

CHAPTER 7

THE EVIDENCE UNDERPINNING CLAIMS ABOUT VACCINES

7.1 Introduction

The aim of this thesis is to assess the rigour of the claims supporting the efficacy, safety and necessity for the use of an expanding number of vaccines in the Australian Government's National Immunisation Program (NIP). I have provided here an examination of the key claims that the Australian government has presented to the public to support current vaccination policies. The information provided to the public discusses vaccines in a general non-specific way yet it is necessary to examine the scientific evidence for *each* vaccine separately to determine its safety and effectiveness in protecting community health. This is because there are many variables that influence pathogenesis that are specific to each disease agent. The risk/benefit equation for each vaccine varies according to the ecological context of the infectious agent and the interaction of multiple variables in pathogenesis. This has been described in chapter 2. This chapter investigates whether the government promotes vaccines to the public in an ecological context recognizing the variables that contribute to the 'risk' of disease to different individuals (due to environment and genetic differences) or in a general way implying that all vaccines are safe, effective and necessary in the prevention of infectious diseases.

In particular, this chapter provides an assessment of key information that is provided to the public to support vaccination policies. I have assessed the Australian government's claims made in the Frequently Asked Questions (FAQ) on the Immunise Australia Program (IAP) website (See Appendix 6) and in the Australian Academy of Science's 2012 document *The Science of Immunisation: Questions and Answers*.

My critical analysis of the claims made by the government includes:

1. Exposing misleading statements (such as equating vaccination and immunisation) and /or
2. Illustrating where the government has not provided (here or elsewhere) evidence to back up its statements, or where there is contrary evidence and/or

3. Illustrating where research has not been done to support the conclusions and/or
4. Illustrating undeclared or unsupported value judgments embedded in or associated with statements.

7.2 Terminology: Vaccination, Immunisation and Vaccine-Preventable Diseases:

On the IAP website the government has used the word *immunisation* to answer public concerns although the correct term is *vaccination*. I have explained the meaning of these terms here and I will use the correct term ‘vaccination’ for this discussion. This is significant to the vaccination debate because receiving a vaccine does not always provide immunity and using the word ‘immunisation’ implies that immunity has been achieved. Similarly I have explained why the term *vaccine-preventable disease* is also a misleading term.

Vaccination is a medical intervention that injects weakened pathogens (antigens) and chemical substances into the tissues of healthy individuals to stimulate the production of antibodies (Stern and Markel, 2005). This is different from *immunisation* which is the process of obtaining immunity from the artificial stimulation of antibodies against an antigen (Martin 2002). These two words are often used interchangeably by members of the public and on the government Immunise Australia Program (IAP) website although they have very different meanings and it is misleading to use them interchangeably. Individuals can obtain immunity to a disease by either natural exposure to the pathogen or by receiving a vaccine. Sometimes individuals are vaccinated but do not obtain immunity to the disease (AG IAP 2012). This can be a result of the vaccine not working or because an individual is exposed to a strain of the disease that is not covered by the vaccine. Conversely individuals can have immunity to a disease without being vaccinated. This is because exposure to the infectious agent can result in natural immunity which is usually of longer duration (often life-long) than that gained from a vaccine, as in the cases of whooping cough, hepatitis B and measles (AG IAP 2012).

The government defines vaccination and immunization on the *Immunise Australia Program* (IAP) website. It states:

- *Vaccination means having a vaccine - that is actually getting the injection.*
- *Immunisation means both receiving a vaccine and becoming immune to a disease, as a result of being vaccinated.*

Most people use the terms 'vaccination' and 'immunisation' interchangeably but their meanings are not exactly the same. The term 'immunisation' is used in this website, as it is most commonly used in the community (AG IAP FAQ 2012).

The government is misusing the word immunisation and misleading the public in the benefits gained from using vaccines. The information discussed on the government website refers only to the physical act of receiving a vaccine therefore the correct word for the government to use is vaccination. The government's language incorrectly implies that all individuals who get vaccinated have gained immunity. This is known to be a false assumption; some vaccinated individuals do not gain immunity so the correct term to use for the act of receiving a vaccine is *vaccination*. In addition, the US Centers for Disease Control and Prevention (CDC) and governments globally are now referring to common infectious diseases as *vaccine-preventable diseases* (CDC 2012). Again this terminology suggests that vaccines create immunity in all individuals and that vaccines can *prevent* infectious diseases. Infectious diseases can only be described as 'vaccine-preventable' if it is demonstrated that protection from disease is a direct response to the use of the vaccine. Epidemics of some diseases are still occurring in areas where vaccines have been used for many years (WHO CSDH 2005 p19) and it is known that a percentage of recipients *do not* gain immunity after vaccination. Therefore it is necessary to establish that any protection from disease is a direct result of the use of vaccines before these diseases are labeled as 'vaccine-preventable diseases'. This empirical scientific evidence can only be provided from *correctly designed* randomized controlled clinical trials of vaccinated and unvaccinated participants. These trials control the variables involved in disease prevention and therefore offer definitive conclusions about the best method of prevention.

The Swedish government regulator for medicinal products, the Medical Products Agency (MPA), states that many conventional vaccines that have a long history of use have never been tested in formal controlled clinical trials to demonstrate their efficacy in preventing

disease (MPA 2007 p5). The Agency states that whilst there are no formal controlled clinical trials demonstrating efficacy in preventing disease ‘there is a well demonstrated relationship between human serum antibody titre and protection against infection’ (MPA 2007 p4). In other words, it is common practice to trial vaccines for efficacy using the surrogate of seroconversion. This end-point is the level of antibody titre in the blood that is believed to be necessary to protect the individual from disease (AG IAP 2012). Whilst antibody titre is used as a surrogate for disease protection, proof that ‘vaccine induced’ seroconversion protects against disease still requires evidence from randomized controlled clinical trials to demonstrate that the artificially induced level of antibody titre is protective against disease and that it was produced by the vaccine. Antibody seroconversion is also achieved by natural infection – with or without clinical symptoms. That is, asymptomatic infections (or sub-clinical infections) also produce seroconversion and immunity to disease. See Chapter 4. Proof that ‘vaccine-induced’ seroconversion results in immunity to disease has not been demonstrated in controlled clinical trials presented by the Australian government on the IAP website, the Australian Academy of Science in the *Science of Immunisation* document or the MPA in the discussion of vaccine efficacy in the Public Assessment Report for Afluria (MPA 2007).

