveness of a vaccine cannot be concluded based upon a reduction in the rate of incidence of diagnosis of merely the particular specific targeted antigen.

58. **Summary for Hib:**

- The total infection chance for Johnny while he is aged between 1 and 4 years is < 1 in 40,000.
- Risk of death negligible
- Vaccine may increase susceptibility to strains that are more virulent

- **Pneumococcal disease (invasive)**

59. Pneumococcal vaccination is not administered to children who have reached 5 years of age (except in exceptional circumstances that do not apply here), so the period of relevance for determining the risk of non-vaccination of Johnny ends at that time.

60. **Notification rate in US:** The annual incidence rate of invasive pneumococcal disease (IPD) caused by (PCV13) vaccine-targeted serotypes in under 5 year olds in the US has been 1 case per 200,000 in 2012-16.[9]

    If we assume a vaccine effectiveness of 90% and average coverage of 93% in 6 month to <5 year olds, the annual average IPD incidence rate of the vaccine-targeted serotypes (1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F) in unvaccinated children under 5 years of age has been about 1 in 50,000 over 2012-2016.[9] The total of that average rate over the years remaining to Johnny before he reaches 5 years of age is about **1 in 13,000**.

61. **Death rate for children in US:** Deaths in unvaccinated children are rarer still. If it is assumed that the average IPD case fatality rate in the US (covering all serotypes) for 1 to 4 year olds, of 2.6% applies to vaccine serotypes in the unvaccinated, then the risk totalled over years remaining to Johnny before he reaches 5 years of age is less than **1 in 500,000**.[9]

62. **Vaccination effectiveness question:** Some published observations call into question the true overall effectiveness of this and the other vaccines:

    - widespread doctor bias against checking and reporting disease cases in those who are vaccinated, including with pneumococcal vaccines,[15]
    - similar or higher vaccination status sometimes observed among reported cases or deaths to that in the broader community,[35]
    - “non-vaccine serotype replacement disease” – after vaccination introduction disease caused by vaccine serotypes rapidly fell but serotypes not covered by the vaccine

rose. "*Virtually complete replacement … with non-vaccine serotypes …has been reported in several randomized controlled trials in South Africa[22], the Netherlands[23], Israel[24], the United States of America[25] and …The Gambia[26]*" Vaccination appears to increase susceptibility to strains that are more virulent and antibiotic-resistant. Findings include that, "*Although after the introduction of (Prevnar 7 pneumococcal vaccine) the overall severity of (invasive pneumococcal disease) cases …remained stable, higher rates of pleural effusion and empyema have been reported[31,34], which may be attributed to a changed frequency of virulence factors in the pneumococcal population*" and "*Replacement is dominated by penicillin-nonsusceptible serotype 19A in several countries"*[76]

In response to this problem, the US in 2010 replaced Prevnar 7 with Prevnar 13, which targets more serotypes. However, after a period of use of Prevnar 13, it has been reported that "*our data suggest rapid effects of pneumococcal vaccines and progression of serotype replacement. Besides invasive potential, the increased prevalence of non-vaccine serotypes highly non-susceptible to penicillin was a concern"* and that *"19A invasive pneumococcal disease persisted …among children less than 5 years old despite widespread use of PCV13".*

63. **Summary for pneumococcal disease:**

- The total infection chance: while Johnny is aged between 1 and 4 years: << 1 in 13,000
- Risk of death negligible
- Vaccine may increase susceptibility to strains that are more virulent

- **Chickenpox**

64. **Notification rate in US:** Chickenpox is a generally a benign, self-limiting illness in children. As the UK Government states, "*the vast majority of children recover quickly and easily*". [xxviii] Most countries around the world do not use the chickenpox vaccine at all, and of those that do, less than twenty, of which only about a dozen are Western countries, routinely recommend two doses of the vaccine. The rest recommend only one dose, either routinely or only for risk groups.[xxix] Varicella is not a notifiable disease nationwide in the US.

65. Chickenpox incidence in recent years is not published for the state of Washington. However, as a rough guide, annual notifications in 1 to 14 year olds in Indiana in 2016 averaged 1 in 9300,[9] which totals about a 1 in 700 chance for a child during that 14 year period.

66. If we also assume an average coverage of 91%, average vaccine effectiveness of 88% over 14 years, the average incidence rate in totally unvaccinated 1 to 14 children year olds during 2016 was about 1 in 2000 which, totaled for the age range of 1 thru 14 years is about **1 in 140**.[9]

67. **Rate of hospitalization:** Population-wide, about 5% of (notified) cases are hospitalized.[9] If that average applied to children, then that would mean a hospitalization chance of [1 in 140 ÷ 5% =] 1 in 2800 for a totally unvaccinated child. However, that average includes adults in whom the risk of severe disease is 25 times higher than in children,[9] so the average rate for totally unvaccinated children (including the more susceptible under 1 year olds) can be estimated to be around **1 in 55,000**.

68. **Risk of Death:** The case fatality rate across the whole population is cited to be 1 in 60,000.[xxx] Based upon that risk, and based upon an annual chance of contraction of 1 in 2,000 for a totally unvaccinated child, the annual risk of death can be estimated to be less than 1 in 120,000,000, totaling about 1 in 8,500,000 over 14 years. However, the 1 in 60,000 case fatality rate includes adults in whom the risk of severe disease is 25 times higher than in children,[9] so it would be much lower still in children.

69. **Risk of shingles in children is only in the vaccinated**: Shingles (herpes zoster), which has considerable morbidity, arises from reactivation of latent virus. It is common in later life but not in younger people. However, as the Handbook states, vaccination itself can establish latent ganglionic infection in vaccinees which may later reactivate to produce clinical zoster (shingles).[xxxi] Accordingly, varicella vaccine-strain "viral reactivation disease"

(shingles), was added to the US National Vaccine Injury Compensation Program's "Vaccine Injury Table"[54] in February 2017. Manufacturer package inserts for chickenpox vaccine list shingles as an adverse event reported in clinical trials, at the rate of 1 in 800 previously *healthy* children.[xxxii]

Johnny, however, is not a healthy child – he has not fully recovered from the eczema or autism spectrum characteristics that he developed after his previous vaccination, and at his last (24 month) M-CHAT autism assessment was judged to still be at risk of autism spectrum disorder. So he would be highly unlikely to be accepted into a vaccine clinical trial, and the risk in his case of developing shingles from vaccination is likely much higher than 1 in 800.

Shingles is also listed on other vaccines' product inserts – it is reported in temporal association with Infanrix-IPV (which is only given to young children, not adults) and within 6 weeks after Priorix MMR, in each case also at a frequency of between 1 in 100 and 1 in 1000 (see respective vaccine product inserts in paragraph 90 herein, starting on page 27).

In light of the post-vaccination shingles reports and other evidence that vaccines increase susceptibility to related and unrelated infections,[76] Johnny's non-receipt of other vaccines is likely to reduce him susceptibility to complications or sequelae of chickenpox compared to if he is fully vaccinated.

70. **Vaccination effectiveness questionable:** After vaccination came into widespread use in the US (after 1995), there was no identifiable acceleration in the decline in morbidity in the targeted age groups.[xxxiii] There is also serological evidence of significant primary vaccine failure.[xxxiv] There have been instances of vaccination rates among cases being found to be no less, or higher, than in the broader community.[12]

Because of the well documented phenomenon of doctors' "observer bias",[15] which is likely to exaggerate the perception of effectiveness, it is difficult to determine the true effectiveness of the vaccine.

Encephalitis and pneumonitis have been recorded to increase a little after vaccination introduction in the age groups targeted for vaccination,[xxxv] though given their very low rates, the increase may not be statistically significant.

71. **Benefits of contracting chickenpox naturally during childhood:**

- **Long term protection from disease risks**: As the UK Government states, in adults, "*chickenpox is more severe and the risk of complications increases with age*", "*when*

they are more likely to develop a more severe infection or a secondary complication".[28] Natural infection in childhood in the unvaccinated is followed by long-lasting natural immunity, which protects against infection during adulthood.

For the above reasons, the UK Government has decided that it is preferable for individual children to *not* routinely receive chickenpox vaccination because it would leave children susceptible to contracting chickenpox as adults, when chickenpox carries higher risks.[28]

- **Long term protection from other risks**: Peer-reviewed medical research has reported natural chickenpox infection leading to long term benefit, including a 60% reduction in the risk of developing glioma (a type of brain tumor) in later life.[xxxvi]

72. **Summary for Chickenpox:**

- It is a benign, self-limiting illness in children
- The average risk of death for a child between 1 and 14 years of age is significantly less than 1 in 8,500,000 (negligible)
- Any vaccination creates a risk of the main complication, shingles, occurring in childhood. Further vaccination increases that risk.
- The chickenpox vaccines' effectiveness is questionable.

- **Measles**

73. **Notification rate in US:** Based upon the annual average of 72 notifications received in 2007-2015 in 1 to 14 year olds (5 notifications per age year group), the average vaccination coverage of about 91.5%,[9] and a conservative estimate of 90% as the average vaccine effectiveness over 14 years (based upon an assumption that vaccine-induced antibodies reliably bring immunity[11] and upon the more conservative measurements of decline in antibody concentration over a 14 year period[xxxvii]), the average annual rate of measles in unvaccinated children between 1 and 14 years of age (inclusive) works out as approximately **1 in 140,000**.

Totaled over the next 10 years, the average chance of an unvaccinated child contracting measles during that period would be approximately **1 in 10,000**.

74. **Risks from disease**: The total risk of complications, of which the most frequent four are cited as convulsions, pneumonia, otitis media and diarrhea, is about 10% per measles

case.[9] Published research indicates that the risk is halved for a child without "*serious chronic disease or disability*"[38] and halved again for a child who is not Vitamin A deficient or is treated with Vitamin A.[6,7]

The complication risk for Johnny over a 14 year period thus works out as less than [1 in 10,000 x 10% x 50% x 50% =] **1 in 400,000**, and the risk of death, which is estimated to now be 1 to 2 cases in 1000 cases,[xxxviii] less than **1 - 2 in 10,000,000**. Based upon the 1963 estimate of only 1 to 2 deaths in 10,000 cases, the risk is **1 in 100,000,000**. No deaths have been reported in children for over two decades, except one in 2003 in a severely immune compromised child.

As can be expected from these negligible rates, no sequelae are being reported today in US, indicating that all, or virtually all, complications fully resolve.

75. **Same types of risk higher from vaccine**: The total of the rates cited on the Priorix product insert for just the above four complications as reported within 6 weeks of the second vaccination dose in previously *(very) healthy* child subjects is [1%-10% + 1%-10% =] **1 to 10 in 50**[32] which is 8,000-80,000 times higher than the risk of the same disease complications from non-vaccination. Similarly, thrombocytopenia and SSPE risks are (resp.) over 400 times and up to 2500 times higher from one vaccination dose.

76. **Benefits of contracting measles during childhood:**

- **Long term protection from measles risks**: The negligible risk that exists from measles is the least during childhood, just after infancy. If a child does contract measles, lifelong immunity develops, providing protection during adulthood when the risks are higher.

- **Long term protection from other risks**: Peer-reviewed medical research has reported significant long term benefits of natural measles infection. They include protection against certain types of cancer, e.g. Rönne et al (1985) found that only 1 out of 230 individuals (0.4%) with a history of measles developed cancer, compared with 21 out of 353 (6%) subjects without a measles history[36] – a 93% reduced risk. They also include resolution of some cancers[xxxix]and reduction in the risk of cardiovascular disease and strokes.[36]

77. **Summary for Measles:**

- The average clinical infection (or notification) chance for Johnny over the next approx. 14 years is less than 1 in 10,000.
- Based upon the notification rate, the risk of a complication for Johnny over the next 14 years is << about 1 in 400,000
- The average risk of death for Johnny over the next 14 years is << 1 in 5,000,000 (zero to negligible)
- The risk of disease complications for Johnny is significantly greater as a consequence of vaccination itself than the risk if they remain unvaccinated
- Multiple benefits exist for the long term of naturally contracting measles, including reduced risk of, and resolution of certain cancers.

- **Mumps**

78. **Notification rate in US:** Based upon the annual average of 331 notifications received in 2007-2015 in 1 to 14 year olds (24 per age year group), the vaccination coverage of about 91.5%,[9] and a conservative estimate of 90% as the average vaccine effectiveness over 14 years (based upon an assumption that vaccine-induced antibodies reliably bring immunity[11] and upon the more conservative measurements of decline in antibody concentration over a 14 year period[37]), the average annual rate of mumps in unvaccinated children between 1 and 14 years of age (inclusive) has been **1 in 30,000**, which totaled over 14 years is about **1 in 2,000**.

79. **Risks from disease for an unvaccinated child**: Meningeal symptoms and signs appear in approx. 10% of mumps cases, but permanent neurologic sequelae are rare. Profound unilateral nerve deafness occurs in about 1 in 15,000 cases and encephalitis at a frequency of 1 in 400 to 1 in 6,000, with the latter more realistic and the death in 1 in 6000 cases. So given the 1 in 10,000 annual risk of contraction, these risks become negligible.

    Not surprisingly, no sequelae are being reported today in US, and no deaths have been reported in any age group for over two decades.

80. **Same risks higher from vaccine**: All mumps complications and sequelae may occur after vaccination and all, or virtually all, have been reported, at higher rates after vaccination than the above calculated rates.

81. **Benefits of contracting mumps during childhood:**

- **Long term protection from mumps risks**: If Johnny does contract mumps, the negligible risk it poses is the least during childhood. At least 30% of infected children suffer no symptoms. Lifelong protection then develops, and as the Centers for Disease Control and Prevention (CDC) states: “Some complications of mumps are known to occur more frequently among adults than children”.[xl]
- **Long term protection from other risks**: Although mumps infection usually causes temporary discomfort, peer-reviewed medical research has reported significant long term benefits. Such observed benefits have included a reduced risk of ovarian cancer (mumps parotitis associated with a 19% lower risk), and which indicates also a likely reduced risk of testicular cancer in men, and cardiovascular disease and strokes.[36]

82. **Summary for Mumps:**

- The average infection (or notification) chance for Johnny over the next 14 years is approximately 1 in 2,000
- Serious complication risk of mumps is negligible
- Risk of mumps disease complications is greater after vaccination
- Natural mumps infection reduces the risk of serious diseases, including cardiovascular disease, strokes and potentially testicular cancer, later in life.

- **Rubella**

83. Rubella poses no risk to Johnny. The reason for vaccination is to prevent rubella in pregnant women.

If Johnny is VACCINATED - risks from the vaccinations….

84. On the following pages 25 thru 62 is an analysis of the risks of the proposed vaccinations as determinable from:

    - manufacturer clinical trials, for a child with excellent pre-existing health status (so Johnny would be highly unlikely to be admitted as a trial subject), and
    - passive surveillance on the public, for an average under 7 year old child healthy enough to be judged by both parents and the doctor to be "eligible" to be vaccinated, prior to each vaccination given, and
    - medical research studies on selected groups.

85. To any extent that the strength of a causal association of vaccination with any post-vaccination adverse event is, if not already widely accepted, at least biologically plausible and not disproven beyond all reasonable doubt, the precautionary principle obliges me to err on the side of overestimation, rather than underestimation, of that strength of causal association.

- **Active surveillance of adverse events by manufacturers, by way of clinical trials**

86. There are three phases of a vaccine's development (after testing on animals) before it is approved for widespread use. All phases are conducted by the vaccine manufacturers themselves, not an independent investigator. Phase III is more extensive than Phase I or II, and it is from Phase III that manufacturers list in their product information inserts adverse events ("**AEs**") reported and their frequencies.

87. Although many of the AEs listed are only judged to be at least "possibly" (and biologically plausibly), and not necessarily 100% proven, causally related, it appears reasonable to assume, based upon the selection of clinical trial subjects based upon pre-existing excellent health status (hence Johnny is highly unlikely to meet the criteria), and upon the limited monitoring period, that the vast majority of reported AEs are caused by the vaccines.

    Indeed Merck had investigators assess the solicited AEs reported from its Engerix-B hepatitis B vaccine clinical trials and they concluded that 80% were causally related.[xli]

88. In paragraph 90 below are the AEs that manufacturers list in their product information/inserts (PIs) from administration of the:

    (a) Infanrix DTaP vaccine, and

(b) Varivax chickenpox vaccine, and

(c) MMR vaccine.[32]

The PI for each of the other proposed vaccinations – Hib, hepatitis b, pneumococcal and polio (IPV) - and for alternative brands of vaccines targeting the same diseases, have similar lists and frequencies of AEs to these.

The AEs listed in paragraph 90 exclude those AEs that the manufacturers list only in relation to post-marketing surveillance, with a couple of exceptions that I have specified. I have also excluded injection site reactions.

Note: In relation to almost every AE listed by the manufacturers, I describe and reference later in this report, in paragraph 119 on page 46 to paragraph 176 on page 60, summary explanations for the biological plausibility of the vaccine causing the relevant AE, given all of the vaccine ingredients, the invasive nature of vaccination, and relevant medical research conducted to date. After some of the clinical trial**[47]** and post-marketing surveillance**[58]** AEs I have superscripted the relevant references to those explanations. (With further time available, the rest of the listed AEs could be superscripted similarly)

Potential symptoms of encephalitis or meningitis after vaccination[84]

89. The AEs listed first are reactions that may, in an unknown number of cases, result from relatively low grade, though sometimes higher grade, *encephalitis* or *meningitis.*

Doctors normally disregard the symptoms in this category as normal reactions, and make no investigation. That said, medical technology that is in widespread use is limited in its capacity for detecting inflammation at a relatively low grade level, due to the limit to its resolution.

However, a young child with encephalitis (inflammation of the brain) or meningitis (inflammation of the brain membrane) may display only two or three of these symptoms, and parents frequently report, following such symptoms after vaccination, a *significant, permanent, neurological deterioration* in their children - in their demeanour, alertness, personality, attention, learning ability and/or behavior, etc.[84] This has been the case for Johnny.

In post-marketing surveillance, clinically obvious serious encephalopathy is occasionally reported but based upon government research, *less than 1% of serious AEs are reported*.[58] So, whilst its frequency is unknown, the occurrence of serious AEs of a neurological nature can be estimated to be more than about 1 in 180 children in total for all of the vaccinations that are proposed for Johnny. (See calculations in paragraph 103 on page 36.)

90. **The observed adverse events listed by vaccine manufacturers from clinical trial testing**

- **for diphtheria-tetanus-pertussis, chickenpox and measles-mumps-rubella vaccines**

(a) **Infanrix DTaP vaccine**

Diphtheria-Tetanus-Pertussis (DTaP) vaccine (Infanrix®)[32] – *five* DTaP-containing doses proposed for Johnny. (Monitoring may have been only 2-3 days where unspecified, likely maximum of 6 weeks)

AEs in 11,400 previously *very healthy*[32,47] subjects	AEs frequencies ***per dose***	**Total of AE frequencies**
AEs that may be symptoms of encephalitis or meningitis:[84]		
1. fever >38.0°C, >39.1°C	1. 20% to 30%	
2. headache	2. (booster) 0.1% to 1%	
3. irritability	3. > 10%	
4. restlessness (agitation)	4. 1% to 10%, booster >10%	
5. loss of appetite	5. 1% to 10%, booster >10%	
6. persistent and/or abnormal crying	6. 1% to 10%	
7. somnolence	7. > 10%	
8. fatigue	8. 0.1% to 1%	
9. nausea, vomiting, diarrhoea &/or abdominal pain (gastro disorders)	9. 1% to 10%	
10. rash	10. 0.1% to 1%	
11. convulsions (afebrile)	11. 0.04% within first 7 days	
	Subtotal for 3 primary course doses plus booster	**Greater than 123%**
Plus:		
"Common" (1% to 10%): pruritus	+ > 1% x 1	
"Rare" (0.01% to 0.1%): urticaria	+ > 0.01% x 1	

	Subtotal for 3 primary course doses plus booster	**Greater than 4%**
After booster:		
"Uncommon" (0.1% to 1%): cough, bronchitis	+ > 0.1% x 2	**Greater than 0.2%**
"Very Rare" (< 0.01%): lymphadenopathy[65,75,76]	Up to 0.01%	**Up to 0.01%**

(b)

(b) **Varivax chickenpox vaccine**

Chickenpox Vaccine (Varivax)[32] – AE reports within 6 weeks of vaccination of previously healthy 1-12 year olds. (For most AEs, trials had 8824 or 8913 total subjects.). **Two doses** are proposed for Johnny.

AEs that may be symptoms of encephalitis or meningitis:[84]	**Frequencies of AEs reported per dose**	**Total of AE frequencies[43]**
1. fever >39°C (oral), >38.9°C (oral equivalent)	1. 14.7%,27%	
2. headache	2. > 1%	
3. irritability/nervousness	3. 6.5%	
4. loss of appetite	4. > 1%	
5. malaise	5. > 1%	
6. nausea	6. > 1%	
7. vomiting	7. > 1%	
8. abdominal pain	8. > 1%	
9. diarrhea	9. > 1%	
10. constipation	10. > 1%	
11. disturbed sleep	11. > 1%	
12. fatigue	12. > 1%	
13. rash	13. > 1%	
14. arthralgia	14. > 1%	
15. myalgia	15. > 1%	
16. neck stiffness	16. > 1% Total:	Greater than **35.2%**
17. febrile convulsions	17. < 0.1%	

Additional systemic AEs reported: "**Very common**" (each ≥10%): upper respiratory illness (26.9%), otitis (12%), cough (11%), "**Common**" to "**very common**" (each ≥1%): rhinorrhea (8.7%),[75] varicella-like rash (generalized) (3.8%), teething inflammation,[75] eye complaints, chills, lymphadenopathy, lower respiratory illness, allergic reactions (including allergic rash, hives),[75] nappy rash/contact rash, heat rash/prickly heat, insect bites, eczema / dry skin / dermatitis,[75] itching.	+ 26.9% + 12% + 11% = **49.9%** + 8.7% + 3.8% + 11 x >1% = **> 23.5%**	
"**Rare**" (each <1%): herpes zoster (shingles) (0.13%), pneumonitis[75]	**> 0.13%**	Greater than **73.5%**
Total of AE frequencies reported from Varivax Total number of previously healthy children suffering one or more AEs after Varivax		Greater than **108.7%** **85.8%**
AEs after **Varilrix** chickenpox vaccine but not listed above: "**Common**" (each between 1 in 10 and 1 in 100): injury, pruritus, toothache, pharyngitis, conjunctivitis (Total: 5 AEs) "**Uncommon**" (each between 1 in 1000 and 1 in 10000): bacterial infection, fungal infection, purpura, sweat gland disorder, dyspepsia, asthma, sinusitis (Total: 8 AEs)	> 1% x 5 + > 0.1% x 7	Greater than **5%** + Greater than **0.7%**

(c)

(c) **MMR vaccine**

Measles-Mumps-Rubella vaccine[32] (Two doses are routinely recommended for this vaccine). The manufacturer product information for the only MMR vaccine licenced in the US, M-M-R II, does not disclose the frequencies of most AEs reported from clinical trial safety testing results. Therefore, the following are the AEs and frequencies cited for the Priorix MMR vaccine, used in the UK, Canada, Australia and NZ		
AEs reported in previously very healthy subjects, within 6 weeks after vaccination	**AE frequencies reported**	**Total of AE frequencies[43]**

	AEs that may be **symptoms of encephalitis or meningitis** (a toddler may suffer only a couple of symptoms),[84] - within 6 weeks after vaccination:	After primary dose:	
	1. fever (> 39.4°C)	1. 6.4%	
	2. headache	2. unknown	
	3. abnormal crying	3. > 0.1%	
	4. anorexia	4. > 0.1%	
	5. fatigue	5. > 0.1%	
	6. vomiting	6. > 0.1%	
	7. abdominal pain	7. > 0.1%	
	8. diarrhea	8. > 1%	
	9. rash	9. 7.1%,	
	10. convulsions	10. 0.1% Total:	>**15.1**%
	Plus after booster dose:	1. > 5.3%	
		2. > 1%	
		6. > 1%	
		8. > 1%	
		9. > 1% Total:	>**9.3%**
	After the first dose of MMR vaccine further systemic reactions reported include, *inter alia*: 1. "Common" (**each** between 1% and 10%): pharyngitis,[75] bronchitis,[75] coughing,[75] other upper respiratory tract infection,[75] rhinitis,[75] otitis media,[75] respiratory disorder,[75] nervousness.[75] (Total: 8 AEs) 2. "Uncommon" (**each** between 0.1% and 1%): allergy**,**[75] eczema,[75] injury, infection,[75] infection bacterial, infection fungal, dermatitis,[75] pruritus, herpes simplex, herpes zoster, pneumonia, laryngitis**,**[75] parotid gland enlargement (parotitis),[75] stridor, gastrointestinal disorder,[75] toothache,[75] enteritis,[75] gastroenteritis,[75] stomatitis,[75] stomatitis aphthous,[75] conjunctivitis,[75] anemia, lymphadenopathy, insomnia. (Total: 24 AEs)	1. > 1% x 8 + 2. > 0.1% x 24	**> 10.4%**
	Measles-Mumps-Rubella vaccine (cont.) AEs reported as occurring in previously very healthy subjects, within 6 weeks after vaccination	**AE frequencies reported**	**Total of AE frequencies[43]**

	After the second dose of MMR vaccine further systemic reactions reported in 4 to 6 year olds include, *inter alia*: 1. “Common” (**each** between 1% and 10%): pharyngitis,[75] bronchitis,[75] coughing,[75] upper respiratory tract infection,[75] rhinitis,[75] otitis media,[75] herpes zoster (varicella), allergy,[75] eczema (Total: 9 AEs) 2.Uncommon” (**each** between 0.1% and 1%): infection viral,[75] dermatitis,[75] herpes simplex, parotid gland enlargement (parotitis),[75] gastroenteritis,[75] colitis,[75] conjunctivitis,[75] epistaxis (nose bleeding), urticaria,[75] dysphonia, sinusitis,[75] asthma,[75] lethargy (Total: 13 AEs)	1. >1% x 9 + 2. > 0.1% x 13	**> 10.3%**
	Additionally **reported in a trial of 12000 trial subjects after the MMR (Priorix)** vaccine were one occasion each of the following serious adverse events: granulocytopenia, exanthema[76] (Total: 2 AEs)	2 x 1/12,000	**0.02%**
	Additionally listed on the PI for the M-M-R II vaccine are the following AEs as having been reported in association with measles vaccines (each described as "rare" which is not defined numerically on that PI): - syncope, angioneurotic edema (including facial and peripheral edema),[75,82] bronchial spasm,[84] dizziness,[84] paresthesia,[84] polyneuritis,[75,84] polyneuropathy,[84] ataxia,[84] acute disseminated encephalomyelitis (ADEM),[84] aseptic meningitis,[76] measles inclusion body encephalitis (MIBE),[76] Stevens-Johnson syndrome,[83] Henoch-Schönlein purpura,[75] optic neuritis,[75,76,84] including retrobulbar neuritis,[75,76,83,84] papillitis,[75,76] retinitis[75,76] panniculitis,[75] ocular palsies,[84] nerve deafness,[84] epididymitis,[75] orchitis,[75,76] respiratory difficulty,[75,76,82] cyanosis, pancreatitis,[75,76] diabetes mellitus,[83] SSPE,[76] death[95]		
	- “**atypical measles**”. This form of measles only occurs in people who have been vaccinated, sometimes when they contract measles naturally. It is significantly more dangerous than the typical form. Its frequency is unknown but it may be higher than the typical form of measles, partly because the atypical symptoms can lead to a failure to correctly diagnose the disease as measles.[15] The virus is the same as in typical measles but the symptoms (defences) are altered by the acknowledged immune-sensitizing effect of vaccination.[76] Hence, the only way to 100% guarantee protection from atypical measles is to not vaccinate.	Frequency is unknown but pneumonia is common and may persist for 3 months or more.[76] Encephalitis and meningitis are also more common with atypical than typical measles.	Frequency unknown

(d)

- **Limitations of clinical trial testing**

  (especially with monitoring period, subject numbers and types, and lack of control groups)

91. As the US Department of Health and Human Services' Food and Drug Administration (FDA) has stated:

> *"In contrast to most drugs… developed to treat ill patients, vaccines …are given to… healthy people, …healthy infants and children. This places significant emphasis on their safety. Also, …the incidence of (several) infectious diseases that they are intended to prevent is quite low... Therefore, a high percentage of… people will never be exposed to the infectious agent… Thus, there is low tolerance for significant adverse events …caused by vaccines."*[xlii]

92. However, as the Australian Government's Therapeutic Goods Association (TGA) states, based upon which it concludes that post-release surveillance is "important":

> "*Clinical trials…do not detect all possible adverse events because:*
>
> *i. they usually do not continue for long enough to detect adverse events that take a long time to develop, and*
>
> *ii. they do not include enough subjects to detect adverse events that occur (more) rarely, and*
>
> *iii. they do not include all of the… types of people who might… use the medicine and... be more susceptible to some adverse events...*"

93. With respect to the above limitations, the manufacturers' product inserts reveal that:

    i. The monitoring periods in clinical trials normally range from a limited period of a few days to only 6 weeks.

       This limitation is very important because many serious adverse events, such as autoimmune diseases and cancer, will not usually become clinically apparent within such a short period. Product inserts explicitly warn that the vaccines are not tested for carcinogenicity, mutagenicity or fertility, and

    ii. The total number of subjects in the relevant trials normally range from less than 300 to approx. 12000, and are usually nearer the lower end of that range. (It may

further be possible that the manufacturers have disregarded trials on the basis of their yielding less favorable results than others.)

This limitation is very important because many serious adverse effects may occur too infrequently for their frequencies to be determined (or occur at all) in trials of such size, yet may still be significantly more frequent than serious adverse effects of the disease(s) that the vaccine targets. Because disease contraction rates are themselves the zero to low, serious adverse effects from the diseases are very rare, so the primary objective of the vaccine - overall protection – clearly remains untested, and

iii. Vaccine manufacturers describe their chosen clinical trial subjects as "healthy", but fail to include how they define "healthy".

This limitation is very important because manufacturers select subjects carefully on the basis of their good health. So the reported frequencies of adverse events cannot automatically be extrapolated to the wider vaccinated population. However, given the absence, or virtual absence, of reported adverse events in the subjects' medical records, the same subjects, in their pre-vaccination state, are able to be viewed as effectively a control group in the trials.

For this reason it appears reasonable to assume that almost all reported events are caused by the tested vaccine, even though most AEs included are only at least "possibly" caused by the vaccines, not technically 100% proven or assessed to be causally related. This may be why it is not generally considered necessary, especially for unsolicited adverse events, to include any comparison with frequencies in *other* types of control groups.

When "control" groups are employed and given a "placebo", the definition of a "placebo" or "control group" in vaccine studies is significantly broadened from common understanding – "placebos" may be other vaccines, sometimes also experimental[32] or injections of almost all of the vaccine's ingredients.[72]

- **Other limitations**

94. Other limitations include the lack of study:

- of individual vaccine batch vaccine toxicity/contamination (the latter evident from product recalls) – it remains the case that, as Menkes and Kinsbourne stated in 1990:

  "Vaccines are not standard from one batch to the next… In fact, the whole question of vaccine detoxification has never been systematically investigated." [47]

  or

- demonstrating the safety of the simultaneous and repeated administration of multiple vaccines as occurs in government vaccination programs - synergistic or cumulative toxicity. A study by Miller in 2016 found increased risk of serious adverse events (morbidity) and death (mortality) in individuals receiving more than one vaccine on a given day.[xliii]

- **Vaccines remain experimental when released to the public**

95. Hence the pre-release testing is too limited to determine the rate and strength of vaccines' association with serious adverse effects, some of which may not be rare**.**

96. It follows that vaccine administration to the general public in the United States is experimental to the extent, at the minimum, to which the clinical trials are thus limited, in such circumstances that exist of inadequate proper scientific investigation of safety.

97. The prestigious Cochrane Library recently conducted an independent review of trials of the MMR vaccine and the author's conclusion was "*The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."* The evidence is that the same can be said of the other relevant vaccines.

- **Frequency of medically significant events published to be around 1-4% per dose**

98. Even with such limitations, the trials are informative enough to reveal frequencies in the range of at least around 1-4% per dose for observed medically significant events ("medical events other than common medical ailments, resulting in an unscheduled physician's office or emergency room visit events").[47]

Such "medically significant events" are typically disregarded on the basis of a judgement being made that "*none of these were considered related to administration of study vaccines"*.

However:

- despite proper safety assessment being the trial's primary purpose, the reasons or particulars leading to the making of those judgments are withheld, and
- these events occur in previously healthy subjects - selected based upon not previously suffering such events, and
- the 1-4% frequencies of these medically significant events, being within the 1-10% range, would conventionally be categorized in manufacturer product information as "common", and
- the frequencies at which the targeted diseases occur in unvaccinated vaccine-eligible children are in most or all cases significantly lower, and
- medically significant events can include serious conditions such as autoimmune diseases, neurological events and respiratory conditions.

99. More detail and references on the acknowledged limitations of clinical trials are included in Note xliv herein.

- **Passive, post-marketing surveillance of vaccine adverse events**

100. Post-marketing surveillance is claimed, in view of the above failings, to *"provide important information…to contribute to a better understanding of…possible adverse effects".*[47]

101. However the reporting completeness from post-marketing surveillance, which involves only passive monitoring, has been estimated at less than 1%.[58]

➢ **Observed adverse events listed by manufacturers from post-release surveillance**

102. The following are the AEs reported by the vaccine manufacturers from post-marketing surveillance from Infanrix DTaP vaccine, Varivax chickenpox vaccine, and MMR vaccine.[32]

Similar lists of AEs are reported by the vaccine manufacturers from post-marketing surveillance from the other relevant vaccines.[32]

Note that any frequency cited in the table below may be less than 1% of the true frequency.[58]

AEs reported from passive post-licensure surveillance
Infanrix vaccine's AEs (no monitoring period stated)**:** *Blood and lymphatic system disorders*: Thrombocytopenia (reported with D and T vaccines) *Immune system disorders*: Allergic reactions, including anaphylactic and anaphylactoid reactions (Note that eczema is an atopic, meaning allergic, condition) *Nervous system disorders*: Collapse or shock-like state (hypotonic-hyporesponsiveness episode), convulsions (with or without fever) within 2 to 3 days of vaccination *Respiratory, thoracic and mediastinal disorders*: Apnoea *Skin and subcutaneous tissue disorders*: Angioneurotic oedema
Varivax (chickenpox) vaccine AEs *Body As A Whole:* Anaphylaxis (including anaphylactic shock) and related phenomena such as angioneurotic edema, facial edema, and peripheral edema; anaphylaxis in individuals with or without an allergic history. *Eye Disorders:* Necrotizing retinitis (reported only in immunocompromised individuals) *Hemic and Lymphatic System:* Aplastic anemia; thrombocytopenia (including idiopathic thrombocytopenic purpura (ITP)) *Infections and Infestations:* Varicella (vaccine strain) *Nervous/Psychiatric:* Encephalitis†; meningitis†; aseptic meningitis; cerebrovascular accident; Guillain-Barre syndrome; transverse myelitis; Bell's palsy; ataxia; paresthesia; dizziness; non-febrile seizures. *Respiratory:* pneumonia *Skin:* Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; including impetigo and cellulitis; herpes zoster†. † Cases caused by wild-type varicella or vaccine strain varicella have been reported in immunocompromised or immunocompetent individuals.

MMR vaccine AEs (Priorix and/or M-M-R II) (with reporting completeness much lower than in active surveillance)	**AE frequencies reported**	**Total of AE frequencies[43]**
- "very rare" (*each* reported in up to 1 in 10,000 doses) • meningitis, arthralgia, thrombocytopenia, thrombocytopenic purpura, allergic reactions (including anaphylactic and anaphylactoid), Guillain Barré syndrome, transverse myelitis, peripheral neuritis, erythema multiforme, arthritis, Kawasaki syndrome (Total: 11 AEs)	Up to 0.01% x 11 (AEs) x 2 doses =	Up to **1 in 450**
- "approximately once every million doses" • "CNS (Central Nervous System) AEs, such as encephalitis and encephalopathy occurring within 30 days after vaccination"	Approx. 0.0001% x 2 doses =	Approx. 0.0002% (1 in 500,000)
- "below 1 per 10 million doses": • encephalitis	Below 0.00001% x 2 doses =	Below 0.00002% (1 in 5,000,000)

Governments also list death,[95] brachial neuritis,[84] reduced sensation,[84] respiratory and/or heart rhythm change,[75] abscess,[76]sepsis[76] and other effects on the brain and nerves, immune system, lungs, blood, heart, gut, liver, kidneys, glands, eyes, ears, muscles, joints, skin, reproductive organs, etc, as possible adverse effects of the relevant vaccinations.[72]

- **Results of post-marketing surveillance – AE frequencies estimable**

103. Figures that indicate the level of vaccine risk in US can be derived by calculations based upon post-marketing surveillance data available from AE reports and causality assessments in Australia (where the same or similar vaccines are used), in combination with reporting completeness investigations in the United States. The following table sets out those calculations for all of the proposed vaccinations other than influenza:

Serious Adverse Event Reporting Rates in Australia, UK and New Zealand

"Serious" adverse events (AEs) ("serious" usually meaning "recovery with sequelae, requiring hospitalization, experiencing a life-threatening event or death") were reported from post-marketing surveillance in 2000-2012 in approximately 1 in 2,800 children, including all vaccinations that a child in Australia would be given by 7 years of age, which include those for diphtheria, tetanus, pertussis, poliomyelitis, chickenpox, measles, mumps and rubella.[72] This rate is similar to the average serious AE frequency reported for under 7 year olds vaccinations in both the UK in 2004-2010 and New Zealand in 2005-2009,[59] which were 1 in 2,300 and 1 in 2,100 respectively. The UK further recorded neurological reactions in 1 in 3,300 and deaths in 1 in 123,000 (2% of serious AEs) and New Zealand reported two deaths (which was also 2% of serious AEs).