The public is expected to accept that vaccine-induced seroconversion is responsible (and necessary) for disease protection. Yet it is known that whilst there is a general correlation between antibody titre and disease protection, a high antibody titre does not always protect against disease and vice versa: individuals with a low antibody titre do not always get the disease (Ryan et al 1998; Granoff and Rappuoli 1997; Smith A 1999; CDC MMWR 2009). This fact is observed with respect to the whooping cough vaccine and it indicates that other factors play a role in immunity to disease. Therefore, without a controlled clinical trial between vaccinated and unvaccinated participants demonstrating protection against the disease, it is only an *assumption* that the person who doesn’t get sick was protected by the antibody titre induced by the vaccine. There is no empirical proof that the vaccine provided protection against the disease because there are other vaccinated children who still get the disease. It may have been the strength of the child’s immune system, natural exposure with a sub-clinical infection or lack of exposure to the wild virus that resulted in the absence of disease.

When epidemics of a disease do not occur there are many factors that could play a role, including the vaccine, but without the qualifications noted above, the term ‘vaccine-preventable disease’ is misleading. This term implies that vaccines can prevent infectious diseases but the fact that formal controlled clinical trials demonstrating that vaccines prevent infectious disease have not been done represents ‘undone science’ in this policy. Hospitalization statistics are another method that could be used to evaluate the effectiveness of vaccines in the population. Recording the vaccination status of individuals hospitalized with infectious diseases indicates whether the most serious cases of disease are vaccinated or unvaccinated. This data, collected in a transparent manner by an independent authority, could be used to promote vaccines to the public, yet it is not presented by the government on the IAP website or in the AAS supportive document.

In the discussion below I have used the terms *vaccination* and *immunisation* according to their correct definitions. I have also used the term *infectious disease* instead of the government’s terminology of *vaccine-preventable disease* to provide clarity to the discussion.

7.3 The Government’s Answers to FAQ on the IAP Website

In the presentation of this discussion I will provide government statements in bold italics followed by a discussion of the claims. A complete list of the FAQ’s on the government website can be found in Appendix 6.

Statement 1

All forms of immunisation work in the same way. When a person is vaccinated, their body produces an immune response in the same way their body would after exposure to a disease, but without the person suffering symptoms of the disease. When a person comes in contact with that disease in the future, their immune system will respond fast enough to prevent the person developing the disease.

Discussion: The scientific literature does not support the claim that all forms of immunisation work the same way. For example, artificial immunity produced by vaccination with inactivated agents is of shorter duration than that produced from natural infection (AAS 2012; AG IAP 2013; NCIRS Fact Sheet VC 2009). This shows that all

forms of immunization – artificial and natural - do not work in the same way. The attenuated, inactivated or genetically engineered pathogen in a vaccine is injected directly into the tissues of the body – as opposed to ingestion or respiration - along with many excipients in the vaccine carrier: preservatives, antibiotics, and adjuvant. Many of these excipients are not inert substances and this means they will have an unpredictable effect in the human body (Pifferi and Restani 2003; Shoenfeld and Agmon-Levin 2011; FDA). The body's defense mechanisms are stimulated in a different way due to the fact that the vaccine is injected into the tissues as opposed to entering the body naturally via the respiratory or digestive systems. Absorption of substances is increased when they are injected into the blood vessels or the tissues as opposed to inhaled or digested (Gilbert 2004 p26). There are also many other factors that come into play in the prevention of disease - host, environmental and agent characteristics – and this interaction of factors must be taken into account when predicting health outcomes (Burnet 1952 p107). Immunity is not just the production of antibodies stimulated by an infectious agent it is a reaction in the body that is produced by a number of integrated systems (Behrman et al 1998).

The human body has many first-line defense mechanisms (non-specific defense) to prevent micro-organisms from entering the body (Friis and Sellers 2004 p403; AAS 2012). Whilst it is true to say that a newborn infant is regularly exposed to multiple pathogens in the first year of life they rarely pass the infant's non-specific defense system. The route of entry plays a fundamental role to the health outcomes that result from exposure to toxins (Gilbert 2004 p25). Outcomes are also affected by the duration and frequency of the exposure. If there is little absorption of the substance/agent then there will be little response.

Metabolism and excretion can also have a modifying effect on the absorption of some substances (Gilbert 2004 p26). Other influential factors include gender, age and genetics which determine the rate at which a person metabolises substances. Some individuals are unable to metabolise substances at all due to their genetics or age. These factors apply to the expression of disease after exposure to an infectious agent and also to exposure to foreign antigens from the injection of vaccines. Mercury, an ingredient that was used in some vaccines for many years, is a good example of the differences between the effects from ingestion and injection of substances and this has been described in Appendix 4.

When the body is exposed to a pathogen naturally the first line of defense is the skin and

the lining of the lungs (AAS 2012 p4; Friis and Sellers 2004 p403). Mucous, cilia, stomach acid, phagocytes and other white blood cells are the first line of defense against foreign particles (antigens). These tissues are referred to as the innate immune system; the white blood cells in these regions (guardian cells) have sensors that detect the antigens (AAS 2012 p4). The guardian cells then activate lymphocytes to produce B-cells and T-cells. It is the B-cells that produce the antibodies that target specific antigens in a lock and key fashion to prevent infection (AAS 2012).

In contrast, a vaccine is injected into the subcutaneous or intramuscular tissues with the excipients of the vaccine, including the foreign proteins and DNA of the altered pathogen and contaminants of the manufacturing process (Eldred 2006; NCIRS VC 2009). The animal-derived protein in the manufacturing process can be calf serum, monkey kidney tissue, chick or human diploid cells, all of which are similar in structure to human proteins (La Rosa 2002; Eldred 2006). Hence the antibodies that are produced in the vaccinated animal can cross-react with its own tissue proteins in a process similar to autoimmunity (Greville 1966; La Rosa 2002; Shoenfeld and Agmon-Levin 2011; Tomljenovic and Shaw 2011). This demonstrates that all forms of immunisation do not ‘work in the same way’ as stated in the FAQ. Vaccination induces auto-antibodies in animal models (including lupus-associated ones) and these are a known cause of autoimmune diseases (La Rosa 2002; Molina and Shoenfeld 2005; Shoenfeld and Agmon-Levin 2011; Tomljenovic and Shaw 2011). The link between vaccines and the autoimmune response has been known for decades (Greville 1966). It has also been known that this response can occur weeks, months or years after exposure (Shoenfeld and Agmon-Levin 2011; Gilbert 2004 p.27; FDA Thimerosal). The immune system functions together with other body systems and interfering with one system can have unpredictable health outcomes. There is evidence that artificial immunity caused by vaccination causes accelerated autoimmunity and inflammation and many scientists consider that individuals with a family history of these diseases are genetically pre-disposed to these conditions after vaccination (NHMRC 1954–1986; Obomsawin 1998; NCIRS VC 2009; Shoenfeld and Agmon-Levin 2011 p6).

Statement 2:

The two main reasons provided by the government for vaccinating every child in Australia are:

- i. *Immunisation is the safest and most effective way of giving protection against the disease. After immunisation, your child is far less likely to catch the disease if there are cases in the community. The benefit of protection against the disease far outweighs the very small risks of immunisation.*
- ii. *If enough people in the community are immunised, the infection can no longer be spread from person to person and the disease dies out altogether. This is how smallpox was eliminated from the world and polio has disappeared from many countries.*

Discussion: To conclusively support these claims further research needs to be done.

- I. The government states that after *immunisation* your child is far less likely to catch the disease. This statement is not correct because not all vaccinated individuals gain immunity. The correct word to use in this statement is *vaccination* and not *immunization*. Some individuals still get the diseases they are vaccinated against and the observation that artificial immunity is different to natural immunity (see statement 1 above) means that the claim cannot be sustained. Formal controlled clinical trials using an inert placebo to demonstrate efficacy in preventing disease have never been performed for most conventional vaccines (MPA 2007) to conclusively support the claim that ‘the benefits of immunity gained from vaccines far outweighs the very small risks of immunisation (vaccination)’.

There are many factors and body functions that interact in health outcomes and a public health policy should not be justified using incorrect statements such as all types of immunisation (artificial and natural) work in the same way. In addition, vaccines have side-effects in some individuals and whilst the FAQ has described these risks as ‘very small’ the fact remains that the frequency and nature of side-effects from vaccines are not fully known because government monitoring systems

are not designed to make causal links regarding the types and frequency of adverse events that occur after vaccination. The statement that the risks are ‘very small’ is a value judgment that is not supported with adequate scientific studies. In other words, this is an area of undone science.

- II. The statement that smallpox and polio were controlled by ‘immunisation’ (meaning ‘vaccination’) is a simplistic description of the control of infectious diseases. Pathogenesis results from a complex interaction of many factors (see chapters 2 and 4) that relate to the host, the agent and the environment. The eradication of smallpox was significantly influenced by the specific nature of the smallpox virus and public health reforms that occurred in the early 20th century (Wallace 1989; Curry 2002; Kleinman et al 2005; Disease Warriors 2005). A vaccine against smallpox was available for 150 years prior to its eradication in the mid-twentieth century. Kleinman et al (2005) ask why the disease took so long to be eradicated if the vaccine was effective (p312). One strategy that has been credited with assisting in the eradication is *case tracing epidemiology* (or the ‘ring strategy’) (Disease Warriors 2005). This strategy involved identifying and isolating cases of the disease and it was successful because the smallpox virus is only communicable once the symptoms have appeared (Curry 2002; Kleinman et al 2005). This isolation of cases prevented transmission of the disease. Consequently only 50% of the global population was vaccinated. The fact that the disease is only transmissible after the symptoms appear was fundamental to the interruption of the life cycle of the virus and this factor combined with improvements in sanitation and hygiene enabled the disease to be eradicated 150 years after the vaccine was first used. Since smallpox has been eradicated scientists have raised serious questions about the safety and efficacy of smallpox vaccine which was never tested in randomized controlled clinical trials prior to its use in the 19th and 20th centuries (Wallace 1889 p217; Kleinman et al 2005). In 1889 Wallace commented on the numerous deaths and injuries caused by smallpox vaccine and described its use as ‘one of the scandals of the 19th century’ (p219). After a trial in US healthcare workers in 2003 it was established that the smallpox vaccine can cause neurological adverse events that

included meningitis, encephalitis, Bell palsy, seizures, Guillain-Barre syndrome and death. The documentation of these events in the smallpox vaccine trial on healthcare workers in 2003 resulted in an early end the trial (Schwenk 2006).

There are many contextual issues surrounding the decline of infectious diseases that are significant to their ability to be eradicated. The variables that are involved in the incidence of an infectious disease include characteristics of the pathogen and host, environmental factors and any changes to case definitions or surveillance methods that occur at the same time as the incidence of disease declines. The government has not discussed any of these factors. Herd immunity was a concept that was first observed after communities were exposed naturally to infectious agents. For many infectious agents this can offer better community protection because exposures can be sub-clinical (asymptomatic) or mild and provide longer-lasting immunity than artificial immunity produced by vaccination. The theory of herd immunity is discussed in chapter 4.

Statement 3

Immunisation protects people against harmful infections before they come into contact with them in the community. Immunisation uses the body's natural defense mechanism - the immune response - to build resistance to specific infections. Immunisation helps people stay healthy by preventing serious infections.

Discussion: This statement is misleading because it is not true if the correct word, *vaccination*, is used. Vaccination does not always produce artificial immunity and it sometimes causes illness and disability (AG IAP 2013). Hence the use of the word 'immunisation' in this statement is misleading. The statement *assumes* that immunity (without any harmful effects) will always be produced by vaccination. Statements about the lack of evidence for vaccine efficacy and safety are often listed on the package inserts or product information (PI) for vaccines. For example, the Commonwealth Serum Laboratory's (CSL) package insert for influenza vaccine (Fluvax/Afluria), a vaccine that has been produced in Australia since the 1960's, states:

‘There have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with Fluvax/Afluria’ and ‘Vaccination with Fluvax/Afluria may not protect all individuals’ (CSL Fluvax PI 2007).

Efficacy is defined by the US Congress Office of Technology Assessment (OTA) as ‘the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.’ Vaccine efficacy trials use the measure of seroconversion as a surrogate for vaccine efficacy in preventing disease in the population (Basch 1994 p69). In addition, the government does not publish independently assessed data of vaccinated and unvaccinated individuals (including socioeconomic status) who are hospitalized due to infectious diseases to promote vaccines to the public. Cases that are hospitalised are the more serious cases of disease and transparent data on vaccination status is needed to evaluate the influence of a vaccine in reducing the disease. This has not been presented by the Australian government on the IAP website to support current vaccination policies (AG IAP 2013).

Statement 4

Vaccines contain either:

- *a very small dose of a live, but weakened form of a virus;*
- *a very small dose of killed bacteria or virus or small parts of bacteria; or*
- *a small dose of a modified toxin produced by bacteria.*

Vaccines may also contain either a small amount of preservative or a small amount of an antibiotic to preserve the vaccine. Some vaccines may also contain a small amount of an aluminium salt which helps produce a better immune response.