Deducting from the rate of 1 in 2,800 children the rates for vaccines not proposed for Johnny (aged 1 year) results in an average serious AE risk of about **1 in 3,500** (for neurological reactions, 1 in 5,000) for a child given the vaccinations proposed for him **(A)**.

Serious Adverse Event Reporting Completeness

The US FDA found the reporting completeness for serious AEs to be **less than 1%**.[58] **(B)**

That accords approximately with the difference in magnitude (of ~150 times) between frequencies from passive surveillance and those of the same adverse events from active surveillance in clinical trials.

Proportion of Serious Adverse Events causally related to the vaccination(s)

Of TGA-assessed serious adverse event reports passively received in 2000-12, the TGA gave a "certain"/"probable" causality rating to **20%**. **(C)**

The causality rating of the remaining reports was left as "possible".[72]

Actual Risk of a Serious Adverse Effect from any/all vaccinations, acknowledged by the TGA as certainly or possibly **causally related**

Combining (A), (B) & (C) above, the risk for Johnny of a serious AE caused by any or all of the relevant vaccines is approximately [1 in 3,500 ÷ <1% x 20% =] **over 1 in 175**.

Based upon an equal apportionment of the number of adverse events reported in 2012 in Australia to each disease component, the following are the estimated risks for each vaccine, assuming contribution by each disease targeted in combined vaccines DTaP-containing vaccines:

Risk of a causally related serious AE, neurological AE or death from vaccination

Risk	**DTaP**	**Polio**	**Hepatitis B**	**Hib**	**Pneumo-coccal**	**Chicken-pox**	**Measles-Mumps-Rubella**	**Total**
Serious AE	**>1 in 500**	**>1 in 1,500**	**>1 in 3,600**	**>1 in 6,700**	**>1 in 1,700**	**>1 in 1,500**	**>1 in 700**	**>1 in 175**
Neurological AE	>1 in 700	>1 in 2000	>1 in 5000	>1 in 10000	>1 in 2600	>1 in 2000	>1 in 1000	>1 in 250
Death	>1 in 27,000	>1 in 80,000	>1 in 190,000	>1 in 360,000	>1 in 96,000	>1 in 80,000	>1 in 37,000	> 1 in 9,000

104.

Note: The following serious AEs are *excluded* from the above results from passive surveillance:

- all serious adverse events that are left rated as "possibly" causally related,[72] and
- some serious conditions that are frequently noted in strong temporal association with vaccination but are not reportable in the Australian Government's passive surveillance system, e.g. autism (see under heading "*Autism - US Government's (Vaccine Court's) and CDC researcher's acknowledgements with respect to causal links with various vaccinations"* in paragraphs 162 to 171 on pages 56 to 58 below), and

- serious conditions whose possible, certain or probable link to vaccination is not suspected due to a delay in the appearance of symptoms.[xlv]

Note also that these are average rates and do not take into account any increased susceptibility arising from Johnny having a higher risk health profile. The above estimated frequency of serious adverse effects of vaccination accords with…

- **US vaccine injury compensation rates**

National Vaccine Injury Compensation Program (NVICP)

104. In the US, already by the late 1970's, the significant frequency of serious adverse events occurring after vaccination had resulted in law suits for dozens of sudden deaths secondary to the DPT vaccine, several thousand cases of Guillain-Barré syndrome and a few hundred deaths from the swine flu vaccine.

105. By 1986, the amount of litigation had become so costly and overwhelming for the vaccine manufacturers that the US government created a no-fault compensation program overseen by special Vaccine Court, just for compensating vaccine injuries and deaths,[xlvi,xlvii] on the basis of vaccines being accepted as "unavoidably unsafe" as stated by the U.S. Court of Appeals**,** as follows:

> "*to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult… Most importantly the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects".*[xlviii]

106. As set out in the *U.S. National Childhood Vaccine Injury Act Vaccine Injury Table*, the US Government Vaccine Court accordingly has been awarding claims since 1989 for:

- death, anaphylaxis and anaphylactic shock, encephalopathy**,** seizure and convulsion, chronic arthritis, brachial neuritis, thrombocytopenic purpura, vaccine-strain measles viral infection, vaccine-strain polio viral infection, and "any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.[xlix]

- **Rate of successful award claims under NVICP**

107. Since 1990, as of 30 March 2018, $3.5 billion has been paid to just a portion of those seeking damages in the Vaccine Court due to vaccine injury or death. The number of claims and awards have steadily increased since the program began. A record number of 706 awards, totaling $252 million, was paid in 2017.[l,li]

108. Based upon the number of awards from 2006 to 2016 and the number of doses of each vaccine on the U.S. vaccination schedule, there are on average successful claims for vaccine injury or death (8% claims were for death) for approximately **1 in 40,000** fully vaccinated children under 7 years of age, though normally when children are injured, the parents stop vaccinating before the child reaches 7 years of age. The average award per injured child in 2006 through 2016 being approximately $600,000

- **Factors seriously limiting chance of successful claim when a vaccination truly causes an injury**

109. The above rate of **1 in 40,000** could be expected to be significantly higher if it were not for these facts:

    i. medical doctors typically deny, as a matter of course, that serious injuries suffered may be causally related to the vaccinations administered, and are evidenced to report only less than 1% of serious injuries,[58] and

    ii. the public, and even the vast majority of medical doctors (as was the case for myself in the past) are unaware of the existence of the vaccine injury compensation program, and

    iii. to lodge and pursue a claim in the Vaccine "Court" through to its end requires significant motivation, commitment and resources (proceedings can be very protracted), and

    iv. only a small proportion of injuries are listed in the *Vaccine Injury Table.*[54] Others may still be compensable but with more difficulty, and

    v. the Vaccine "Court" operates under legislative restrictions which, such as the very restrictive criteria in relation to time periods associated with the injury.[lii]

- **Limitations of post-marketing surveillance** (References and further details are in Note liii)

Passive surveillance is not conducted scientifically

110. Despite the heavy reliance upon it in view of the serious limitations of pre-marketing clinical trials, post-marketing surveillance also is not conducted scientifically, so has serious limitations. Reports are received only arbitrarily without any enforcement, and as the New Zealand Government states: "The limitations of using spontaneous reports include *under-reporting* …heavily subject to *reporting bias* …not very effective at detecting adverse reactions that occur a long time after starting the medicine. For this reason these reports are only used to identify safety signals. These signals require further formal epidemiological study before they can be validated or discounted. Information obtained from spontaneous reports needs to be interpreted with caution."[liv]

111. The evident reporting completeness of less than 1% is in itself a clear signal of the serious limitations, for the important objective of safety evaluation, of post-marketing surveillance for filling in the large gaps left by clinical trials that are conducted pre-release.

- **Examples evidencing serious inadequacies of post-marketing surveillance inadequacies**

112. Recent well publicized cases of serious adverse events occurring after vaccination include:

    - Sabah Button who became severely disabled after an influenza vaccine that she was given in April 2010 (in Perth, Australia), and
    - Ben Hammond, who developed ADEM (acute disseminated encephalomyelitis) after a dTpa vaccine that he was given in September 2012 (also in Perth, Australia).

    Yet reports for *neither* of these serious adverse events, in which the causal relationship to the vaccines is opined by medical experts to be certain or probable, are included in the relevant tables in the Australian "*Adverse events following immunisation annual reports"* for the relevant years.

- **U.S. Institute of Medicine (IOM): concluded vaccination causes certain serious injuries, and that testing is inadequate to show non-causation of others**

113. The IOM was formed in the United States in 1863 by congressional charter to "provide expert advice on some of the most pressing challenges facing the nation and the world." Its members were historically "among the world's most distinguished scientists, engineers,

physicians, and researchers; more than 300 members are Nobel laureates". Under the 1986 Act, the IOM was charged with issuing reports on injuries from vaccination. (For references and further detail, see Note 58.)

➢ **IOM 1991 Report**

114. In 1991, the IOM examined 22 commonly reported serious injuries following the DTP vaccine. The IOM concluded the scientific literature supported a causal relationship between the DTP vaccine and 6 of these injuries:

- (***causal relationship found:***) acute encephalopathy, chronic arthritis, acute arthritis, shock and unusual shock-like state, anaphylaxis, protracted inconsolable crying.

The IOM further found that the scientific literature was insufficient to conclude whether or not the vaccine can cause 12 other serious injuries commonly reported afterwards:

- (***lack of scientific studies:***) aseptic meningitis (serious inflammation of the brain membrane); chronic neurologic damage; learning disabilities and attention-deficit disorder; hemolytic anemia; juvenile diabetes; Guillain-Barre syndrome; erythema multiforme; autism; peripheral mononeuropathy (nerve damage); radiculoneuritis and other neuropathies; thrombocytopenia; thrombocytopenic purpura.

The IOM:

- remarked on the poor design of vaccine studies, stating that these "studies are too small or have inadequate length of follow-up to have a reasonable chance of detecting true adverse reactions" and that "existing surveillance systems of vaccine injury have limited capacity to provide persuasive evidence of causation" and
- lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines" and
- thus cautioned that "if research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped.

➢ **IOM 1994 Report**

115. As charged under the 1986 Act, the IOM issued another report in 1994 entitled "*Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causation*".

This second IOM report examined the scientific literature for evidence that could either prove or disprove a causal link between commonly reported serious injuries and vaccinations for diphtheria, tetanus, measles, mumps, poliomyelitis, hepatitis B, and Hib.

For this report, the IOM did locate sufficient science to support a causal connection

between these vaccines and 12 injuries, including:

- (***causal relationship found:***) death, anaphylaxis, thrombocytopenia, and Guillain-Barre syndrome.

It also rejected a causal relationship for 4 conditions. However, the problem persisted of a lack of basic scientific studies. The IOM could not determine whether there was a causal connection between vaccination and 38 of the most common serious injuries parents reported their children experienced following these vaccines, including:

- (***lack of scientific studies:***) demyelinating diseases of the central nervous system, sterility, arthritis, neuropathy, residual seizure disorder, transverse myelitis, sensorineural deafness, optic neuritis, aseptic meningitis, insulin-dependent diabetes mellitus and SIDS (though the US Vaccine Court has since, recently, ruled that vaccination had caused a case of SIDS[lv]).

The IOM again lamented: "The lack of adequate data regarding many of the adverse events under study …many parents and physicians share this concern."

The potential risks posed by combining vaccines was another acute concern raised by the IOM in 1994. The IOM noted that this subject simply had not been studied: "The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously. This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use."

➢ **IOM 2011 Report**

116. In 2011, the U.S. Department of Health and Human Services ("**HHS**") paid the IOM to conduct another assessment regarding vaccine safety. The resultant report, entitled "*Adverse Effects of Vaccines: Evidence and Causality*", was the culmination of the largest review by the IOM regarding vaccine safety since the IOM's reports from 1991 and 1994.

This third IOM Report reviewed the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and/or rubella. The IOM located science which "convincingly supports a causal relationship" for 14 of these serious injuries, including:

- (***causal relationship found:***) pneumonia, meningitis, hepatitis, MIBE (deadly brain inflammation a year after vaccination), febrile seizures, and anaphylaxis.

The review also found sufficient evidence to support "acceptance of a causal relationship"

for 4 additional serious injuries.

However, the IOM found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

- (***lack of scientific studies:***) encephalitis (brain inflammation), encephalopathy (gradual degeneration of brain function, including memory, cognitive ability, concentration, lethargy, and eventually consciousness), infantile spasms, afebrile seizures, seizures, cerebellar ataxia (inflammation of and/or damage to the cerebellum), ataxia (the loss of full control of bodily movements), acute disseminated encephalomyelitis (brief but widespread attack of inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibers), transverse myelitis (neurological disorder caused by inflammation across both sides of one level, or segment, of the spinal cord that typically results in permanent impairments), optic neuritis (inflammation of the optic nerve and symptoms are usually unilateral, with eye pain and partial or complete vision loss), neuromyelitis optica (body's immune system over time repeatedly mistakenly attacks healthy cells and proteins in the body, most often those in the spinal cord and eyes resulting in permanent disability), multiple sclerosis, Guillain-Barre Syndrome (body's immune system attacks part of the peripheral nervous system), chronic inflammatory demyelinating polyneuropathy (autoimmune inflammatory disorder of the peripheral nervous system resulting in loss of nerve axons), brachial neuritis (auto- immune reaction against nerve fibers of the brachial plexus), Amyotrophic Lateral Sclerosis (rapidly progressive, invariably fatal neurological disease that attacks the nerve cells responsible for controlling voluntary muscles), small fiber neuropathy (damage to the small unmyelinated peripheral nerve fibers), chronic urticaria (chronic hives), erythema nodosum (skin inflammation in the fatty layer of skin), systemic lupus erythematosus (autoimmune disease in which the body's immune system mistakenly attacks healthy tissue), polyarteritis nodosa (inflammation resulting in injury to organ systems), psoriatic arthritis, reactive arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, arthralgia (joint pain), autoimmune hepatitis, stroke, chronic headache, fibromyalgia, Sudden Infant Death Syndrome, hearing loss, thrombocytopenia, immune thrombocytopenic purpura

Thus, out of the 158 most common serious injuries reported to have been caused by the vaccines under review, the evidence

- "convincingly supports a causal relationship" for 14,

- "favors acceptance of a causal relationship" for 4, and
- "favors rejection of a causal relationship" for only 5 of them.

For the remaining 135 vaccine-injury pairs, over 86% of those reviewed, the IOM found that the science simply had not been performed.

➢ **CDC has ignored IOM's calls to identify children susceptible to vaccine injury**

117. Compounding the lack of adequate science to simply ascertain whether the most commonly reported serious adverse reactions following vaccination are caused by vaccines, the IOM Reports discussed above have consistently acknowledged that there is individual susceptibility to serious vaccine injuries.

The IOM has acknowledged that research on such susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, intercurrent illness, and present and past environmental exposure.

In 1994, the IOM, building on concerns raised in its 1991 Report, stated:

> "*The committee was able to identify little information pertaining to why some individuals react adversely to vaccines when most do not."*

The IOM urged that:

> *"research should be encouraged to elucidate the factors that put certain people at risk*."

Yet, seventeen years later, in 2011, the IOM stated that this research had still not been done:

> "*Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few— all of which can interact ….Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine. [M]uch work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients*."

Unfortunately, HHS has still not conducted this research. It is only outside of HHS that

such research has been conducted to some extent, such by Soriano et al (2015).[100,47]

➢ **IOM 2013 Report**

118. In 2013, HHS commissioned the IOM to review the safety of the entire vaccine schedule. "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy" were investigated.

The IOM again reported that while "most children who experience an adverse reaction to immunization have preexisting susceptibility," it "found that evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes."

The IOM has found no valid studies conducted of the entire vaccine schedule on a population level, or portions or variations thereof, and that no study compared the differences in health outcomes between entirely unimmunized populations of children and fully immunized children or (still) the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule.

HHS had failed to even define the terminology for the study of susceptible subpopulations; hence IOM admonished HHS to "develop a framework that clarifies and standardizes definitions of ... populations that are potentially susceptible to adverse events." While every vaccine brand is the same, *it is plain that every child is different*.

The lack of any investigation of safety of the immunization schedule was found by IOM to be not due to any reason of impracticality, time or expense, stating that "it is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD" (Vaccine Safety Datalink Project) which would be cheap and efficient and able to be done in minutes. Only political/commercial reason(s) appear to remain not discounted.

The IOM had correctly pointed out in 2011 that given the "widespread use of vaccines" and "state mandates requiring vaccination of children ... it is essential that safety concerns receive assiduous attention." This is the same call for diligent attention that the IOM made in 1991 and 1994. Unfortunately, all of these calls for action have gone unheeded. The critical scientific inquiry to identify individuals susceptible to serious vaccine injury has simply never commenced.

Since the IOM's first call for this science in 1991, HHS has spent tens of billions promoting and purchasing vaccines, and vaccine makers have accumulated hundreds of billions in vaccine revenue. Yet still no material funds have been allocated to identify susceptible subpopulations, let alone which injuries are caused by the vaccines.

The CDC itself acknowledges that assessing "adverse events require more detailed epidemiologic studies (than have been conducted to date) to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons."

The HHS has nonetheless consistently refused to study health outcomes of the completely unvaccinated. So-called "control" groups used are not proper controls – either they include vaccinated persons or other critical characteristics that do need to match between the test and control groups do not match. Again, it is only small-scale studies, conducted outside of the HHS, that have been performed comparing vaccinated with completely unvaccinated children, such as those described in paragraphs **176 and 177 on pages 60 to 62 herein.**

- **Examination of causality, and additional risks not included in government surveillance**

119. I will now cover a more in-depth analysis of the adverse effects of vaccinations as resulting from the ingredients that are/can be included and separately or simultaneously directly injected.

Vaccine ingredients

120. The vaccines being proposed to be administered to Johnny may, in total, contain the following ingredients (lists are not in order of quantity), administered by way of a total of about 16 to 21 direct injections[73]:

Ingredients listed by the vaccine manufacturers (in the product inserts)
• **72 antigen doses** (in the vaccines that have been proposed for Johnny), and

- **foreign organism components, neurotoxins and multiple chemicals** (called "**inactive**"[72] ingredients, but are not inert) directly injected, residual components, including DNA and proteins, (aborted) human embryonic lung cells, human fetal MRC-5 diploid cells[66] and embryonic guinea pig cell cultures, polysorbate 80 (Tween 80), genetically engineered yeast[83], aluminum hydroxide[78,81,83,84,83,84], aluminum phosphate[77,83], amino acids, ammonium sulfate, fetal bovine and calf serum, other bovine derived materials,[62] Latham medium or modified Latham medium derived from bovine casein, chick embryo cell culture[83], Eagle MEM modified medium (containing fetal calf serum and glutamine), EDTA, Fenton medium (containing bovine extract[62]), formaldehyde, gelatin, hydrolyzed porcine gelatine, glutamate, MSG, glutaraldehyde, lactose, modified Stainer-Scholte liquid medium (also contains MSG), neomycin (antibiotic)[64], monkey kidney cells[94], embryonated hens' eggs, phosphate, phosphate buffers, polymyxin B (antibiotic), potassium chloride, potassium phosphate monobasic, sodium phosphate monobasic, sodium phosphate dibasic, semi-synthetic medium, sodium chloride, sodium dihydrogen phosphate dehydrate, sodium deoxycholate, sodium hydroxide, sorbitol, soy peptone broth, streptomycin (antibiotic), succinate buffer, sucrose and urea.

Other known or potential vaccine ingredients (*not* listed in the product inserts)

Although this state's government may claim that vaccines comply with strict manufacturing and production standards, the following contaminants are known and permitted:

- nanocontaminant biopersistent particles only recently detected in vaccines. Those in the proposed vaccines include: tin, aluminum precipitates, aluminum, gold, barium, iron, titanium, tungsten, zirconium, calcium, silicon, calcium, magnesium, chromium, copper, sulphur, zinc and nickel.

  These contaminants' discoverers wrote, "*The inorganic particles identified are …biopersistent and can induce effects that can become evident either immediately …or after a certain time. … Particles (crystals and not molecules) are bodies foreign to the organism and they behave as such. More in particular, their toxicity is in some respects different from that of the chemical elements composing them, …they induce an inflammatory reaction. …Those microparticles, nanoparticles and aggregates …can …be carried by the blood circulation, escaping any attempt to guess what will be their final destination …it is …likely that, in some circumstances, they reach some organ, none excluded …including the microbiota, in a fair quantity. …All foreign bodies, particularly that small …induce an inflammatory reaction that is chronic because most of those particles cannot be degraded. Furthermore, the protein-corona effect (due to a nano-bio-interaction [18]) can produce organic/inorganic composite particles capable of stimulating the immune system in an undesirable way [19-22]. It is impossible not to add that particles the size often observed in vaccines can enter cell nuclei and interact with the DNA [23]" and that the nano-bio-interaction "generates an unfolding of the proteins that can induce an autoimmune effect once those proteins are injected into humans*".[77,83,75,]

In spite of such safety warnings, also echoed in other prestigious medical literature such as the British Medical Journal (3 Feb 2017), the US, including the state of Washington, has continued administration of these potentially contaminated vaccines.

- glyphosate (key active chemical in Monsanto's herbicide Roundup®) and
- ethylmercury-containing thimerosal, found in 80% of influenza vaccines in as high an amount as 25 mcg, and in trace amounts in other vaccines, in spite of the government directive in 2000 to remove mercury from all childhood vaccines. Ethylmercury has multiple dangers, including that it specifically inhibits ERAP1, a protein used to properly fold proteins used by the human adaptive immune system. Additionally, the issue of synergistic toxicity from simultaneous injection of other toxins, such as aluminum, has not been addressed,[68] and
- in the case of each viral vaccine, potentially animal viruses (e.g. simian or bovine), prions[94] and bacteria (e.g. Campylobacter jejuni and mycoplasma).

121.

The safety of the "inactive" ingredients or contaminants in vaccines has not been scientifically demonstrated, because "inactive" ingredients, and frequently potentially contaminants also, are included in "placebo"s in vaccine safety trials, despite not being inert.[lvi]

Any claims that vaccines comply with strict manufacturing and production standards are further undermined by mishaps and recalls that have occurred post-release, usually involving the discovery of contaminated batches.[47]

Invasive nature of vaccination procedure – how experimental is it?

121. Vaccination of Johnny will involve a direct, invasive injection[78,lvii] of some or all of the above ingredients past the following defensive, filtering, and chemical/enzymic breakdown bodily processes:

- his entire secretory immune system, and
- his primary defence mechanisms, including in the gut, which is lined by 80% of the immune system in the form of the *gut-associated lymphoid tissue* (GALT), and
- his entire digestive system, which has a very important role of breaking down all that is ingested into simpler forms that the body can use before they are absorbed,

among the most notable examples being foreign proteins which the digestive system must break down into their component amino acids before absorption.

In terms of our biological history, vaccination is a very new type of invasion for the body to encounter. The body has been designed without any inbuilt preparedness for an invasion of quite such a type, such preparedness being needed to reliably avert all potential biochemical pathways by which such an invasion could be harmful.

Medical research findings about resulting adverse effects of vaccinations

- **Allergies, autoimmune/inflammatory diseases, neurological disorders and other chronic diseases**

122. In 1991, David Eddy, Prof. of Health Policy and Management at Duke University, North Carolina, estimated that only 1% of the articles in medical journals are scientifically sound and only about 15% of medical interventions are supported by solid scientific evidence (BMJ 1991).[47] Vested commercial interests are able to wield significant influence funding misleading poor research, and even fraud itself. These practices appear to be inevitable when vested interests are involved, especially when, as here, the adverse repercussions of admission of a link are enormous.

123. Peer-reviewed medical research has nevertheless linked vaccines and/or direct injection of various of their ingredients to *autoimmune diseases*,[83] development of *allergies and asthma*,[82] *chronic low-grade inflammatory*[77,75] and/or *neurological disorders* (which may manifest as learning and/or behavioral deficits, mental illness, persistent pain, loss of muscle control, etc),[84] *DNA changes*[66] and other chronic conditions,[lviii] especially in certain types of individuals.[86]

124. Such disorders have far greater frequency and seriousness than any unavoidable health risk posed today by the targeted pathogens, via which the frequency of discomfort (especially any of a lasting nature) ranges from zero to negligible and have been demonstrated to be conquerable by other means. Only decades ago, prior to mass vaccination, most of the above serious conditions now linked in medical research to vaccinations were only rare, but have since become very common. Autoimmune disease alone now affects 10% of the population in Western countries and allergies and asthma are more common still.

125. Regardless of any debate about the strength of the proof, to date, of a causal relationship between vaccination and these serious conditions, the onus in medical ethics is to apply the precautionary principle, meaning that before recommending a

medical procedure, the practitioner must assume a lack of safety or at least that that the benefits do not outweigh the risks until it is scientifically proven otherwise, not the opposite principle.

➢ **Sensitization**

126. Vaccination is designed to purposefully provoke a response from the immune system, and it is assumed that the response will lead to long term immunity. However, the response is not the same as the normal response that occurs during natural infection.

127. Instead, vaccines are well documented to sensitize the immune system[lix] which broadly means modification (to a minimal or more severe degree) of the behavior of the immune system towards altered responses to antigens, and generally towards increased and/or chronic reactivity.[lx]

128. The sensitization effect has been attributed to both:

- the inclusion in the vaccines of immune-sensitizing ingredients, or “adjuvants”, such as aluminum (which is a toxic heavy metal included for the purpose of provoking a response),[lxi] and
- the sensitizing effect of direct injection of foreign proteins or toxins,[lxii] which are otherwise denied entry by our skin and mucosal layers or subjected to breakdown into their simpler, smaller components, processing and filtering in the gastrointestinal system before any absorption might be permitted.

129. In accordance with the adverse nature of the original meaning of “sensitization” as being “anaphylaxis” (in ranging degrees), which is a term that was coined to describe an observed effect that contrasted to “prophylaxis”[78,77,82] (the latter meaning "for protection”), the term “sensitization” is employed, understood and accepted generally in all contexts other than that of vaccination of humans and non-laboratory animals, to mean altered responses that are unfavorable in their effect, and associated with increased susceptibility to harm.

130. In laboratory animals, vaccines are in fact routinely used for the very purpose of sensitizing them and inducing adverse inflammatory and autoimmune conditions, in order to test drugs for the treatment of such conditions.[lxiii]

Johnny’s immune system is evidently already sensitized.

➢ **Inflammatory effect of vaccination**

131. Vaccination involves direct injection (bypassing important natural outer defences) of biologically active products and heavy metals.[68,65]

132. A large body of evidence has accumulated that this is followed by self-directed tissue inflammation occurring along a continuum from innate to adaptive immune-driven diseases, resulting in oxidative stress. Oxidative damage is proposed as a major mechanism for disease and ageing. Aluminum in vaccines has also been found to cause depletion of gluthathione,[lxiv] which is an important antioxidant that protects against oxidative stress. The result for Johnny would likely be, *inter alia*, a reduction his ability to properly detoxify ethyl mercury and other toxic vaccine ingredients and to protect against enterotoxins that are produced by any resultant bacterial infection.

133. In vivo experiments have found that aluminum's adjuvant effect appears to result from it destroying cells, causing "*release of the endogenous danger signal uric acid, thus inducing the differentiation of nature's adjuvant, the inflammatory dendritic cells, from recruited monocytes*".[77]

134. Given the proinflammatory effect of vaccination, it is noteworthy that all or virtually all adverse events reported after vaccination are either inflammatory conditions themselves (condition names ending in "-itis") or symptoms or effects of inflammation.

    Johnny has already developed atopic dermatitis (eczema) shortly after vaccination.

135. Vaccines containing aluminum, and other vaccines (such as MMR) given with or after administration of aluminum-containing vaccines, have been observed to induce chronically elevated immune activation.[lxv] Positive associations have further been established between aluminum exposure at the level at which it is in vaccines (as opposed to at higher doses), high aluminum concentrations found in human brain tissue, immune activation, gastrointestinal inflammation, gut microbiota, and neurological disorders including autism and mental illnesses such as schizophrenia, bipolar disorder, depression and anxiety.

    Johnny has already developed autistic features shortly after vaccination. For more about autism and the evidently increased susceptibility to it in Johnny's case especially, see paragraphs 162 to 173 on pages 56 to 58 below and paragraph 190.1 on page 63.

➢ **Forms of manifestation of the sensitization/inflammatory effects of vaccination**

136. The sensitizing and inflammatory effects of vaccination have been evidenced to manifest in various ways, including but not limited to the development of:

- chronic inflammatory conditions, and/or
- atopy (a tendency to develop allergic diseases),[lxvi] which is deliberately induced in animals by the use of some vaccine adjuvants such as aluminum compounds and pertussigen,[82] for other experimental purposes, and/or
- increased susceptibility to targeted, related and unrelated pathogens,[77,95] and/or
- autoimmune diseases.[83]

Johnny has evidently already suffered at least the first two of these effects – chronic inflammatory conditions and atopy (atopic dermatitis).

137. The development of any of a plethora of inflammatory conditions and/or allergies, and especially their symptoms, are commonly reported after vaccination, as can be seen from vaccine product inserts' lists of adverse effects.[32]

138. Sensitization causes an abnormal immune response which can also result in an altered progression and/or set of symptoms and compromised or ineffectual resolution of an infection.

An example of this is atypical measles, which has been observed only in vaccinated persons, and where the rash moves from peripheral to more important central regions of the body instead of the usual reverse direction, indicating an increased instead of decreased threat from the virus (see Note 77).

139. There is an increasing understanding of the causal mechanisms of these disorders and research findings are increasingly implicating vaccine exposure, especially during early development. However, because of the multiple obstacles to investigating these relationships directly, especially in humans and non-laboratory animals, most of the relevant studies that have been conducted are in laboratory animals and some of the evidence therefrom is indirect, though there is also some direct evidence from studies on humans.

140. The IOM itself has repeatedly reported that there is insufficient quality vaccine safety research to demonstrate that the risk is acceptably low of many such long term

neurological and/or immune outcomes.[47]

141. The risk of such damage can reasonably be expected to be higher in individuals who are genetically susceptible or have certain pre-existing conditions, such as Johnny.[100]

➢ **Depletion of nutritional resources**

142. Any and all of the above effects and associated physiological stress will inevitably deplete the body of nutritional resources, including Vitamin C, with the results, in turn, including a weakening of the immune system[75] and potentially a resultant reduction in the integrity of dependent vital structures, such as bones, vascular walls, etc.

➢ **Autoimmune diseases** (For more detail and references, see Note lxvii)

143. There is significant evidence of vaccination causing, or increasing the risk for, autoimmune conditions, which has become an important problem – occurring now in about 10% of the population in Western countries, worldwide 5%.

144. Despite its usually gradual development and hence only delayed appearance, the propensity of vaccines to cause autoimmune disease has been known since at least as early as 1956 when vaccination was used to induce arthritis in Wistar rats – known as "adjuvant's disease".

145. An investigation by the US military, culminating in a 1980 report, found convincing evidence from studies in animals and man that chronic antigenic stimulation by vaccination may be associated with autoimmune diseases in those genetically predisposed.

146. The CDC acknowledges that MMR vaccination can cause the autoimmune disease thrombocytopenic purpura. This condition may occur in a chronic form (overall, in 18% of sufferers between 2 and 10 years old) and hence may not resolve quickly, or at all. The Government also acknowledges that Guillain-Barré syndrome, another autoimmune disease, may occur as an effect of the influenza vaccine. The Government thus acknowledges the biological plausibility and overall potential for vaccination to lead to autoimmune disease.

- **A.S.I.A. (Autoimmune/inflammatory Syndrome Induced by Adjuvants)**

147. There is now an established large body of evidence that the direct injection of various immune stimulants in vaccines, including antigens, several adjuvants (aluminum and various squalene compounds) and fragmented DNA, may induce autoimmune reactions that fall under the "ASIA" spectrum (“Autoimmune Syndrome Induced by (vaccine) Adjuvants”).

148. A large collection of supporting studies by more than 75 doctors and scientists, is published in a medical textbook called “*Vaccines and Autoimmunity*”, edited by pre-eminent immunologist Yehuda Shoenfeld, Nancy Agmon-Levin and Lucija Tomljenovic. The studies have explored, with primary focus on aluminum in vaccines, how adjuvants can induce diverse autoimmune clinical manifestations in genetically prone individuals. They have investigated the mechanism of action (including its long-term persistence in the body and migration in apparent “Trojan Horse” style to the brain, lymph, and spleen, resulting in inflammation and neurological damage), and cover the subjects of experimental models, resultant syndromes, safe vaccines, toll-like receptors, reviews of literature evidencing links between specific vaccines and specific autoimmune conditions, and the potential for the link to exist on a wider scale.

149. In Note 83 also I cite some (of many) studies that link relevant vaccines to specific autoimmune diseases including multiple sclerosis, lupus, rheumatoid arthritis, myofascial fasciitis, and Guillain-Barre.

150. Attempts, based upon untruths and false assumptions, have been made by entities with conflicts of interest to discredit such researchers, especially Christopher Shaw and Lucija Tomljenovic in relation to their retraction, after they discovered an error, of their own October 2017 article, published in *J Inorg Biochem*, entitled “*Subcutaneous injections of aluminium at vaccine adjuvant levels activate innate immune genes in mouse brain that are homologous with biomarkers of autism*”. However, this was only one of many articles authored by them evidencing a link between vaccination and autoimmune/inflammatory conditions, including autism. No other articles authored or co-authored by them have been retracted except for one temporarily retracted in 2016.

- **Debate about the existence of A.S.I.A**. (Details and references are in Note 83).

151. Ameratunga et al (2017) recently (Nov-Dec 2017) published an article that they alleged contained “evidence refuting the existence of A.S.I.A.” However their arguments were based upon a set of unsubstantiated and/or false assumptions and assertions, which were described in responses in Letters to the Editor of *J Allergy Clin Immunol Pract* March-April 2018, primarily by Crépeaux et al (2018). Ameratunga et al’s research team forthwith published a reply to those responses but they continued to make unsubstantiated assumptions and failed to properly address the issues raised by Crépeaux et al (2018).

152. Ameratunga et al did express “agreement with Crépeaux et al in asking for an independent expert panel to evaluate the existence of ASIA and the specificity of its diagnostic criteria.”

153. So Ameratunga et al accepted that they were not “an independent expert panel to evaluate the existence of ASIA and the specificity of its diagnostic criteria” wholly refute ASIA and the precautionary principle favors erring on the side of an assumption of the risk of A.S.I.A. existing.

- **Injection of antigen repeatedly – autoimmune disease evidenced to become inevitable**

154. The result of research published in 2012 on mice was that in all who were otherwise not prone to spontaneous autoimmune diseases, vaccination at least 8 times was sufficient for autoimmunity to become not just possible, but inevitable.

155. Research suggests that autoimmune disease is also a possible causal or contributory mechanism for the vaccines’ reported link to autism.

➢ **Neurological disorders** (For more detail and references, see Note lxviii)

156. Generally the most serious effects of vaccine-induced inflammation and/or autoimmunity are those involving the brain or neurological system (via encephalitis - “minimal” or more widespread), and because the injection process bypasses important outer immune system defences, it is possible for permanent brain damage to occur as an outcome. This is especially the case in younger children whose brain barrier is less developed.

157. Most non live viral vaccines contain aluminum compounds such as aluminum hydroxide which when intramuscularly injected (as is the case with vaccination) at a *low dose, but not high dose*, may selectively induce long-term aluminum cerebral accumulation and neurotoxic effects. The injected suspensions corresponding to the lowest dose, but not to the highest doses, exclusively contained small agglomerates in the bacteria-size range which are known to favor capture and, presumably, transportation by monocyte-lineage cells. 'In any event, the view that (aluminum hydroxide) neurotoxicity obeys "the dose makes the poison" rule of classical chemical toxicity appears overly simplistic.'

158. Many vaccine injury compensation awards globally have been for permanent brain injury. Some product inserts name encephalitis and/or meningitis as adverse events directly reported, though only in the rarer categories.

159. Potential symptoms of encephalitis or meningitis are very commonly reported after vaccination, as disclosed in product inserts. Because they are so common, they are considered "normal" and assumed to not indicate any harm occasioned or threatened, so are not investigated, or (in more than 99% cases) reported.

160. However, a young child with encephalitis or meningitis may have only 2 or 3 of the relevant symptoms, and parents frequently state that, following such symptoms after vaccination, a significant, often even permanent, neurological deterioration in their children - in their demeanour, alertness, personality, attention, learning ability and/or behavior (including ADHD), etc. Symptoms that more specifically indicative of encephalitis are also included in lists of AEs in vaccine product inserts. Entire books have been written devoted entirely to covering the evidence in existence at the time of vaccination causing behavioral problems, including autism and criminality.

161. It may be highly relevant that in lock step with the CDC's childhood vaccine schedule having increased from 11 injections of 4 vaccines in 1986 to 56 injections of 30 vaccines in 2017, plus (in relation to any effects on offspring) an additional generation having been vaccinated, childhood chronic illness and developmental disabilities have precipitously risen during this same period from 12.8% to 54% of American children.

- ➢ **Autism - US Government's (Vaccine Court's) and CDC researcher's acknowledgements with respect to causal links with various vaccinations**

162. Autism, from whose features Johnny suffers, has become an increasing serious problem for public health. The rate has recently alarmingly reached more than 1 in 59 children.

Whilst the increase is partly accounted for by changing diagnostic criteria and greater awareness of the condition, it is accepted that there has been a significant true increase.[lxix]

163. A small proportion of unvaccinated children have had mild autistic features apparent from when first observable (which may be attributable to vaccines given to the mother before pregnancy, evidence indicates). However, amongst the large number of cases of autism that I have either known first hand or learnt about, none occurred in any unvaccinated children who had been initially quite healthy and symptom-free, but just after an age when vaccines would normally be given, but *without* any vaccines being given, have then regressed into autism.

164. The most typical age for autism developing is just after MMR vaccination is given at 12-15 months. Notably however, Johnny began to develop autistic characteristics immediately after a DTaP vaccination given at 8 months. It is not the age that these circumstances have in common, but the administration of a vaccination.

165. Prior to 2014 the US Government, whilst not making any broad, direct concession that any vaccine can cause autism (the repercussions would obviously be considerable):

- had concluded that a set of vaccinations had caused "autistic encephalopathy" in at least one child with an underlying mitochondrial disorder,[86] and
- had "compensated cases in which children exhibited an encephalopathy, or general brain disease" including where that illness has been "accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures."[lxx]
- had been underwriting autism treatments such as ABA (applied behavioral analysis) for children in its vaccine-injury program.[lxxi]

166. In 1998, gastroenterologist Dr Andrew Wakefield *et al* published a paper documenting gut disorders and accompanying autism in 12 children, soon after MMR vaccination. The team did not claim to have found a causal link but merely called for research investigating whether one existed.[89] Instead of well-resourced entities urgently conducting any such investigation, Dr Wakefield's team were attacked by the medical establishment and the licenses of Dr Wakefield and his more senior colleague in the team, highly respected Dr John Walker-Smith, were revoked by the General Medical Council (GMC). None of the GMC's stated reasons were directly or indirectly related to the integrity of the study's conclusions (which, as I have said, were very limited). Dr John Walker-Smith appealed,

successfully. However, Dr Wakefield lacked the financial resources to lodge an appeal within the 28 day time limit. False hearsay has been widely spread that Dr Wakefield was found to have committed fraud but he has never been charged with fraud, nor any other crime.