Discussion: This statement is misleading because it uses the word ‘small’ to imply that it would not cause significant harm and it does not list all the possible ingredients of the combined schedule of vaccines. The government has used qualitative descriptions of the amount of each ingredient and not actual ‘quantities’ with the known effects of these substances in humans. Yet it is known that ‘very small’ amounts of many toxic substances,

including antibiotics and preservatives, can have severe health effects in humans, particularly in children and infants (Gilbert 2004 p21). The Australian government even states in its framework for risk assessment for environmental health hazards that the health effects of low doses of many toxic substances have not yet been established (AG EHRA 2013; Gilbert 2004 Preface). These effects are often synergized when injected into the body in combination with other chemical compounds (Gilbert 2004 p32). Yet this knowledge about the risks of vaccines is not provided in the government's discussion about the ingredients of vaccines. The exact ingredients of vaccines are not provided to consumers on the IAP website. The government has listed 'components of vaccines' in Appendix 3 of its Immunisation Handbook (10th Ed) (DHA IH 2013). Most community members would not access this handbook for information and doctors are not required to provide it to patients.

Statement 4 also omits to mention the serious adverse events that are known to be caused in some recipients by vaccines. These include allergies, hypersensitivity, anaphylaxis and autoimmune diseases that are discussed in the medical literature and in the product information sheets for vaccines (NCIRS VC 2009; NHMRC 1954-86; Obomsawin 1998; Tomljenovic and Shaw 2011; CSL PI Afluria /Fluvax 2007). These possible adverse events are often not discussed with doctors before vaccination and this is particularly the case now that vaccines are being administered in schools. A family history of these conditions was traditionally a contraindication to some vaccines (NCIRS VC 2009; NHMRC 1954-86; Obomsawin 1998) but these conditions were removed as a barrier to universal vaccination in school programs in the 1990's (AG NHMRC 1991; Obomsawin 1998). The possible serious adverse events that are listed on the CSL package insert for the influenza vaccine, Fluvax (2007), include allergic reactions (including anaphylactic shock), neuralgia, thrombocytopenia, paresthesia, encephalopathy, neuritis (neuropathy), transverse myelitis and Guillain-Barre Syndrome (GBS), vasculitis, pruritus, urticaria, influenza-like illness, partial facial paralysis and brachial plexus neuropathy (CSL PI Afluria/Fluvax 2007). Yet neither these, nor adverse events from other vaccines are mentioned in the FAQ's on the government's website.

Statement 5

Thimerosal (or thimerosal) is a compound used in small amounts to prevent bacterial and fungal contamination of vaccines. Thimerosal is partly composed of mercury in the form of ethyl mercury. Mercury causes a toxic effect after it reaches a certain level in the body. Whether or not it reaches a toxic level depends on the amount of mercury consumed and the person's body weight. As a result of these concerns, in particular for newborn babies and very young children, thimerosal was removed or reduced from vaccines.

Currently, all vaccines on the National Immunisation Program for children under 5 years of age are now either thimerosal free or have only trace amounts of Thimerosal. It is not possible to completely remove thimerosal from all vaccines; some vaccines like Energix-B are still most effectively manufactured using a trace amount of thimerosal as a preservative.

Discussion: This information is selective and it justifies the use of a toxic substance in infant vaccines whilst confirming that thimerosal is not demonstrated to be safe in infants.

1. The statement does not provide evidence that any level of thimerosal in vaccines is *safe*; indeed it specifically states that mercury has toxic effects. It also downplays the significance of mercury in vaccines. Parents have a right to be fully informed about the ingredients of vaccines and thimerosal should be correctly defined to parents as a compound that is made up of 49% ethyl mercury which is a known neurotoxin (FDA Thimerosal).

In the 60 years that vaccines have been used this knowledge has never been provided to parents before they gave consent for their children to be vaccinated. The government states that the toxicity of thimerosal 'depends on the amount of mercury consumed and the person's body weight'. It does not say *what amount* of mercury is safe. The safety of this ingredient will vary for each infant/child according to body weight and with the number of vaccines that are used. A safe level in humans has never been determined because establishing a safe level of a known neurotoxin in humans would be unethical (FDA Thimerosal). However the government does not

consider it unethical to use mercury compounds in infant vaccines without knowledge of its safety, and without the consent of parents.

The Public Health Agency of Canada (2002) states ‘High dose, acute or chronic mercury exposure of children and adults can cause neuro- and nephrotoxicity.....there are limited data examining the effects of low-dose, intermittent mercury exposure in infants immunised with thimerosal-containing vaccines’.

This statement was made after many thimerosal-containing vaccines had been used in infants for 60 years and particularly in the 1990’s when the number of thimerosal-containing vaccines increased significantly (AG IAP 2012; PHAC 2002). There were over 20 vaccines that had been licensed that contained thimerosal in quantities ranging from 0.005%-0.01% (Varughese and Calver 1999 in PHAC 2002). The amount of mercury is cumulative with each vaccine that is given.

2. The US Food and Drug Administration (FDA Thimerosal) revealed in 1999 that the cumulative exposure of American infants (6 months of age) to ethylmercury from vaccines exceeded the recommended US Environmental Protection Agency (EPA) guidelines that were established for the closely related organic mercury compound methylmercury (AAP 1999 in PHAC 2002). It is also documented that exposing the fetus or infant in the first 6 months of life to organic mercury compounds poses a risk of neurological damage due to mercury toxicity (PHAC 2002). The symptoms of neurological damage due to mercury toxicity are similar to those of autism (Kirby 2005; PHAC 2002). A case study on mercurial toxicity and its links to autism has been discussed in Appendix 2.
3. Energix-B is the hepatitis B vaccine given to babies at birth (day 1 – 7) (DHA IAP 2013). It is a vaccine manufactured by GlaxoSmithKline (GSK) and the prescribing information states that the ‘pediatric formulation contains a trace amount of thimerosal (< 0.5 mcg mercury) from the manufacturing process’ (GSK 2005). This

trace amount of mercury is combined with aluminium hydroxide, sodium chloride and phosphate buffers in the Hepatitis B (Energix-B) vaccine and given to infants before their excretory systems and the blood brain barrier have developed. The government does not address these issues in the FAQ even though the scientific literature does not provide a consensus that it is safe to combine these substances in developing infants and adults.

A study to investigate the health effects of using Hepatitis B vaccine in neonates (infants under 4 weeks of age) was carried out in 2010 on children born before 1999. This was *before* thimerosal-free vaccines were available. The study reported that male neonates had a 3-fold increased risk for autism diagnosis than males never vaccinated or vaccinated after the first month of life. Non-white boys bore a greater risk than white neonates (Gallagher and Goodman 2010 p1671). Universal vaccination with hepatitis B vaccine was recommended to all neonates in the US in 1991 and findings from studies regarding the safety of this vaccine have been mixed. Until 2000 this vaccine contained thimerosal and some studies have shown links between hepatitis B vaccine and autism, neurodevelopmental disorders, central nervous system inflammatory demyelination in childhood, liver problems, chronic arthritis and receipt of early education intervention services (Gallagher and Goodman 2010 pp1665-6). Yet the Institute of Medicine (IOM) stated in 2004 that there was no link between thimerosal-containing vaccines (TCV) and autism based on a selection of studies from countries *that did not have recommendations for universal vaccination with hepatitis B vaccine for neonates* (EUVAC.net, 2010 in Gallagher and Goodman 2010 pp1671). Some of the risk factors that have been identified for autism diagnosis include a family history of an autoimmune disorder, aberrant metabolic dysfunction, impaired methylation, early antibiotic use, genetic variants among subjects of European ancestors, porphyrin biomarkers of metal inhibition of the heme synthesis pathway and jaundice (Gallagher and Goodman 2010 pp1672).

Statement 6

Another reason why children get many immunisations is that new vaccines against

serious infections continue to be developed. The number of injections is reduced by the use of combination vaccines, where several vaccines are combined into one shot.

Discussion: The government does not mention that since 1950 the introduction of vaccines in the Australian population has been for diseases that represent a small risk to the majority of children (Com Yearbook 1953; Stanley 2001). The introduction of most vaccines in Australia was not to control epidemics of disease but to see if these diseases could be eliminated. See Chapters 2 and 3. This claim by the government implies that it is worthwhile to combine an unlimited number of vaccines in the infant body and that this can be done without producing significant side-effects or chronic illness. Yet the risks are not mentioned in the FAQ's and the long-term safety of using multiple vaccines has not been established. The chronic illnesses that have increased in the Australian population as the use of vaccines has increased include autism, asthma, allergies, anaphylaxis, neurological damage (learning and behavioural difficulties), speech delay and autoimmune diseases, e.g. arthritis and type 1 diabetes mellitus.

Statement 7

Many children experience minor side effects following immunisation. Most side effects last a short time and the child recovers without any problems. Common side-effects of immunisation are redness, soreness and swelling at the site of an injection, mild fever and being grizzly or unsettled. You should give extra fluids to drink, not overdress the baby if hot and may consider using paracetamol to help ease the fever and soreness.

Serious reactions to immunisation are very rare, however if they do occur consult your doctor immediately. It is important to remember that vaccines are many times safer than the diseases they prevent.

Discussion: This information is misleading because it does not describe the serious side-effects that are listed on the PI inserts for all vaccines (WAVE). For a significant but unknown number of children, vaccines will not be safer than the disease they are designed to prevent. This is because of genetics but also because the majority of children in

developed countries, like Australia, are not at risk of getting the disease. Some of the serious side-effects that are not listed by the government include neurological disorders such as encephalopathy, convulsions, seizures, Guillain-Barre syndrome, autoimmune diseases, allergies and anaphylaxis are possible adverse events to vaccines (Coulter 1995; Shoenfeld and Agmon-Levin 2011; CSL PI Fluvax/Afluria, PI MMR). These conditions are listed in the PI for vaccines yet not mentioned in the government's FAQ. Furthermore doctors are not required to provide this information to parents.

The claim that 'serious reactions to immunisation are very rare' does not provide the frequency or probability of a child being harmed by individual vaccines. The government is unable to provide accurate statistics of the risk of adverse reactions because the clinical trials for vaccines that are funded by the vaccine manufacturers do not compare vaccinated children with unvaccinated children using an inert placebo (Downing 2011; Future II 2007; CSL Fluvax PI 2007) and they do not establish the long-term health effects (5-20 years) of using vaccines in humans (AG TGA 2013). The passive post-vaccination surveillance systems used by government regulators globally are unable to determine the frequency and types of causally related adverse events linked to vaccines – in the short-term or the long-term – because they are dependent upon 'voluntary' reporting of health outcomes and not the mandatory reporting of all health outcomes for vaccinated individuals (AG TGA 2013; US CDC VAERS 2013).

Whilst the government FAQ states 'it is important to remember that vaccines are many times safer than the diseases they prevent' this cannot be sustained because the appropriate studies and surveillance systems have not been funded. Information on the government website downplays the side-effects of vaccines and over-emphasizes the benefits without definitive evidence. Vaccines and drugs can cause serious damage, or even death and it is known that phase III clinical trials are not large enough to characterize the risk from the vaccine/drug (Basch 1994 p93). The monitoring of vaccines/drugs and acceptance of adverse events linked to these products is influenced by the pharmaceutical companies that sponsor the trials, employ many of the researchers and fund the government regulators to monitor the safety of these drugs in the population after they are approved. See chapters 6, 9 and 10. This illustrates that public safety is dependent upon government regulators

establishing an *active* post-approval surveillance system that can make causal links between vaccines and adverse events.

Statement 8

Natural immunity and vaccine-induced immunity are both natural responses of the body's immune system. The body's immune response in both circumstances is the same. In some cases, vaccine-induced immunity may diminish with time; natural immunity, acquired by catching the disease is usually life-long. The problem is that the wild or natural disease has a high risk of serious illness and occasionally death. Children or adults can be re-immunised (required with some vaccines but not all) if their immunity falls to a low level. It is important to remember that vaccines are many times safer than the diseases they prevent.

Discussion: This information does not address all the differences between natural and artificial immunity, it is selective (See Statement 1 above). There is no risk/benefit analysis of immunity gained naturally and immunity gained artificially with the probability of risk for each disease. There is a risk on both sides of this equation – from the disease and the vaccine - and it will vary for each disease. The government has not provided quantitative evidence of the risk presented to the majority of individuals from both the infectious agent and the vaccine. In developed countries like Australia, the majority of children are not at serious risk from infectious diseases even when they are exposed to the infectious agent. The reasons for this are discussed in chapters 2 and 4.

The placebos used in safety trials always contain *all the adjuvants and often neomycin (an antibiotic and known neurotoxin and allergen)* that are also in the vaccine (Virtanen et al 2000). This means that comparing the safety of the vaccinated group to the unvaccinated group does not provide complete information about the safety of the vaccines in the human body. It assesses the safety of the vaccine when compared to the adjuvant (and/or antibiotic) in the human body and these substances are known to be *non-inert* meaning they are known to cause adverse events, immediate and delayed, in the human body (Shoenfeld

and Agmon-Levin 2011; Tomljenovic and Shaw 2011). Therefore it cannot be sustained that ‘vaccines are many times safer than the diseases they prevent’.

Statement 9

The FAQ about ‘Overloading the Immune System’:

No. Children and adults come into contact with many antigens (substances that provoke a reaction from the immune system) each day, and the immune system responds to each antigen in specific ways to protect the body. Without a vaccine, a child can only become immune to a disease by being exposed to infection, with the risk of severe illness. If illness occurs after vaccination, it is usually insignificant.