167. The CDC did respond in due course with a large study, published in 2004. Purportedly it found no link so has been much quoted. However, in 2014 the CDC research team leader, Dr William Thompson, confessed that the team had fraudulently hidden data that had in fact shown significant associations between the MMR vaccine and autism - in children with "isolated autism" (no mental retardation nor cerebral palsy nor visual or hearing impairment) and also in African-American boys. He stated, *inter alia*, that:

> *"The…co-authors… [put the relevant documents]…into a huge garbage can. However,… I kept hardcopies of all documents in my office, and I retain all associated computer files. I believe we intentionally withheld controversial findings from the final draft of the Pediatrics paper".*[lxxii]

168. Voluminous peer-reviewed medical research has been published supporting a link with the MMR vaccine and also with mercury.[lxxiii]

169. A properly controlled study of sheep, published in 2018, found that only those given repeated vaccinations or vaccine adjuvant injections (compared to no vaccinations) "exhibited behavioral changes: affiliative interactions were significantly reduced and aggressive interactions and stereotypies increased significantly." (See paragraph 176 herein.) All of these behaviors are key features within the autistic spectrum.

170. A number of studies (of thimerosal or the MMR vaccine) have not found a link, but proper analyses of those same studies reveal flaws in the science.[lxxiv] (See paragraph 122 herein.)

171. Regarding the DTaP vaccine, the IOM's 2011 vaccine safety review could locate only one statistical investigation of a link. That had study concluded that a link exists. The IOM concluded: "The evidence is inadequate to accept or reject a causal relationship between (DTaP)–containing vaccine and autism."[lxxv]

172. Dr Andrew W. Zimmerman, Pediatric neurologist and Director of Medical Research at the Center for Autism and Related Disorders at the Kennedy Krieger Institute, has acted as government expert witness in the Omnibus Autism Proceedings in the Vaccine Court, in which he provided testimony that led to the HHS conceding that vaccination caused autism in the case of Hannah Poling.

He has described the factors of underlying mitochondrial dysfunction, vaccine-induced fever and immune stimulation (or "conditions of stress, such as infections and immune stimulation"[86]), as, in combination, able to cause metabolic energy reserves to be exceeded and hence lead to regressive encephalopathy with features of autism spectrum disorder.[lxxvi]

He also made reference to additional factors that each increase the risk of same - vaccination during illness, administration of antibiotics, and previously suffered symptoms consistent with a severe adverse vaccine reaction.[92]

173. Not just one or two, but almost all, of these factors listed by Dr Zimmerman (all of the factors except for the administration of antibiotics) are evidenced by direct observation or medical evidence to apply, or potentially apply, to Johnny:

- vaccination is evidenced to lead to mitochondrial dysfunction, for example:
    - the vaccine ingredient aluminum has been found to inhibit the enzyme NADP-isocitrate dehydrogenase in mitochondria, the only enzyme supplying NADPH in mitochondria,[80] and
    - vaccination's pro-inflammatory effect (see paragraphs has the potential to cause an excess of Reactive Oxygen Species (ROS) and Reactive Nitrogen Species (RNS). This excess damages cellular structures, especially mitochondrial membranes,[lxxvii] and
    - the above adverse effect on mitochondrial function by vaccination has been directly evidenced occur in practice, such as hepatitis b vaccination inducing "loss of mitochondrial integrity",[25] and
- Johnny has exhibited vaccine-induced fever (ref. paragraph 190.1 on page 63), and
- vaccination is well known to cause immune stimulation (as covered in paragraphs 126 to 155 on pages 50 to 55 above), and
- only a week prior to the DTaP vaccination that Johnny received he had developed a high fever and lethargy, so likely had not fully recovered by the time of vaccination, and
- it must be considered prior to any future vaccination(s) that Johnny has now previously suffered symptoms consistent with a severe adverse vaccine reaction - immediately after the DTaP he was given he suffered high fever and inconsolable cry which is potentially indicative of encephalopathy (likely encephalitis) and there is substantial evidence that vaccination may cause that (see Neurological Disorders in

paragraphs 156 to 161 on pages . This was followed immediately by neurological dysfunction.

With respect to the additional neurological dysfunction that did not develop until 3 to 4 months following vaccination, and also the potential for what may occur in the future, it is notable that Dr Zimmerman has further stated:

> "*such cellular metabolic injuries in the brain during early childhood typically evolve over time as the child develops and may express themselves as the child grows …The child may improve and make progress developmentally, but then later develops ...neurological impairments (e.g. learning disorders). Thus, the time delay between vaccination, encephalopathy, and (such neurological impairments) does not preclude a causal relationship*."[50]

- **Cancer** (References and more detail are contained in Note[lxxviii])

174. Vaccine product inserts explicitly warn that the vaccines are not tested for carcinogenicity or mutagenicity. However the risk for cancer from vaccines has been acknowledged as biologically plausible. A link has been accepted in vaccinated animals for some time (e.g. vaccine-associated feline sarcoma discovered in cats in 1991) and it has been reported in humans. An example is that of previously very healthy young girls developing ovarian or cervical cancer soon after HPV vaccination. However, adverse event surveillance and medical research conducted to date on humans is far too inadequate to make even a very rough estimate as to how frequently vaccines cause cancer in humans.

175. Some potential mechanisms involved include that:

- inflammation has been identified as a causative factor and vaccines are highly pro-inflammatory, and
- many viral vaccines contain animal tissue culture 'cell lines' which are immortalized cells and considered neoplastic (cancerous cells), e.g. the polio virus used in vaccines is grown in cultures of VERO cells, and
- virus inactivation process limitations. Due to this process being subject to the (mathematical) asymptotic factor, the inactivation of the virus is incomplete. Further, the inactivation that does occur is limited in duration, because the inactivated virus is able to revert to its former virulence. Therefore, vaccines are potentially contaminated with animal virus(es). These continue to include the SV40 monkey virus contaminant, which was discovered in Salk polio vaccines in 1960 and which may be dormant for many years and has been implicated in many increasingly

common cancers, such as mesothelioma and multiple myeloma. Potential contaminants also include EBV, mycoplasma and retroviruses, all of which (such as HERVs, BLVs, Foamy Viruses) have been associated with cancers, chronic liver disease, AIDS, ALS, ME/CFS and autism.

- **Comparison studies of adverse effect rates from vaccination versus non-vaccination**

176. Some direct numerical risk comparisons have been made in peer-reviewed medical research, including with respect to deaths, e.g.

- Mogensen et al (2017)[lxxix] found the whole cell DPT vaccine, which was in widespread use in Australia for about 47 years and whose safety profile is comparable with that of the DTaP vaccine which is in present use, was associated with *10-fold higher mortality* than that suffered by the unvaccinated. The researchers stated that "*all currently available evidence suggests that DTP vaccine may kill more children from other causes than it saves from diphtheria, tetanus or pertussis*".[95] Notably:
  - Mogensen et al (2017) suggested as the reason for this result that the vaccination may *"increase susceptibility to unrelated infections*", which would indicate that in an unknown and potentially significant proportion of the cases of morbidity and death that do still occur in the community from infections generally, vaccinations that target unrelated infections may have an unrecognised causative or contributory role, and
  - After a reasonable search I have not found any scientific research that has found the DTaP vaccine, which is in present use in Australia, to be more than 10 times safer than the DTP. On the contrary, based upon the vaccine-specific reporting rates to the US VAERS system from the DTaP vaccine being *no less than half* those from the DPT vaccine (to whatever extent that data is indicative),[lxxx] the available evidence is that the DTaP vaccine is significantly less than 10 times safer than the DTP vaccine, and
  - Although reduction that has been observed in adverse reporting rates after replacement of the DPT vaccine with the DTaP vaccine is suggestive of the DTaP vaccine being safer, such comparisons must still be interpreted cautiously because reporting rates are not the same as incidence rates, and

- Mogensen et al (2017) stated that past studies may have underestimated the negative effect of vaccination because of “unvaccinated” subjects being too frail, sick or malnourished to receive the vaccination being studied, and
- Mogensen et al (2017) further made reference to the fact that “no prospective study has shown beneficial survival effects of DTP” and expressed concern that “the effect of routine vaccinations on all-cause mortality was not tested in randomized trials”, and
- In the United States in modern times, the mortality suffered by unvaccinated vaccine-eligible children today is zero, so it could be said that there is even less tolerance for vaccine risk than there was in the children in the Mogensen et al (2017) study.

- Based upon US National Health and Nutrition Examination Survey 1999–2000 data, Hepatitis B triple series vaccination was found to be associated with a nine times increased rate of developmental disability in boys aged 1-9 years, after adjustment for confounders.
- Miller and Goldman (2011) studied infant mortality rates and found a statistically significant positive correlation between the number of vaccine doses on a country’s vaccination schedule and infant mortality rate,[lxxxi] and
- A recent pilot study by Mawson (2017) comparing vaccinated and unvaccinated subjects found that exposure to the full vaccine schedule (per the US CDC) was strongly associated with numerous adverse health outcomes, compared to zero vaccine exposure.[lxxxii] (The retraction of this article was only temporary), and
- A small study by Spanish researchers (primarily from the University of Zaragoza) (2018) of sheep found that those in the repeatedly vaccinated and vaccine adjuvant-receiving groups (and not the control group) “exhibited behavioral changes: affiliative interactions were significantly reduced and aggressive interactions and stereotypies increased significantly.”[lxxxiii]

177. No studies have compared health outcomes in vaccinated versus unvaccinated individuals, matching for age, pre-existing health status and socioeconomic status, and found the vaccinated to have better outcomes. Matching is important because some non-vaccination reasons include factors that are known to independently increase the probability of adverse health outcomes.

Johnny's individual risk profile

178. In relation to all vaccines, the Institute of Medicine has consistently stated, as evidenced in the medical literature,[83] that there is individual susceptibility to serious vaccine injuries. Relevant factors include a child's personal genome, behaviors, microbiome, developmental stage, intercurrent illness, and present and past environmental exposure, all of which factors can also interact.

179. If all individual risk factors had already been identified and encompassed in the list of medical contraindications, vaccinations would be avoided for all susceptible individuals. Hence, no serious adverse effects of vaccination would occur (except in exceptional circumstances, such as administration errors). However, the above reported frequencies, reporting completeness and government assessments of "certain" or "probable" causation by vaccination of serious adverse events indicate that such a scenario is far from the case.

180. Therefore it is important to consider Johnny's individual circumstances before any vaccination can be considered.

- **Johnny's medical history**

181. I have received a copy of Johnny's medical records.

Based upon the information in these records, supplemented by additional details provided by Johnny's mother, his medical history is as follows, to the best of my knowledge:

1. **Johnny's medical history**

- **Johnny's deteriorating condition soon after vaccination**

(a) Johnny was healthy prior to vaccination, but immediately after the single vaccination that he received, he suffered adverse conditions symptomatic of encephalopathy, followed by visible neurological deterioration in the form of multiple autism characteristics, and also the development of severe eczema.

The following table provides more details, from which a strong temporal link can be clearly seen between Johnny's vaccination and the conditions that he subsequently developed:

Period post-vaccination	**Development of chronic conditions**

Pre-vaccination (prior to DTaP given at age 8 months)	Had none except for umbilical hernia and (likely related) constipation: - language was developing normally (saying “momma”, “dadda”, “babba”), had normal eye contact, had a bright, happy demeanour and enjoyed all activities, and had no eczema. 11 days prior to vaccination he developed a vesicular rash which had not completely cleared prior to vaccination.
Night following vaccination	High fever and inconsolable cry (potentially indicative of encephalopathy – see paragraph 89 on page 26 herein).
5 days following vaccination	Fever returned, lethargy for several days Flare up of vesicular rash that had almost resolved pre-vaccination.
1 to 2 weeks following vaccination	Developed characteristics of autism: - language regressed (stopped saying “momma”, “dadda”, “babba”) - reduced eye contact - lost joyful demeanour - sensory balance aversion
3 to 4 months following vaccination	Developed additional characteristics of autism: - head banging, rocking, new sensory aversion (to sliminess or wet objects on hands) Also developed: - eczema (atopic dermatitis) with recurrent severe bleeding.

(b) All of the above conditions that Johnny developed after vaccination have been reported in others following DTaP vaccination and have been causally linked to DTaP and other vaccinations in published studies (neurological disorders and autism are covered in paragraphs 156 to 173 on pages 55 to 58 above, and eczema (atopic dermatitis) in paragraphs 126 to 141 on pages 50 to 52 above and Notes 82 and 98), to the varying strengths that such conclusions can be drawn within the varying limitations of the relevant studies. Hence the available evidence to date indicates a reasonably high

likelihood that Johnny's DTaP vaccination was, at the least, a substantial contributor to all, or almost all, of the conditions that he immediately proceeded to develop.

- **Johnny's improvement after no vaccinations, but evidenced susceptibility**

(c) I am also informed that over the remaining two years since about 4 months after Johnny was vaccinated (i.e. since the age of about 12 months), without any vaccinations and with speech therapy and a wholesome diet, all of these issues have gradually improved and mostly resolved.

(d) However:

- at the age of 24 months, Johnny was given an M-CHAT assessment (for autism), as a result of which he was categorized as at high risk for autism, and
- a medical history such as Johnny's has been found in medical research to increase the risk of suffering an autoimmune/inflammatory condition as a result of vaccination,[lxxxiv] and
- children who have developed autism characteristics following vaccination have been reported to me to have regressed again immediately upon further vaccination, after which it has then been much more difficult than after the initial regression to bring about improvement in their condition. This is likely due at least in part to the sensitizing effect of vaccination. The challenge–dechallenge–rechallenge result is also further evidence of the causal link between the vaccinations and the development of the autism characteristics.

(e) Hence, Johnny's history of development of these conditions, especially so soon after vaccination, evidence an apparent probable serious increased risk of him being seriously adversely affected by even one vaccination(s), as listed and explained in this report and documented in published medical research. In particular there is a high risk that he will regress again into autism.

Further, based upon others' experience, there is a significant risk that the deterioration will be deeper and partly or wholly irreversible. This accords with the known sensitizing effect of vaccination (see paragraphs 126 to 130 on pages 50).

Additionally, in the event that he receives not just one more vaccination, but the 16 more doses that are proposed for the short term, the increase in risk can be estimated to be approximately much higher still, potentially at least 16 times as high *still*.

Summary, conclusion and recommendation

- **Summary**

182. Pursuant to the precautionary principle of medical ethics, it needs to be provable beyond all reasonable doubt that the risks to Johnny from not being vaccinated are greater than from being vaccinated, before any vaccination can be judged to be in him best interests. The existing evidence overwhelmingly fails to provide any such proof.

183. Paragraphs 18 to 83 on pages 8 to 24 herein, cover an analysis of the level of risk to Johnny if he is not vaccinated, taking into account the estimable notification rates of the diseases in unvaccinated children in his age group, the disease risks cited as most significant, generous assumptions or assessments of vaccine effectiveness, researched benefits of contracting the diseases, and Johnny's individual nutritional profile and exposure risk profile for contracting or suffering complications or sequelae from the diseases.

184. It is apparent that risk-free methods available and already being utilized have reduced and continue to reduce the risk to him of serious adverse effects (SAEs) from the targeted infectious diseases to zero to minimal levels, and that vaccinations in her childhood may increase the disease-associated risks themselves, especially when the longer term outlook is taken into consideration.

185. The results of vaccine clinical trial testing as set out in paragraph 86 to 90 on pages 25 to 31 provide further information about the frequencies of serious or potentially serious risks from the vaccinations, including disease-related complications themselves.

    In spite of the "*Limitations of clinical trial testing*", as covered in paragraphs 91 to 99 on pages 31 to 34, it already becomes evident at that stage that the risks are far higher to Johnny from vaccination than non-vaccination, in the case of all of the relevant diseases/vaccinations.

- **Preliminary risk comparison of risk over 14 years to a healthy child now 1 year of age**

186. In paragraphs 100 to 109 on pages 34 to 39 I have used available information from various government sources *only* (passive surveillance reports and related frequency and causality assessments, not clinical trial results nor medical research findings) to derive an approximation of the frequency of vaccination SAEs observed in the wider population, post-licensure, of children with average prior health for vaccinated children.

187. The table on the following page puts together only the results described in paragraph 182 with the results described in paragraph 186.

188. Despite the limit to what is taken into consideration in relation to the vaccination risks, those risks that are included are sufficiently high as to greatly outweigh the risks determinable to Johnny as an individual from non-vaccination.

In particular the results are that for diphtheria-tetanus-pertussis, poliomyelitis, hepatitis b, pneumococcal, chickenpox, and measles-mumps-rubella vaccinations, the risk of a serious AE "certainly"/"probably" caused by the vaccination (row marked "(b)") appears to outweigh the risk of a serious disease-associated AE caused by non-vaccination (row marked "(a)") by, respectively, factors of more than (">") 800, 670 million, 7, 6, 7, 36 and 560, and overall more than 35.

Vaccine	**DTaP**	**Polio**	**Hepatitis B**	**Hib**	**Pneumo - coccal**	**Chicken-pox**	**Measles-Mumps -Rubella**	**To**
***Increase,* due to non-vaccination, of disease-associated serious risk (SAE)** (unadjusted by immunity already gaine								
Disease contraction annual**	zero*, zero*,N/A	zero*	<1 in 140,000	<1 in 160,000	<1 in 50,000	<1 in 2,000	<1 in 140,000	N/
Disease contraction overmaterial period**	zero*, zero*,N/A	zero*	<1 in 10,000	<1 in 40,000	<1 in 13,000	<1 in 140	<1 in 10,000	N/
Disease SAE over material period (a)**	**<1 in 400,000**	**<1 in 1 trillion**	**negative**** to <1 in 25,000**	**<<1 in 40,000**	**<<1 in 13,000**	**negative**** to <<1 in 55,000**	**negative**** to <1 in 400,000**	**<1 6,0**
Disease death over material period **	zero*	zero*	zero*	zero* (<<1 in 1 million)	zero* (<<1 in 500,000)	zero* (<<1 in 8,500,000)	negative to zero* (<<1 in 5 million)	<<1 300, 0
Vaccine serious risk (SAE) 'certainly'/'probably' causally related, based on government surveillance/assessment								

Vaccine SAE (b)**	**>1 in 500**	**>1 in 1,500**	**>1 in 3,600**	**>1 in 6,700**	**>1 in 1,700**	**>1 in 1,500**	**>1 in 700**	**>1 17**
Vaccine neurological AE	>1 in 700	>1 in 2000	>1 in 5000	>1 in 10000	>1 in 2600	>1 in 2000	>1 in 1000	>1 25
Vaccine death	>1 in 27,000	>1 in 80,000	>1 in 190,000	>1 in 360,000	>1 in 96,000	>1 in 80,000	>1 in 37,000	>1 9,0
Comparison result: factor by which Vaccine SAE risk (b) greater than Disease-associated SAE risk (a)								
Vaccine SAE (b) ÷ Disease SAE (a)**	**> 800**	**> 670 million**	**>>>> 7 to infinite**	**>>>> 6**	**>>>> 7**	**>>>36 to infinite**	**>>> 560 to infinite**	**>>>**

Notes: ***** "zero" in this table means "zero to negligible", less than 1 in 500,000.

****** In the standard risk comparison tables provided to doctors to assist provision of information parents, *none* o these critical figures are included - those tables:

(a) re the diseases, falsely imply that all those unvaccinated (and none vaccinated) will contract each targete disease, and at the most vulnerable age, and

(b) re the vaccines, simply and falsely state, for each vaccine, "Serious adverse events are very rare".

******* With DTaP-containing vaccines that include other vaccine components (polio & Hepatitis B), it is assumed t each component contributes equally to the AEs reported.

******** "negative" because of evidence described earlier in document of the risk of disease sequela being decreas not increased, from non-vaccination c/f vaccination.

189. Notably, the comparison result figures in the table do *not* take into account any evidence of *additional* risk from vaccination, such as:

- the observed results of active surveillance, by way of clinical trials (as summarised in paragraph 184 herein), nor
- the results of published medical research that have examined more deeply additional biologically plausible serious risks arising from injecting individual vaccine ingredients and combined ingredients and vaccinations (paragraph 119 on page 46

to paragraph 177 on page 62), in particular, types of serious adverse events that are frequently noted in strong temporal association with vaccination but are not reportable in the Australian Government's passive surveillance system (from which the rates cited herein of vaccine serious adverse events are derived), e.g. autism, nor

- the evident increase in vaccination risk arising from characteristics of Johnny's individual higher risk profile, nor
- the plain unknown – the uncertainty arising from the serious limitations of active and passive surveillance for demonstration of safety, and from the serious lack of studies that have been conducted to date in relation to the causation by vaccination for multiple biologically plausible risks (as covered in paragraph 119 on page 46 to paragraph 177 on page 62 herein).

  The lack of studies demonstrating vaccination safety applies to healthy children but especially to children with higher risk profiles as applies to Johnny.

- **Conclusion**

190. There are a great many factors that have shown themselves very clearly to affect susceptibility to infectious diseases. From a scientific perspective there is undue perception of the necessity and/or power of vaccination with respect to the goal of reducing that susceptibility for Johnny. Indeed vaccination itself has been found to pose risks with respect to susceptibility to targeted, related and unrelated infectious diseases and adverse conditions, and the level of those risks to Johnny as an individual cannot be judged, easily or at all, as relatively insignificant when viewed against the evidently very low threat that the vaccinations are intended to thwart.

191. Based upon my research of government surveillance, other government publications and published relevant estimates available, and Johnny's nutritional status and lifestyle, and him presently compromised health condition, the risk of each vaccination for Johnny significantly outweighs any benefit.

192. Further, based, in addition to that information, upon my extensive directly relevant research and education in relation to known and potential adverse effects of vaccinations, and the information that I have received about Johnny's personal profile as an individual, the balance of risks is further tilted against the vaccinations. The available evidence is that Johnny especially would be at a substantially higher than average risk of developing an autoimmune/inflammatory/hypersensitivity condition.

193. In view of all of the above, it reasonably follows, especially given the absence of evidence to the contrary, that there is an unacceptably high risk to benefit ratio, from each of the proposed vaccinations, in Johnny's case as an individual.

- **Recommendation**

194. A judgment based upon the precautionary principle alone, considering the lack of scientific evidence to judge that the benefits of any of the vaccinations outweigh their risks, but especially after additionally incorporating the substantial evidence herein that the risks of each of the vaccinations significantly outweigh the benefits, I am strongly obliged as a professional to recommend against all of the proposed vaccinations.

195. I therefore strongly recommend that Johnny not be given any of the proposed vaccinations.

196. In the alternative, that is, in the event that any vaccination(s) is/are nevertheless permitted by this court, then given his evident heightened susceptibility, the risk can be reduced of immune or neurological sequelae as outcomes by delaying each vaccination, providing significant nutritional supplementation, and thoroughly monitoring him condition after each vaccination for adverse effects and for ensuring full recovery prior to any subsequent vaccination.

    Hence, in the event that any vaccination(s) is/are permitted for Johnny by this court, I strongly recommend:

    i. that prior to each further vaccination, serology testing be conducted for all relevant targeted diseases in relation to which pre-existing level of immunity can thus be effectively measured (e.g. chickenpox), and

    ii. that only one vaccination injection be administered in any one session, to minimise the burden on the immune system. Separation of vaccinations will also permit easier identification of the culprit vaccine in the case of any adverse effect(s), and

    iii. that each vaccination be separated by a minimum period of three months, and

    iv. that prior to any further vaccinations and six weeks after each vaccination, a blood test be performed to check for elevated CRP and/or IL-18 levels, which would signal a chronic inflammatory condition, and

    v. if after any vaccination Johnny develops any sign or symptom of an inflammatory condition, then the next vaccination not be given until at least one month after all of

his inflammatory symptoms and such abnormal blood test results have returned to normal, and

vi. that in the case of each vaccination, Johnny be in his mother's care in the week leading up to the vaccination, at the time of the vaccination and for 2 weeks after the vaccination, so that the mother is able to provide supportive measures for the immune system such as Vitamin C, especially immediately after the vaccination.

Toni Lynn Bark MD, MHEM, LEED, AP
Evanston, Illinois

Date: February 28, 19

Notes and References for Report of Toni Lynn Bark

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[i] What is vaccine adversomics?

Jennifer A. Whitaker, MD, MSc, Inna G. Ovsyannikova, PhD, and Gregory A. Poland, MD. Adversomics: a new paradigm for vaccine safety and design. *Expert Rev Vaccines*. 2015 Jul; 14(7): 935–947. doi: [10.1586/14760584.2015.1038249]

[ii] By 1950, the Australian Government had already considered whooping cough (WC) and measles to be no longer important enough to even be notifiable

Commonwealth Year Book, Jan 1953, Chapter 8, pg 289.

http://www.ausstats.abs.gov.au/ausstats/free.nsf/0/6D34CFB7F684C572CA257AF30015A5C3/$File/13010_1953%20section%208.pdf

[iii] In 1956, similarly, it was declared in Australia that "*as causes of infant mortality in Australia all the infective diseases have been overcome"*

Lancaster, H.O. 1956a, "Infant Mortality in Australia". The Medical Journal of Australia, 2:104.

[iv] Factors credited by Australian Commonwealth Government for overcoming infectious diseases

"Improvements over time in the general health of the population and in medical care are also important factors."

Immunisation Myths and Realities 5th edition (2013) (page 43)
(http://www.health.gov.au/internet/immunise/publishing.nsf/content/uci-myths-guideprov)

Coercive and Mandatory Immunisation, by Judy Wilyman. Australasian College of Nutritional & Environmental Medicine 10/2008; Vol 27(No 2):p 6-9, quoting

- Gillespie J.A., 1991, "The Price of Health: Australian Governments and Medical Politics 1910 – 1960", Cambridge University Press, Cambridge, UK.
  (re impact of sanitary reform, greater emphasis placed on social medicine and public health officials becoming aware that malnutrition increased the susceptibility of children to disease by weakening the immune system)

- O'Connor K., 1989, "A History of 75 years of baby health services in NSW". NSW Department of Health
  (re impact of the medical profession's increased support for breastfeeding in 1929 and new relief policies regarding the minimum nutritional requirements in food provisions for the unemployed)

- Lancaster, H.O., 1956, "The Mortality of childhood in Australia: Part 1 Early Childhood", Medical Journal of Australia, 2: p. 889-894.
  (re decline of pertussis before routine immunisation programs were implemented, and its high sensitivity to social conditions and hygiene)

- Lancaster, H.O. 1956a, "Infant Mortality in Australia", The Medical Journal of Australia, 2: p.100-108;

- Burnet, M., 1952 andLewis MJ. (ed.), 1989.
http://www.researchgate.net/publication/228389163_Coercive_and_Mandatory_Immunisation

[v] Factors credited by Government for continued protection against infectious diseases

Australia's Food & Nutrition 2012. Australian Government AIHW 2012.
"Good nutrition contributes to quality of life, helps maintain healthy body weight, protects against

infections, and reduces the risk of chronic disease and premature death" etc (pages 9 and 103 and 184 - nutrition, 141 – breastmilk)
http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737422837

[vi] *Joint WHO/UNICEF statement on vitamin A for measles*. Expanded Programme on Immunization. *Wkly Epidemiol Rec* 1987;62:133-134. Measles fact Sheet for tsunami affected populations (WHO) (http://www.searo.who.int/entity/emergencies/documents/general_information_measles100105.pdf http://www.searo.who.int/LinkFiles/General_Information_Measles100105.pdf);

Sudfeld CR, Navar AM, Halsey NA; Effectiveness of measles vaccination and vitamin A treatment. *Int J Epidemiol*. 2010 Apr;39 Suppl 1:i48-55. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2845860/)

[vii] Scientific research now informs how to prevent and manage infectious diseases

Vitamin A administration has been found to halve measles risks.

(Stephens D, Jackson PL, Gutierrez Y. *Subclinical vitamin A deficiency: a potentially unrecognized problem in the United States*. *Pediatr Nurs.* 1996 Sep-Oct;22(5):377-89, 456. http://www.ncbi.nlm.nih.gov/pubmed/9087069);

Vitamin A treatment of measles. Committee on Infectious Diseases. *Pediatrics.* Vol 91:5, May 1993:1014

(http://pediatrics.aappublications.org/content/pediatrics/91/5/1014.full.pdf)

Beck M. The role of nutrition in viral diseases, *Nutritional Biochemistry* 7:683-690, 1996

(http://www.birdflubook.org/resources/beck683.pdf)

A couple of several relevant findings noted therein:

> *"Studies in the United States have found that in **50%** children infected with measles were vitamin A deficient.47 Other studies have demonstrated that children in U.S. hospitals treated with vitamin A for severe measles have a shorter duration and less severe course of illness.48,49… Increased levels of measles-specific IgG and increased total numbers of lymphocytes have been found in vitamin A-treated measles-infected children as compared with placebo treated measles-infected children.52"*
>
> *"Vitamin A-deficient adult mice challenged with rotavirus also develop decreased antibody responses as compared with vitamin A-adequate mice.61"*;

McCormick WJ, *Vitamin C in the Prophylaxis and therapy of Infectious Diseases*, *Archives of Pediatrics*, Vol 68:1, Jan 1951, pp. 1-9, 1951

(http://www.seanet.com/~alexs/ascorbate/195x/mccormick-wj-arch_pediatrics-1951-v68-n1-p1.htm);

Hemila and Louhiala 2007.*Vitamin C may affect lung infections*. J R Soc Med; Nov; 100(11): 495–498. doi: 10.1258/jrsm.100.11.495

(**http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2099400/**)

The Vitamin C treatment for Whooping Cough ~ Suzanne Humphries, MD, 7 Sep, 2012

(**http://drsuzanne.net/2017/10/sodium-ascorbate-vitamin-c-treatment-of-whooping-cough-suzanne-humphries-md/**, 17 Oct 2017;

http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.666.2209&rep=rep1&type=pdf, 7 Sep 2012)

Curing the Incurable: Vitamin C, Infectious Diseases, and Toxins (with over 1,200 scientific references), by Thomas E. Levy MD JD, Medfox Publishing; 3rd edition, 1 Aug, 2011

Note also that Dr Frederick Klenner published and presented a paper to the American Medical Association in 1949 detailing the complete cure of 60 out of 60 of his patients with polio using high doses of intravenous sodium ascorbate (Vitamin C)

(Klenner, FR. The Treatment of Poliomyelitis and Other Virus Diseases with Vitamin C. *Southern Medicine & Surgery*, July 1949. Volume 111; No. 7:209-214. http://www.seanet.com/~alexs/ascorbate/194x/klenner-fr-southern_med_surg-1949-v111-n7-p209.htm)

[viii] Most of the targeted diseases – very difficult or impossible to develop from day-to-day contact. Other factors important.

NSW Health Fact Sheets: www.health.nsw.gov.au/Infectious/factsheets/Pages/default.aspx

NSW Health Control Guidelines:
http://www.health.nsw.gov.au/Infectious/controlguideline/Pages/default.aspx

Diphtheria: not very contagious - "The probability of spread depends on the closeness and duration of contact.
Prolonged contact (eg sleeping in the same room as a case rather than casual contact) is usually required."
(http://www.health.nsw.gov.au/Infectious/controlguideline/Pages/diphtheria.aspx)

Tetanus: "Tetanus is not passed on from one person to another."
(Source: http://www.health.nsw.gov.au/Infectious/factsheets/Pages/Tetanus.aspx)

Haemophilus Influenzae B (Hib): *"Haemophilus influenzae* is a Gram-negative coccobacillus that is a normal part of upper respiratory tract flora… Before Hib immunisation, invasive disease caused by Hib rarely occurred after the age of 5 years. This was because the prevalence of antibody to Hib progressively increased from the age of 2 years, thought to be related to exposure to Hib (or cross-reacting organisms) colonising the nasopharynx or other sites."

(In other words, by 5 years of age natural immunity will develop in an unvaccinated child, normally asymptomatically.)

(*The Australian Immunisation Handbook* 10th edition (2013), *4.3.1 Bacteriology* http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part4~handbook10-4-3,)

and "Hib bacteria can live harmlessly in the throat of healthy people."
(http://www.health.nsw.gov.au/Infectious/factsheets/Pages/Haemophilus_Influenzae_B.aspx)

Yet Hib disease itself is very uncommon. Hence it can be seen that transmission of this *already* ubiquitous bacteria is not one of the significant factors leading to the development of disease associated with Hib.

Meningococcal C: Like Hib, "Asymptomatic respiratory tract carriage of meningococci occurs in 5%–10% of the population." (http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3901g5.htm#other)

Yet meningococcal disease is rare. Hence it can be seen that transmission of this bacteria is not one of

the significant factors leading to the development of meningococcal disease itself.

Further, "meningococcal bacteria are not easily spread from person to person and the bacteria do not survive well outside the human body. The bacteria are passed between people in the secretions from the back of the nose and throat. This generally requires close and prolonged contact with a person carrying the bacteria."
http://www.health.nsw.gov.au/Infectious/factsheets/Pages/Meningococcal_disease.aspx

Pneumococcal: Like Hib, "The bacteria often live harmlessly in the throat of healthy people."
(http://www.health.nsw.gov.au/Infectious/factsheets/Pages/Pneumococcal-Disease.aspx)

"In a large majority of hosts, pneumococci are carried with no apparent symptoms."
(http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part4~handbook10-4-13).

Yet pneumococcal disease is uncommon. Hence it can be seen that transmission of this bacteria is not one of the significant factors leading to the development of pneumococcal disease itself.

Hepatitis B: "is usually transmitted by contact with bodily fluids (such as blood, semen, vaginal secretions or saliva) of an infected (HBsAg positive) person… The virus must be introduced through broken skin or the placenta or come in contact with mucous membranes for infection to occur… Faecal-oral and vector-borne modes of transmission have not been demonstrated. Hepatitis B is not transmitted by kissing on the cheek, coughing or sneezing, sharing food or sharing eating utensils."
(http://www.health.nsw.gov.au/Infectious/controlguideline/Documents/hepatitisB.PDF)

Polio: Australia has been (officially) certified polio-free ever since 2000 and the Australian Government reports that "The last reported case of locally acquired wild-type polio in Australia was in 1972." *(Poliomyelitis vaccines for Australian children*, NCIRS Fact sheet: December 2009 http://www.ncirs.edu.au/immunisation/fact-sheets/polio-fact-sheet.pdf)

However, that 1972 case was "not confirmed virologically… Virological investigations of stored viruses from Australia indicate that the last wild poliovirus was isolated from a patient with clinical poliomyelitis in 1967…. it is possible that wild poliovirus may have disappeared from Australia in the 1960s and that cases notified later were all VAPP or imported cases, as were all the cases notified after 1972."

(http://www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-2002-cdi2602-cdi2602l.htm)

Hence, the Australian Government reports: "*Local transmission of wild polio virus in Australia probably ceased in 1962*."

(Vaccine–associated paralytic poliomyelitis, Burgess M, McIntyre P, NCIRS 1999; Vol 23, No 10.

http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-1999-cdi2303-cdi2303g.htm)

Since 1972, more than 20 million, and since 1962, about 25 million, unvaccinated child years have transpired.

Based upon this, it is reasonable to conclude that the only possible sources for transmission are:

- vaccination itself. The Government has not admitted, though, the possibility of that occurring from the currently used vaccine, IPV (in spite of it acknowledging that vaccine associated paralytic polio

(VAPP) occurred when the earlier IPV vaccine was recommended and funded, between 1956 and 1966), or

- importation from overseas. In spite of the many millions of people who have entered Australia from overseas in the past half century, there have been only 2 cases reported of imported wild polio virus since the 1950s or 1960s – they were in 1977 (assumed acquired in Turkey) and 2007 (acquired in Pakistan). No secondary clinical cases, i.e. no transmission resulted. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2857217/)

  The WHO states, e.g. in its most recent update (2014), that with the number of cases having globally declined by 99.99% from 1988 (27 years ago) when it was endemic in more than 125 countries, polio remains endemic in only 3 countries. Hence the risk of importation could be estimated to be about 10,000 times less still than in 1988. Further, of the 3 strains of wild poliovirus (type 1, type 2, and type 3) included in the vaccine, wild poliovirus type 2 was considered globally eradicated in 1999.
  (Poliomyelitis Fact sheet N°114 Updated October 2014. World Health Organisation **http://www.who.int/mediacentre/factsheets/fs114/en/**)

  If a third case were to occur of importation of wild polio virus, the Government itself states: "Transmission occurs primarily from person to person via the faecal-oral route" and that the "likelihood of local transmission following importation will be dependent upon… the living conditions, primarily relating to the likelihood of faecal contamination of the water supply." It cites only "rural and remote areas of Australia" as areas where "such contamination remains a possibility". It states that elsewhere, i.e. in urban areas, "adequate treatment of sewerage and provision of safe drinking water and foods" is an important factor for preventing the disease from spreading. (http://www.health.nsw.gov.au/Infectious/factsheets/Pages/Poliomyelitis.aspx)

Even if polio virus transmission were to occur, the Government admits that "*There may be… up to 1,000 cases of asymptomatic infection for each paralytic case in children*":

(*Immunisation Myths and Realities, 5th edition* (2013). Aust. GovtDept of Health http://www.health.gov.au/internet/immunise/publishing.nsf/content/uci-myths-guideprov)

[ix] US disease notification and death rates and vaccination coverage

Disease and mortality rates

CDC *MMWR: Summary of Notifiable Diseases* http://www.cdc.gov/mmwr/mmwr_nd/

The annual incidence of invasive pneumococcal disease caused by (PCV13) vaccine-targeted pneumococcal disease serotypes in under 5 year olds in the US has been 1 case per 200,000 in 2012-16 (https://www.cdc.gov/pneumococcal/surveillance.html)

The annual death rates of invasive pneumococcal disease in the US, by age group (2016): https://www.cdc.gov/vaccines/pubs/surv-manual/chpt11-pneumo.html

State of Indiana varicella notifications for 2016 are here: https://www.in.gov/isdh/files/2016%20Annual%20Report%20of%20Infectious%20Diseases.pdf

Notes re disease morbidity and mortality rates and numbers cited in this paragraph:

(1) Accuracy of data

These figures are sourced from what is reported in government disease surveillance publications.