Discussion: This statement is inaccurate because it fails to address the different ways that children/adults come into contact with multiple antigens naturally and artificially by vaccination. As described in **statement 1** above, the route of entry for pathogens has a major influence on the health outcome of the individual. The risk of severe illness due to natural exposure to infectious agents in developed countries is very low. Again the claim that ‘if illness occurs after vaccination, it is usually insignificant’ is questionable if it is not supported by evidence. Vaccination stimulates a different chain of events than natural exposure due to the injection of substances into the body where components have access to the organs and body systems. The final sentence of the FAQ answer could be re-written in the following way: ‘Without a vaccine a child can become immune to a disease by being exposed to infection with little risk of severe illness in Australia. However, in genetically-diverse populations there is real risk that many children will suffer severe adverse events after vaccination’.

Statement 10

The government’s statement for ‘why vaccines are still necessary’:

Many diseases prevented by immunisation are spread directly from person to person, so good food, water and hygiene do not stop infection. Despite excellent hospital care,

significant illness, disability and death can still be caused by diseases which can be prevented by immunisation.

Discussion: This statement is misleading because it generalizes the risks of all infectious diseases. Whilst it is true that illness and disability can still be caused by infectious diseases in developed countries, vaccines are being introduced for diseases that are not a risk for the *majority* of people in these countries. If the government is implementing a management strategy to prevent death and disability and the adopted management strategy *also causes death and serious disability*, then it is deceptive not to address the risks of the management strategy as well as the risks of the disease. Public health policy should be beneficial to the majority of individuals in that community.

The government's statement also ignores the fact that vaccinated children can still get the diseases they are vaccinated against. Therefore if the appropriate studies have not been funded to provide empirical evidence of the influence of vaccines in preventing disease, then the weight of evidence for the benefits of vaccines has not established.

7.4 A Discussion of the Australian Academy of Science Document *The Science of Immunisation*

The Australian Academy of Science (AAS) produced a supportive document for the Australian government's vaccination policies in 2012. At this time many parents were questioning the number of vaccines being recommended by the government and this document was developed to address parental concerns (AAS 2012). I am addressing the AAS claims in this chapter because this document represents another example of the type of information used to promote vaccines to the public.

In the following discussion AAS statements are in bold italics followed by discussions of the claims. The terms 'vaccination' and 'immunisation' have been conflated by the AAS; I will use the correct terms in my discussion.

- 1. Immunisation has transformed human health by preventing the deaths of hundreds of millions of people.***

2. *The widespread use of vaccines has been highly effective globally in reducing the incidence of infectious diseases and their associated complications, including death.*
3. *As a result of vaccination several infectious diseases have been controlled or eliminated in Australia which would never have occurred just due to improvements in healthcare, sanitation or nutrition.*
4. *Vaccines are the most successful form of disease prevention available and will continue to be an essential tool in controlling infections and complications.*

Discussion:

These four claims from the foreword and summary (pp2-3) are about the achievements of vaccination programs. The claims have been made by ignoring the historical evidence that infectious diseases declined prior to the use of the majority of vaccines in all developed countries (Commonwealth Yearbook of Australia 1945–1986; Stanley 2001). This historical decline has been described in chapter 2. The claims have been made without providing historical data to support the statements and without definitive evidence to demonstrate the influence of vaccines in reducing infectious diseases. This is because definitive studies of the efficacy and safety of vaccines have not been funded.

Statements 1 and 2 claim hundreds of millions of deaths have been prevented by vaccines but the claims do not address the many deaths and cases of illness that have been caused by vaccines (Wallace 1889; Allen A 2007; Habakus and Holland 2011; US VICP). Value judgments about the benefits of vaccines must be founded on the weight of evidence not selective evidence for the use of the procedure. This was discussed in FAQ 9 above.

In statement 3 the AAS claims ‘As a result of vaccination several infectious diseases have been controlled or eliminated in Australia’. This is a general statement and it does not list any disease that has been controlled or eliminated by a vaccine. Similarly, the claim in statement 4 that ‘vaccines are the most successful form of disease prevention available’ is not sustained by evidence. The AAS has not provided empirical evidence

of the influence of vaccines in controlling specific diseases. This could be done by providing independent data on the number of vaccinated and unvaccinated individuals in the Australian population, with their socioeconomic status, that are hospitalized in outbreaks of a disease.

The Commonwealth Yearbook of Australia (1953) and prominent public health authorities clearly illustrate that the infant mortality rates declined significantly *before* the introduction and widespread use of all vaccines except diphtheria. Voluntary mass vaccination programs in Australia were not strongly promoted in Australia until after 1954 (NHMRC 1954). This evidence has not been discussed or countered by the AAS to make the general claim above. Although diphtheria vaccine was used prior to 1950 prominent public health officials such as Lancaster and Cumpston noted that the rate of the decline for diphtheria was no greater than the decline for all the other infectious diseases for which there was no vaccine (chapter 1). Proof of the influence of diphtheria vaccine in the control of this disease would also require data on the percentage of the susceptible population that had been vaccinated. This has not been provided.

5. *Immunisation is based on scientific knowledge.*

Discussion:

This claim implies that the information presented as *scientific knowledge* to support this claim is proof that vaccines are safe, effective and necessary. This ignores the processes by which science is produced and assumes that all *scientific knowledge* is produced with integrity and rigor. This is not the case and the cultural and political influences on the production of scientific knowledge have been described in chapters 6 and 7. Much scientific knowledge is distorted by vested interests and the knowledge base is incomplete due to undone science. Furthermore, there is scientific knowledge that does not support vaccination and this has not been provided in this AAS document.

6. *We know there are a very small number within a vaccinated population who can have adverse reactions as a consequence of vaccination. No medical intervention is completely without risk.*

7. Immunisation with each vaccine protects an individual from a serious infectious disease and from associated long-term complications.

Discussion:

These statements fail to mention that many people are not at risk from the infectious diseases they are being vaccinated against in Australia, even if they are exposed to the infectious agent. The claims also do not address the fact that accurate knowledge about the health risks of vaccines is unknown because the appropriate studies and monitoring systems have not been funded. The statements are based on selective information and are therefore misleading the public on the risks and benefits of using multiple vaccines to protect the community.

8. Before release for use in the population a vaccine must undergo a series of rigorous clinical trials each of which involves a greater number of participants.