Disease notification sensitivity: Although health professionals are required to notify all cases diagnosed of notifiable diseases, some disease cases may be missed. However, what is of ultimate concern in relation to any infectious disease is only the risk of complications and (especially) sequelae, and cases that are not clinically significant enough to be reported are unlikely to be among those that lead to such serious issues.

Observer bias: Medical doctors have been found to show what the medical literature terms "observer bias**"** against diagnosing targeted diseases in vaccinated children, even when the disease appears in the form that is typical and hence would be recognizable when it occurs in unvaccinated children, but especially when the sensitization effect of the vaccine leads to the disease to appear in an atypical form, such as atypical measles. This leads to an artificially low disease notification rate in those vaccinated, and an exaggerated measurement of vaccination effectiveness. Research properly investigating its extent is lacking. See Note 15 and 85.

Deaths – underlying versus contributory cause: The deaths referenced include only those in which the disease of interest is recorded as the underlying cause of death. There have been additional deaths where the disease of interest was a contributing cause of death. However, in the cases of the relevant diseases, the latter types of cause can be seen to not make a significant difference to the total, especially in the relevant age groups. US Ministry Health have recorded (Annual Report of 2007, 2009, 2012 and 2013) both types of cause between 2003 and 2011 inclusive for pertussis and tetanus. Total deaths for those diseases across all age groups, from both types of cause, were 3 and 2 respectively for pertussis and tetanus and in none of those cases of death was the relevant disease only a contributing cause of death.

Other potentially limiting factors include potential inaccuracies of disease classification coding and incomplete follow-up. Although a coding error can lead to a failure to correctly attribute a death to a targeted disease, it also can lead to the opposite – incorrect attribution of a death to a targeted disease.

(2) Complications versus sequelae – difference in seriousness: There is a significant difference between complications and sequelae. Complications are conditions that can develop during infection but, although they represent an increased risk of sequelae developing, they usually resolve with full recovery. Sequelae, in contrast, are ongoing, generally permanent conditions of dysfunction or absence of function, significantly adversely affecting quality of life.

(3) Disease complications/sequelae reported after vaccination: Some brief mention is included regarding disease-related conditions that have been reported or evidenced to occur as also a possible effect of the relevant vaccination. These mentions are not intended to represent an exhaustive list of all adverse conditions that have been reported or evidenced to occur as a possible effect of that vaccination.

(4) Harm (death(s) or sequelae) may have been avoidable: Death or sequelae that are published to have occurred as a result of the targeted disease were not necessarily unavoidable regardless of the medical treatment employed. Some medical treatments carry their own risks, and alternative choices of treatments might have resulted in better outcomes.[7]

(5) Size of child population – context for death numbers: The number of deaths over the past 25 years needs to be viewed in the context that there was an annual average of about 4 million children in *each* age year group living in US *each year* over the 2007 to 2015 period, of which an average of about 5-10% were not fully vaccinated against any particular disease.

Vaccination Coverages

https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6135a1.htm

https://www.cdc.gov/mmwr/volumes/65/wr/mm6539a4.htm

https://catalog.data.gov/dataset/selected-trend-table-from-health-united-states-2011-vaccination-coverage-among-children-19

Vaccination coverages have increased in the relevant age group during the 2007-2015 period, so to whatever extent any vaccination is effective for preventing transmission of the targeted disease, the chance of that disease occurring today is less still than the average rate over that period.

[x] NSW Health Communicable Diseases Protocol – Diphtheria.http://www.health.nsw.gov.au/Infectious/controlguideline/Pages/diphtheria.aspx

[xi] Vaccine-induced antibodies – to what extent, if any, do they destroy the targeted antigen?

Vaccines are designed to elicit the production of antigen-specific antibodies, and it is assumed that these antibodies will destroy the targeted antigen, at least before they significantly wane.

However, investigations into their neutralizing functionality have found:

- that some vaccine-induced antibodies have "low avidity" and are "non-protective",

  e.g. Gauger PC, Vincent AL et al. Kinetics of Lung Lesion Development and ProInflammatory Cytokine Response in Pigs With Vaccine-Associated Enhanced Respiratory Disease Induced by Challenge With Pandemic (2009) A/ H1N1 Influenza Virus. *Veterinary Pathology*, Nov 2012;49(6):900-912 http://lib.dr.iastate.edu/cgi/viewcontent.cgi?article=1078&context=vmpm_pubs; and

- that severe disease, and even death, has occurred in fully vaccinated patients with high titres, e.g. Crone NE, Reder AT. Severe tetanus in immunized patients with high anti-tetanus titers. *Neurology*. 1992 Apr;42(4):761-4. https://www.ncbi.nlm.nih.gov/pubmed/1565228; and

- that even a high concentration of high-avidity antibodies has failed to prevent disease cases, e.g. measles https://academic.oup.com/jid/article/206/10/1542/858893

This may be one of the explanations for the observations of vaccination coverage being similar amongst the cases of targeted diseases to the coverage in the wider population,[12] notwithstanding the bias in doctors' diagnosis and reporting.[15]

Vaccination rate amongst notifications has been reported to be 90%-100%, similar to, or higher than, rate in population

Pertussis

Some examples of pertussis outbreaks published therein or elsewhere, including vaccination status data of notified cases are (in reverse chronological order):

1) *70 diagnosed with Whooping Cough in Reno County* (Kansas) Eyewitness News, Jul 30, 2015

   http://www.kwch.com/news/local-news/70-diagnosed-with-whooping-cough-in-reno-county/34378784
   "*Hutchinson Schools' spokesman, Ray Hemman… says (100% of) the cases the district has heard about were people who've been vaccinated*"

2) *19 kids in Summit Co. (Utah) diagnosed with whooping cough despite (100% of the cases) being up to date on vaccinations.* March 27, 2015, by KierstenNuñez

http://fox13now.com/2015/03/27/19-kids-in-summit-co-diagnosed-with-whooping-cough-despite-being-up-to-date-on-vaccinations/ "all of the children infected are up to date on their vaccinations."

3) In January 2015 it was published that in Parana, Brazil, in 2007-2013, of the cases where vaccination status was available, 98% of the 1-9 year olds, and 96% of the 1-19 year olds were vaccinated, and 91% and 90% respectively had had 3 or more doses.

(Torress et al. *Resurgence of pertussis at the age of vaccination: clinical, epidemiological, and molecular aspects.*Jornal de Pediatria. Received 2 June 2014, Accepted 8 September 2014, Available online 23 January 2015. doi:10.1016/j.jped.2014.09.004http://www.sciencedirect.com/science/article/pii/S0021755715000066)

4) *15 Falmouth High Students Diagnosed With Whooping Cough.* November 14, 2014 8:29 PM http://boston.cbslocal.com/2014/11/14/whooping-cough-outbreak-on-cape-cod/

"A school official tells WBZ that all the students had been immunized."

5) In an outbreak in the Triad (North Carolina) in 2012, it was reported in February (2012) that 100% of confirmed cases to date had received the pertussis vaccine.
(*Whooping Cough Is In The Triad*, WFMY News 2 (Mark Geary), Feb 24, 2012 http://www.digtriad.com/news/article/216176/57/What-You-Need-To-Know-About-Whooping-Cough)

6) Chuk et al, Pertussis in infants: how to protect the vulnerable? *CDI* 2008;32;4:449-456. http://www.health.gov.au/internet/main/publishing.nsf/content/cda-cdi3204h.htm

This study, published by the Government, was conducted in relation to 55 infants hospitalised with pertussis between 1997 and 2006 in the Royal Children's Hospital, Brisbane, Australia.
In summary, the results were as follows:

1. **Of the 30 hospitalised infants who had been old enough to be eligible for vaccination**

   - **93% (28/30) infants had been vaccinated**. Only 2 were unvaccinated, and one of those, a 3 month old, was only a little older than when the first dose is scheduled in Australia (between 2 and 2½ months). In some countries (e.g. Japan, Italy and all in Scandinavia) the first dose is not scheduled before 3 months of age. The other unvaccinated infant was 5 months of age. The disease in neither unvaccinated infant was serious enough to require admission to intensive care (unlike 5 infants who had been vaccinated), and
   - 83% (25/30) had been vaccinated "on time", meaning within 2 weeks after reaching the scheduled age. In the population at large, on average only 69% infants are given the 3rd vaccine dose "on time".[xii]

2. The single death among the "vaccine eligible" was in a 2 month old infant than who had, in fact, been vaccinated at just 6 weeks of age, a week before presenting with clinical pertussis.

   The infection source, which was not identified, may have been the vaccine that the infant had just been given. This would appear to be a reasonable possibility because:

   – pertussis is a toxin-mediated disease

(Pittman M. *The concept of pertussis as a toxin-mediated disease*.*Pediatr Infect Dis*. 1984 Sep-Oct;3(5):467-86. http://www.ncbi.nlm.nih.gov/pubmed/6093069)

and

– the pertussis "toxoid" in the vaccine (both the old and new vaccines) can remain pathogenic

(J. H. Menkes, M. Kinsbourne·*Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination.*Neuropediatrics 1990; 21(4): 171-176. https://www.thieme-connect.com/DOI/DOI?10.1055/s-2008-1071488)

The infant's susceptibility may have been further increased by the mother having been vaccinated herself in the past, as it may weaken an infant's transplacental immunity

(Mullholland K, *Measles and pertussis in developing countries with good vaccine coverage*. Lancet 1995.; 345: 303-307)

3. Of the 15 hospitalised infants aged 2 months, 9 (60%) had received the 1st (2 month) dose and in 7 of those 9 cases no contact was identified, so some or all of those also may have contracted pertussis from the vaccine.
4. Of the 20 infants older than 3 months, the **only one who required admission to intensive care was a 9 month old who had been fully vaccinated**, and on time. He also required ventilation. The generally accepted upper age limit today for the potential danger period from pertussis may therefore be higher than 6 months for the vaccinated.
5. Only one of the 6 infants who were at least 7 months of age had not had the 3rd dose (he was just 7 months, and had received the other 2 doses). The other 5 (83%) had received the 3rd dose on time.
6. In the cases of those 5 who were more than 2 weeks "overdue", the average period of time that they were "overdue" was less than 1½ months.

7) De Serres G, Shadmani R et al. *Morbidity of Pertussis in Adolescents and Adults*. J Infect Dis. (2000) 182 (1): 174-179. doi: 10.1086/315648

(http://jid.oxfordjournals.org/content/182/1/174.full. Table 1 shows that 78% + 19% = 97% of the 280 cases in 12 - 17 year olds were believed to be in the vaccinated)

8) Srugo I et al. Pertussis Infection in Fully Vaccinated Children in Day-Care Centers, Israel. *Emerg Infect Dis.* Oct 2000, Vol 6, #5.http://wwwnc.cdc.gov/eid/article/6/5/00-0512_article.htm

9) Harnden A. Whooping cough in school age children with persistent cough: prospective cohort study in primary care.*BMJ* 22 July *2006; 333:174* http://www.bmj.com/content/333/7560/174;

10) In a 1997 pertussis outbreak in the Bonner County of the Panhandle Health District in North Idaho (US), 85% cases had 4 out of 4 doses and 15% had 3 out of 4 doses (100% vaccinated). Among those who had 2 out of 4, 1 out of 4 or even no doses there were no reported cases. The CDC concluded: "*The myth of vaccine refusal played no role in this outbreak*."

(Testimony before Idaho Legislature, by Angie Vasquez, Director, South Idaho Chapter, Vaccination Information and Liberation. Burley, Idaho, Feb. 26, 2003http://www.vaclib.org/news/boise.htm)

Hib (Haemophilus Influenzae b)

In the 3 years 2009 through 2011 in Australia, there were 21 to 23 Hib notifications in vaccine eligible children under 5 years of age. Of those cases, at least 19, and potentially 100%, were vaccinated, and 18 were fully vaccinated for their ages.

Chickenpox

In 2012 in Australia, 87% cases of chickenpox cases had been vaccinated (where vaccination status was known), which was **higher** than the vaccination coverage, especially given that the vaccine was only introduced in November 2005 and initial uptake was slow - 20% for the March 2006 cohort (as at March 2008), 71% for the September 2006 cohort, 79% for the March 2008 cohort, and still only 84% in the most recently vaccinated cohort in 2012.
(See Reference41 including disease notifications for 2012 and *Immunisation coverage annual reports* for 2007 (Fig 8) and2012 (Fig 3))

Many more examples can be found, *inter alia*, in Note 9.

It is not the case that in all outbreaks the vaccination rate amongst reported cases is as high as (or higher than) the vaccination rate in the population. However, there are various biasing factors that misleadingly discourage diagnosis and reporting – see Note 15.

[xiii] Recent large study published confirming the ineffectiveness of the cocooning strategy

An article published in October 2015 studied the effect (if any) of the cocooning program in Western Australia during 2011-2012, and further confirmed that:

> *"vaccinating parents with dTpa during the four weeks following delivery did **not** reduce pertussis diagnoses in infants*."
>
> (Carcione D. et al.*The impact of parental postpartum pertussis vaccination on infection in infants: A population-based study of cocooning in Western Australia*. Vaccine.**doi:10.1016/j.vaccine.2015.08.066Volume 33, Issue 42**, 13 October 2015, Pages 5654–5661 http://www.sciencedirect.com/science/article/pii/S0264410X15012049)

(An article in Australian Doctor magazine describes the same research:

> *Cocooning ineffective against pertussis.*Australian Doctor. **Michael Woodhea**d, 31 August 2015 **http://www.australiandoctor.com.au/news/latest-news/cocooning-ineffective-against-pertussis**)

Another 2015 study conducted in Texas also found the cocooning strategy to be ineffective.
Healy CM, Rench MA, Wootton SH, Castagnini LA. Evaluation of the impact of a pertussis cocooning program on infant pertussis infection. *Pediatr Infect Dis J*. 2015 Jan;34(1):22-6. doi: 10.1097/INF.0000000000000486. https://www.medscape.com/viewarticle/837717_1

[xiv] Australian states end free parent whooping vaccine (May 2012)

"Parents across Australia will no longer receive free whooping cough vaccinations because it is not effective in protecting newborns from the potentially deadly illness, a parliamentary committee has heard."
https://www.news.com.au/breaking-news/states-ending-free-parent-whooping-vaccine/news-story/03235c4dc2b3fe6456b7e6c3aeae1d83 (8 May 2012)

[xv] Observer bias in reporting of vaccination coverage and targeted diseases

Misleading vaccination coverage rates in the infected

In assessments of vaccination effectiveness in outbreaks, those who have not been vaccinated due to a pre-existing health condition, whether vaccination was considered medically contraindicated by the doctor or the parents themselves judged their child to not be well enough, are likely to be, or at least may be, on account of their ill health, more susceptible to contract the targeted infection or develop a complication or sequelae from it.

Hence, in vaccination effectiveness calculations that compare the number of cases in the vaccinated versus unvaccinated, these disease cases ought to be excluded so as to prevent a biased or misleading result. Typically however this exclusion does not occur.

Bias in diagnosis and reporting

Multiple factors have been documented to bias doctor's diagnosis of targeted diseases in the vaccinated, leading to misdiagnosis and underreporting of disease cases in the vaccinated:

- doctors rely for their diagnoses primarily upon a historically determined checklist of disease symptoms that are traditionally typical, and hence recognisable. Any alteration by vaccination of how the body subsequently outwardly expresses a disease will hence reduce the likelihood of recognition (e.g. atypical measles, which is listed as an adverse effect on the M-M-R II product insert[38]),[9,84,85] and
- doctors are relatively disinclined to make a diagnosis that is at odds with what they have been taught, which includes that vaccines are effective

  (e.g. Harnden A. *Whooping cough in school age children with persistent cough: prospective cohort study in primary care. BMJ* 22 July *2006; 333:174* http://www.bmj.com/content/333/7560/174;

  Weinberger DM, Malley R, Lipsitch M. Serotype replacement in disease following pneumococcal vaccination: A discussion of the evidence. *Lancet*. 2011;378(9807):1962-1973. doi:10.1016/S0140-6736(10)62225-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3256741/)

  and that vaccine-induced, presumed protective antibody titers will prevent the disease
  (e.g. Crone NE, Reder AT. Severe tetanus in immunized patients with high anti-tetanus titers. *Neurology*. 1992 Apr;42(4):761-4. https://www.ncbi.nlm.nih.gov/pubmed/1565228)

Prominent researcher James D Cherry, after studying observer bias, concluded:

"Our data suggest that observer compliance (observer bias), can significantly inflate calculated vaccine efficacy. It is likely that all recently completed efficacy trials have been effected by this type of observer bias and all vaccines have considerably less efficacy against mild disease than published data suggest."

(Cherry JD, Heininger U, Stehhr K, Christenson P. The effect of investigator compliance (observer bias) on calculated efficacy in a pertussis vaccine trial. *Pediatrics*1998 Oct;102(4 Pt 1):909-12. http://www.ncbi.nlm.nih.gov/pubmed/9755264)

[xvi] Medical research finds pertussis vaccination may result in "*silent reservoirs*" of infection

Srugo et al. *Pertussis Infection in Fully Vaccinated Children in Day-Care Centers, Israel.Emerg Infect Dis*. Oct 2000;6(5).**http://wwwnc.cdc.gov/eid/article/6/5/00-0512_article**: "The whole-cell vaccine for

pertussis is protective only against clinical disease, not against infection…. Our results indicate that children ages 5-6 years and possibly younger, ages 2-3 years, play a role as silent reservoirs in the transmission of pertussis in the community."
Study:Is the whooping cough resurgence due to vaccinated people not knowing they're infectious? 24 Jun 2015 **BMC Medicine** (**http://www.santafe.edu/news/item/althouse-scarpino-whooping-cough-asymptomatic/**);

[xvii] Medical research finds infection "*readily transmitted*" by vaccinated

Warfel, Zimmerman and Merkel. Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model *PNAS 2014 111 (2) 787-792; published ahead of print November 25, 2013, doi:10.1073/pnas.1314688110.* http://www.pnas.org/content/111/2/787.full

[xviii] Pertussis vaccination may increase, instead of decrease, the risk of transmission

Torress et al. Resurgence of pertussis at the age of vaccination: clinical, epidemiological, and molecular aspects. *Jornal de Pediatria*. Volume 91, Issue 4, July–August 2015, Pages 333-338. doi:10.1016/j.jped.2014.09.004http://www.sciencedirect.com/science/article/pii/S0021755715000066

Wendelboe AM et al. Transmission of Bordetella pertussis to young infants. Pediatr Infect Dis J. 2007 Apr;26(4):293-9. http://www.ncbi.nlm.nih.gov/pubmed/17414390

Nelson JD. The changing epidemiology of pertussis in young infants.The role of adults as reservoirs of infection.Am J Dis Child. 1978 Apr;132(4):371-3 - http://www.ncbi.nlm.nih.gov/pubmed?cmd=Retrieve&list_uids=645653

[xix] Medical research findings of *pertussis* vaccine increasing susceptibility to *B pertussis*

Does immunological evidence indicate that pertussis vaccination is likely to increase susceptibility?

Researchers have identified a flaw in relation to the pertussis vaccines, referred to as "Original Antigenic Sin". It not only provides an explanation for the ineffectiveness of pertussis vaccines, but further explains why the vaccines may, on the contrary, increase susceptibility to the disease.

(*Vaccinating pregnant women "halves the risk of pertussis in infants' first four months" ~ A critique by Dr Suzanne Humphries.* 21 March 2013 http://www.vaccinationcouncil.org/2013/03/21/vaccinating-pregnant-women-halves-the-risk-of-pertussis-in-infants-first-four-months-a-critique-by-dr-suzanne-humphries/)

Does other medical research find that the vaccine increases susceptibility to infection with non-targeted, and widespread, *B pertussis* strain(s)?

A 2010 study published in the Proceedings of the Royal Society B concluded that vaccination resulted in an approximately 40-fold increase in *B. parapertussis* lung colony-forming units (CFUs).

(Long et al. Acellular pertussis vaccination facilitates Bordetella parapertussis infection in a rodent model of bordetellosis. *Proc. R. Soc. B*, 2010; published ahead of print March 3, 2010, doi:10.1098/rspb.2010.0010 1471-2954.http://www.ncbi.nlm.nih.gov/pmc/)

Research in Australia published in 2012 has further found that the *B pertussis* strains that have been predominant in Australia in recent times, circulating in this country since at least 2000, are *not* amongst those targeted by the vaccine.

(L Ruiting. Newly Emerging Clones of Bordetella pertussis Carrying prn2 and ptxP3 Alleles Implicated in Australian Pertussis Epidemic in 2008–2010. *J Infect Dis*. 2012, http://jid.oxfordjournals.org/content/205/8/1220.full.pdf)

Research in the US has made a similar significant finding. A key antigen component of the acellular pertussis vaccine is pertactin (PRN). The CDC findings have indicated that 85% of the *B. pertussis* strains isolated in 2012:

"*were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains. Moreover, when patients with up-to-date DTaP vaccinations were compared to unvaccinated patients, the odds of being infected with PRN-deficient strains increased, suggesting that PRN-bacteria may have a selective advantage in infecting DTaP-vaccinated persons.*"

(http://www.cdc.gov/maso/facm/pdfs/BSCOID/2013121112_BSCOID_Minutes.pdf page 6)

Do historic epidemiological trends indicate that pertussis vaccines (old or new) increase susceptibility to infection with *B pertussis* overall?

Pertussis notifications have been rising significantly in the United States ever since 1978-80, which was when vaccination was mandated for school entry.

(CDC *MMWR: Summary of Notifiable Diseases* http://www.cdc.gov/mmwr/mmwr_nd/)

In Australia also, since pertussis became a notifiable disease in 1991, and along with several Government incentives since instituted on a number of occasions that have increased vaccination uptake, pertussis notifications have sustained a significant persistent overall rise.

(*National Notifiable Diseases Surveillance System* summary tables http://www9.health.gov.au/cda/source/cda-index.cfm)

Immunisation Coverage Annual Reports http://www6.health.gov.au/internet/main/publishing.nsf/Content/cda-immunanrep.htm)

See also Note 85for evidence of other vaccines increasing susceptibility to targeted, related and unrelated infections.

Duration of vaccine-induced immunity to pertussis

Antibody levels have been found to have "declined nearly 50% by 1 year after vaccination"

(Meyer et al. Cellular Immunity in Adolescents and Adults following Acellular Pertussis Vaccine Administration.Clinical and Vaccine Immunology, Mar. 2007, p. 288–292. Vol. 14, No. 3. doi:10.1128/CVI.00364-06.http://cvi.asm.org/content/14/3/288.full.pdf)

"No vaccine trial (has) examined immunity from these vaccines beyond 22 months", as at 2012

(Witt et al. Unexpectedly limited durability of immunity following acellular pertussis vaccination in preadolescents in a North American outbreak. Clin Infect Dis. 2012;54:1730-1735. http://cid.oxfordjournals.org/content/early/2012/03/13/cid.cis287.abstract, with [2] referencing Zhang L, Prietsch SO, Axelsson I, Halperin SA. Acellular vaccines for preventing whooping cough in children. *Cochrane Database Syst Rev*. 2011 Jan 19;(1)(1):CD001478. http://www.ncbi.nlm.nih.gov/pubmed/22419280)

"When only considering the age distribution of cases… between 1996 and 1999, the mean duration of immunity is estimated to be… three to four years."[xx])

(Lavine et al. Short-lived immunity against pertussis, age-specific routes of transmission, and the utility of a teenage booster vaccine. *Vaccine*. 2012 January 11; 30(3): 544–551. doi:10.1016/j.vaccine.2011.11.065. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246080/pdf/nihms340699.pdf)

[xxi] Duration of natural immunity to pertussis - lasts several decades or lifelong

Wearing et al. Estimating the Duration of Pertussis Immunity Using Epidemiological Signatures. PLoS Pathog. Oct 2009;5(10). http://www.plospathogens.org/article/info%3Adoi%2F10.1371%2Fjournal.ppat.1000647

[xxii] Klenner, FR. *The Treatment of Poliomyelitis and Other Virus Diseases with Vitamin C,*

Southern Medicine & Surgery 1949; Vol 111;No. 7:209-214. http://www.nutri.com/49/

Dr Klenner published and presented this paper to the American Medical Association detailing the complete cure of 60 out of 60 of his patients with polio using high doses of intravenous sodium ascorbate (Vitamin C)

[xxiii] 112 reports of chronic HBV in the US in the 1 to 14 year old age group in 2014-2015

112 was the average annual number of chronic hepatitis b cases reported from a total of 42 states. Reports might not reflect unique cases. (Summary of Notifiable Infectious Diseases and Conditions — United States, 2015.*Weekly* / August 11, 2017 / 64(53);1–143)

[xxiv] Conversion of the population average disease incidence rate to the average incidence rate in an unvaccinated child

The standard formula for determining vaccine effectiveness is:

VE = 1 – (DV / %V) / (DU / %U),

where DV = # Disease notifications in Vaccinated,
DU = # Disease notifications in Unvaccinated,
%V = % persons vaccinated in age group,
%U = % persons unvaccinated in age group,
VE = assumed Vaccine Effectiveness (as a proportion) averaged over the period, incorporating its waning rate, which varies slightly depending on # doses received by age group,
(Torvaldsen S, McIntyre PB. Observational methods in epidemiologic assessment of vaccine effectiveness, *CDI*Vol 26, No 3, Sep 2002
http://www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-2002-cdi2603-htm-cdi2603o.htm)

From the above formula, the following formulas can be derived:
DU = DT / (1 + (%V / %U x (1 – VE))), and
DRU = DRP / (1 – (%V x VE)),

where (in addition to above definitions in the first formula above):

DT = Total # Disease notifications (= DV + DV),
DRP = Disease notification Rate in the Population, and
DRU = Disease probability in the Unvaccinated.

[xxv] Hepatitis B vaccine – observed adverse effects on the liver

Hepatitis B vaccine has been found in experiments with mice to, *inter alia*, damage the liver and its function by:

- changing the expression of 144 genes associated with liver function, including some associated with inflammation and metabolism
  (Hamza H, Cao J, Li X, Zhao S. In vivo study of hepatitis B vaccine effects on inflammation and metabolism gene expression. *Mol Biol Rep*. 2011 Jun 21 http://www.ncbi.nlm.nih.gov/pubmed/21691704), and
- induction of "loss of mitochondrial integrity, apoptosis induction, and cell death"
  (Hamza H, Cao J, Li X, Li C, Zhu M, Zhao S. Hepatitis B vaccine induces apoptotic death in Hepa1-6 cells. *Apoptosis* 2012 May;17(5):516-27 http://www.ncbi.nlm.nih.gov/pubmed/22249285), and

In accord with these results, a study of U.S. children less than 6 years old in 1993 and 1994 found that those given hepatitis B vaccinations were approximately twice as likely to suffer from liver problems.

(M A Fisher, S AEklund.Hepatitis B vaccine and liver problems in U.S. children less than 6 years old, 1993 and 1994.*Epidemiology.* 1999 May;10(3):337-9 http://www.jstor.org/discover/10.2307/3703605?uid=3737536&uid=2&uid=4&sid=21101987300301)

Abnormal liver function is listed on the Engerix®-B hepatitis b vaccine product insert as reported after vaccination at a frequency of between 0.1% and 1%.[38]

Hepatitis B vaccine was found to be associated with prevalent arthritis [odds ratio (OR) = 5.91, 95% confidence interval (CI) = 1.05-33.14], incident acute ear infections (OR = 1.60, 95% CI = 1.00-2.58), and incident pharyngitis/nasopharyngitis

[xxvi] Hepatitis B vaccine – other adverse effects demonstrated

A study of U.S. children in the general population less than 6 years old in 1993 and 1994 found that those given hepatitis B vaccinations Hepatitis B vaccination were at an increased risk of adverse health outcomes, in particular, prevalent arthritis [odds ratio (OR) = 5.91, 95% confidence interval (CI) = 1.05-33.14], incident acute ear infections (OR = 1.60, 95% CI = 1.00-2.58), and incident pharyngitis/nasopharyngitis:

(M A Fisher, S AEklund. Adverse events associated with hepatitis B vaccine in U.S. children less than six years of age, 1993 and 1994 Ann *Epidemiol* 2001 Jan;11(1):13-21. **https://www.ncbi.nlm.nih.gov/pubmed/11164115**)

[xxvii] Overall Hib case fatality rate in 1987 was 4%
https://www.cdc.gov/vaccines/pubs/surv-manual/chpt02-hib.html#f1

[xxviii] UK Government does not routinely vaccinate against chickenpox

The UK Government chooses not to routinely vaccinate against chickenpox, because:

- "*the vast majority of children recover quickly and easily*" (from which they develop natural, lifelong immunity), whereas
- "*in adults, chickenpox is more severe and the risk of complications increases with age."*

- "*If you vaccinate children against chickenpox, you lose this natural boosting so current levels of immunity in adults will drop and more shingles will occur*."

  (Why isn't the chickenpox vaccination part of the routine childhood immunisation schedule? Chickenpox vaccine FAQs. National Health Service (UK). **http://www.nhs.uk/Conditions/vaccinations/Pages/chickenpox-vaccine-questions-answers.aspx#routineschedule**)

Many other countries also do not routinely vaccinate against chickenpox, e.g. the Netherlands, in which it is evidently not seen as a cause for concern: https://www.youtube.com/watch?v=n0xga_lcG7g

The following are the only countries that vaccinate against chickenpox, and in many of those countries the vaccination is given only to people in certain groups that are considered to be at higher risk: http://apps.who.int/immunization_monitoring/globalsummary/schedules?sc%5Br%5D%5B%5D=AFRO&sc%5Br%5D%5B%5D=AMRO&sc%5Br%5D%5B%5D=EMRO&sc%5Br%5D%5B%5D=EURO&sc%5Br%5D%5B%5D=SEARO&sc%5Br%5D%5B%5D=WPRO&sc%5Bc%5D%5B%5D=NLD&sc%5Bd%5D=&sc%5Bv%5D%5B%5D=VARICELLA&sc%5BOK%5D=OK

[xxix] Countries around the world whose vaccination schedules include chickenpox

WHO vaccine-preventable diseases: monitoring system. 2018 global summary

http://apps.who.int/immunization_monitoring/globalsummary/schedules?sc%5Br%5D%5B%5D=AFRO&sc%5Br%5D%5B%5D=AMRO&sc%5Br%5D%5B%5D=EMRO&sc%5Br%5D%5B%5D=EURO&sc%5Br%5D%5B%5D=SEARO&sc%5Br%5D%5B%5D=WPRO&sc%5Bd%5D=&sc%5Bv%5D%5B%5D=VARICELLA&sc%5BOK%5D=OK

[xxx] Risk of death from chickenpox cited as 1 in 60,000 cases

Atkinson, William (2011). *Epidemiology and Prevention of Vaccine-Preventable Diseases* (12 ed.). Public Health Foundation. pp. 301–323. *ISBN 9780983263135*.*Archived* from the original on 7 February 2015.*Retrieved4 February 2015.*

[xxxi] Vaccination can cause clinical zoster (shingles) in child vaccine recipients. Otherwise the risk is only in later life

New Zealand Immunisation Handbook 2017, Chapter 21: Varicella (chickenpox) https://www.health.govt.nz/system/files/documents/publications/immshandbook-21-varicella-mar18-v2.pdf

e.g. Levin MJ, DeBiasi RL, Bostik V, Schmid DS. Herpes zoster with skin lesions and meningitis caused by 2 different genotypes of the Oka varicella-zoster virus vaccine.*J Infect Dis.* 2008 Nov 15;198(10):1444-7. doi: 10.1086/592452.**https://www.ncbi.nlm.nih.gov/pubmed/18826373**

[xxxii] Vaccines available in Washington (and schedule)

Manufacturer product information inserts for all vaccines licensed for use in the United States: https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

The so-called "inactive" (despite not being inert) ingredients for many of the above vaccines, listed in one place: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf

Proposed catch-up vaccination schedule:
https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html (Also see Note 9)

Infanrix DTaP vaccine product information:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-PI-01955-1

Priorix MMR vaccine product information:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-3

[xxxiii] Lack of identifiable acceleration in the decline in chickenpox morbidity in the targeted age groups

Kristine K. Macartney and Margaret A. Burgess.Varicella Vaccination in Australia and US. The Journal of Infectious Diseases 2008; 197:S191-5 (in particular, page S193).
http://jid.oxfordjournals.org/content/197/Supplement_2/S191.full.pdf;
Vaccine Preventable Diseases in Australia, 2005 to 2007: Figure 3.16.4: Varicella notifications, South Australia, 2002 to 2007,* by month of notification
http://www.health.gov.au/internet/publications/publishing.nsf/Content/cda-cdi34suppl.htm~cda-cdi34suppl-3-vpd.htm~cda-cdi34suppl-3-vpd16.htm

[xxxiv] Primary vaccine failure of chickenpox vaccination

e.g. David E Michalik Sharon P Steinberg Philip S LaRussa Kathryn M Edwards Peter F Wright Ann M Arvin Haley A Gans Anne A Gershon. Primary Vaccine Failure after 1 Dose of Varicella Vaccine in Healthy Children.*The Journal of Infectious Diseases*, Volume 197, Issue 7, 1 April 2008, Pages 944–949, https://doi.org/10.1086/529043

[xxxv] Disease notifications and annual population cohort sizes in Australia

Disease notifications reports only (1994-2014)

National notifiable diseases: Australia's notifiable diseases status: Annual report of the National Notifiable Diseases Surveillance System. NNDSS Annual Report Writing Group, CDI, Aust. GovtDept of Health.
http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-annlrpt-nndssar.htm

Disease notifications and vaccination coverage reports(1993-2011)

Vaccine Preventable Diseases (and Vaccination Coverage) in Australia reports, 1993 through 2011 - Supplements, CDI, Aust. GovtDept of Health.http://www.health.gov.au/internet/main/publishing.nsf/content/cdisupplements-1-lp

Note: As in the United States and New Zealand, disease surveillance in Australia may not necessarily catch 100% of disease incidence or deaths. However, it was concluded from active measles surveillance conducted in Victoria that an insignificant number of cases of transmission are missed, at least in the case of measles (Bull WHO 2009).

[xxxvi] Properly managed natural exposure to some targeted diseases prevents some cancers and other chronic conditions

- Rønne T. *Measles virus infection without rash in childhood is related to disease in adult life*. The Lancet 1985, Vol 325, Issue 8419:1-5
  http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2885%2990961-4/abstract

  "*Rønne could associate a missing history of measles in childhood with increased cancer risk for a variety of tumors in a historical prospective study. Out of 353 individuals with a negative history of measles 21 developed cancer versus only 1 case out of 230 controls with a positive history of measles ($p < 0.001$)*."

(Kleef R, Dieter Hager E. *Fever, Pyrogens and Cancer. In: Madame Curie Bioscience Database [Internet]*. Austin (TX): Landes Bioscience; 2000 (http://www.ncbi.nlm.nih.gov/books/NBK6084/)

- Kondo N et al. *Improvement of food-sensitive atopic dermatitis accompanied by reduced lymphocyte responses to food antigen following natural measles virus infection*. Clin Exp Allergy 1993; 23: 44-50.
- Shaheen SO et al. *Measles and atopy in Guinea-Bissau*. Lancet 1996; 347: 1792-96.
- Albonico HU, Braker HU, Husler J. *Febrile Infectious Childhood Diseases In The History Of Cancer Patients And Matched Controls,* Dept of Mathematical Statistics, University of Berne, Switzerland. Medical Hypotheses 1998 Oct; 51(4):315-20.
- Wrensch M et al. *Prevalence of antibodies to four herpesviruses among adults with glioma and controls*. Am J Epidemiol. 2001;154:161–165. (http://aje.oxfordjournals.org/content/154/2/161.full.pdf)
  "***Glioblastoma*** *cases were (*60%) *less likely than controls to have immunoglobulin G antibodies to varicella-zoster virus*" (A glioma is a type of tumor that starts in the brain or spine. It is called a "glioma" because it arises from glial cells.)
- Cramer et al. *Mumps and ovarian cancer: modern interpretation of an historic association* Cancer Causes Control. 2010 Aug; 21(8): 1193–120110.1007/s10552-010-9546-1 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951028/pdf/nihms235805.pdf)
  "…suggesting a 19% decrease in risk of ovarian cancer associated with history of mumps parotitis."
- Kubota et al. *Association of measles and mumps with cardiovascular disease: The Japan Collaborative Cohort (JACC) study*. Atherosclerosis. 2015 Jun 18;241(2):682-686
  http://www.atherosclerosis-journal.com/article/S0021-9150%2815%2901380-5/abstract
  Highlighting the most significant results, men who had had mumps had a 48% reduced risk of total stroke and 79% reduced risk of hemorrhagic stroke. Men who had had both measles and mumps had a 20% reduced risk of cardiovascular disease, and 29% reduced risk of myocardial infarction.
- Maletzki et al. Cancer Immunology, Immunotherapy. August 2013, Vol 62, Issue 8, *Table 1 Anti-correlation between acute, cured infections, and the likelihood to develop cancer*, on pages 1284-1285.

[xxxvii] Measles, mumps and rubella vaccine-induced antibodies' limited duration

Secondary vaccine failure

A 2007 study found that after the second MMR dose, measles vaccine-induced antibodies declined rapidly, within 6 months, to pre-booster levels:

(LeBaron C et al. Persistence of Measles Antibodies After 2 Doses of Measles Vaccine in a Postelimination Environment. *Arch Pediatr Adolesc Med.* 2007;161(3):294–301. doi:10.1001/archpedi.161.3.294 **http://jamanetwork.com/journals/jamapediatrics/fullarticle/569784**).

A 1990 study concluded that after the second MMR dose, close to **5%** of fully-vaccinated children become potentially susceptible to clinical measles within **10 years**, and **33%** within **20 years**, i.e. by 25 years of age.

(Chen et al. Measles Antibody: Reevaluation of Protective Titers. *The Journal of Infectious Diseases*. Vol. 162, No. 5 (Nov., 1990), pp. 1036-1042. **https://www.ncbi.nlm.nih.gov/pubmed/2230231**).

A 2012 study found that seropositivity declined by approximately **50%** by **21–25** years of age:

(Chen et al. Waning population immunity to measles in Taiwan. *Vaccine 2012;* **Vol 30, No. 47**:6721–7. **http://www.sciencedirect.com/science/article/pii/S0264410X12007207**).

A 2008 study found that after second MMR dose measles, mumps and rubella vaccine-induced antibodies had fallen respectively by **50%**, 58% and 69% within only **8 years**, and **62%**, 76% and 67% within **15 years**.

(Davidkin et al. Persistence of Measles, Mumps, and Rubella Antibodies in an MMR-Vaccinated Cohort: A 20-Year Follow-up, *The Journal of Infectious Diseases*, Volume 197, Issue 7, 1 April 2008, Pages 950–956, **https://doi.org/10.1086/528993**

"During the first 8 years after the second dose (1987–1995), the decline in levels of antibodies against all 3 viruses was significant (P<.001); the decline was 50%, 69%, and 58% for measles, mumps, and rubella, respectively (figure 3). From then on, the antibody decline was substantially smaller but still significant: 23% for measles…; 22% for mumps…; and 21% for rubella…

Figure 3: Measles, mumps, and rubella IgG antibody levels were measured in samples collected from 58 vaccinees 1, 8, and 15 years after the second measles-mumps-rubella vaccination. The decline in geometric mean antibody levels is shown as the percentage of change from the level in 1987 (100%) to 1995 and to 2002, for measles (solid line) mumps (dashed line) and rubella (dotted line)")

Also, can vaccine-induced antibodies be validly assumed to be protective? See Notes 11 and 15.

[xxxviii] Chance of measles complication/death in child without "serious chronic disease or disability": 50% reduction

The average death rate for those **not** chronically ill was estimated in 1963 to be half of the average (i.e. 1 in 10,000, half of 2 in 10,000).

Miller (1964) stated (in the first paragraph of his article) that:

' "the need or desire" for large-scale vaccination in this country is subject to debate (British Medical Journal, 1963b). One of the major sources of doubt about the need for immunization stems from the belief among many parents and doctors that measles is a mild disease in which serious complications are rare and almost never fatal in normal children. Deaths have indeed declined rapidly in recent years to about 2 per 10,000 notifications, and a recent study has shown that about ***half*** *the deaths occur in persons with* ***serious chronic disease or disability****.'*

(Miller (1964) (*Frequency of Complications of Measles*, 1963. BMJ Jul 11, Vol 2: 75 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1815949/pdf/brmedj02558-0019.pdf)

So if we assume that the same halving of risk applies also today, the rate is reduced to **50%** of the overall rate.

[xxxix] Properly managed natural exposure to measles resolves some cancers

Pasquinucci G. Possible effect of measles on leukaemia. *Lancet*. 1971 Jan 16;1(7690):136.

Bluming A, Ziegler J. Regression of Burkitt's lymphoma in association with measles infection. *Lancet.* 1971 Jul 10; 298(7715):105–106

Ziegler JL. Spontaneous remission in Burkitt's lymphoma. *Natl Cancer Inst Monogr*. 1976 Nov;44:61-5.

H C Mota. Infantile Hodgkin's disease: remission after measles. *Br Med J.* 1973 May 19; 2(5863): 421.

Taqi et al. Regression of Hodgkin's Disease After Measles (Letters to the Editor) *Lancet*,16 May 1981; 317(8229): 1112.

Stephen J Russell, M.D., Ph.D. and Kah Whye Peng, Ph.D. Measles virus for cancer therapy. *Curr Top Microbiol Immunol*.2009; 330: 213–241.

[xl] Mumps complications described by the US CDC
https://www.cdc.gov/mumps/hcp.html

[xli] 80-100% solicited Engerix-B vaccine adverse events assessed to be causally related to the vaccination
Engerix-B vaccine manufacturer product insert
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-06573-3&d=201812141016933

[xlii] Food and Drug Administration (FDA).*Workshop on Non-clinical Safety Evaluation of Preventative Vaccines: Recent Advances and Regulatory Considerations*. 2002.
http://www.fda.gov/downloads/biologicsbloodvaccines/newsevents/workshopsmeetingsconferences/transcriptsminutes/ucm054459.pdf (pgs 12-13)

[xliii] Miller, Z. 2016. Combining Childhood Vaccines at One Visit Is Not Safe. JPANDS 21:1-49
https://www.jpands.org/vol21no2/miller.pdf

xliv How adequate is the safety testing in clinical trials of vaccines prior to their release

Acknowledged limits of clinical trial testing prior to vaccines' release to the public

The Australian Government's Academy of Science has published a booklet entitled "*The Science of Immunisation*" (2016)
(https://www.science.org.au/learning/general-audience/science-booklets/science-immunisation)

The booklet states (in Section "*5. How are vaccines shown to be safe?"*) that there are three phases of vaccine development (after it is tested on animals) before it is approved for widespread community use
(https://www.science.org.au/learning/general-audience/science-booklets/science-immunisation/5-how-are-vaccines-shown-be-safe):

I. Phase I trials, in which *"the vaccine candidate is given to small numbers (25–50) of healthy adults with the primary goal of assessing safety".* These trials can be seen to be extremely limited in their ability to detect risks, especially the risks of administering the vaccine to a more susceptible age group in the outside population - young children or infants, and

II. Phase II, which still involves a relatively small number of subjects (between 100 and 1000) and look primarily at vaccination efficacy, though with some short-term monitoring of adverse effects.

III. Phase III, which, "*usually requires administration of the vaccine to many thousands of potentially susceptible people*". Most phase III trials that are relied on in reality have only a few hundred subjects, but of those trials that do have thousands, the frequencies of observed post-vaccination medically significant events ("medical events other than common medical ailments resulting in an unscheduled physician's office or emergency room visit events") are in the range of around 1-4% per dose.

This frequency range of medically significant events is deemed to be within acceptable safety limits, even though:

- such frequencies (all that are within the range 1-10%) are conventionally categorised in manufacturer product information as "common", and
- the frequencies at which the targeted diseases occur in unvaccinated children are in most or all cases significantly lower,
- medically significant events include serious conditions such as autoimmune diseases, neurological events and respiratory conditions, and

Serious adverse events are typically disregarded on the basis of a judgement being made that "*none of these were considered related to administration of study vaccines",* without reasons or particulars included, despite proper safety assessment being the trial's very primary purpose.

For example, in a 2012 phase IIIstudy by Sanofi Pasteur evaluating the safety of the meningococcal vaccine (referenced by the Australian Immunisation Handbook as evidence of the vaccine's safety) medically significant events were observed in "approximately 2–4% of children" and included serious adverse events such as insulin-dependent diabetes mellitus, respiratory distress and febrile seizures. Yet of all of the medically significant events "none… were considered related to administration of study vaccines".

(Pina LM et al. Safety and immunogenicity of a quadrivalent meningococcal polysaccharide diphtheria toxoid conjugate vaccine in infants and toddlers: three multicenter phase III studies. *Pediatric Infectious Disease Journal* 2012;31:1173-83. http://journals.lww.com/pidj/Fulltext/2012/11000/Safety_and_Immunogenicity_of_a_Quadrivalent.20.aspx)

The trials are conducted by the vaccine manufacturers themselves (not an independent investigator), but their product information inserts (which can be accessed here for each available vaccine: https://www.ebs.tga.gov.au), reveal that:

i. The monitoring periods in clinical trials range from a limited period of a few days to only 6 weeks, and

ii. Rather than "*usually… many thousands",* the total number of subjects in the relevant trials range from less than 300 to approx. 16000, and are usually nearer the lower end of that range. (Is it further possible that even in the case of one or more of these small trials, they have been selected by manufacturers from a number of trials on the basis of having yielded the most favourable results?).

iii. Vaccine manufacturers select as trial subjects only those who the manufacturers define as "healthy", but fail to include how they define "healthy", e.g.

- Priorix-Tetra® vaccine (for measles, mumps, rubella and chickenpox): "In a study with an earlier formulation of the GSK MMRV combination vaccine (with a reduced mumps content) a total of 300 healthy infants aged 9 to 10 months, without previous history of varicella…*PRIORIX-TETRA* given in a 2-dose schedule in healthy children in the second year of life…"
- H-B-VAX II vaccine (for hepatitis B): "1636 doses of H-B-VAX II were administered to 653 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose."

- "Vaccine trials have routinely excluded vulnerable individuals with a variety of pre-existing conditions. Some of these include personal or immediate family history of developmental delay or neurologic disorders (including convulsive disorders of any origin), hypersensitivity to vaccine constituents and any condition that in the opinion of the investigators may interfere with the study objectives."

  (Soriano A, Nesher G, Shoenfeld Y. Predicting post-vaccination autoimmunity: who might be at risk? *Pharmacol Res.* 2015 Feb;92:18-22. doi: 10.1016/j.phrs.2014.08.002 https://www.ncbi.nlm.nih.gov/pubmed/25277820)

Accordingly, the Government's Therapeutic Goods Association (TGA) states:

"When a medicine (or vaccine) is first registered and made available in Australia, information about its safety and efficacy is usually available only from clinical trials",

yet

"*Clinical trials…do not detect all possible adverse events because:*

i. *they usually do not continue for long enough to detect adverse events that take a long time to develop, and*
ii. *they do not include enough subjects to detect adverse events that occur (more) rarely, and*
iii. *they do not include all of the… types of people who might… use the medicine and... be more susceptible to some adverse events...*"

("Reporting adverse events", subheading "*Why report adverse eventsto the TGA?"*Aust. Govt. Dept Health and AgeingTGA.https://www.tga.gov.au/reporting-adverse-events#why)

Acknowledged limits to testing of toxicity or contamination of individual vaccine batches

- **Inadequate investigation of vaccine detoxification**

Menkes and Kinsbourne (1990) in published the results of aWorkshop on Neurologic Complications of Pertussis and Pertussis Vaccination in 1990:

"Vaccines are not standard from one batch to the next… In fact, the whole question of vaccine detoxification has never been systematically investigated."

(J. H. Menkes, M. Kinsbourne·Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination.Neuropediatrics 1990; 21(4): 171-176. https://www.thieme-connect.com/DOI/DOI?10.1055/s-2008-1071488)

Relevant uninvestigated questions have included, *inter alia*, any potential synergistic and/or cumulative toxicity arising from the multiple ingredients being delivered simultaneously in a single vaccination, as occurs in government vaccination programs.

- **Inadequate testing of individual vaccine batch toxicity/contamination evident from product recalls**

The Government's claim that vaccines comply with strict manufacturing and production standards appears to be contradicted by government itself elsewhere, and vaccine recalls that have occurred.

The Australian Government's "*The Science of Immunisation*" booklet states that the pre-licensure testing is insufficient to rule out a significant risk of adverse events that are infrequent but are sufficiently common and/or serious to render the vaccine unfit for use in the community.

It cites an example, being the Rotashield rotavirus vaccine which was initially administered to the public but subsequently withdrawn within only 1 year of use due to the unacceptable rate at which it was found to be causing intussusception. Then, with the replacement vaccine, *again* it was only after it had been used on the public that a higher number of cases of intussusception was detected with that replacement vaccine also.

Other examples have included:

- *Meningitec meningococcal serogroup C conjugate vaccine suspension for injection, single dose syringe - Recall - potential for particulate contamination*. 29 September 2014. **TGA**

  The announcement that ***"****Emerge Health has advised that a review of batches manufactured since October 2012 found a small number of syringes had been contaminated with iron oxide (rust) and oxidised stainless steel"* and consequent recall did not occur until **29 September 2014, which was 2 years after the said detected contamination was found to have begun.** **https://www.tga.gov.au/alert/meningitec-meningococcal-serogroup-c-conjugate-vaccine-suspension-injection-single-dose-syringe**

  It took 2 years after the release of these potentially contaminated vaccines to the public before the testing occurred that detected that contamination.

- *"On 25 March 2011, TGA issued a recall of Batch N3336 of the 23 valent pneumococcal polysaccharide vaccine 23vPPV, Pneumovax® 23. In April 2011 health professionals were advised not to administer a second or subsequent dose of Pneumovax 23 vaccine. In December 2011 revised recommendations regarding which patients should be re-vaccinated under the National Immunisation Program were provided."*

  (Annual report: surveillance of adverse events following immunisation in Australia, 2011. *CDI* Vol 36 No 4, Dec 2012. **http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3604a.htm)**

- "*MSD has recalled lots of PedvaxHIB and Comvax, because it has been unable to guarantee sterility.*"
  (7 Jan 2008). http://www.kiallamedical.com.au/Home/patient-information/infectious-diseases/hib

Concluding question re reliability of claims of vaccine safety prior to release for public use

The BMJ (1991) published an estimate that "only about 15% of medical interventions are supported by solid scientific evidence" and "only 1% of the articles in medical journals are scientifically sound"

(Smith R. Where is the wisdom? The quality of medical evidence. *BMJ*. October 1991;303(6806):798-799. https://liberationchiropractic.com/wp-content/uploads/research/1991Smith-MedicalEvidenceMissing.pdf)

- Are the claims of safety of one or more of the proposed vaccinations and consequent release for public use possible example(s) of the fragility of the scientific basis of medicine?

Cochrane Library states that MMR vaccine safety testing is "largely inadequate"

The prestigious Cochrane Library appears to have answered the previous question with respect to the MMR vaccine. It recently did an independent review of trials of that vaccine and the author's conclusion was "*The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."* (Cochrane Database Syst Rev. 2012 Feb 15;2. http://www.ncbi.nlm.nih.gov/pubmed/22336803)

Adverse events/effects observed only post release

Hence the pre-release testing is too limited to determine the rate and strength of vaccines' association with serious adverse effects that may not in fact be rare. It follows that the administration of the vaccines available for public administration essentially remains experimental to the extent, at the minimum, to which the clinical trials are thus limited.

Virtually all of the government surveillance and medical research referenced in this document describe dangers and adverse events identified only post release - some possibly, others certainly, causally linked to vaccines, including numerous serious adverse effects listed by the manufacturers and acknowledged as possibly caused by the vaccine.

The inadequacy of safety testing post release is covered in Note 67 herein.

[xlv] An example of a vaccine-caused adverse effect occurring a long time (6 years) after monitoring period

The following relates to the documented onset of seizures (epilepsy) (in Hannah Poling) in April, 2006, almost 6 years after she was vaccinated in July 2000, at 19 months of age.

Dr Andrew W. Zimmerman (Pediatric Neurologist, Director of Medical Research, Center for Autism and Related Disorders at the Kennedy Krieger Institute) concluded this in relation to Hannah Poling who was financially compensated for having developed encephalopathy from vaccine injury:

> "The developing brain is especially vulnerable to mitochondrial dysfunction because of its high metabolic energy demands and may be critically injured by marginal energy supplied by mitochondria under conditions of stress, such as infections and immune stimulation. Such cellular metabolic injuries in the brain during early childhood typically evolve over time as the child develops and may express themselves as the child grows. An analogy to this situation is birth injury followed by cerebral palsy (ep).
> Patients with ep may develop epilepsy months or years after the brain insult, but the original insult is still the cause of the epilepsy. The child may improve and make progress developmentally, but then later develops epilepsy or other neurological impairments (e.g., learning disorders). Thus, the time delay between vaccination, encephalopathy, and seizure onset does not preclude a causal relationship.
>
> The following are my opinions regarding Hannah Poling:
>
> 1. The cause for regressive encephalopathy in Hannah at age 19 months was underlying mitochondrial dysfunction, exacerbated by vaccine-induced fever and immune stimulation that exceeded metabolic energy reserves. This acute expenditure of metabolic reserves led to permanent irreversible brain injury.
> 2. Epilepsy is a result of the original brain injury in Hannah. *Its appearance was delayed but was part of the same pathogenesis that led to autistic encephalopathy…*
>
> I hold these opinions to a reasonable degree of medical certainty."
> (http://www.rescuepost.com/files/rh-4.pdf, Exhibit 3)

[xlvi] Brief of Vaccine Injured Petitioners Bar Association et al. as Amici Curiae in Support of Petitioners,Bruesewitz v. Wyeth, Inc., No. 09-152 (filed June 1, 2010) [hereinafter Brief of Vaccine Injured Petitioners Bar Association] (citing H.R. REP. NO. 99-908, pt. 1, reprinted in 1986 U.S.C.C.A.N. 6344).

[xlvii] Holland, M. (2010, September).Reconsidering Compulsory Childhood

Vaccination.http://ssrn.com/abstract=1677565

[xlviii] U.S. Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects

US Supreme Court, Bruesewitz et al. v. Wyeth LLC, Certiori to the U.S. Court of Appeals for the Third Circuit, No. 09–152. Argued 12 Oct 2010, decided 22 Feb 2011. http://www.supremecourt.gov/opinions/10pdf/09-152.pdf

White v. Wyeth (1988), No. 87-1657, Ohio Supreme Court.http://www.leagle.com/xmlResult.aspx?xmldoc=198843040OhioSt3d390_1339.xml&docbase=CSLWAR2-1986-2006;

Ackley v. *Wyeth* Laboratories (1990), 919 F.2d 397, Sixth Circuit (applying *Ohio* law).https://bulk.resource.org/courts.gov/c/F2/919/919.F2d.397.89-3821.html;

Mazur v. Merck (1992), No. 91-1613, Third U.S. Circuit Court of Appeals.http://biotech.law.lsu.edu/cases/vaccines/mazur_v_merck.htm.

[xlix] U.S. National Childhood Vaccine Injury Act Vaccine Injury Table.

The relevant legislation, including the Vaccine Injury Table: https://www.law.cornell.edu/cfr/text/42/100.3

An alternatively formatted version of the Vaccine Injury Table is available on the CDC site here: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/d/injury-table.pdf

[l] U.S. Dept Health and Human Services HSRA Statistics Report – March 2018.
https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/monthly-website-stats-3-30-18.pdf

[li] Holland, M. (2010, September).Reconsidering Compulsory Childhood Vaccination.http://ssrn.com/abstract=1677565

[lii] Vaccine injuries – circumstances in which claims can be made
"Who Can File" U.S. Dept Health and Human Services, Health Resources and Services Administration.
https://www.hrsa.gov/vaccine-compensation/eligible/index.html (last accessed 18 Dec 2017)

An example of the restrictive criteria is that there is a 3 year statute of limitations (or 4 years in cases where death ultimately results) starting from when a doctor first notes in the patient's medical records any condition that is a symptom of the injury, and 2 years from the date of a death. Doctors often fail to record information that is needed and/or do not inform the patient/carer that they are making the notation.

[liii] How adequate is the safety testing **subsequent** to vaccines' release (post-marketing surveillance and studies)?

Limitations of what is scientifically determinable from post-marketing surveillance

The TGA explains that it is due to the three types of limitations it lists to the testing in clinical trials (see Note 56) that it relies upon passive surveillance of adverse events subsequent to the release of vaccines to the public to *"provide important information for the TGA's safety monitoring program" "to contribute to a better understanding of their possible adverse effects when they are used outside the controlled conditions of clinical trials".*

However, with a post-marketing passive surveillance system that:

- lacks incentives for the reporting of adverse effects, even serious ones, and
- lacks robustness to any bias and/or limitations in knowledge amongst medical doctors, and
- lacks measurements of the ultimate reporting completeness,

how is it possible for it to provide meaningful information about the frequency of any adverse effects?

- **The post-marketing surveillance reporting rate for serious adverse events estimated to be less than 1%.**

  The reporting completeness of a similar passive surveillance system in the United States was found to be only less than **1%**.

  (Kessler D, *Introducing MEDWatch - A New Approach to Reporting Medication and Device*, JAMA, June 2, 1993-Vol 269, No. 21 http://www.fda.gov/downloads/Safety/MedWatch/UCM201419.pdf;
  Lazarus, R. *Electronic Support for Public Health – Vaccine Adverse Event Reporting System.* 2011 https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf)

  If the reporting frequencies from Australia's post-marketing passive surveillance are compared to those for matching adverse events listed in vaccine manufacturer product inserts (which are accessible here: https://www.ebs.tga.gov.au), the latter of which frequencies result from the active surveillance performed in clinical trials, a similar difference in magnitude is found as was found to be the case with the US passive surveillance system.

  (Reference: product information available here https://www.ebs.tga.gov.au compared to *Adverse events following immunisation annual reports* (for 2003 thru 2015), CDI, Aust. Govt. Dept Health http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-aefi-anrep.htm and "*Surveillance of adverse events following immunisation: Australia, 2000–2002*" report http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-2003-cdi2703-htm-cdi2703a.htm)

- **Examples evidencing serious inadequacies of post-marketing surveillance**

  Recent well publicized cases of serious adverse events occurring after vaccination include those of:

  - Sabah Button who became severely disabled after an influenza vaccine that she was given in April 2010 (in Western Australia), and
  - Ben Hammond, who developed ADEM (acute disseminated encephalomyelitis) after a dTpa vaccine that he was given in September 2012 (also in Western Australia).
    (https://thewest.com.au/news/wa/family-seek-vaccine-compo-ng-b88344054zBen Hammond's condition is described as a "one-in-a-million bad reaction" to the whooping cough vaccination, but there is no scientific evidence that ADEM and/or other adverse effects of comparable seriousness are so rare.)

  In the case of both adverse events, the causal relationship to the vaccines that had been given is not just suspected but opined by medical experts to be certain or probable. Yet *neither* of these two cases of very serious adverse events are included in the relevant tables in the "*Adverse events following immunisation annual reports"* reports for the relevant years. With adverse events such as

these not included therein, how reliable overall can Australia's post-marketing passive surveillance system be considered to be for capturing adverse events after vaccines?

U.S. Institute of Medicine (IOM): testing inadequate to show non-causation of serious conditions

Note: The quotes herein from the IOM are available together with analysis of these findings from this 2017 paper: **http://www.icandecide.com/white-papers/VaccineSafety-Version-1.0-October-2-2017.pdf**.

The IOM was formed in the United States in 1863 by congressional charter, to "provide expert advice on some of the most pressing challenges facing the nation and the world". Its members were historically "among the world's most distinguished scientists, engineers, physicians, and researchers; more than 300 members are Nobel laureates (**http://www.national-academies.org/about/whoweare/index.html**). Under the 1986 Act, the IOM was charged with issuing reports on injuries from vaccination.

In 1991, the IOM found that the scientific literature was insufficient to conclude whether or not the DTP vaccine can cause 12 serious injuries reported from this vaccine:

> aseptic meningitis; chronic neurologic damage; learning disabilities and attention-deficit disorder; hemolytic anemia; juvenile diabetes; Guillain-Barre syndrome;erythema multiforme; autism; peripheral mononeuropathy (nerve damage); radiculoneuritis and other neuropathies; thrombocytopenia; thrombocytopenic purpura (**https://www.nap.edu/read/1815/chapter/2#7**)

The IOM lamented that it "encountered many gaps and limitations in knowledge bearing directly and indirectly on the safety of vaccines." (**https://www.nap.edu/read/1815/chapter/2#8**)

The IOM also remarked on the poor design of the few vaccine studies that had been conducted, stating these "studies are too small or have inadequate length of follow-up to have a reasonable chance of detecting true adverse reactions" and that "existing surveillance systems of vaccine injury have limited capacity to provide persuasive evidence of causation." (**https://www.nap.edu/read/1815/chapter/9**)

The IOM thus cautioned in its 1991 report that: "If research capacity and accomplishment in this field are not improved, future reviews of vaccine safety will be similarly handicapped." (**https://www.nap.edu/read/1815/chapter/9**)

As in 1991, the IOM's 1994 report stated: "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee. Presentations at public meeting indicated that many parents and physicians share this concern." (**https://www.nap.edu/read/2138/chapter/12**)

The additional experimental aspect arising from the Government's vaccination program…

Another acute concern raised in the IOM's 1994 report was the potential risks posed by combining vaccines. The IOM noted that this subject simply had not been studied: "The committee was able to identify little information pertaining to the risk of serious adverse events following administration of multiple vaccines simultaneously. This is an issue of increasing concern as more vaccines and vaccine combinations are developed for routine use." (**https://www.nap.edu/read/2138/chapter/12#307**)

The relevant potential types of additional toxicity include:

- synergistic, arising from the simultaneous injection of the different ingredients from multiple vaccinations administered simultaneously, and
- cumulative, arising from the injection of the same ingredients from multiple vaccinations administered simultaneously.

Another potential source of additional toxicity includes:

- cumulative, arising from the injection of the same and/or different ingredients from the same and/or multiple vaccinations administered on multiple occasions.

IOM 2011 Report

In 2011, HHS paid the IOM to conduct another assessment regarding vaccine safety. This Report, entitled "*Adverse Effects of Vaccines: Evidence and Causality*", was the culmination of the largest review by the IOM regarding vaccine safety since the IOM's reports from 1991 and 1994. (**http://nationalacademies.org/hmd/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx**)

This third IOM Report reviewed the 158 most common vaccine injuries claimed to have occurred from vaccination for varicella, hepatitis B, tetanus, measles, mumps, and/or rubella. The IOM located science which "convincingly supports a causal relationship" for 14 of these serious injuries, including*, inter alia*:

a. (***causal relationship found:***) pneumonia, meningitis, hepatitis, MIBE (deadly brain inflammation a year after vaccination), febrile seizures, and anaphylaxis.

With respect to the **varicella (chickenpox) vaccine**, the IOM found that despite the paucity of epidemiological studies, there was enough other type of evidence to conclude "convincingly" that the "vaccine against chickenpox can induce brain swelling (encephalitis), pneumonia, hepatitis, meningitis, shingles, and chickenpox in …some who apparently have *competent* immune function" (as well as those immunocompromised) (**http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13164**)

The review also found sufficient evidence to support "acceptance of a causal relationship" for 4 additional serious injuries.

However, the IOM found the scientific literature was insufficient to conclude whether or not those vaccines caused 135 other serious injuries commonly reported after their administration, including:

b. (***lack of scientific studies:***) encephalitis (brain inflammation), encephalopathy (gradual degeneration of brain function, including memory, cognitive ability, concentration, lethargy, and eventually consciousness), infantile spasms, afebrile seizures, seizures, cerebellar ataxia (inflammation of and/or damage to the cerebellum), ataxia (the loss of full control of bodily movements), acute disseminated encephalomyelitis (brief but widespread attack of inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibers), transverse myelitis (neurological disorder caused by inflammation across both sides of one level, or segment, of the spinal cord that typically results in permanent impairments), optic neuritis (inflammation of the optic nerve and symptoms are usually unilateral, with eye pain and partial or complete vision loss), neuromyelitisoptica (body's immune system over time repeatedly mistakenly attacks healthy cells and proteins in the body, most often those in the spinal cord and eyes resulting in permanent disability), multiple sclerosis, Guillain-Barre Syndrome (body's immune system attacks part of the peripheral nervous system), chronic inflammatory demyelinating polyneuropathy (auto- immune inflammatory disorder of the peripheral nervous system resulting in loss of nerve axons),

brachial neuritis (auto- immune reaction against nerve fibers of the brachial plexus), Amyotrophic Lateral Sclerosis (rapidly progressive, invariably fatal neurological disease that attacks the nerve cells responsible for controlling voluntary muscles), small fiber neuropathy (damage to the small unmyelinated peripheral nerve fibers), Chronic Urticaria (chronic hives), erythema nodosum (skin inflammation in the fatty layer of skin), Systemic Lupus erythematosus (autoimmune disease in which the body's immune system mistakenly attacks healthy tissue), polyarteritisnodosa (inflammation resulting in injury to organ systems), psoriatic arthritis, reactive arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, arthralgia (joint pain), autoimmune hepatitis, stroke, chronic headache, fibromyalgia, Sudden Infant Death Syndrome, hearing loss, thrombocytopenia, immune thrombocytopenic purpura

IOM 2013 Report - finds no valid studies conducted of the entire vaccine schedule on a population level

In 2013, the IOM was engaged by the United States Department of Health and Human Services (HHS) to review the safety of the entire vaccine schedule on a population level (**https://www.nap.edu/read/13563/chapter/1**). The "committee's literature searches and review were intended to identify health outcomes associated with some aspect of the childhood immunization schedule." "Allergy and asthma, autoimmunity, autism, other neurodevelopmental disorders (e.g., learning disabilities, tics, behavioral disorders, and intellectual disability), seizures, and epilepsy were included as search terms." The IOM found that no studies had been conducted to validly assess the safety of the entire vaccine schedule or even portions of the vaccine schedule: [F]ew studies have comprehensively assessed the association between the entire immunization schedule or variations in the overall schedule and categories of health outcomes, and no study …compared the differences in health outcomes …between entirely unimmunized populations of children and fully immunized children. Experts who addressed the committee pointed ..to the fact that existing research has not been designed to test the entire immunization schedule. …[Also,] studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." (**https://www.nap.edu/read/13563/chapter/2#5**).

- **The lack of any investigation of that nature was found by IOM to be <u>not</u> due to any reason of impracticality, time or expense**, stating that"it is possible to make this comparison [between vaccinated and unvaccinated children] through analyses of patient information contained in large databases such as VSD" (Vaccine Safety Datalink Project) (https://www.nap.edu/read/13563/chapter/2#13) which would be cheap and efficient and able to be done quickly. Only political/commercial reason(s) appear to remain not discounted.

The CDC's own internal vaccine committee also acknowledges that assessing "adverse events require more detailed epidemiologic studies (than have been conducted to date) to compare the incidence of the event among vaccinees to the incidence among unvaccinated persons." (**https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm**)

The HHS has nonetheless consistently refused to study health outcomes of the completely unvaccinated. Outside of the HHS, however, small-scale studies have been performed comparing vaccinated with completely unvaccinated children, and these smaller studies have consistently reported that the unvaccinated have much better health outcomes (e.g. see Notes 104, 106, 107)

Re individual susceptibility, the IOM has called for research into factors affecting individual susceptibility – call has been unheeded by HHS, to date

The IOM has consistently stated there is individual susceptibility to serious vaccine injuries. The IOM has also acknowledged that research on individual susceptibility must be done on an individual basis, considering a child's personal genome, behaviors, microbiome, developmental stage, intercurrent illness, and present and past environmental exposure all of which can interact.

The IOM stated in its 1991 report that it has been "able to identify little information pertaining to why some individuals react adversely to vaccines".

With this research still not having been done by 2011, it continued to urge in the 2011 report that "[M]uch work remains to be done to elucidate and to develop strategies to document the immunologic mechanisms that lead to adverse effects in individual patients", but the CDC still ignores these calls. (**https://www.nap.edu/read/13164/chapter/5#82**, **https://www.nap.edu/read/13563/chapter/9#130**, **https://www.nap.edu/read/2138/chapter/12#307**, **https://www.nap.edu/read/1815/chapter/9**.

In its 2013 report the IOM stated that "evidence assessing outcomes in sub populations of children who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely) was limited and is characterized by uncertainty about the definition of populations of interest and definitions of exposures and outcomes".

Again, it is only outside of the HHS that such research has been conducted to some extent, such by Soriano (2015).[109,56] That study found four groups of individuals who might have significantly increased susceptibility to develop vaccination-induced ASIA (Autoimmune/inflammatory Syndrome Induced by Adjuvants - see Note 92) – those with proneness to develop autoimmunity (family history of autoimmune diseases; asymptomatic carriers of autoantibodies; carrying certain genetic profiles, etc), a history of allergic reactions, prior post-vaccination autoimmune phenomena, and/or a medical history of autoimmunity.

Result of inadequacies in post-marketing surveillance and studies

Considering all of the above, as well as the multiple references herein to research findings about the toxicity of ingredients that are deliberately included in vaccines, their contamination with other toxins – organic and inorganic, and links observed between vaccines and multiple adverse effects, to what extent are claims of the safety of the proposed vaccinations able to be scientifically substantiated?

[liv] Adverse Event Information to be released to the Health Select Committee (New Zealand)
https://www.health.govt.nz/system/files/documents/topic_sheets/adverse-event-summary.pdf

[lv] US Vaccine Court's 2017 ruling that "SIDS" case was caused by vaccination

The mechanism by which vaccination was judged to have caused the "SIDS" case was described as "vaccine-stimulated inflammatory cytokines as neuro-modulators in the infant medulla".

https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2013vv0611-73-0

Claim (on page 1):

> *"Petitioners allege that as a result of receiving vaccinations for Diphtheria-Tetanus-acellular Pertussis ("DTaP"), inactivated polio ("IPV"), haemophilus influenzae ("HiB"), Pneumococcal*

Conjugate ("PCV"), and Rotavirus vaccinations on September 2, 2011, J.B. (the deceased minor child) *passed away from Sudden Infant Death Syndrome ("SIDS") on September 3, 2011."*

Ruling (on page 55):

"IV. CONCLUSION
In this case, I have concluded, after review of the evidence, that it is more likely than not that the vaccines played a substantial causal role in the death of J.B.without the effect of which he would not have died. The role of inflammatory cytokines as neuro-modulators in the infant medulla has been well described and is likely the reason for a significant number of SIDS deaths occurring in conjunction with mild infection. I have concluded that it is more likely than not that the vaccine-stimulated cytokines had the same effect in this vulnerable infant during sleep."

[lvi] Causality - "certain" or "probable" rating given by the TGA to 19% of serious effects assessed

Adverse events following immunisation annual reports (2000 thru 2012), CDI, Aust. Govt. Dept Health
http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-aefi-anrep.htm
Virtually all of the remaining adverse events the TGA left with a causality rating of "possible".
Causality ratings are defined as follows:

Certain
A reaction in association with a single drug/vaccine which is confirmed by re-challenge; or
a. reaction in association with a single drug/vaccine which is confirmed by laboratory data specifically implicating that drug/vaccine; or
b. reaction whose onset is immediately following the administration of a single drug/vaccine (within five minutes if injection was the method of administration); or
c. reaction with a precise spatial correlation with the administration of a single drug/vaccine (e.g. at the exact site of injection).

Probable
a. A reaction with a close temporal or spatial (e.g. skin) correlation with the administration of a single drug/vaccine; or
b. reaction is in reasonable temporal association with a single drug/vaccine and recovery on withdrawal of the drug/vaccine if no other drug/vaccine is withdrawn and no therapy given; or
c. an uncommon clinical phenomenon associated with the administration of a single drug/vaccine and the reasonable exclusion of other factors.

Possible
a. An alternative explanation exists; or
b. more than one drug/vaccine is suspected; in association with the adverse event; or
c. data are incomplete; or
d. recovery follows withdrawal of more than one drug/vaccine; or
e. the time relationship is not clear; or
f. the outcome of the reaction is not recorded; or
g. recovery follows therapy in addition to withdrawal of the drug/vaccine.

(Surveillance of adverse events following immunisation: Australia, 2000–2002 report
http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-2003-cdi2703-htm-cdi2703a.htm)

The 20% figure (rounded from 19%) is not directly provided by the Australian Government but is calculable from the figures in the aforesaid annual adverse events reports. The calculation excludes those reports where recovery had not occurred by the time of the report, i.e. the latter reports are treated as having not been assessed for level of seriousness.
The details of the calculation are available from this author.

TGA finds serious adverse effects to occur far more frequently than publicly stated

Without taking into account any underreporting of adverse effects, the above *Adverse events following immunisation annual report*sindicate that serious adverse events are reported in approximately 1 in 2,700 children, taking into account all of the vaccines that a child receives while under 7 years old in accordance with the present benefits schedule.

The Australian Government seeks to cast doubt on causation based upon a study that does not use a true placebo

The Australian Government asserts in its *The Science of Immunisation* booklet (2016): "*many common symptoms that occur after a vaccine is given are not caused by the vaccine, but occur by chance at that time*".

> ("*The Science of Immunisation"*, "Chapter 4. Are vaccines safe?" Australian Academy of Science, 2016 https://www.science.org.au/learning/general-audience/science-booklets/science-immunisation/4-are-vaccines-safe)

However, as substantiation for that statement, *The Science of Immunisation* booklet relies only upon what it describes as a "valuable" "placebo"-controlled 1986 Finland study of the M-M-R II vaccine.

In scientific studies and the understanding of the general public, a placebo is a preparation that is already known to be innocuous and inert or at least have no potentially significant effect, and on this basis is given to the "control" groupin a trial as a comparator.

However, in vaccine studies, the definition of a "placebo" has been significantly broadened. Instead, a "Placebo Control" is defined as "a comparator in a vaccine trial that does not include the antigen under study. In studies of monovalent vaccines this may be an inert placebo (e.g. saline solution or the vehicle of the vaccine), or an antigenically different vaccine. In combined vaccines, this may be a control arm in which the component of the vaccine being studied is lacking."