Discussion:

There are no formal controlled clinical trials of vaccines that compare the safety and efficacy of vaccines against the disease or against an inert placebo. In addition, the recent introductions of HPV vaccines and the 'Swine Flu' 2009 vaccine have demonstrated that comprehensive testing was not carried out before the vaccines were used in the population. See chapters 9 and 10. HPV vaccines were fast-tracked for approval by the FDA before the clinical trials for efficacy and safety against cervical cancer were completed. Similarly, the influenza vaccine was recommended to Australian children under 5 years of age in Western Australia in 2008 without being tested for long-term safety and efficacy in children prior to its recommendation (Jefferson et al 2008; AG TGA 2010). When companies can make significant profit from the research they sponsor it is known that they can influence the design and hence the outcome of the clinical trials. See chapter 6. This throws into question the claim that vaccine trials are rigorous. An independent assessment of the clinical trials is necessary before the claims stated by vaccine manufacturers are accepted.

9. Vaccines undergo stringent monitoring once they are in widespread use in the community to ensure their ongoing safety and effectiveness.

Discussion:

This claim is incorrect. There is no stringent monitoring of adverse events or evaluation of the effectiveness of vaccines in the population that would provide meaningful data on their effects in the population. This is because all countries use a ‘passive’ or voluntary post-vaccination surveillance system that is unable to provide data on causal relationships between vaccines and the frequency of adverse events that are observed in the population (US FDA; AG TGA).

10. There is no credible evidence to suggest that any vaccine in current use can cause these particular diseases (multiple sclerosis and diabetes 1) (AAS Box 9 p.12).

Discussion:

Whilst the AAS claims there is no credible evidence of a link between vaccines and autoimmune diseases, they have made this statement by ignoring the studies that are showing this link – not by addressing why the studies are not credible. They have also made this claim without providing evidence from a properly controlled long-term clinical trial (5 or more years) of the health effects of using the combined schedule of vaccines (against 16 diseases) in infant animals or infant humans. A link between vaccines and autoimmune diseases has been postulated in the medical literature for over fifty years and the combined schedule of vaccines is a plausible cause of these diseases. The *Medical Journal of Australia* reported the link between vaccines and autoimmune diseases in 1966 (Greville 1966) and Burnet discussed the association between hypersensitivity and vaccines in 1952 (Burnet 1952). There are also many recent studies that have demonstrated this link (La Rosa 2002; Shoenfeld and Agon 2011; Tomljenovic and Shaw 2012) and in particular the link with multiple sclerosis (Fourrier et al 1999; Marshall 1998, Confavreux et al 2001; Geier et al 2005) and diabetes mellitus (Blumberg et al 1993; Feery 1982; Stewart 1977). The AAS has made the claim that ‘there is no credible evidence’ without stating *why* these studies are not ‘credible’. In fact there is clear evidence from animal studies from

1965 that foreign protein and adjuvants produce auto-antibodies which are a known cause of autoimmune diseases. Burnet and Mackay stated in 1965 ‘There is no doubt that conditions basically resembling certain human autoimmune diseases can be produced in originally healthy experimental animals by injections of normally inaccessible autologous antigens’ (in Grigor 1965 p83). Whilst there are studies in the medical literature that discount a causal link between vaccines and autoimmune diseases, there are no studies that have discounted this link using empirical evidence from properly designed RCT’s in animals or humans. In addition, a public hearing into the adverse events associated with HPV vaccines held in Paris in 2014 included this statement:

‘Current scientific knowledge and progress has revealed that aluminium is responsible for what can be called vaccine-induced illness or illnesses that did not naturally exist pre-vaccination and which the individual therefore contracted through aluminium toxicity.’ (Vanlangendonck P. 2014). Aluminium adjuvants are also found in most childhood vaccines.

Here is a description by Basch of the knowledge scientists had of adjuvants and their effects in 1994 when the use of vaccines was expanding. This information gives an insight into the potential effects of adjuvants and is relevant today in light of recent knowledge about the effects of aluminium adjuvants in the functioning of the human body. Adjuvants enhance the immune response of the body. That is, they operate to increase the production of antibodies in vaccine recipients (Basch 1994 pp227-8). Vaccines that are not made with the complete organism (bacteria/virus) are known to be less immunogenic. These vaccines require more adjuvant to raise the antibody titre to the protective level. Many of the vaccines produced with new biotechnology are made without using the whole organism as the antigen. These vaccines use acellular components, chemical synthesis or recombinant DNA as the antigen and therefore they require more adjuvant to raise the antibody level of the vaccine recipient. Adjuvants also influence the class of immunoglobulin antibodies that are produced in the body (Basch 1994 p227). One class of antibody produced is immunoglobulin E which plays a major role in allergic diseases; asthma, hayfever, dermatitis, gastroenteritis and anaphylaxis (Martin 2002). These conditions have increased 5-fold in Australian children over the last decade (ASCIA 2015). See section 1.1.

Examples of novel vaccines include hepatitis B, acellular pertussis (DTap) and HPV. The HPV vaccine has three times as much aluminium adjuvant as any other vaccine and three times as many adverse events (chapter 9). The most common adjuvants used in vaccines are aluminium hydroxide and aluminium phosphate. In 1984 it was stated that the complexity of vaccine adjuvants means that they produce a variety of responses in the host some of which are irrelevant to the immunogenic effect. The immune response is a multistep process and can occur through a variety of pathways therefore they can theoretically act in unknown ways on many cells in multiple pathways. These processes are not fully known and understanding of the immune response is unclear (Bomford 1984 in Basch 1994 p228). It is also known that there are significant differences in the effect of adjuvants from species to species and between individuals within a species. Basch (1994) stated that the extent of genetic variability with respect to adjuvant function is unknown but believed it may be significant to health outcomes in human populations (p228).

11. The vast majority of people (mainly adults) who develop autoimmune diseases have no recent history of being vaccinated (AAS p12).

Discussion:

This statement is misleading for two reasons. Scientists know that the autoimmune diseases show a delayed response (Eldred 2006; Shoenfeld 2011; Gilbert 2004; FDA). Autoimmune diseases and hypersensitivity (allergies) can develop months or years after exposure so even if patients do not have a ‘recent history’ of vaccination, vaccination could still be responsible. The statement also ignores the fact that autoimmune diseases such as diabetes 1 and autism are rapidly increasing in children - not just adults. This increase has occurred at the same time as the number of vaccines has increased (AIHW 2005). Two diseases that the AAS admits have increased due to vaccines are Guillain-Barre syndrome and idiopathic thrombocytopenic purpura (ITP). The suggestion that they are less of a risk than the infectious diseases is a value judgment that is not sustained with specific evidence of the risks and benefits of different vaccines and infectious agents.