> (WHO *Guidelines on clinical evaluation of vaccines: regulatory expectations.*Adopted by the WHO Expert Committee on Biological Standardization at its 52nd meeting.© World Health Organization WHO Technical Report, Series No. 924, 2004.http://docplayer.net/39858375-Annex-1-guidelines-on-clinical-evaluation-of-vaccines-regulatory-expectations.html)

Accordingly, in the referenced "placebo"-controlled 1986 Finland study of the M-M-R II vaccine, the study authors (not the Government) provide the fuller information that the so-called "placebo" groupreceived "*the same product including neomycin and phenol-red indicator but without the viral antigens*", i.e. neomycin, sorbitol and hydrolysedgelatine, Medium 199 (vitamins, amino acids, fetal bovine serum, sucrose, glutamate), Minimum Essential Medium, phosphate, recombinant human albumin, chick embryo cell culture and WI-38 human diploid lung fibroblasts. (See Note38 for the vaccine's ingredients list)

The study was also limited to only 10 types of solicited reactions other than local reactions and fever, and the monitoring period before the crossing over of the two compared groups wasonly 3 weeks (the clinical trial for the Priorix MMR vaccine was 6 weeks). Nevertheless, the M-M-R II group after one to two weeks still suffered significantly more reactions of almost all types than the group that received the incomplete vaccine (the so-called "placebo").

[lvii] Direct injection - bypass of immune system's first line of defence

Direct injection bypasses the body's physical *epithelial* surfaces, which act as the innate immune system's first line of defense against foreign organisms. They form a physical *barrier* that is (otherwise) impermeable to most infectious agents.
Research has found that **80%** of the immune system lines the gut in the form of the Gut-Associated–Lymphoid Tissue (GALT)

(Salminen S, Bouley C, et al. *Functional food science and gastrointestinal physiology and function.* British Journal of Nutrition 1998;80 (S1): S147-S171 http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=887904&fulltextType=RA&fileId=S0007114598001226)

Direct injection also bypasses the *entire digestive system*, whose important functions include the breakdown of foreign proteins, so that only their component amino acids are absorbed.

[lviii] Other disorders that have been linked to vaccines.

Note that disorders that have been linked to vaccines are not limited to neurological disorders (Reference 93), autoimmune disease (Reference 92) and DNA changes (Reference 75). Nor is the research that has linked to those conditions them limited to the examples cited herein under those headings. Further information and references are available upon request.

[lix] Effect of sensitizing injection of sensitizing, foreign ingredients – sensitization and inflammation

Sensitizing effect of vaccination

Sensitization, which very broadly means modification (to a minimal or more severe degree) of the behavior of the immune system towards altered responses to antigens, and generally towards increased and/or chronic reactivity, has been consistently observed to occur after vaccination.
The sensitization effect is attributable both of the following features of vaccination:

- the sensitizing **ingredients**, especially adjuvants included deliberately for their sensitizing effect, based upon the hypothesis that it is possible to thus artificially alter the natural immune response in a way that will increase its effectiveness (see Note 86)

and

- the sensitizing effect of **parenteral injection** of a colloid or protein substance or toxin (see Note 87). Notably, vaccines contain all three of these - colloids *and* protein substances *and* toxins.

In accordance with the adverse nature of the original meaning of "sensitization" as being "anaphylaxis" (in ranging degrees), which is a term that was coined to describe an observed effect that contrasted to "prophylaxis"[87,85,91] (the latter meaning "for protection"), the term "sensitization" is employed and understood generally in all contexts *other* than vaccination of humans and non-laboratory animals to mean altered responses that are unfavourable in their effect, and associated with increased susceptibility to harm.

Inflammatory effect of vaccination

Vaccination involves direct injection (bypassing important natural outer defences) of biologically active products and heavy metals.[77,74]

A large body of evidence has accumulated that this is followed by *self-directed tissue inflammation* occurring along a continuum from innate to adaptive immune-driven diseases, resulting in oxidative stress.

(Koenig HC, Application of the immunological disease continuum to study autoimmune and other inflammatory events after vaccinations. *Vaccine* 2011.29(5): 913–919 http://www.sciencedirect.com/science/article/pii/S0264410X10015288;

Phillips et al. Effect of influenza vaccination on oxidative stress products in breath.*J Breath Res*. 2010 Jun;4(2):026001. https://www.ncbi.nlm.nih.gov/pubmed/21383469;

"Could the Flu Shot Make You Depressed?" Kelly Brogan, MD https://kellybroganmd.com/could-the-flu-shot-make-you-depressed/)

Oxidative damage is proposed as a major mechanism for disease and ageing.

(Hybertsonet al. Oxidative stress in health and disease: the therapeutic potential of Nrf2 activation. Mol Aspects Med. 2011 Aug;32(4-6):234-46).

See Note 86 for further information about the/a mechanism that leads to the sensitizing and inflammatory effects of vaccination.

Forms of manifestation of the sensitization/inflammatory effects of vaccination

The sensitizing and inflammatory effects of vaccination have been found to manifest in various ways, including but not limited to the development of:

- atopy, which is deliberately induced in animals by the use of some vaccine adjuvants such as aluminum compounds and pertussigen,[91] for other experimental purposes, and/or
- increased susceptibility to targeted, related and unrelated pathogens,[85,104] and/or
- autoimmune diseases.[92]

The development of allergies and/or any of a plethora of inflammatory conditions (names ending in "-itis"), and especially their symptoms, are commonly reported after vaccination, as can be seen from vaccine product inserts' lists of adverse effects.**38**

Sensitization causes an abnormal immune response which can result in an altered progression and/or set of symptoms and compromised or ineffectual resolution of the infection.
An example of this is atypical measles, which has been observed only in vaccinated persons, and where the rash moves from peripheral to more important central regions of the body instead of the usual reverse direction, indicating an increased instead of decreased threat from the virus – see Note 85.

Any part of the body can be affected. Potentially most seriously they include the brain (via encephalitis - "minimal" or more widespread), and because the injection process bypasses important outer immune system defences, it increases the propensity for permanent damage as an outcome.[93]Consistent with this, marked adverse personality changes, loss of mental alertness, learning and behavioral disorders (including ADHD) and mental illnesses have all been reported to develop soon after vaccination.[93] Entire books have been written devoted entirely to covering

the evidence in existence at the time of vaccination causing behavioral problems, including autism and criminality, e.g. "*Vaccination, Social Violence and Criminality*", by Barbara Loe Fisher and Harris Coulter, PhD (1990), and "*Vaccination and Behavioral Disorders*" by Greg Wilson (2000).

It may be highly relevant that in lock step with the CDC's childhood vaccine schedule having increased from 11 injections of 4 vaccines in 1986 to 56 injections of 30 vaccines in 2017, plus (in relation to any effects on offspring) an additional generation having been vaccinated, childhood chronic illness and developmental disabilities have precipitously risen during this same period from 12.8% to **54%** of American children (https://www.ncbi.nlm.nih.gov/pubmed/20159870).

The causal mechanisms of these disorders are increasingly becoming understood and findings increasingly implicate vaccine exposure especially during early development, but with the multiple obstacles to investigating the relationship directly, especially in humans and non-laboratory animals, most of the relevant studies that have been conducted are in laboratory animals and much of the evidence therefrom is indirect.

An example is the *indirect* evidence for a causal link between vaccines and chronic inflammatory conditions is by way of the vaccines' induction of immune activation,[90] especially those vaccines that contain aluminum, but also other vaccines (such as MMR) that are given after, or together with, administration of aluminum-containing vaccines and also cause immune activation, which could be expected to lead to the transport to the brain of more of the aluminum that is present in the body from the aluminum-containing vaccines.

However, there is also *direct* evidence from studies on humans, e.g. the following double-blind placebo-controlled crossover study which also used a proper (saline) placebo:

> LJT Balter, S Hulsken et al. Low-grade inflammation decreases emotion recognition – Evidence from the vaccination model of inflammation. *Brain Behav Immun.* 2018 May 6. pii: S0889 1591(18)30177-6. doi: 10.1016/j.bbi.2018.05.006 (**https://www.sciencedirect.com/science/article/pii/S0889159118301776)**

The U.S. IOM itself has repeatedly reported that there is *insufficient quality vaccine safety research to demonstrate that the risk is acceptably low* of such long term neurological and/or immune outcomes.[56]

The risk of such damage can reasonably be expected to be higher in individuals who are genetically susceptible or have certain pre-existing conditions.[109]

Depletion of nutritional resources

Any and all of the above effects and associated stress will inevitably deplete the body of nutritional resources, including Vitamin C, with the results, in turn, including a weakening of the immune system[85] and potentially a resultant reduction in the integrity of dependent vital structures, such as bones, vascular walls, etc.

> (Chatterjee IB, Majumder AK, et al. Synthesis and some major functions of vitamin C in animals. *Ann NY AcadSci* 1975; 258:24-47.https://www.ncbi.nlm.nih.gov/pubmed/1106297;
>
> Clemetson CA. Vaccinations, inoculations, and ascorbic acid.*J Orthomolecular Med* 1999; 14:137-142 http://orthomolecular.org/library/jom/1999/pdf/1999-v14n03-p137.pdf;
>
> Clemetson CA. Elevated blood histamine caused by vaccinations and Vitamin C deficiency may mimic the shaken baby syndrome. *Med Hypotheses*. 2004;62(4):533-6.)

[lx] Vaccine-induced sensitization – effect on susceptibility to targeted, related and unrelated infections

Research findings have included that "non-protective (vaccine-induced) antibody is associated with *immune complex(IC)-mediated disease* after infection" and that "Preexisting *vaccine* antibodies may *enhance other viral infections in humans"*.

(Gauger et al. Kinetics of Lung Lesion Development and ProInflammatory Cytokine Response in Pigs With Vaccine-Associated Enhanced Respiratory Disease Induced by Challenge With Pandemic (2009) A/ H1N1 Influenza Virus. Veterinary Pathology, Nov 2012;49(6):900-912 http://lib.dr.iastate.edu/cgi/viewcontent.cgi?article=1078&context=vmpm_pubs)

This effect has been documented both in animals and in humans, and a term has been coined to describe the effect in some cases: VAERD (vaccine-associated enhanced respiratory disease).

Some examples of findings of relevant vaccinations increasing susceptibility to targeted, related and unrelated infections include:

- **after vaccination in general** – adverse effects reported and/or listed on vaccine product inserts include the targeted diseases and/or known complications and sequelae thereof
- after influenza vaccination

  (Gauger et al. 2012 article cited above; and

  Monsalvo AC, Batalle JP, Lopez MF, et al. Severe pandemic 2009 H1N1 influenza disease due to pathogenic immune complexes. Nat Med 2011;17:195–199 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3034774/; and

  Vaccine-Induced Anti-HA2 Antibodies Promote Virus Fusion and Enhance Influenza Virus Respiratory Disease. August 2013 http://stm.sciencemag.org/content/5/200/200ra114.full; and

  Cowling BJ, Fang VJ, Nishiura H, et al. Increased Risk of Noninfluenza Respiratory Virus Infections Associated With Receipt of Inactivated Influenza Vaccine. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*. 2012;54(12):1778-1783 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404712/, which found that in the vaccinated group the rate of influenza infection did not differ significantly but the rate of non-influenza was 440% higher)
- **after measles vaccination**, leading to a new, more serious form of measles called "**atypical measles**", partly referenced in the above articles, and also here: http://www.medterms.com/script/main/art.asp?articlekey=6593

  Serious complications are more frequent than with typical measles and include pneumonia (http://www.medicinenet.com/pneumonia_facts/article.htm)
- **after Hib vaccination**:
  - vaccination may select for increased virulence of non-targeted, more virulent strains

    (Brown et al. 2009.Invasive Haemophilus influenzae disease caused by non-type b strains in Northwestern Ontario, Canada, 2002-2008.*Clin Infect Dis*; 49: 1240-1243. https://www.ncbi.nlm.nih.gov/pubmed/19761408)
  - Daum et al. (1989) found that "a decrease in (non-vaccine-induced, protective) serum capsular antibody occurs in most children and adults vaccinated with PRP… and that such a decrease

might transiently increase the risk of invasive diseases if it occurred during a period of asymptomatic colonization with H. influenza type b."

(Daum RS, Sood SK, Osterholm MT, et al. 1989.Decline in serum antibody to the capsule of Haemophilus influenza type b in the immediate post-immunization period. J Pediatrics; 114: 742-747 http://www.jpeds.com/article/S0022-3476(89)80130-1/pdf)

- **after pneumococcal vaccination**:
  - vaccination may select for increased virulence of non-targeted, more virulent strains

"Our data suggest rapid effects of pneumococcal vaccines and progression of serotype replacement. Besides invasive potential, the increased prevalence of non-vaccine serotypes with highly non-susceptible to penicillin was a concern."

(Miyazaki H. Serotype distribution and antimicrobial susceptibility of Streptococcus pneumoniae strains isolated in Japan after introduction of the routine immunization program. *J Infect Chemother*. 2017 Apr;23(4):234-240. doi: 10.1016/j.jiac.2016.12.016. Epub 2017 Feb 1. https://www.ncbi.nlm.nih.gov/pubmed/28161295)

"*Although after the introduction of PCV7 (7-valent pneumococcal conjugated vaccine) the overall severity of IPD (invasive pneumococcal disease) cases (measured by pneumonia severity index) remained stable, higher rates of pleural effusion and empyema have been reported[31,34], which may be attributed to a changed frequency of virulence factors in the pneumococcal population. For instance zinc metalloproteinase C (zmpC), mainly present in nVTs, has been associated with a more severe clinical manifestation of IPD and was shown to be expanding[17]. This illustrates that elimination of VTs may result in substitution by nVT strains that potentially confer more severe disease. Modeling of vaccination-induced changes in frequency of disease associated genes may therefore be of interest to optimize target selection in new generations of pneumococcal vaccines. Such an approach would require further exploration of the role of pneumococcal genotypes in the manifestation of human infection*."

(Cremers, A. J. H. et al. The post-vaccine microevolution of invasive *Streptococcus pneumoniae.Sci. Rep.* 2015.5, 14952; doi: 10.1038/srep14952. https://www.nature.com/articles/srep14952)

"*serotype shifting may elude the antibody response and displace the vaccine strain. A major event of this kind has been the replacement of vaccine serotypes with nonvaccine serotype 19A, a serotype of* S. pneumoniae *that is prevalent worldwide, is clinically important, and has the potential for multidrug resistance (2, 3).*"

(Cassone, A., and R. Rappuoli. Universal vaccines: shifting to one for many. *American Society for Microbiology*. 2010. 1(1):e00042-10. http://mbio.asm.org/content/1/1/e00042-10.full)

- **after pertussis vaccination** (whole cell - DTP)

(Parfentjev 1959. Bacterial allergy increases susceptibility to influenza virus in mice. ProcSoc Biol Med; 90: 373-375. http://journals.sagepub.com/doi/abs/10.3181/00379727-90-22037 found that pertussis vaccination increased susceptibility of mice to infection with several unrelated species of gram-negative bacteria and to viruses; and

Aaby P, Jensen H et al. The introduction of diphtheria-tetanus-pertussis vaccine and child mortality in rural Guinea-Bissau: an observational study. *Int. J. Epidemiol. (2004)* 33 (2): 374-

380. doi:10.1093/ije/dyh005. https://academic.oup.com/ije/article/33/2/374/715842/The-introduction-of-diphtheria-tetanus-pertussis found that DPT vaccination increased mortality 10-fold, and suggested the reason to have been that the vaccination "increased susceptibility to unrelated infections". For more detail see Note 104)

- **after pertussis vaccination** (acellular - DTaP) – see Note 19.
- **after inactivated microbial vaccines** - Craighead JE. 1975. Report of a workshop: disease accentuation after immunization with inactivated microbial vaccines. J Infect Dis; 1312 (6):749-754 (https://doi.org/10.1093/infdis/131.6.749): 'inactivated vaccines could "**sensitize**" the recipient and result in an accentuated pattern of disease upon natural or experimental exposure.'
- **after vaccination in general** (non-specifically) - Sabath, L, Kelly, J, Liebeler, C, Seggern, K, Markovitz, D, Rice, M. Antigen-induced transient hypersusceptibility: a cause of sporadic and fulminant infection in normals**.** *Clin Res*. 1987;35:617A - described antigen-induced transient hypersusceptibility in mice and infants, found in a controlled study that childhood purulent meningitis victims had a higher record of recent vaccination than children of comparable age who were free from meningitis, and concluded that "*many antigens (injected) induce global changes in hosts' immunological response;* this transient defect is an *important cause of infections in normals*".

See also Notes 91, 84 and 104.

[lxi] Sensitizing effect of some vaccine ingredients, in particular adjuvants

Many vaccine ingredients are known to sensitize[84] the immune system.

Some, such as aluminum compounds and pertussigen, are deliberately included in vaccines, as "adjuvants", to intensify, or "adjuvate", the sensitization effect. (See Note 91.)

Purpose of sensitization effect (and of adjuvants included to enhance it) – assumptive bases

The inclusion of adjuvants in vaccines appears to be based upon these assumptions, or hypotheses:

(1) that without interference, the condition, or responsiveness, of the immune system of a normal, healthy, well nourished, well rested, well sunned, well supplied with oxygen, unstressed, vaccine-free person (or non-laboratory animal) is suboptimal - in a state of some form and level of "hyposensitivity", such that it would be brought to, or towards, optimality by sensitization, and

(2) that an increase in production of antibodies ("humoral immunity" – part of the adaptive immune response), which is an observed effect of adjuvants, represents a beneficial, or supportive, alteration of the immune system response, resulting in enhanced future protection, in the event of subsequent exposure to the targeted antigen, and

(3) that the injection of the adjuvant will have no specific and/or non-specific counterproductive or adverse effect(s) to any significant degree, in terms of seriousness and/or frequency.

With respect to the degree to which each of these assumptions, respectively, have been validated:

(1) Has any scientific research validated that assumption?

(2) See Note 11 for references to some relevant published research.

(3) Of significant direct relevance to the safety of the adjuvant is the mechanism of adjuvanticity. Aluminumhas been used as an adjuvant for humans since the 1920s, without knowledge of the mechanism of its adjuvanticity. However that subject has been studied intensively in the last 10-15 years…

Proposed mechanism(s) of aluminum's adjuvanticity

Three potential mechanisms have been frequently cited to explain the mechanism of adjuvanticity:

(a) the formation of a depot that slowly releases the antigen is, enhancing the antibody production;

(b) the conversion of soluble antigen into a particulate form so that it is phagocytosed by antigen-presenting cells such as macrophages, dendritic cells, and B cells, and

(c) the induction of inflammation, thus recruiting and activating antigen-presenting cells.

Observed mechanism of aluminum's adjuvanticity – necrosis, sensitization and inflammation

In vivo experiments have found that the last of these mechanisms, (c), does apply to aluminum adjuvant – it causes "*release of the endogenous danger signal uric acid, thus inducing the differentiation of nature's adjuvant, the inflammatory dendritic cells, from recruited monocytes*".

(Kool M, Soullié T, et al. Alum adjuvant boosts adaptive immunity by inducing uric acid and activating inflammatory dendritic cells. *J Exp Med* 2008, 205:869–882. http://jem.rupress.org/content/205/4/869)

Immunologist Tatyana Obukhanych (PhD) provides an explanation of this further as follows:

"*It appears that alum's adjuvant effect depends on its ability to kill cells, its 'cytotoxic' property. This cellular damage releases intracellular contents, such as DNA and uric acid into the extracellular space, which is now accessible to the cells of the immune system to act upon. This cellular damage is sensed by the immune system, which then initiates the immune response against a "foreign" protein that showed up in the context of such damage… since the whole point of vaccination is to induce antibody production, then whatever alum is doing to induce antibody production, is considered favorable*."

(http://www.vaccinationcouncil.org/2012/06/13/interview-with-phd-immunologist-dr-tetyana-obukhanych-by-catherine-frompovich/)

Shoenfeld (2012) similarly summarises, when describing tetanus, hepatitis b and influenza vaccinations being confirmed to cause the autoimmune disease anti-phospholipid syndrome:

"The mild cytotoxic activity of alum may act as an endogenous danger signal (DAMP) (damage-associated molecular pattern) *and can alert the innate immune system through the activation of various PRR signalling pathways.*[27] *Lately, Marichal et al.*[28] *showed using mice models, that alum-induced cytotoxicity resulted in the release of host DNA, which acts as a DAMP, mediating the adjuvant activity of alum on adaptive immune responses. Extracellular host DNA is known to be a DAMP, involved in an increasing number of immune processes and diseases, for example, lupus or chronic polyarthritis.*[29]*"*

(M Blank, E Israeli, Y Shoenfeld. When APS (Hughes syndrome) met the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). *Lupus.* May 25, 2012; pp. 711–714.http://journals.sagepub.com/doi/full/10.1177/0961203312438115)

Other adjuvants (glycerol and Complete Freund's Adjuvant) have also been observed to cause or contribute to the development of anti-phospholipid syndrome from tetanus vaccination.

(Dimitrijević L, Živković I, Stojanović M, Petrusić V and Živančević-Simonović S. Vaccine model of antiphospholipid syndrome induced by tetanus vaccine. *Lupus* (2012) 21, 195–202. DOI: 10.1177/0961203311429816.

https://www.researchgate.net/publication/221738385)

Outcomes of hypersensitivity and inflammatory conditions

For references to published research on these effects of adjuvants, see Note 84.

[lxii] Sensitizing effect of parenteral injection of a colloid or protein substance or toxin

In 1913, Charles Richet was awarded the Nobel Prize for his research on “anaphylaxis”, which is a word that he invented to mean "against protection," (the Greek word “phylaxis” meaning "protection") to *contrast* with the word “prophylaxis”, meaning "for protection". He devised the word to designate the sensitivity developed by an organism after it had been given a parenteral injection of a colloid or protein substance or a toxin (1902)… He found that *parenteral injection of protein substance “modifies profoundly and permanently the chemical constitution of the body fluids*”.

(https://www.nobelprize.org/nobel_prizes/medicine/laureates/1913/richet-bio.html)

Richet said: “We are so constituted that *we can never receive other proteins into the blood than those that have been modified by digestive juices. Every time alien protein penetrates by effraction, the organism suffers* and becomes resistant. This resistance lies in increased *sensitivity*, a sort of revolt against the …parenteral injection” (Please note the very significant difference between the meanings of “resistant” and “immune”)

(https://www.nobelprize.org/nobel_prizes/medicine/laureates/1913/richet-lecture.html)

“Anaphylaxis” definition in Mosby’s Medical Dictionary

“an·a·phy·lax·is (àn´e-fe-làk¹sîs) *noun:* **1.** Hypersensitivity especially in animals to a substance, such as foreign protein or a drug, that is induced by a small preliminary or sensitizing injection of or exposure to the substance.”

Note the distinction between the meaning of “anaphylaxis”, which merely means the resultant state of increased sensitivity/susceptibility regardless of the level of that increase, and “anaphylactic shock”, which means “a severe and sometimes fatal systemic hypersensitivity reaction”.

For the resultant effect of the development of *atopy*, including its frequency as an effect of vaccination, see Note 91.

(Richet was not the first to document the sensitizing effect of parenteral injection. For example, Dr Wright, a British army surgeon, wrote in 1901 about the observed reduced bactericidal power of the blood effected by anti-typhoid inoculation. Wright AE. 1901. Lancet (Sep 14):715-723.)

[lxiii] Animal experiments utilizing vaccination or adjuvants in order to sensitize the animal models in order to induce and then study inflammatory/autoimmune conditions

The following is an incomplete list of some studies which do so:

- Authier, F.J., Sauvat, S., Christov, C., et al. (2006). Al(OH)3-adjuvanted vaccine-induced macrophagic myofasciitis in rats is influenced by the genetic background. Neuromuscul Disord, 16(5): 347–52.
- Bassi, N., Luisetto, R., Del Prete, D., et al. (2012a). Induction of the “ASIA” syndrome in NZB/NZWF1 mice after injection of complete Freund’s adjuvant (CFA). Lupus, 21(2): 203–9.
- Bassi, N., Luisetto, R., Ghiardello, A., et al. (2012b). Vaccination of mice for research purpose: alum is as effective as and safer than complete Freund adjuvant. Reumatismo, 64(6): 380–7.
- Bersani-Amado, C.A., Barbuto, J.A., and Jancar, S. (1990). Comparative study of adjuvant induced arthritis in susceptible and resistant strains of rats. I. Effect of cyclophosphamide. J Rheumatol, 17(2): 149–52

- Bossé, J.T., Janson, H., Sheehan, B.J., et al. (2002). Actinobacillus pleuropneumoniae: pathobiology and pathogenesis of infection. Microbes Infect, 4(2): 225–35.
- Branch, D.R. (2009). Gender-selective toxicity of thimerosal. Exp Toxicol Pathol, 61(2): 133–6.
- Burbacher, T.M., Sackett, G.P., and Mottet, N.K. (1990). Methylmercury effects on the social behavior of Macaca fascicularis infants. Neurotoxicol Teratol, 12(1): 65–71.
- Burbacher, T.M., Shen, D.D., Liberato, N., et al. (2005). Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. Environ Health Perspect, 113(8): 1015 – 21.
- Cannon, G.W., Woods, M.L., Clayton, F., and Griffiths, M.M. (1993). Induction of arthritis in DA rats by incomplete Freund's adjuvant. J Rheumatol, 20(1): 7–11.
- Carlson, B.C., Jansson, Å.M., Larsson, A., et al. (2000). The endogenous adjuvant squalene can induce a chronic T-cell-mediated arthritis in rats. Am J Pathol, 156(6): 2057–65.
- Destexhe, E., Prinsen, M.K., van Schöll, I., et al. (2013). Evaluation of C-reactive protein as an inflammatory biomarker in rabbits for vaccine nonclinical safety studies. J Pharmacol Toxicol Methods, 68(3): 367–73.
- Di Benedetto, G., Pierangeli, M., Scalise, A., and Bertani, A. (2002). Paraffin oil injection in the body: an obsolete and destructive procedure. Ann Plast Sur, 49(4): 391–6. Experimental Models of Adjuvants
- N. Bassi, M. Gatto, A. Ghirardello, and A. Doria
- Dupuis, M., Murphy, T.J., Higgins, D., et al. (1998). Dendritic cells internalize vaccine adjuvant after intramuscular injection. Cell Immunol, 186(1): 18–27.
- Dupuis, M., McDonald, D.M., and Ott, G. (2000). Distribution of adjuvant MF59 and antigen gD2 after intramuscular injection in mice. Vaccine, 18(5–6): 434–9.
- Eisenbarth, S.C., Colegio, O.R., O'Connor, W., et al. (2008). Crucial role for the Nalp3 inflammasome in the immunostimulatory properties of aluminium adjuvants. Nature, 453(7198): 1122–6.
- Evensen, Ø., Brudeseth, B., and Mutoloki, S. (2005). The vaccine formulation and its role in inflammatory processes in fish - effects and adverse effects. Dev Biol (Basel), 121: 117–25.
- Fodey, T.L., Delahaut, P., Charlier, C., and Elliott, C.T. (2008). Comparison of three adjuvants used to produce polyclonal antibodies to veterinary drugs. Vet Immunol Immunopathol, 122(1–2): 25–34.
- Gao, Y., Yan, C.H., Tian, Y., et al. (2007). Prenatal exposure to mercury and neurobehavioral development of neonates in Zhoushan City, China. Environ Res, 105(3): 390–9.
- Geier, D.A. and Geier, M.R. (2005). A case–control study of serious autoimmune adverse events following hepatitis B immunization. Autoimmunity, 38(4): 295–301.
- Germolec, D., Kono, D.H., Pfau, J.C., and Pollard, K.M. (2012). Animal models used to examine the role of the environment in the development of autoimmune disease: findings from an NIEHS Expert Panel Workshop. J Autoimmun, 39(4): 285–93.
- Gherardi, R.K. (2003). Lessons from macrophagic myofasciitis: towards definition of a vaccine adjuvant-related syndrome. Rev Neurolog, 159(2): 162–4.
- Griffiths, M.M., Sawitzke, A.D., Harper, D.S., et al. (1994). Exacerbation of collagen-induced arthritis in rats by rat cytomegalovirus is antigen-specific. Autoimmunity, 18(3): 177–87.
- Gronseth, G.S. (2005). Gulf war syndrome: a toxic exposure? A systematic review. Neurol Clin, 23(2): 523–40. Gunderson, V.M., Grant, K.S., Burbacher, T.M., et al. (1986). The effect of low-level prenatal methylmercury exposure on visual recognition memory in infant crab-eating macaques. Child Dev, 57(4): 1076–83. Gunderson, V.M., Grant-Webster, K.S., Burbacher, T.M., and Mottet, N.K. (1988). Visual recognition memory deficits in methylmercury-exposed Macaca fascicularis infants. Neurotoxicol Teratol, 10(4): 373–9.

- Haugarvoll, E. and Koppang, E.O. (2005). Vaksinering av oppdrettsfisk – sjukdomsvern med attåtsmak. Nor Vet Tidsskr, 117: 286–90.
- Haugarvoll, E., Bjerkås, I., Szabo, N.J., et al. (2010). Manifestations of systemic autoimmunity in vaccinated salmon. Vaccine, 28(31): 4961–9.
- Hewitson, L., Houser, L.A., Stott, C., et al. (2010). Delayed acquisition of neonatal reflexes in newborn primates receiving a thimerosal-containing hepatitis B vaccine:
- influence of gestational age and birth weight. J Toxicol Environ Health A, 73(19): 1298–313.
- Holmdahl, R. and Kvick, C. (1992). Vaccination and genetic experiments demonstrate that adjuvant-oil-induced arthritis and homologous type II collagen-induced arthritis in the same rat strain are different diseases. Clin Exp Immunol, 88(1): 96–100.
- Holmdahl, R., Goldschmidt, T.J., Kleinau, S., et al. (1992). Arthritis induced in rats with adjuvant oil is a genetically restricted, alpha beta T-cell dependent autoim- mune disease. Immunology, 76(2): 197–202.
- Holmdahl, R., Lorentzen, J.C., Lu, S., et al. (2001). Arthritis induced in rats with non-immunogenic adjuvants as models for rheumatoid arthritis. Immunol Rev, 184: 184 – 202.
- Katzav, A., Kivity, S., Blank, M., et al. (2012). Adjuvant immunization induces high levels of pathogenic antiphospholipid antibodies in genetically prone mice: another facet of the ASIA syndrome. Lupus, 21(2): 210 – 16.
- Kleinau, S., Erlandsson, H., Holmdahl, R., and Klareskog, L. (1991). Adjuvant oils induce arthritis in the DA rat. I. Characterization of the disease and evidence for an immunological involvement. J Autoimmun, 4(6): 871 – 80.
- Kleinau, S., Erlandsson, H., and Klareskog, L. (1994). Percutaneous exposure of adjuvant oil causes arthritis in DA rats. Clin Exp Immunol, 96(2): 281–4.
- Koppang, E.O., Bjerkås, E., Bjerkås, I., et al. (2003). Vaccination induces major histocompatibility complex class II expression in the Atlantic salmon eye. Scand J Immunol, 58(1): 9–14.
- Koppang, E.O., Haugarvoll, E., Hordvik, I., et al. (2004). Granulomatous uveitis associated with vaccination in the Atlantic salmon. Vet Pathol, 41(2): 122–30.
- Koppang, E.O., Haugarvoll, E., Hordvik, I., et al. (2005). Vaccine-associated granulomatous inflammation and melanin accumulation in Atlantic salmon, Salmo salar L., white muscle. J Fish Dis, 28(1): 13–22.
- Koppang, E.O., Bjerkås, I., Haugarvoll, E., et al. (2008). Vaccination-induced systemic autoimmunity in farmed Atlantic salmon. J Immunol, 181(7): 4807 – 14.
- Krejci, J., Nechvatalova, K., Kudlackova, H., et al. (2013). Effects of adjuvants on the immune response of pigs after intradermal administration of antigen. Res Vet Sci, 94(1): 73–6.

[lxiv] Aluminum in vaccines has been found to cause depletion of gluthathione

Murakami, K and Yoshino, M. 2004. Aluminum decreases the glutathione regeneration by the inhibition of NADP-isocitrate dehydrogenase in mitochondria. *J Cell Biochem*. 2004 Dec 15;93(6):1267-71.

Abstract: "Effect of aluminum on the NADPH supply and glutathione regeneration in mitochondria was analyzed. Reduced glutathione acted as a principal scavenger of reactive oxygen species in mitochondria. Aluminum inhibited the regeneration of glutathione from the oxidized form, and the effect was due to the inhibition of NADP-isocitrate dehydrogenase, the only enzyme supplying NADPH in mitochondria. In cytosol, aluminum inhibited the glutathione regeneration dependent on NADPH supply by malic enzyme and NADP-isocitrate dehydrogenase, but did not affect the glucose 6-

phosphate dehydrogenase dependent glutathione formation. Aluminum can cause oxidative damage on cellular biological processes by inhibiting glutathione regeneration through the inhibition of NADPH supply in mitochondria, but only a little inhibitory effect on the glutathione generation in cytosol." https://onlinelibrary.wiley.com/doi/abs/10.1002/jcb.20261

[lxv] Immune activation

The term "*immune activation",* used in this context, does not refer to the normal immune response(s) instigated during natural infection, but describes abnormal high activation of the cellular components of the immune system, which may arise from sensitization, which vaccination is known to cause.[84]

Immune activation may in turn lead to chronic systemic inflammation (https://link.springer.com/content/pdf/10.1007/978-1-4614-9610-6_178-1.pdf).
It is now known:

- that immune activation, especially in early life (including maternally), can cause autism and mental illnesses, such as schizophrenia, bipolar disorder, depression and anxiety

  (Estes ML and McAllister AK. Maternal immune activation: implications for neuropsychiatric disorders. *Science.* 2016 Aug 19; 353(6301): 772–777.doi: 10.1126/science.aag3194 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5650490/;

  http://vaccinepapers.org/wp-content/uploads/Maternal-immune-activation-and-abnormal-brain-development-across-CNS-disorders-1.pdf),

  with evidence existing of an ongoing, permanent immune-system activation in the brains of autistic people, in particular that:

  "*neuroglial reactions, in the form ofinnate immune responses, are important in the mechanisms associated with neural dysfunction in autism and that the cerebellum is the focus of an active and chronic neuroinflammatory process in autistic patients. The presence of proinflammatory chemokines such as macrophage chemoattractant protein as well as antiinflammatory cytokines such as tumor growth factor-ß1 supports the idea that a chronic state of specific cytokine activation occurs in autism*"
  (http://gmtmanila.com/wp-content/uploads/pdf/Neuroglial-Activation-In-The-Brain-Of-Patients-With-Autism-2005.pdf;

  http://vaccinepapers.org/wp-content/uploads/Activation-of-the-maternal-immune-system-during-pregnancy-alters-behavioral-development-of-rhesus-monkey-offspring.pdf and http://vaccinepapers.org/wp-content/uploads/Brain-IL-6-elevation-causes-neuronal-circuitry-imbalances-and-mediates-autism-like-behaviors.pdf) and

- that aluminum, including in the particular low doses that vaccines contain (more than higher doses) can, when injected, be carried to the brain where it can cause the types of immune activation that are known to cause, in the short or longer term, autism

  (Crépeaux G, Eidi H, et al. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. *Toxicology*. 2017 Jan 15;375:48-57. doi: 10.1016/j.tox.2016.11.018. Epub 2016 Nov 28. https://www.ncbi.nlm.nih.gov/pubmed/27908630)

or another neurological disease

(https://vaccinepapers.org/wp-content/uploads/Neuroprotective-Effect-of-Nanodiamond-in-Alzheimers-Disease-Rat-Model.pdf),

with direct evidence existing also of aluminum-containing vaccines causing the same types of immune activation

(e.g. Li Q, Qi F, Yang J, Zhang L, Gu H, Zou J, Yuan Q, Yao Z. Neonatal vaccination with bacillus Calmette-Guérin and hepatitis B vaccines modulates hippocampal synaptic plasticity in rats. *J Neuroimmunol.* 2015 Nov 15;288:1-12. doi: 10.1016/j.jneuroim.2015.08.019. Epub 2015 Sep 2. https://www.ncbi.nlm.nih.gov/pubmed/26531688), and

- that some of the highest values for aluminum in human brain tissue yet recorded have been found in samples obtained from donors who have died with a diagnosis of autism (https://www.sciencedirect.com/science/article/pii/S0946672X17308763?via%3Dihub); and
- that there is a relationship between immune activation, the gut microbiota (which are very imbalanced in many autistic people) and autism (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3897394/pdf/nihms543590.pdf),

in relation to which there is evidence of the aluminum adjuvant in vaccines causing or contributing to gastrointestinal inflammation (https://www.nature.com/articles/mi201378.pdf); and

- that a phenomenon exists called "microglial priming" (Hugh V. Perry; Clive Holmes Microglial priming in neurodegenerative disease, *Nature Reviews Neurology*. 10(4):217–224, Apr 2014 DOI: 10.1038/nrneurol.2014.38 https://search.proquest.com/openview/f2764eb6b4efb06a76d077ce7ad68f34/1?pq-origsite=gscholar&cbl=2041930)

which may help to elucidate the mechanism for the development of these conditions after multiple immune sensitizing/activating events, such as multiple vaccinations.