7.5 Political Decisions in Government Policy

The discussion in this chapter illustrates that there is credible evidence for a causal link between vaccines and many serious and debilitating diseases that are increasing in the population. Yet political decisions are being made in government policies that do not acknowledge the medical literature supporting these links. This allows those with vested interests in vaccination programs to downplay the risks of vaccination. This is possible because governments have reversed the precautionary principle to place the onus of proof of harmfulness on the general public *and not the proponent*. It is difficult for the public to prove with ‘hard evidence’ that vaccines are causing many diseases in the population because governments have not funded the studies that might establish causal links with the vaccines. This allows political decisions to be made that ignore the evidence from small scale studies that harm is being caused by using multiple vaccines. Decision-makers use political and scientific criteria in deciding whether a procedure should be implemented and these decisions can include transient and subjective (value-based) reasons regarding the evidence. Not all evidence is of equal value or produced with equal integrity and rigour (Basch 1994 p79). The evidence that is used in policy decisions is provided by the dominant network of scientists that gains power through the cultural and institutional structures that exist in the prevailing political ideology. See chapter 8.

After the considerable public concern about the safety and efficacy of hepatitis B vaccine in the 1990’s, due to its association with multiple-sclerosis, the Virus Hepatitis Prevention Board reviewed these safety issues. Several members authored a paper to downplay the risks and to promote the vaccine in neonatal and adolescent vaccination programs in many countries. This was done by promoting the studies, mostly funded by industry, that do not show a link between vaccines and chronic illness. The other studies showing links to diseases were ignored. This allowed the authors to claim ‘no scientific data currently allow the conclusion that hepatitis B vaccine or other childhood vaccines represent a significant risk.....’ (Guido et al 2005 p958). This is the type of value judgment that is being made to develop vaccination policies and it is not the same as stating ‘vaccines do not cause significant harm in the population’. The claim can be re-framed ‘it has not been proven that hepatitis B vaccine is not the cause of autoimmune and other diseases in the population’.

Scientists are succeeding in hiding the possibility of causal links because the relevant research is not carried out. Governments have not funded the studies that might provide the evidence showing vaccines are causing many chronic diseases in the population. See chapter 8.

The article concludes that the media should be seen as ‘reliable key partners in countering vaccination scares and the anti-vaccination movement’ (Guido et al 2005 p958). The authors claim that ‘cultivating optimal professional working relations with them is imperative’. They continue ‘Open debate about vaccine safety issues and the performance of sound scientific studies are powerful instruments to be used against vaccine scares and should be encouraged’ (Guido et al 2005 p958). However in Australia the public is not encouraged to participate in debates on vaccination. Powerful pro-vaccination lobby groups such as the Australian Skeptics and Stop the Australian Vaccination Network (SAVN) influence politicians and the media. They also use social blogs to ridicule and abuse individuals, including academics and professionals, who are questioning the safety and efficacy of vaccines (Martin 2015). There is evidence that lobby groups in many countries are being funded by industry to promote industry interests (Michaels 2008). These groups discredit people’s reputations and promote disinformation to suppress scientific debate.

7.6 The Evidence not Provided by the Government and AAS

Evidence for the Necessity of each Vaccine Recommended in Australia

- The diseases for which vaccines are recommended have not been demonstrated to be a serious risk to the majority of children in Australia.
- Quantified data of the risks of vaccines and the risks of each infectious disease to the majority of children have not been provided to demonstrate the weight of evidence for the necessity and safety of each vaccine.

Evidence for the Efficacy of each Vaccine Recommended in Australia

- There is no definitive evidence from formal controlled clinical trials comparing vaccinated participants to unvaccinated participants and demonstrating the efficacy of each vaccine against the infectious disease they are designed to prevent.
- The surrogate of seroconversion has been used for proof of efficacy of each vaccine but the models of seroconversion demonstrating a protective level of antibody titre against the disease have not been provided.
- Many vaccinated individuals still get the diseases they are vaccinated against and the government has not provided complete evidence, including SES, of the percentage of vaccinated individuals who are still getting the diseases.

Evidence for the Safety of each Vaccine Recommended in Australia

- There is no definitive evidence from formal controlled clinical trials comparing vaccinated participants to unvaccinated participants, using an inert placebo that demonstrates the safety of each vaccine or the combined schedule of vaccines.
- Definitive evidence of vaccine related causal adverse events and their frequency in the population has not been provided.
- A post-vaccination surveillance system that can establish the short and long-term causal events and their frequency in the population is not used by government regulators.
- The known link between a family history of autoimmune diseases and allergies/anaphylaxis is not discussed and is no longer presented as a contraindication for vaccination programs implemented in school settings.
- The correlation between mercury poisoning and autistic symptoms has not been acknowledged by governments even though the US Government regulator, the FDA, admitted that the cumulative level of mercury in infants under 6 months of age had exceeded the EPA's guidelines in the 1990's. This correlation needs to be acknowledged and investigated to demonstrate that vaccines are not causing autism.

- Adverse events that are listed on the Prescribing Information (PI) for each vaccine are not mentioned to parents. E.g. encephalopathy, convulsions, seizures, Guillane-Barre Syndrome, autoimmune diseases, allergies and anaphylaxis.
- The risk of each disease and vaccine in genetically diverse communities has not been provided.

7.7 Conclusion

The evidence provided by the Australian government and the AAS for vaccinating with multiple vaccines does not include an assessment of the ecological complexity of the cause of infectious diseases or account for the genetic diversity of the population. It also does not provide direct evidence of the influence of vaccines in controlling any infectious diseases. In addition, the adverse events from using multiple vaccines in infants/adults should be considered in the adoption of a management strategy that is implemented in public health policy. The government information analysed here does not provide estimates of the frequency and type of risk associated with each vaccine - or with the combination of vaccines. It also does not provide evidence that policy-decisions about infectious diseases are being made for the benefit of the majority of the community. The value judgments made by policy advisors in Australia are emphasising the *assumed* benefits of vaccines and downplaying the risks. This is illustrated in the selective evidence and misleading statements that are used to promote vaccines to the public in the FAQ and by the AAS. Conflated terminology has been used to mislead the public about the efficacy of vaccines. The government has not provided evidence that the ‘best judgments’ for public policy are being made on comprehensive and independent evidence. Australia’s vaccination policies include undone research and a lack of transparency in the rigour of scientific trials and the assumptions used in the evaluation of vaccines. This is a consequence of a culture that promotes scientific research for ‘profit’ as opposed to its contribution to progressing knowledge. In the 21st century industry is sponsoring vaccine clinical trials without evaluation from independent experts. This is not disinterested science and it is being promoted in public policy by experts with vested interests.

The culture in which research and policy development is occurring in Australia is described in chapters 6 and 8. An example of the influence of corporations in global vaccination policies is provided with the HPV vaccine in chapter 9 and the 'Swine Flu' 2009 vaccine in chapter 10. These case studies demonstrate how vaccines can be implemented into global vaccination policies even though the underpinning science is incomplete. Chapter 11 presents the conclusions to this investigation.