For further references, elaboration of these findings and associated debates, see https://jbhandleyblog.com/home/2018/4/1/international2018

[lxvi] Sensitization effect resulting in development of atopy

Frequent manifestation of sensitizing effect - atopy

A frequently (and increasingly) occurring form of sensitization is the development of atopy, especially allergies to foreign proteins that are vaccine ingredients. This has been observed in:

- animals, e.g.
  (sometimes atopy being vaccine-induced deliberately for experimental purposes):
  - Teuber et al. The atopic dog as a model of peanut and tree nut food allergy. Journal of Allergy and Clinical Immunology, vol. 110, no. 6, pp. 921–927, 2002, (https://doi.org/10.1067/mai.2002.130056), in which aluminum was used for the purpose of deliberate invocation of atopy for experimental purposes. Dogs were sensitized by subcutaneous injection of commercial extracts of either 1 µg of PN, English walnut or Brazil nut proteins, together with aluminum hydroxide (Alum) as adjuvant, and

- JJ Munoz, M G Peacock, and W J Hadlow. Anaphylaxis or so-called encephalopathy in mice sensitized to an antigen with the aid of pertussigen (pertussis toxin). Infect Immunol, April, 1987; 55(4): 1004–1008. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC260453/), and
- Terpstra. Comparison of vaccination of mice and rats with Haemophilus influenzae and Bordetella pertussis as models of atopy. Clin Exp PharmacolPhysiol, 1979, and
- Huber HC. The pathogenesis of postvaccinal complications. Fortschr Med 1981 Mar 19;99(11):380-1 (https://www.ncbi.nlm.nih.gov/pubmed/6112195)
- Sewell WA, Munoz JJ, Scollay R, Vadas M A (1984) Studies on the mechanism of the enhancement of delayed-type hypersensitivity by pertussigen. J Immunol 133:1716–1722
- Kosecka U, Berin MC, Perdue MH. Pertussis adjuvant prolongs intestinal hypersensitivity. Int Arch Allergy Immunol. 1999 Jul;119(3):205-11.https://www.ncbi.nlm.nih.gov/pubmed/10436392 and

- directly in humans, e.g.
  - Odelram H et al, Immunoglobulin E and G responses to pertussis toxin after booster immunization in relation to atopy, local reactions and aluminium content of the vaccines. *Pediatr Allergy Immunol*, 1994 May;5(2):118-23 (https://www.ncbi.nlm.nih.gov/pubmed/8087191 - "The addition of aluminium to the pertussis vaccine, and also the use of a two-component as opposed to monocomponent acellular vaccine, both tended to induce stronger IgE antibody responses. The correlation between total IgE and PT-IgE, which was most prominent in children with atopy, indicates that the role of immunization for the development of allergy merits further studies") and
  - Hedenskog S et al. Immunoglobulin E Response to Pertussis Toxin in Whooping Cough and after Immunization with a Whole-Cell and an Acellular Pertussis VaccineInt Arch Allergy Immunol 1989;89:156–161 (https://www.karger.com/Article/Abstract/234939#). The acellular pertussis vaccine was found to invoke the production of an PT-IgE response and its propensity to do so was greater than that of a monovalent whole cell vaccine, and
  - Trinca JC. Over-immunization-anever present problem.AustFam Physician 1976, Jul;5(6):734-55 (https://www.ncbi.nlm.nih.gov/pubmed/999560), and
  - Kelso JM. The gelatin story.Jrnl of Allergy and Clinical Immunol, Feb 1999, Volume 103, Issue 2 , 200 - 202(http://www.jacionline.org/article/S0091-6749(99)70490-2/fulltext)
    ("Thus prior injection with gelatin-containing DTaP vaccine may be the cause of sensitization to gelatin and the subsequent reaction to other gelatin-containing vaccines."), and
  - N. Kiraly, J. J. Koplin, N. W. Crawford, et al. Timing of routine infant vaccinations and risk of food allergy and eczema at one year of age. Allergy 2016: Volume 71, Issue 4: 541–549 (http://onlinelibrary.wiley.com/doi/10.1111/all.12830/full), in which a delay of the first dose alone of DTaP by just one month was found to reduce the risk of eczema by an average of 43% in the 12 month old infants studied. It has further been found that "eczema, across the clinical severity spectrum in infancy, is a strong risk factor for IgE-mediated food allergy". (http://onlinelibrary.wiley.com/doi/10.1111/cea.12406/full)

Frequency of adverse effect of atopy?

The development of allergies and hypersensitivity reactions are amongst the adverse events listed on manufacturer product inserts as frequently reported after vaccination.

Research has also more specifically found, after tetanus vaccination, that:

- **delayed cutaneous hypersensitivity** occurred in **80%** of nonhuman primates after being vaccinated 3 times with tetanus toxoid intramuscularly at 1 month intervals
  (Davis JA[1], Hayre M, Linn JM. Delayed cutaneous hypersensitivity response in tetanus toxoid sensitized rhesus monkeys: predictor of anergy and value in tuberculin skin testing. Lab Anim Sci. 1988 Aug;38(4):413-6. **https://www.ncbi.nlm.nih.gov/pubmed/3184848**)

and

- **delayed hypersensitivity** skin test reactions to tetanus toxoid in 47 healthy humans was also **80%** and that the frequency of **immediate hypersensitivity was 8%**.
  (Christine Johnson, R. S. Walls & A. Ruwoldt.Delayed Hypersensitivity to Tetanus Toxoid in Man: In Vivo and in Vitro Studies. Pathology Vol. 15 ,Iss. 4,1983 http://www.tandfonline.com/doi/abs/10.3109/00313028309085161)

See also Notes 84, 85 and 104.

lxvii Autoimmune disease

Autoimmunity is the destruction by the immune system of the host's own functioning cells.

The first disease to be recognized as an autoimmune disease was Hashimoto's thyroiditis or chronic lymphocytic thyroiditis. It was not recognised and described until 1912, which was after vaccination had been implemented on a large scale.

The development of autoimmune diseases has since exploded to what is now described as an "epidemic".

(Nakazawa, Donna (2008). *The Autoimmune Epidemic*. New York: Simon & Schuster. pp. 32–35. ISBN 978-0-7432-7775-4.)

Based on a review published in 2015 (in particular Table 1 and the estimate for the MS in temperate areas as ">200 cases per 100 000 persons", or more than1 per 500 people), the present frequency of an autoimmune disease in Europe and North America is about 10% of the population.

(Wang L, Wang F-S, Gershwin ME. Human autoimmune diseases: a comprehensive update. (Review).*J Intern Med* 2015; 278: 369–395. http://onlinelibrary.wiley.com/doi/10.1111/joim.12395/full)

Worldwide it is estimated to affect about 5% of the worldwide population. (Vadalà et al (2017) referenced below)

Because autoimmune disease progresses gradually, the symptoms are likely to not appear immediately, especially within the limited monitoring period after vaccination in clinical trials.

However, evidence has been published of a link between vaccines and autoimmune diseases. The propensity of vaccines to cause autoimmune diseases has been known since at least as early as 1956 when vaccination was used to induce arthritis in Wistar rats – known as "adjuvant's disease".

(Pearson, C. M. Development of arthritis, periartthritis and periostitis in rats given adjuvants. *ProcSoc Exp Biol Med*. 1956 Jan;91(1):95-101. https://www.ncbi.nlm.nih.gov/pubmed/13297719)

An investigation by the US military, culminating in a 1980 report, found that studies in animals and humans provided convincing evidence that chronic antigenic stimulation by vaccination may be associated with autoimmune diseases in those genetically predisposed.

(Effects of long term Immunization with Multiple Antigens. Committee on the Effects of Multiple Immunizations 1980. Supported by U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, Maryland 21701, http://www.dtic.mil/dtic/tr/fulltext/u2/a088766.pdf)

The CDC acknowledges that MMR vaccination can cause the autoimmune disease thrombocytopaenic purpura. (https://www.cdc.gov/vaccinesafety/vaccines/mmr-vaccine.html)

It also states that Guillain-Barré syndrome,another autoimmune disease, may occur as an effect of the influenza vaccine. (https://www.cdc.gov/flu/protect/vaccine/guillainbarre.htm)

The CDC thus acknowledges the biological plausibility and overall potential for vaccination to lead to autoimmune disease, possibly including also other autoimmune diseases, in relation to which not only is there already existing evidence, but also further research, resulting in clearer evidence of such a link, might be done in the future.
Here are some examples of evidence of the causal link extending to other autoimmune diseases:

Injection of antigen, repeatedly - autoimmunity evidenced to become inevitable

An “antigen” is any substance that when introduced into the body stimulates the production of an antibody.

The result of research published in 2012 on mice was that:

“Repeated immunization with antigen causes systemic autoimmunity in mice otherwise not prone to spontaneous autoimmune diseases.”

In all mice tested, their being vaccinated with an antigen at least 8 times was sufficient for autoimmunity to become not just possible, but inevitable. The research found:

“Systemic autoimmunity appears to be the inevitable consequence of over-stimulating the host's immune 'system' by repeated immunization with antigen, to the levels that surpass system's self-organized criticality.”

(Tsumiyama K, Miyazaki Y, Shiozawa S. *Self-Organized Criticality Theory of Autoimmunity*. PLoS ONE, 2009; 4(12): e8382. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0008382)

A.S.I.A. Syndrome (Autoimmune/inflammatory Syndrome Induced by Adjuvants)

There is now an established body of evidence that various immune stimulants, either antigens or several adjuvants (aluminum and various squalene compounds) may induce autoimmune reactions that fall under the "ASIA" spectrum (“Autoimmune Syndrome Induced by (vaccine) Adjuvants”).

Most non live viral vaccines contain large amounts of aluminum, which is a known neurotoxin and acts as a stimulant for autoimmunity and chronic inflammatory syndromes.

(Aachoui, Y. and Ghosh, S.K. (2011). Immune enhancement by novel vaccine adjuvants in autoimmune-prone NZB/W F1 mice: relative efficacy and safety. BMC Immunol, 12: 61.)

ASIA is summarised here by Yehuda Shoenfeld, the lead or primary researcher responsible for the coining of the term and many of the relevant studies:

Shoenfeld Y. Video Q&A: what is ASIA? An interview with Yehuda Shoenfeld. *BMC Med*. 2013;11:118 (http://www.biomedcentral.com/1741-7015/11/118/)

ASIA is now widely accepted as a significant cause for autoimmune/inflammatory disorders of various kinds.

(Agmon-Levin et al, 2009. Vaccines and Autoimmunity.*Nat. Rev. Rheumatol. 2009;5:*648-652*;*

Shoenfeld Y and Agmon-Levin N. ASIA - Autoimmune/inflammatory syndrome induced by adjuvants.*Journal of Autoimmunity* 2011 Feb;36(1):4-8;

Shoenfeld Y and Aron-Maor A. Vaccination and Autoimmunity "Vaccinosis"; A Dangerous Liaison?*Journal of Autoimmunity 2000;14:1-10;*

Zafrir Y et al. Autoimmunity following Hepatitis B Vaccine as part of the spectrum of "Autoimmune (Autoinflammatory) Syndrome induced by Adjuvants" (ASIA): analysis of 93 cases. *Lupus 2012;21:146*

Perricone et al. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA): Unveiling the pathogenic, clinical and diagnostic aspects. *Journal of Autoimmunity 2013;*47:*1-16.* (This study covers identification of which auto-immune conditions are most associated with which vaccines, and re-challenge issues) https://pdfs.semanticscholar.org/dc62/9d11c0deab26fb3c420dd5176d8ba47f5a76.pdf;

Agmon-Levin N et al. Immunization with hepatitis B vaccine accelerates SLE-like disease in a murine model. *Journal of Autoimmunity* 2014 Nov;54:*21-32.* https://www.ncbi.nlm.nih.gov/pubmed/25042822;

Karussis and Petrou.The spectrum of post-vaccination inflammatory CNS demyelinating syndromes.*Autoimmunity Reviews 2014;*13:*215-224.*

Tsumiyama et al. Self-Organized Criticality Theory of Autoimmunity. PLoS ONE *December 2009, Volume* 4, *Issue 12, e8382.*

Colafrancesco et al. Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/inflammatory Syndrome induced by Adjuvants. *American Journal of Reproductive Immunology 2013.*

A Watad, P David, S Brown, Y Shoenfeld. Autoimmune/Inflammatory Syndrome Induced by Adjuvants and Thyroid Autoimmunity. Front. Endocrinol, 24 January 2017 doi.org/10.3389/fendo.2016.00150 https://pdfs.semanticscholar.org/fed0/7dba3353a7bf5b3c6f4cf5180f294b206e4a.pdf;

Bassi, N., Luisetto, R., Del Prete, D., et al. (2012a).Induction of the "ASIA" syndrome in NZB/NZWF1 mice after injection of complete Freund's adjuvant (CFA). Lupus, 21(2): 203–9 - the full ASIA Syndrome was induced by injecting rat models with aluminum adjuvants;

M Blank, E Israeli, Y Shoenfeld.When APS (Hughes syndrome) met the autoimmune/inflammatory syndrome induced by adjuvants (ASIA). *Lupus.*May 25, 2012; pp. 711–714.http://journals.sagepub.com/doi/full/10.1177/0961203312438115

Adjuvants glycerol and Complete Freund's Adjuvant observed to cause or contribute to the development of anti-phospholipid syndrome from tetanus vaccination: https://www.researchgate.net/profile/Ljiljana_Dimitrijevic3/publication/221738385_Vaccine_model_of_antiphospholipid_syndrome_induced_by_tetanus_vaccine/links/584a933808aee436cbff0683.pdf

Vadalà, M., Poddighe, D., Laurino, C. et al. Vaccination and autoimmune diseases: is prevention of adverse health effects on the horizon?EPMA Journal (2017) September 2017, Volume 8, Issue 3, pp 295–311 https://link.springer.com/article/10.1007%2Fs13167-017-0101-y

Also see http://www.greenmedinfo.com/toxic-ingredient/aluminum-hydroxide)

Medical textbook "*Vaccines and Autoimmunity*" is a collection of studies published by more than 75

doctors and scientists, edited by pre-eminent immunologist Yehuda Shoenfeld, Nancy Agmon-Levin and Lucija Tomljenovic. ISBN: 978-1-118-66343-1. Jun 2015, Wiley-Blackwell (384 pages) https://www.wiley.com/en-au/Vaccines+and+Autoimmunity-p-9781118663431

The studies have explored, with primary focus on aluminum in vaccines, how adjuvants can induce diverse autoimmune clinical manifestations in genetically prone individuals. They have investigated the mechanism of action (including its long-term persistence in the body and migration in apparent "Trojan Horse" style to the brain, lymph, and spleen, resulting in inflammation and neurological damage), experimental models, resultant syndromes, safe vaccines, toll-like receptors, reviews of literature evidencing the link with respect to specific vaccines and specific autoimmune conditions and the potential for the link to exist on a wider scale.

- **Controversy and debate about the existence of A.S.I.A.**

There has been a recent (Nov-Dec 2017) publication of an article whose authors allege to contain "evidence refuting the existence of A.S.I.A." by way of the publication of this article:

> Ameratunga R, Gillis D, Gold M, Linneberg A, Elwood JM. Evidence refuting the existence of autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA). J Allergy Clin Immunol Pract 2017;5:1551-5.e1 http://refhub.elsevier.com/S2213-2198(17)30902-9/sref1). ("Ameratunga et al")

However, responses to this article have been published in Letters to the Editorin *J Allergy Clin Immunol Pract* March–April 2018. The responses were by:

1. Crépeaux et al (2018)

   > (Crépeaux G, Gherardi RK and Authier, F-j.ASIA, chronic fatigue syndrome, and selective low dose neurotoxicity of aluminum adjuvants.*J Allergy Clin Immunol Pract* March–April 2018, Vol 6, Issue 2:707))

   who stated to the effect that Ameratunga et al's refutation invalidly relies on unsubstantiated or false assertions and assumptions, including:

   - an incorrect assumption that causal association requires the effect to be greater with higher doses.
     A dose-response relationship has indeed been observed but therelationship is *not* as Ameratunga et al appear to assume. The observed dose-response curve of aluminum hydroxide neurotoxicity has been that it is low, but not high, doses of the adjuvant that are selectively associated with aluminum translocation to brain and neurobehavioral changes 6 months after injections in mice.
     In contrast, the highest doses, forming large adjuvant aggregates, remained *trapped* at the periphery, and consequently were nontoxic. Thus the dose does not ''make the poison'' in case of aluminum adjuvants.

     More evidence relevant to the mechanism of aluminum hydroxide's toxicity at that level is in Note 90 herein, and
   - a false assertion that a conclusion can reasonably be drawn from a small series of 28 patients with lupus who were not reported to have exacerbations after hepatitis B immunization, and.
   - an assumption that the route of administration, for example, intramuscular (in vaccination) versus subcutaneous or intradermal injections, would not significantly influence the result. That has never been established,

and that “assertions based on indirect arguments (such as Ameratunga et al’s reliance upon the above assumptions) cannot satisfactorily replace epidemiological studies specifically designed to assess aluminum-containing vaccines’ long-term safety that are notoriously lacking in both adults and children.”

and

2. Luis Miguel Blasco, Refutation is a strong word for partial evidence in ASIA. *J Allergy Clin Immunol Pract* March–April 2018, Vol 6, Issue 2:707.

Both responses are at https://www.jaci-inpractice.org/article/S2213-2198(17)30904-2/pdf

Ameratunga et al replied to these responses, in the same issue of the journal.

(Reply to Crepeaux et al and Blasco: *J Allergy Clin Immunol Pract* March–April 2018, Vol 6, Issue 2:708-710) https://www.jaci-inpractice.org/article/S2213-2198(17)30903-0/fulltext)

In that reply Ameratunga et al, *inter alia,* made an unsubstantiated assumption that ASIA is “a rare event” and stated

”the symptoms of ASIA such as pyrexia, arthralgias, and irritable bowel syndrome are nonspecific and are commonly experienced in the community. The criteria for ASIA could include the entire community.“ Although some of the symptoms are individually common in an acute form, the occurrence of multiple of the symptoms simultaneously and chronically do not apply to the entire community, or close to it. It may not be “very rare” to meet the criteria but that does not preclude causation by vaccination, given that vaccination is a widespread procedure and that autoimmunity alone occurs now in about 10% of populations in developed countries.

Ameratunga et al also failed to also address the combined issues of dosage and route of administration, raised by Crepeaux et al with respect to the Denmark study that Ameratunga et al believed constituted evidence that aluminum injections reduce, not increase, the risk of such autoimmune conditions.

Nevertheless, Ameratunga et al expressed “agreement with Crépeaux et al in asking for an independent expert panel to evaluate the existence of ASIA and the specificity of its diagnostic criteria.” Thus Ameratunga et al accepted that they themselves lack sufficient independence and authority to make a reliable judgment.

Hence, at the least, the precautionary principle continues to favor an assumption of A.S.I.A.’s existence.

Genes in those genetically susceptible to autoimmune disease may be switched on by vaccine ingredients

The role of pre-existing risk factors including genetic predisposition and environmental factors in autoimmunity is largely accepted. “Vaccination could enhance the risk of autoimmunity in genetically susceptible individuals when exposed to certain environmental chemicals”, and many such triggers are themselves found in vaccines - heavy metals, chemicals, viruses and bacteria.

(Ravel G, Christ M, Horand F, Descotes J. Autoimmunity, environmental exposure and vaccination: is there a link? *Toxicology.* 2004 Mar 15;196(3):211-6. **http://www.ncbi.nlm.nih.gov/pubmed/15036747**)

Injection of aluminum adjuvants, linked to autoimmune and other disorders

Aluminum adjuvants are increasingly being identified, along with some other vaccine ingredients,

as a contributing cause of autoimmune disease and other disorders in vaccinated populations.

Most non live viral vaccines contain large amounts of aluminum, which is a known neurotoxin and acts as a stimulant for autoimmunity and chronic inflammatory syndromes.

(Aachoui, Y. and Ghosh, S.K. (2011). Immune enhancement by novel vaccine adjuvants in autoimmune-prone NZB/W F1 mice: relative efficacy and safety. BMC Immunol, 12: 61.)

Aluminum compounds are included in vaccines deliberately as "adjuvants", i.e. to sensitize the immune system enough to produce what is considered, or assumed, to be a "protective" level of antibodies. Immunologist Tatyana Obukhanych (PhD) explains:

"*It appears that alum's adjuvant effect depends on its ability to kill cells, its 'cytotoxic' property. This cellular damage releases intracellular contents, such as DNA and uric acid into the extracellular space, which is now accessible to the cells of the immune system to act upon. This cellular damage is sensed by the immune system, which then initiates the immune response against a "foreign" protein that showed up in the context of such damage. Without alum and without damage that it creates, the immune system would simply disregard the injected foreign protein as innocuous and not make any antibodies against it. But since the whole point of vaccination is to induce antibody production, then whatever alum is doing to induce antibody production, is considered favorable*."

(http://www.vaccinationcouncil.org/2012/06/13/interview-with-phd-immunologist-dr-tetyana-obukhanych-by-catherine-frompovich/)

So it appears to be due to its cytotoxic effect that aluminum achieves its "purpose" of sensitization.

Routine use of vaccination to induce autoimmunity in laboratory animals

Autoimmunity is deliberately vaccine-induced in laboratory animals for study purposes.

The following are a few of many studies that use animal models to create autoimmune disease` by using vaccine or their adjuvants:

- Waksman, B.H. (2002). Immune regulation in adjuvant disease and other arthritis models: relevance to pathogenesis of chronic arthritis. Scand J Immunol, 56: 12 – 34.
- Whitehouse, M.W. (2007). Adjuvant arthritis 50 years on: the impact of the 1956 article by C. M. Pearson, "Development of arthritis, periarthritis and periostitis in rats given adjuvants." Inflamm Res, 56: 133 – 8.
- Aachoui, Y. and Ghosh, S.K. (2011). Immune enhancement by novel vaccine adjuvants in autoimmune-prone NZB/W F1 mice: relative efficacy and safety. BMC Immunol, 12: 61.
- Authier, F.J., Sauvat, S., Christov, C., et al. (2006). Al(OH)3-adjuvanted vaccine-induced macrophagicmyofasciitis in rats is influenced by the genetic background. NeuromusculDisord, 16(5): 347–52.
- Bassi, N., Luisetto, R., Del Prete, D., et al. (2012a). Induction of the "ASIA" syndrome in NZB/NZWF1 mice after injection of complete Freund's adjuvant (CFA). Lupus, 21(2): 203–9.
- Bersani-Amado, C.A., Barbuto, J.A., and Jancar, S. (1990). Comparative study of adjuvant induced arthritis in susceptible and resistant strains of rats. I. Effect of cyclophosphamide. J Rheumatol, 17(2): 149–52

Insulin-dependent Diabetes (Type 1)

The autoimmune disease diabetes mellitus type 1 has been linked to various vaccines, including, *inter alia,* the hepatitis B and Hib vaccines.

(Classen JB. The timing of immunization affects the development of diabetes in rodents. *Autoimmunity*. 1996;24(3):137-45. **https://www.ncbi.nlm.nih.gov/pubmed/9020406**)

Classen JB. The diabetes epidemic and the hepatitis B vaccines.*N Z Med J*. 1996 Sep 27;109(1030):366. http://www.ncbi.nlm.nih.gov/pubmed/8890866;

Classen JB, Classen DC.Association between type 1 diabetes and hib vaccine. Causal relation is likely. *BMJ.* 1999 Oct 23;319(7217):1133 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1116914/);

Classen JB, Classen DC.Clustering of cases of insulin dependent diabetes (IDDM) occurring three years after hemophilus influenza B (HiB) immunization support causal relationship between immunization and IDDM.*Autoimmunity.* 2002 Jul;35(4):247-53 http://www.ncbi.nlm.nih.gov/pubmed/12482192)

"Diabetes mellitus" is also listed on the US product insert for the M-M-R II vaccine. Hence it can be seen that the manufacturer considers a causal association to be at least possible.

Multiple Sclerosis

Multiple sclerosis (MS) has also been associated with various vaccines and continues to be listed on both of the Hepatitis B vaccines' product inserts (Engerix B and H-B-Vax-II). Hence it is evident that a causal association is still considered by both manufacturers to be at least possible.

MS-like symptoms have been reported many times after HPV vaccinations. A 2009 study found that five cases of MS patients who had such symptoms within 21 days of receiving the Gardasil (HPV) vaccine "may be explained by the potent immuno-stimulatory properties of HPV virus-like particles which comprise the vaccine."

(http://www.realfoodhouston.com/2012/07/30/gardasil-and-cervarix-whats-the-controversy-about-the-hpv-vaccine/;

Sutton I, Lahoria R, Tan I, Clouston P, Barnett M. CNS demyelination and quadrivalent HPV vaccination. *MultScler.* 2009 Jan;15(1):116-9. http://www.ncbi.nlm.nih.gov/pubmed/18805844)

Some further (of many) studies linking specific vaccines to autoimmune diseases

Agmon-Levin N1, Zafrir Y, Paz Z, Shilton T, Zandman-Goddard G, Shoenfeld Y. Ten cases of systemic lupus erythematosus related to hepatitis B vaccine. Lupus. 2009 Nov;18(13):1192-7. doi: 10.1177/0961203309345732.

Soldevilla HF1, Briones SF, Navarra SV. Systemic lupus erythematosus following HPV immunization or infection?Lupus. 2012 Feb;21(2):158-61. doi: 10.1177/0961203311429556.

D P Symmons and K Chakravarty Can immunisation trigger rheumatoid arthritis? Ann Rheum Dis. 1993 Dec; 52(12): 843–844.

Pope JE1, Stevens A, Howson W, Bell DA.The development of rheumatoid arthritis after recombinant hepatitis B vaccination.J Rheumatol. 1998 Sep;25(9):1687-93.

B J Harrison, W Thomson, L Pepper, W E Ollier, K Chakravarty, E M Barrett, A J Silman Patients who develop inflammatory polyarthritis (IP) after immunization are clinically indistinguishable from other patients with IP. Oxford Journals Medicine & Health Rheumatology Volume 36, Issue 3Pp. 366-369.

Romain K. Gherardi* and François-JérômeAuthierMacrophagicmyofasciitis: characterization and pathophysiology; Lupus. 2012 Feb; 21(2): 184–189. doi: 10.1177/0961203311429557

Zafrir Y1, Agmon-Levin N, Paz Z, Shilton T, Shoenfeld Y. Autoimmunity following hepatitis B vaccine as part of the spectrum of 'Autoimmune (Auto-inflammatory) Syndrome induced by Adjuvants' (ASIA): analysis of 93 cases. Lupus. 2012 Feb;21(2):146-52. doi: 10.1177/0961203311429318.

Khamaisi M1, Shoenfeld Y, Orbach H. Guillain-Barré syndrome following hepatitis B vaccination.Clin Exp Rheumatol. 2004 Nov-Dec;22(6):767-70

Autoimmune disease as possible causal or contributory mechanism for the reported link to autism

Singh VK[1], Lin SX, Newell E, Nelson C. Abnormal measles-mumps-rubella antibodies and CNS autoimmunity in children with autism. *J Biomed Sci*. 2002 Jul-Aug;9(4):359-64. https://www.ncbi.nlm.nih.gov/pubmed/12145534

"*Research suggests that a combination of genetic, autoimmune, environmental, and perhaps in utero risk factors leading to neuroinflammation can contribute to the pathogenesis of ASD*".

(Maria Fiorentino M, SaponeA et al. Blood–brain barrier and intestinal epithelial barrier alterations in autism spectrum disorders. *Molecular Autism, Brain, Cognition and Behavior*, 29 November 2016;7:49. doi:10.1186/s13229-016-0110-z. http://molecularautism.biomedcentral.com/articles/10.1186/s13229-016-0110-z)

See also see Note 80, 83 and 109

lxviii Neurological disorders

Symptoms of encephalitis(inflammation of the brain) or meningitis (inflammation of the brain membrane)

Adverse effects reported include many symptoms that are possible symptoms of some degree of encephalitis or meningitis, and are reported quite commonly within 48 hours after the vaccination. Those symptoms include various symptoms that:

- are directly identifiable as neurological in nature:
  convulsions, abnormal crying, irritability, somnolence, headache, neck stiffness, and
- are of a more general nature:
  fever (>38°C), fatigue, reduced appetite, malaise, abdominal pain, diarrhoea, vomiting, arthralgia, myalgia and rash.

(James F. Bale Jr, MD, Current Management in Child Neurology, Third Edition, © 2005 Bernard L. Maria, Chapter 79, Meningitis and Encephalitis http://web.squ.edu.om/med-Lib/MED_CD/E_CDs/CHILD%20NEUROLOGY/docs/ch79.pdf;

H Schmidt et al. Sleep disorders are long-term sequelae of both bacterial and viral meningitis. *Neurosurg Psychiatry*. 2006 April;77(4): 554–558. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2077506/;

J. H. Menkes, M. Kinsbourne·Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination.*Neuropediatrics* 1990; 21(4): 171-176. https://www.thieme-connect.com/DOI/DOI?10.1055/s-2008-1071488)

A young child with encephalitis or meningitis may have only 2 or 3 of the above symptoms.

- small children with meningitis "*may only be irritable and look unwell*"

  (Sáez-Llorens X, McCracken GH Bacterial meningitis in children. *Lancet*, June 2003. 361 (9375): 2139–48. http://www.thelancet.com/journals/lancet/article/PIIS0140673603136938/abstract)

- young children or infants with encephalitis may present only "*irritability, poor appetite and fever*"

  (*Symptoms of Encephalitis.NHS*.Retrieved 5 Jan 2015. http://www.nhs.uk/Conditions/Encephalitis/Pages/Symptoms.aspx)

These potential symptoms themselves will usually be temporary, but that does not mean that there has been no lasting adverse effect (sequela).

In the case of several of these symptoms, when they are seen in circumstances other than vaccination, they meet with a concerned response by doctors. However, when seen after vaccination they are considered "normal" or "expected" and dismissed with no investigation or explained reason. Doctors' usual only response is to advise the parent to give the child an antipyretic. See under heading "*Minimal encephalopathy - cognitive dysfunction not clinically overt, but demonstrable"* in this Note below.

Product inserts directly list encephalitis, meningitis and encephalopathy

In addition to these symptoms frequently reported after vaccination, encephalitis, meningitis and encephalopathy are explicitly included on several vaccine manufacturer product inserts in their lists of adverse effects reported (e.g. Engerix B hepatitis B vaccine, pertussis vaccines, Priorix MMR vaccine and Priorix Tetra MMRV vaccine – Note38provides the location of the product inserts).

Medical research articles documenting case histories conclude the causal link to be probable

Medical research case histories have also supported a causal link between vaccines administered and encephalopathy, e.g.

- in a case of "recurrent seizures and acute encephalopathy" the researchers concluded that "pertussis fraction of DPT vaccine is responsible" for said adverse effects.

  The acellular pertussis vaccine, which also includes pertussis fraction though modified with the purpose of making it "less" reactive, has also been associated with "neurological complications, such as seizures, encephalopathy, and hypotensive episodes", just at a "lower frequency".

  Consequently, "occurrence of neurologic complications is a contraindication for… the acellular type."

  (Patel MK, Patel TK, Tripathi CB. Diphtheria, pertussis (whooping cough), and tetanus vaccine induced recurrent seizures and acute encephalopathy in a pediatric patient: Possibly due to pertussis fraction. *Journal of Pharmacology &Pharmacotherapeutics*. 2012;3(1):71-73. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3284047/)

- Researchers from Yale School of Medicine and Penn State College of Medicine found, in a tightly controlled study, a strong association between the timing of vaccines and onset of certain brain disorders - anorexia, OCD, anxiety disorder and tics - in a subset of children aged 6 to 15 years.

Those with newly diagnosed anorexia were 80% more likely than controls to have been vaccinated in the previous 3 months. A strong association was found in particular of Hepatitis B vaccination with anorexia; and meningitis vaccination with anorexia and chronic tic disorder.

(Leslie DL, Kobre RA, et al. Temporal Association of Certain Neuropsychiatric Disorders Following Vaccination of Children and Adolescents: A Pilot Case–Control Study. *Frontiers in Psychiatry*, Vol 8, 19 Jan 2017. **https://doi.org/10.3389/fpsyt.2017.00003**)

- *"There seem to be a straight forward time relationship between the third HB vaccine, the event of convulsion and the sudden death of the patient. We suggest that, in some cases, vaccination may be the triggering factor for autoimmune and neurological disturbances in genetically predisposed individuals, and physicians should be aware of this possible association.*"

(deCarvalho J.F., Shoenfeld Y.Status epilepticus and lymphocytic pneumonitis following hepatitis B vaccination. *European Journal of Internal Medicine* 2008;19(5):383-385. http://www.sciencedirect.com/science/article/pii/S0953620507002944**)**

Institute of Medicine (IOM) concludes causal relationship between DTP vaccine and encephalopathy

The IOM was formed in the United States in 1863 by congressional charter, to "provide expert advice on some of the most pressing challenges facing the nation and the world" and claims that its "members are among the world's most distinguished scientists, engineers, physicians, and researchers; more than 300 members are Nobel laureates (http://www.national-academies.org/about/whoweare/index.html). Under the 1986 Act, the IOM was charged with issuing reports on injuries from vaccination.

In 1991, the IOM concluded that the scientific literature:

- supported a causal relationship between the DTP vaccine and, *inter alia*, acute encephalopathy and protracted inconsolable crying (https://www.nap.edu/read/1815/chapter/2#7), and
- was insufficient to conclude whether or not the DTP vaccine can cause the following serious neurological conditions commonly reported from this vaccine:
  - aseptic meningitis; chronic neurologic damage; learning disabilities and attention-deficit disorder; Guillain-Barre syndrome;autism; peripheral mononeuropathy (nerve damage); radiculoneuritis and other neuropathies (https://www.nap.edu/read/1815/chapter/2#7).

Minimal encephalopathy - cognitive dysfunction not clinically overt, but demonstrable

- **Dr. Andrew Moulden BA, MA, MD, PhD**

Dr. Moulden determined, based upon his extensive, over 21 years, ofaward-winning medical study, clinical practice and research observations, especially in neuroscience, that the immune system'snon-specific hyperreactiveresponse to the injection ofthe heavy metals (including aluminum which alone lowers zeta potential and causes microvessel coagulation**)**and the other toxic or foreign substancesin vaccines, results in (varying degrees of) impaired blood flow processwhich causes microvascular hypoxia, resulting in (depending upon the degree and location(s) of the hypoxia) a spectrum of syndromes,including encephalopathy. He explained that*medical technology that is in widespread use is limited in terms of its ability, due to insufficient resolution, to observe the harm at the level at which it occurs.*

(http://barbfeick.com/tolerance_lost/tolerance_lost/tolerance_lost__dr.html, and

"*Dr. Andrew Moulden:Every Vaccine Produces Harm*.**"** by John P. Thomas, edited by Brian Shilhavy, Publisher: Sophia Media, 2015. ISBN, 0976057883, 9780976057888**)**

(Note also Dr. Moulden's qualifications:

University degrees (in which he obtained almost 100% grades) were in biological psychology (BA), child development (MA - thesis in developmental neuropsychology and language development in children, ranked top), Clinical Neuropsychology (PhD, including extra specialization in basic and applied neuroscience, also ranked top) andmedicine (also completing electives in Neurology, Genetics, Physiatry, Family Medicine), followed by aneuropsychiatry residency at the University of Ottawa and Toronto

He also received 27 scholarships and awards for academic, research, and clinical excellence during his 13½ years of formal University training, was a regional, provincial, and national scholar, an Ontario Mental Health Foundation scholar, taught brain and behavior courses at the university level for 12 years during and after his studies, and was appointed to the Scientific Advisory Board for the **BIT Life Sciences' 1st Annual World Congress of Vaccine,** in Foshan (near Guangzhou),Guandong, China Dec 1- 5, 2008.)

- **Gerhard Buchwald, MD (with doctorate) stated (in 2002):**

"For every vaccination, minimal encephalopathy (does not lead to clinically overt cognitive dysfunction, but can be demonstrated with neuropsychological studies) destroys brain cells. As a result, in Germany, there are 1.2 million children who have contracted hyperkinetic syndrome who are then treated with Psychopharmeca (a drug similar to Ritalin) used to calm them down... We have hundreds of thousands of so-called minimal cerebral dysfunction cases and millions of neurodermatitis patients"

(Testimony of Dr Gerhard Buchwald MD before the Quebec College of Physicians Medical Board. Extracted to here: http://www.doctorbob.com/vd--dr-buchwald-testimony.html from *The Trial of the Medical Mafia,* by Jochim Schafer, ISBN 2921783029, with permission of *Here's The Key Inc.,*CP309, Waterloo, Qc JOE 2NO, Canada.)

Vaccine ingredients identified as causing and/or triggering encephalopathy

Multiple components contained in vaccines have not been demonstrated individually and/or synergistically (see Note77) to be harmless to the central nervous system.

On the contrary, known and possible mechanisms by which vaccine-induced neurological damage may occur have been published in medical research. Some examples follow:

- **Adjuvants**

Some medical researchers, prompted by case histories indicating that:

"*in some cases, vaccination may be the triggering factor for autoimmune and neurological disturbances in genetically predisposed individuals, and physicians should be aware of this possible association.*"

(deCarvalho J.F., Shoenfeld Y.Status epilepticus and lymphocytic pneumonitis following hepatitis B vaccination. *European Journal of Internal Medicine* 2008;19(5):383-385. http://www.sciencedirect.com/science/article/pii/S0953620507002944)

have conducted further in-depth investigation of the possible association, resulting in their defining and naming a syndrome "Autoimmune Syndrome Induced by Adjuvants"

(http://www.biomedcentral.com/1741-7015/11/118/)

- **Aluminum adjuvant (and other nanomaterials in vaccines)**
  - **neurotoxic potential – penetration of brain, and selectively when injected at low, not high, doses**

    The neurotoxic potential, in various neurological diseases, of aluminum have been described, including specifically the potential of the aluminum adjuvant to penetrate the brain and cause neuronal damage.

    (Tomljenovic L. Aluminum and Alzheimer's disease: After a century of controversy: is there a plausible link? *Journal of Alzheimer's Disease*2011;23:567-598 https://www.researchgate.net/profile/Lucija_Tomljenovic/publication/49682395_Aluminum_and_Alzheimer's_Disease_After_a_Century_of_Controversy_Is_there_a_Plausible_Link/links/00b7d52015410e54c0000000.pdf;

    Tomljenovic L and Shaw CA. Aluminum vaccine adjuvants: Are they safe? *Current Medicinal Chemistry.* 2011;18:2630-2637 http://xa.yimg.com/kq/groups/22088204/1684753731/name/Tomljenovic_Shaw-CMC-published.pdf;

    Petrik, M *et al*. Aluminum adjuvant linked to Gulf War Illness induces motor neuron death in mice. *Journal of Neuromolecular Medicine.*2007;9:83-99 https://www.researchgate.net/profile/Christopher_Shaw2/publication/6682741_Aluminum_adjuvant_linked_to_Gulf_War_illness_induces_motor_neuron_death_in_mice/links/0deec521fbfd51c686000000.pdf

    Khan Z, Combadière C et al. Slow CCL2-dependent translocation of biopersistent particles from muscle to brain, *Biomed Central Medicine.* 2013;11:99 (relevant to both aluminum adjuvant and other nanomaterials in vaccines)[74]http://www.biomedcentral.com/1741-7015/11/99*:*

    > *"Nanomaterials (in vaccines) can be transported by monocyte-lineage cells to DLNs, blood and spleen, and similarly to HIV, may use CCL2-dependent mechanisms to penetrate the brain. This occurs at a very low rate in normal conditions explaining good overall tolerance of alum despite its strong neurotoxic potential. However, continuously escalating doses of this poorly biodegradable adjuvant in the population may become insidiously unsafe, especially in the case of overimmunization or immature/altered blood brain barrier or high constitutive CCL-2 production."*)

    How alum can be transported from the site of injection to the brain by macrophages has also been published.

    (Gherardi RK and Authier, F-j.Macrophagicmyofasciitis: characterization and pathophysiology. *Lupus*. 2012 February; 21(2): 184–189. doi: 10.1177/0961203311429557)

    It has been found that aluminum hydroxide intramuscularly injected (as is the case with vaccination) at a *low dose,* but *not high dose*, may selectively induce long-term aluminum cerebral accumulation and neurotoxic effects. The injected suspensions corresponding to the lowest dose, but not to the highest doses, exclusively contained small agglomerates in the bacteria-size range known to favour capture and, presumably, transportation by

monocyte-lineage cells. “In any event, the view that (aluminum hydroxide) neurotoxicity obeys "the dose makes the poison" rule of classical chemical toxicity appears overly simplistic.

(Crépeaux G, Eidi H, David M-O et al. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective low dose neurotoxicity. *Toxicology*, Volume 375, 2017, pp. 48-57. http://eprints.keele.ac.uk/2553/1/exley_1-s2.0-S0300483X16303043-main.pdf)

- **causal link of aluminum to autism - Bradford Hill criteria for causation fulfilled**

The cumulative body burden of aluminum contributed by paediatric vaccine schedules in western countries (each time injected at a relatively low dose – see previous paragraph), has been found to have a highly significant correlation with the rising rates of autism spectrum disorders (ASD), with the correlation fulfilling eight of nine of the Bradford Hill criteria for causality.

(Tomljenovic L and Shaw CA. Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *Journal of Inorganic Biochemistry*2011;105:1489-99. http://www.sciencedirect.com/science/article/pii/S0162013411002212; full text: http://omsj.org/reports/tomljenovic%202011.pdf)

Detailed analyses have been conducted of aluminum adjuvant neurotoxicity and its potential, in widespread pediatric vaccine formulation, to contribute to the rising prevalence of autism spectrum disorders.

(Tomljenovic L and Shaw CA. Mechanism of aluminum adjuvant toxicity and autoimmunity in pediatric populations.*Lupus 2012;*21(2):223-230 http://www.vaccineliberationarmy.com/wp-content/uploads/2012/01/LTShaw-Lupus-2012-Mechanism-of-adjuvant-toxicity-in-pediatric-populations.pdf)

Experimental studies using newborn mice confirm that aluminum adjuvants alone are capable of inducing ASD-like features in these animals.

(Shaw CA, Li Y, Tomljenovic L. Administration of aluminium to neonatal mice in vaccine-relevant amounts is associated with adverse long term neurological outcomes. *J Inorg Biochem*. 2013 Nov;128:237-44. http://vaccinepapers.org/wp-content/uploads/Shaw-Administration-of-aluminium-to-neonatal-mice-in-vaccine-relevant-amounts-is-associated-with-adverse-long-term-neurological-outcomes.pdf)

There is also now indirect evidence for a causal link between vaccines and autism by way of the vaccines’ induction of immune activation,[90] especially those vaccines that contain aluminum, but also other vaccines (such as MMR) that are given after, or together with, administration of aluminum-containing vaccines and also cause immune activation, which could be expected to lead to the transport to the brain of more of the aluminum that is present in the body from the aluminum-containing vaccines.

The risk of such damage can reasonably be expected to be higher in individuals who are genetically susceptible or have certain pre-existing conditions.[109]

- **Pertussigen/pertussis toxoid**
  - **Conversion of pertussigen to pertussis toxoid - how effective and permanent is it?**

In relation to inactivating viruses (not bacterial toxins), research has found the effectiveness of formaldehyde to be limited with respect to:

- extent (coverage), due to the process being subject to the (mathematical) asymptotic factor

  (Gerber et al. 1961. Inactivation of vacuolating virus (SV40) by formaldehyde, ProcSoc Exp Biol & Med; 108: 205-209. http://ebm.sagepub.com/content/108/1/205.short), and

- duration, due to the ability of the inactivated virus to revert to its former virulence

  (Fenner.Reactivation of animal viruses. BMJ 1962; July 21: 135-142. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1925408/)

In light of this finding with respect to virus inactivation, has it been scientifically demonstrated that inactivation of bacterial toxins and in particular the pertussigen toxin is, instead, reliably 100% successful and permanent, including after the vaccine is injected?

- **Pertussis toxin is used to deliberately induce encephalopathy in mice**

Injection of pertussigen is known to be able to abrogate tolerance to antigens and increase inflammatory responses and is consequently used as a potent adjuvant in eliciting experimental encephalomyelitis in mice (without having to be injected intracerebrally), and has also been directly linked to vaccine-induced brain damage (including a suggestion made by researchers as to the particular mechanisms involved)

Steinman L, Weiss A, Adelman N, et al. Pertussis toxin is required for pertussis vaccine encephalopathy. *Proceedings of the National Academy of Sciences of the United States of America*. 1985;82(24):8733-8736.

(http://www.ncbi.nlm.nih.gov/pmc/articles/PMC391511/pdf/pnas00364-0469.pdf)

Sewell WA, de Moerloose PA, McKimm-Breschkin JL, Vadas M A (1986) Pertussigen enhances antigen-driven interferon-production by sensitized lymphoid cells. C ell Immunol 97:238–247

Sewell WA, Munoz JJ, Scollay R, Vadas M A (1984) Studies on the mechanism of the enhancement of delayed-type hypersensitivity by pertussigen. J Immunol 133:1716–1722.

Sewell WA, Munoz JJ, Vadas M A (1983) Enhancement of the intensity, persistence, and passive transfer of delayed-type hypersensitivity lesions by pertussigen in mice. J Exp Med 157:2087–2096

- **Suggested mechanism for pertussigen-induced encephalopathy (in humans)**

Menkes and Kinsbourne (1990) suggested the following mechanism for how the whole-cell pertussis vaccination is able to cause brain damage, suggesting that the pertussis toxin itself has a central role:

> *"In implicating pertussis vaccination in the evolution of subsequent neurologic residua, a careful consideration of the mechanism for vaccine-induced brain damage plays an important supporting role. Pertussis toxin has been shown to alter cellular signalling. It also affects the catecholaminergic and GABAergic systems in brain. Although normally a protein of the size of pertussis toxin would not be able to cross the blood-brain barrier, factors known to disrupt the blood-brain barrier include brief hypertensive episodes such as might occur during a coughing paroxysm, hypoxia, and prolonged seizures, whether or not they are accompanied by hypoxia. In addition, a direct, endotoxin-mediated attack on the endothelial cells could create a local defect of the blood-brain barrier."*

(J. H. Menkes, M. Kinsbourne.Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination.*Neuropediatrics* 1990; 21(4): 171-176. https://www.thieme-connect.com/DOI/DOI?10.1055/s-2008-1071488)

- **Monosodium glutamate (MSG) and neomycin**

MSG and neomycin are in live viral vaccines. Both are neurotoxic, and specifically to the NMDA receptors in the brain. NMDA receptor toxicity can lead to encephalitis and encephalopathies. See Note 73.

Anti-NMDA receptor antibodies, indicative of an autoimmune condition, have been detected immediately following TdaP-IPV (tetanus-diphtheria-pertussis-polio) vaccination, which is one of the vaccinations that are proposed to be administered. See Note 92.

Compensation awards by the U.S. Government for vaccine-induced encephalopathy and autism - see also Notes 63 (US Vaccine Injury Table), (Gene P), 100,95,96 and 80 (Mycop). See also Note 84 for further information regarding the evidence of a link to neurological disorders.

[lxix] Autism rate in the United States

"HRSA-led study estimates 1 in 40 U.S. children has diagnosed autism", HRSA media release (26 Nov 2018) **https://www.hrsa.gov/about/news/press-releases/hrsa-led-study-estimates-children-diagnosed-autism**

That was the rate for 2017, an apparent increase from the 2014 estimated rate of 1 in 59 for 8 year olds, from the CDC's Autism and Developmental Disabilities Monitoring (ADDM) Network (27 Apr 2018): https://www.cdc.gov/ncbddd/autism/data.html

A 2018 study published in the Journal of Autism and Developmental Disorders found that "While the b_{snap}:b_{track} method involves substantial uncertainty, it nevertheless provides an empirical, quantitative estimate of the real fraction of the increase in autism across CDDS birth cohorts over time, suggesting that ~82–87% of the tracked increase since birth year ~1990 may be due to a true rise in the condition. By implication, the residual ~13–18% of the increase is likely not real and may be due instead to immigration or better and expanded diagnosis."

(Nevison C, Blaxill M, Zahorodny W. California Autism Prevalence Trends from 1931 to 2014 and Comparison to National ASD Data from IDEA and ADDM. *J Autism Dev Disord* 2018 Dec;48(12):4103-4117. doi: 10.1007/s10803-018-3670-2. https://www.ncbi.nlm.nih.gov/pubmed/29974300)

Scientists baffled at rise in autism | Stuff.co.nz: http://www.stuff.co.nz/dominion-post/comment/6044577/Scientists-baffled-at-rise-in-autism

[lxx] US Vaccine Injury Compensation Program (VICP): awards for encephalopathy, and autistic encephalopathy

The US National Childhood Vaccine Injury Act 1986 Vaccine Injury Table (http://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf) lists awardable injuries, which include encephalopathy and encephalitis, but not autism.

Vaccine-induced encephalopathy resulting from underlying mitochondrial dysfunction

However, vaccine injury compensation has been awarded on the basis of the autism ("autistic encephalopathy") being found to have developed as a result of vaccination in combination with pre-existing (though not previously detected) condition of mitochondrial dysfunction.

(J.S. Poling. Developmental Regression and Mitochondrial Dysfunction in a Child With Autism. Journal of Child Neurology, February 2006; Volume 21, Number 2.

Excerpt: "Children who have (mitochondrial-related) dysfunctional cellular energy metabolism might be more prone to undergo autistic regression between 18 and 30 months of age if they also have infections or immunizations at the same time."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536523/;

Vaccines and Autism Revisited. N Engl J Med 2008; 359:655-656, August 7, 2008 http://www.nejm.org/doi/full/10.1056/NEJMc086269

J. Jay Gargus and FaiqaImtiaz. Mitochondrial Energy-Deficient Endophenotype in Autism. Am *J* Biochem Biotechnol 4 (2): 198-207, 2008;

Matthew P. Anderson, Brian S. Hooker and Martha R. Herbert. Bridging from Cells to Cognition in Autism Pathophysiology: Biological Pathways to Defective Brain Function and Plasticity. Am *J* Biochem Biotechnol 4 (2): 167-176, 2008;

Daniel A. Rossignol, J. Jeffrey Bradstreet. Evidence of Mitochondrial Dysfunction in Autism and Implications for Treatment. Am *J* Biochem Biotechnol 4 (2): 208-217, 2008;

Oliveira, Ataíde et al. Epidemiology of autism spectrum disorder in Portugal: prevalence, clinical characterization, and medical conditions.Dev Med Child Neurol, 2007)

Dr Andrew W. Zimmerman (Pediatric Neurologist, Director of Medical Research, Center for Autism and Related Disorders at the Kennedy Krieger Institute) concluded:

"The developing brain is especially vulnerable to mitochondrial dysfunction because of its high metabolic energy demands and may be critically injured by marginal energy supplied by mitochondria under conditions of stress, such as infections and immune stimulation…

The cause for regressive encephalopathy in Hannah at age 19 months was underlying mitochondrial dysfunction, exacerbated by vaccine-induced fever and immune stimulation that exceeded metabolic energy reserves. This… led to permanent irreversible brain injury…

I hold these opinions to a reasonable degree of medical certainty." (http://www.rescuepost.com/files/rh-4.pdf, Exhibit 3)

The Vaccine Court found that "the vaccinations (Hannah) received… significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder."

The Vaccine-Autism Court Document Every American Should Read, by David Kirby, 27/2/2008, Huffington Post
http://www.huffingtonpost.com/david-kirby/the-vaccineautism-court-d_b_88558.html

Federal Court Compensated 83 Vaccine-Injured Autistic Children (by 2011)

In addition, among other compensated cases of vaccine-induced encephalopathy, are many in which the encephalopathycan be reasonably concluded to have caused the autism, based *inter alia* upon the timing of the exactly coinciding development of the child's autistic behavior. That is regardless of whether or not the Special Master presiding over the matter acknowledged any such causal link to the autism. The Vaccine Court is not a court in the true sense, so is not bound by the rules that govern how courts hear evidence and submissions and make judgments.

The authors of this peer-reviewed study, relying on evidence recorded in the U.S. federal Vaccine

Injury Compensation Program (VICP) court documents, reviewed 170, and uncovered among those who have been compensated for vaccine-induced brain damage – most notably, *"encephalopathy",* "residual seizure disorder," "developmental regression", 83 children with autism. That number, the authors noted, was probably the tip of an iceberg.

(An article by the Alliance for Human Research Protection, summarizing its findings is at http://ahrp.org/federal-court-compensated-83-vaccine-injured-autistic-children/) which references:

Mary Holland, Louis Conte, Robert Krakow, and Lisa Colin, *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury*, 28 Pace Envtl. L. Rev. 480 (Jan 2011) http://digitalcommons.pace.edu/pelr/vol28/iss2/6

A news story about the above was published on 10 May 2011:

83 Cases of Autism Associated with Childhood Vaccine Injury Compensated in Federal Vaccine Court, WASHINGTON, May 10, 2011 /PRNewswire-USNewswire/ http://www.prnewswire.com/news-releases/83-cases-of-autism-associated-with-childhood-vaccine-injury-compensated-in-federal-vaccine-court-121570673.html

Other successfully adjudicated cases of vaccine-induced encephalopathy

Some other examples can be found here: **https://www.mctlawyers.com/vaccine-injury/cases/**

Further examples can be found by a direct search on the U.S. Court of Federal Claims web site here: **http://www.uscfc.uscourts.gov/opinion-search**

The US Health Resources and Services Administration responded in 2008 by email to some relevant questions by journalist Sheryl Attkisson

(**https://childhealthsafety.files.wordpress.com/2011/01/attkisson-cbs-hrsa-email-exchanges-autistic-conditions-vaccines.pdf**)

[lxxi] *Vaccine Court Awards Millions to Two Children With Autism*. David Kirby, Huffington Post. 15/01/2013 04:03 AEST Updated: 16/03/2013 20:12 AEST (http://www.huffingtonpost.com/david-kirby/post2468343_b_2468343.html)

[lxxii] Statement by Dr William Thompson read on Congress house floor on 29 July 2015.

Statement released by Dr William Thompson on 27 August, 2014:

http://legislature.vermont.gov/assets/Documents/2016/WorkGroups/House%20Health%20Care/Bills/H.98/Witness%20Testimony/H.98~Jennifer%20Stella~William%20Thompson%20Statement~5-6-2015.pdf

Statement by Dr William Thompson read on Congress house floor on 29 July 2015:

Video: http://www.c-span.org/video/?327309-1/us-house-morning-hour&live

Transcript : Congressional Record--House. Proceedings and debates of the US Congress.Research and scientific integrity. July 29, 2015. 114th Congress, 1st Session Issue: Vol. 161, No. 121 — Daily Edition, pageH5602. July 29, 2015 https://www.congress.gov/crec/2015/07/29/CREC-2015-07-29.pdf;

(Some extracts of the transcript are in:

CDC Scientist: *'We scheduled meeting to destroy vaccine-autism study documents'* by SharylAttkisson. July 29, 2015. https://sharylattkisson.com/cdc-scientist-we-scheduled-

meeting-to-destroy-vaccine-autism-study-documents/)

Dr. Thompson was referring to this paper that had been published in 2004 and that claimed to debunk the link:

DeStefano et al. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. *Pediatrics.* 2004;113:259–266 (http://www.ncbi.nlm.nih.gov/pubmed/14754936)

Further details, including additional previously hidden data since released by Dr. Thompson, that showed strong associations between vaccination and autism, are also disclosed in the film *Vaxxed: from Cover-Up to Catastrophe* (***http://vaxxedthemovie.com/stream/***)(2016), and can be heard in more detail in a 2 hour 42 min voice recording of Dr Thompson's relevant admissions (***https://www.youtube.com/watch?v=hlxdWfTLHH0***), including (at 58:05) "*I have great shame now when I meet families with kids with autism, because I have been part of the problem… I shoulder that the CDC has put the research 10 years behind… because the CDC has not been transparent we have missed 10 of research because the CDC is so paralyzed now by anything related to autism. They're not doing what they should be doing because they are afraid to look for things that might be associated… the higher-ups wanted to do certain things and I went along with it… I cannot believe that we did what we did, but we did*." and are also available from Dr Brian Hooker (*Dr. Brian Hooker's official statement regarding William Thompson*, April 26, 2016, Brian S. Hooker, Ph.D., P.E. | Science Adviser, Focus For Health (***https://www.focusforhealth.org/dr-brian-hooker-statement-william-thompson/***).
(***https://www.facebook.com/WorldMercuryProject/?inf_contact_key=144b77cbbbf65ea2de11c744ee3ec2dae062df9af4c58c0b92cd8844b69427c8***)

A reanalysis by Dr Hooker of the data collected in the DeStefano et al 2004 study has been published (after double-blind peer-review) in the Journal of American Physicians and Surgeons

(Hooker BS. Reanalysis of the U.S. CDC Data on Autism Incidence and Time of First MMR Vaccination. *JPandS* 2018, Vol 23;4 http://www.jpands.org/vol23no4/hooker.pdf).

The findings of this reanalysis are a strong, statistically significant relationship between the timing of:

- the first MMR vaccine and autism, specifically in African American males, and
- the MMR vaccine and individuals diagnosed with autism without mental retardation.

[lxxiii] Medical Research Linking Vaccines to Autism (directly or indirectly)

The 1998 Lancet paper by Wakefield et al did not, contrary to what has repeatedly been alleged, claim to have shown a link between vaccination and autism. To the contrary, it stated: "*We did* not *prove an association between measles, mumps, and rubella vaccine and the syndrome described. Virological studies are underway that may help to resolve this issue …We have identified a chronic enterocolitis in children that may be related to neuropsychiatric dysfunction. In most cases, onset of symptoms was after measles, mumps, and rubella immunisation. Further investigations are needed to examine this syndrome and its* possible *relation to this vaccine."*

(Retracted: Wakefield AJ, Murch SH, Anthony A et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet.* 1998; 351: 637-641 **https://www.thelancet.com/journals/lancet/article/PIIS0140673697110960/fulltext**)

However other studies have found evidence of a link….

22 Medical Studies That Show Vaccines Can Cause Autism, by ArjunWalia, Activist Post, Sep 12,

2013.
This article presents a collection of 22 such studies, and adds there are many more published papers that document the link. http://www.activistpost.com/2013/09/22-medical-studies-that-show-vaccines.html
30 Scientific Studies Showing the Link between Vaccines and Autism, by Lisa Joyce Goes, 18 June 2011.
This article states that the original author had found 49 studies but was not able to fit all of them into the note character range available on Facebook.
http://healthimpactnews.com/2013/30-scientific-studies-showing-the-link-between-vaccines-and-autism/

Some further studies contributing, directly or indirectly, to the body of evidence of a link between vaccination and autism are as *follows:*

- http://www.ncbi.nlm.nih.gov/pubmed/19043938
- http://www.ncbi.nlm.nih.gov/pubmed/21907498
- http://www.ncbi.nlm.nih.gov/pubmed/21993250
- Some articles relevant to mercury-containing vaccinations for mercury's relevance, or potential relevance:[77]
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3364648/
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3697751/
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3774468/
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3878266/
  - http://www.ncbi.nlm.nih.gov/pubmed/11339848
  - http://www.ncbi.nlm.nih.gov/pubmed/12142947
  - http://www.ncbi.nlm.nih.gov/pubmed/15780490
  - http://www.ncbi.nlm.nih.gov/pubmed/17674242
  - http://www.ncbi.nlm.nih.gov/pubmed/19106436
  - http://www.ncbi.nlm.nih.gov/pubmed/24675092
  - http://www.ncbi.nlm.nih.gov/pubmed/24995277
  - http://www.ncbi.nlm.nih.gov/pubmed/25198681
  - http://www.ncbi.nlm.nih.gov/pubmed/25377033

Many other relevant medical research studies are referenced in the following collections:
http://www.experimentalvaccines.org/wp-content/uploads/2015/02/86-Research-Papers-Supporting-the-Vaccine-Autism-Link.pdf
https://www.scribd.com/doc/220807175/147-Research-Papers-Supporting-the-Vaccine-Autism-Link

See also Note 93.

[lxxiv] Medical papers with conclusion that no link between vaccination and autism but not supported by own data

e.g. Honda H, Shimizu Y, Rutter M. No effect of MMR withdrawal on the incidence of autism: a total population study. J Child Psychol Psychiatry 2005 Jun;46(6):572-9.
https://www.ncbi.nlm.nih.gov/pubmed/15877763

[lxxv] Institute of Medicine (IOM) conclusion re existence of a link between DTaP-containing vaccine and autism

The IOM concluded in 2011: "The evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid–, tetanus toxoid–, or acellular pertussis–containing vaccine and autism." (https://www.nap.edu/read/13164/chapter/12#545)

Former Director of the National Institutes of Health, Dr. Bernadine Healy, also stated on national television in 2008 that this question "*has not been answered*". She went on to say:

> "*This is the time when we do have the opportunity to understand whether or not there are susceptible children, perhaps genetically, perhaps they have a metabolic issue, mitochondrial disorder, immunological issue, that makes them more susceptible to vaccines plural, or to one particular vaccine, or to a component of vaccine. …What a susceptible group will tell us is that maybe there is a group of individuals, or a group of children, that shouldn't have a particular vaccine or …the same schedule.*
>
> *…I think the government, or certain health officials in the government …have been too quick to dismiss the concerns of these families without studying the population that got sick. I haven't seen major studies that focus on - three hundred kids, who got autistic symptoms within a period of a few weeks of a vaccine.*
>
> *…I think that they often have been too quick to dismiss studies in the animal laboratory, either in mice, in primates, that do show some concerns with regard to certain vaccines. … The reason …was because they're afraid if they found them— however big or small they were—that that would scare the public away*
>
> *…I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show!*" (http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/)

See also Note 95 regarding such a case of individual increased susceptibility to vaccination causing autism (in that case due to a mitochondrial disorder), which causation was accepted by the US Vaccine Court.

It may be further noteworthy that the IOM has found a causal relationship between DTP vaccine and encephalopathy (https://www.nap.edu/read/1815/chapter/2#7), and the US Vaccine Court has awarded compensation for cases of autistic encephalopathy from the DTaP vaccine.

[lxxvi] Dr Andrew W. Zimmerman re factors that can lead to autism

On September 7, 2018, Dr Andrew W. Zimmerman swore an affidavit (https://namelyliberty.com/dr-andrew-zimmermans-full-affidavit-on-alleged-link-between-vaccines-and-autism-that-u-s-govt-covered-up/) in which he stated:

- that he told the Department of Justice (DOJ) lawyers in another (not Hannah Poling's) O.A.P. case that "in a subset of children with an *underlying mitochondrial dysfunction, vaccine induced fever and immune stimulation that exceeded metabolic energy reserves* could, and in at least one of my patients (Yates Hazlehurst) did, cause regressive encephalopathy with features of autism spectrum disorder", immediately upon which the DOJ lawyers sacked him as an expert witness in the forthcoming O.A.P. hearing, and

- that the same DOJ lawyers then misrepresented what he had said in the Michelle Cedillo case, in which he had concluded that vaccination had not caused her autism, as being a broad statement instead of limited to only Michelle Cedillo's circumstances.

[lxxvii] Vaccination's pro-inflammatory effect has the potential to cause mitochondrial dysfunction.

Garth L. Nicolson, Robert Settineri and Rita R. Ellithorpe. Neurodegenerative and Fatiguing Illnesses, Infections and Mitochondrial Dysfunction: Use of Natural Supplements to Improve Mitochondrial Function. Review. *Functional Foods in Health and Disease* 2014; 4(1):23-65.

"Chronic infections collectively result in induction of excess Reactive Oxygen Species (ROS) and Reactive Nitrogen Species (RNS) that damage cellular structures, especially mitochondrial membranes [15-17]."

https://www.ffhdj.com/index.php/ffhd/article/view/26/318

[lxxviii] Cancer

Some examples of the mechanisms and evidence of vaccines causing cancer include:

Injection of animal cells considered cancerous

Viruses used in vaccines require the use of (human foetus and/or) animal tissue culture 'cell lines' in which to grow the vaccine virus. Hence, one vaccine can include multiple types of serum and tissue proteins from several types of animals, such as bovine (cow), avian (chicken), porcine (pig) and monkey (simian).

The three strains of poliovirus in the polio vaccine IPOL (Sanofi Pasteur S.A.) and vaccines that contain a polio component (the relevant vaccines here being Infanrix hexa and Infanrix IPV), are grown in cultures of VERO cells, a continuous line of monkey kidney cells, as stated on the manufacturer's product insert.**38**

Vero cells are cells that were extracted from the African Green Monkey kidney epithelial cells. The lineage was created in 1962 in Japan. They are immortalized cells such as the HELA cells of the famed book on Henrietta Lacks, and are considered neoplastic (cancerous cells).

There has long been concern regarding Vero cells and tumor or carcinogenicity. Certain Vero cell lines are known to cause cancer.

(Barrett PN, Mundt W, Kistner O, Howard MK. Vero cell platform in vaccine production: moving towards cell culture-based viral vaccines. *Expert Rev Vaccines*. 2009 May;8(5):607-18. doi: 10.1586/erv.09.19 http://www.ncbi.nlm.nih.gov/pubmed/19397417

Refers to "*fears regarding… potential oncogenic properties*" of "*continuous cell lines (CCLs)*".

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM319573.pdf

"*Deliberations of a WHO Study Group in 1997*

The value of 100 pg of host cell DNA per vaccine dose remained the recommended standard for a decade. However, the issue was revisited in 1997 for several reasons. First, vaccine manufacturers could not always meet this level of residual cell-substrate DNA for some viral vaccines... The outcome of the 1997 WHO meeting was that the amount of residual cell-substrate DNA allowed per dose in a vaccine produced in a continuous cell line and one

administered by the parenteral route was raised from 100 pg to 10 ng."

and "*at a VRBPAC meeting in 2000… Some members expressed the concern that Vero cells had the capacity to become tumorigenic with prolonged passage in culture*"

Injection of animal viruses known to be cancerous

Viruses used in vaccines require the use of (human foetus or) animal tissue culture 'cell lines' in which to grow the vaccine virus. Hence, one vaccine can include multiple types of serum and tissue proteins and potential bacterial or viral contaminants from several types of animals, such as bovine (cow), avian (chicken), porcine (pig) and monkey (simian). Hence one of the sources of risk arising from vaccination is contamination. Multiple mishaps have occurred, and are continuing to be reported, as a consequence.

Examples

- **SV40**

The most well documented example is the SV40 monkey virus, which has been implicated in many increasingly common cancers, such as mesothelioma and multiple myeloma.

A risk has also been identified of bovine serum being contaminated with viral species or prions

(which are known to be "extremely difficult to destroy due" to being "resistant to high temperatures and chemicals, which would normally kill bacteria and viruses": http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/09/WC500003715.pdf)

and the cancer-causing (or cancer-"associated") SV40 virus contaminant in monkey kidney tissue, with admitted resultant risks including cancers, such as hepatocellular carcinoma which is the fifth leading cause of all cancer deaths around the world.

Even when the Australian Commonwealth Government was aware, in the 1960s, of contamination of polio vaccine batches with the cancer-causing SV40 monkey virus, it withheld this information from the public and continued releasing these batches. This was unlike the US authorities who "adopted the policy of not releasing any new batches of vaccine until it had been shown to be free of SV40."

(*Deadly shots: the polio vaccine saga*, SMH October 23, 2004 http://www.smh.com.au/articles/2004/10/22/1098316860457.html)

- **retroviruses**

Researcher Judy A. Mikovits, PhD, formerly with the National Cancer Institute, states:

"*Every vaccine may be contaminated with at least one animal retrovirus family, all of which have been associated with cancers, chronic liver disease, AIDS, ALS, ME/CFS and autism.*

Receiving one or two injections of an adventitious retrovirus likely does little damage to a healthy immune system. However, the aggressive vaccine schedule currently in place means that the number of retroviruses injected into infants, children, and teenagers—including at vulnerable/immune compromised times in their lives—is unknown.

Combining vaccines, each of which could be carrying HERVs, BLVs, Foamy Viruses, EBV, mycoplasma and potentially more while the immune system is already crippled by mercury, aluminum, polysorbate 80 and formaldehyde is a dangerous and even deadly practice."

(*Retroviruses: Poorly Understood Agents of Change*, Judy A. Mikovits, PhD, 7 September 2017

https://worldmercuryproject.org/news/retroviruses-poorly-understood-agents-of-change/)

Limitations to effectiveness of method of virus inactivation

It is assumed by many that the process used to inactivate viruses is 100% effective. However, due to the process being subject to the (mathematical) asymptotic factor, the inactivation of the virus is incomplete.

(Gerber et al. 1961. Inactivation of vacuolating virus (SV40) by formaldehyde, ProcSoc Exp Biol & Med; 108: 205-209. http://ebm.sagepub.com/content/108/1/205.short)

Further, the inactivation is limited in duration, as the inactivated virus is able to revert to its former virulence

(Fenner. Reactivation of animal viruses. BMJ 1962; July 21: 135-142. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1925408/)

Vaccines causing cancer in non-humans is fully acknowledged

Wilcock B, Wilcock A, Bottoms K. Feline postvaccinal sarcoma: 20 years later. *The Canadian Veterinary Journal*. 2012;53(4):430-434. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3299519/

Also see Note 75

[lxxix] Death caused by vaccination

Research by Peter Aaby and team directly related to vaccine-associated mortality

One of the most well respected vaccine researchers, publishing for over three decades, Peter Aaby, and his respective teams, found:

(1) a very clear increase in mortality rates of children in the 6 months after receiving DPT, polio vaccines or any of them individually.

(Aaby P, Jensen H et al. The introduction of diphtheria-tetanus-pertussis vaccine and child mortality in rural Guinea-Bissau: an observational study. *Int. J. Epidemiol. (2004)* 33 (2): 374-380. doi:10.1093/ije/dyh005. https://academic.oup.com/ije/article/33/2/374/715842/The-introduction-of-diphtheria-tetanus-pertussis), and

(2)a 10-fold (95% CI 2.61–38.6) higher mortality among 3–5-month-old children who had received the whole-cell DTP-only vaccinecompared with not-yet-DTP-vaccinated children, and that "all-cause infant mortality after 3 months of age increased after the introduction of these vaccines (HR = 2.12 (1.07–4.19))."

After finding that "differences in background factors did not explain the effect" they provided as an explanation that the vaccine may "increase susceptibility to unrelated infections".

They also noted that "no prospective study has shown beneficial survival effects of DTP… It should be of concern that the effect of routine vaccinations on all-cause mortality was not tested in randomized trials."

(Mogensen So.W., Andersen A., Rodrigues A., Benn C.S., Aaby P. The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment. *EBioMedicine*. March 2017 Vol 17:192–198. http://www.ebiomedicine.com/article/S2352-3964(17)30046-4/fulltext)

It was also concluded over 40 years ago "*that, in children living in non-deprived circumstances in Britain, the risk of pertussis vaccine during the period 1970-83 exceeded those of whooping cough."*

(Stewart GT. Whooping cough and pertussis vaccine: a comparison of risks and benefits in Britain during the period 1968-83. *Dev Biol Stand.* 1985;61:395-405. https://www.ncbi.nlm.nih.gov/pubmed/3835080*)*

Since the acellular vaccine (DTaP) has not been found to have a higher than 10-fold reduction in mortality compared to the DPT vaccine, currently available evidence suggests that the DTaP vaccine also "may kill more children from other causes than it saves from diphtheria, tetanus or pertussis".

There is an especially low tolerance for such an adverse effect of the vaccination in Western countries now that there are zero deaths in children from diphtheria or tetanus and virtually zero deaths in vaccine-eligible unvaccinated children from pertussis.

Other evidence of vaccine-associated mortality

- **sudden unexpected deaths recorded by vaccine manufacturer GSK following Infanrix hexa**

  Jacob Puliyel MD, Head of Department of Pediatrics, St Stephens Hospital, Delhi, and a member of the National Technical Advisory Committee in the Indian government, has called out the many "sudden unexpected deaths" recorded by vaccine manufacturer GlaxoSmithKline (GSK) following administration of its Infanrix hexa vaccine (i.e. DTPa-HBV-IPV/Hib, which includes the newer acellular pertussis vaccine) as not coincidental. He has been a vocal proponent of ceasing its use due to its high death rate.

  (Puliyel, Jacob & Sathyamala, Ch. Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency. *Indian J Med Ethics*. 2018 Jan-Mar;3(1):43-47. doi: 10.20529/IJME.2017.079. Epub 2017 Sep 5. PMID: 28918379. http://ijme.in/articles/infanrix-hexa-and-sudden-death-a-review-of-the-periodic-safety-update-reports-submitted-to-the-european-medicines-agency/?galley=html)

- **SIDS case conceded by US Vaccine Court to be caused by vaccination**

  It is notable that the deaths for which successful claims have been made in the US Vaccine Court have included SIDS ("Sudden Infant Death Syndrome") – see Note 69.

- **statistically significant correlation between national infant mortality and scheduled doses of vaccines**

  A large-scale study of mortality rates regressed against vaccination doses also found that mortality rates increased with increasing numbers of vaccine doses. Westernized countries such as the USA, UK and New Zealand were found to have higher infant mortality rates than at least 22 other countries.

  (Goldman G. Infant mortality rates regressed against number of vaccine doses routinely given: is there a biochemical or synergistic toxicity? *Human Experimental Toxicology* 2009,30(9),1420-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3170075/) (Re synergistic toxic effect, see Note77)

Research indirectly related to vaccine-associated mortality

Additionally, to whatever extent vaccination causes serious conditions that may themselves lead to death, as other research such as that referenced elsewhere herein may scientifically demonstrate, it may be reasonable to conclude that it causes death therefrom, be it in the short or longer term.

[lxxx] Comparison of serious adverse events reported after DPT versus DTaP vaccines

Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) ---

United States, 1991—2001, CDC MMWR Surveillance Summaries, Jan 24, 2003 / 52(ss01);1-24

https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5201a1.htm

"VAERS reports from 1991 (when whole cell pertussis vaccines were used exclusively) through 2001 (when acellular pertussis vaccines were used predominantly) documented that the overall vaccine-specific reporting rates of both serious and nonserious reports for DTaP had decreased to less than one half of that for DTP among children aged <7 years (Table 10)."

[lxxxi] Infant mortality rates higher in countries that schedule more vaccines doses

Miller and Goldman (2011) studied infant mortality rates and found a statistically significant positive correlation between the number of vaccines doses on a country's vaccination schedule and its infant mortality rate.
Hum Exp Toxicol. 2011 Sep; 30(9): 1420–1428. doi: 10.1177/0960327111407644

[lxxxii] Comparison between vaccinated and unvaccinated subjects' health outcomes

Mawson et al. Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children, Journal of Translational Science 3(3): 1-12.

http://www.oatext.com/Pilot-comparative-study-on-the-health-of-vaccinated-and-unvaccinated-6-to-12-year-old-U-S-children.php

This study found that, compared to the completely unvaccinated children, the fully vaccinated children had increased rates of 390% for allergies, 420% for ADHD, 420% for autism, 290% for eczema, 520% for learning disabilities, and 370% for any neurodevelopmental delay. The fully-vaccinated preterm infants had an increased rate of 1,450% for a neurodevelopmental disorder, which includes a learning disability, ADHD or autism, compared to the completely unvaccinated preterm infants.

[lxxxiii] Comparison between repeatedly vaccinated and unvaccinated sheep – behavioural outcomes

Javier Asín, María Pascual-Alonso, Pedro Pinczowski, Marina Gimeno, ... Lluís Luján. Cognition and behavior in sheep repetitively inoculated with aluminum adjuvant-containing vaccines or aluminum adjuvant only. Pharmacol Res. 2018 Nov 2. pii: S1043-6618(18)31373-2. doi:10.1016/j.phrs.2018.10.019. [Epub ahead of print] Available online 3 November 2018.
https://www.ncbi.nlm.nih.gov/pubmed/30395948

[lxxxiv] Medical histories that are associated with an increased risk of post-vaccination autoimmune conditions

Four groups of individuals have been identified with increased risk of vaccination-induced ASIA Syndrome (Autoimmune Syndrome Induced by vaccine Adjuvants - see Note 92) – those with:

- a history of allergic reactions, or
- prior post-vaccination autoimmune phenomena, or
- a medical history of autoimmunity, or
- proneness to develop autoimmunity (having a family history of autoimmune diseases; asymptomatic carriers of autoantibodies; carrying certain genetic profiles, etc.).

Soriano A, Nesher G, Shoenfeld Y. Predicting post-vaccination autoimmunity: who might be at risk? *Pharmacol Res*. 2015 Feb;92:18-22. doi: 10.1016/j.phrs.2014.08.002

https://www.ncbi.nlm.nih.gov/pubmed/25277820