Extract of Chapter Conclusions

Thesis Title: *A critical analysis of the Australian government's rationale for its vaccination policy*

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Chapter 2 Conclusion
Chapter Title: Controlling Infectious Diseases in Australia
Chapter pages: 11-44

2.9 Conclusion

The epidemiological triad illustrates that infectious diseases are a result of the interaction of multiple causal factors in pathogenesis. In other words, infectious agents (bacteria/viruses) are necessary but do not always result in disease; exposure to these agents can result in a diversity of health outcomes. This is why the assessment of the severity of each infectious agent in the community cannot be made outside the ecological context. Global public health policies are resulting in a 'one size fits all' vaccination program that ignores the context in which infectious diseases occur and the diversity of outcomes that are expected. There are a range of health outcomes that can arise after exposure to an agent – no disease, mild or severe disease, or death - and the health outcome is dependent upon the host, environment and agent characteristics. Humans develop immunity by adapting to their environment through a process known as homeostasis. Homeostasis is part of the process by which humans develop resistance

(immunity) to disease and it develops through natural interactions and exposure with the organisms in an ecological context. The immune system interacts with the environment and other body systems in complex ways to develop long-term protection against disease: it is not simply the production of antibodies to an antigen in the process of seroconversion induced by vaccination. In this way communities are protected by herd immunity developed by natural exposure to the agents.

The infant mortality rate in Australia declined primarily due to improvements in the ecological context including sanitation, hygiene, nutrition, breast feeding, smaller family sizes, less crowding and improved infrastructure. The risk of death and illness due to infectious diseases had declined by 1950 *before* most mass vaccination programs were introduced. In 1950 only two vaccines were in voluntary use in mass vaccination programs in Australia, diphtheria and smallpox, and these diseases did not decline any more quickly than other infectious diseases. Whilst outbreaks of infectious diseases still occurred after 1950, the risk of death and severe illness was low to negligible to the majority of Australian children and long-term herd immunity to the diseases was gained by natural infection during childhood. Many mass vaccination campaigns were introduced in Australia from 1952–1990 but participation was voluntary and without coercive government strategies. Infectious diseases continued to decline as living standards and education improved. Despite the low infant mortality rate in the early 1990's and the lack of significance of infectious diseases in Australia at this time, the government implemented a new strategy to increase the vaccination rates in the population and to expand the recommended schedule of vaccines. This policy change was in response to WHO global health directives, and not a specific recommendation for the ecological context of the Australian situation.

A decision was made in the mid-twentieth century to medicate all children to prevent disease, despite the diversity of outcomes that arise after exposure to an infectious agent. At this time the health of Australians was measured using the decline in the infant mortality rate and since 1990 vaccination coverage has been used as the surrogate measure for 'health'. These surrogates have been used even though it is known that mortality rates and vaccination coverage are unable to inform authorities about the illness/disability associated with each disease. The well-being and quality of life of individuals in communities cannot be accurately measured using these surrogates. This

is relevant to vaccination policies because there has been a significant increase in chronic illness in Australian children that has occurred at the same time as the government increased the participation rates and the number of vaccines listed on the childhood vaccination schedule in the 1990's. Authorities that depend upon infant mortality rates and vaccination coverage alone to inform public health policy will not detect or recognize a correlation between vaccines and increased morbidity in the population.

Overview of Chapters

The expansion of the Australian government's vaccination program within the global framework for public health policy directed by the WHO/GAVI is described in chapter 3. Chapter 4 discusses the federal governance of the NIP and the way in which risk assessment for infectious diseases is performed and communicated to the public. A discussion of the principles of public health policies and ethical codes of conduct for health promotion is provided in chapter 5. Chapter 6 investigates the rigour of the science that is produced in academic-industry partnerships in research institutions and chapter 7 provides a discussion of the evidence the Australian government provides to support the claims used to promote vaccines to the public. Public health policies are a reflection of the cultural and political beliefs of the time. Chapter 8 discusses the political framework that results in *undone science* and how public health policy is being designed on political decisions made without complete scientific knowledge. It provides the political framework for the existence of undone science and explains the consequences of its existence in public policies to population health. These influences in the development of global vaccination programs are illustrated in a case study of the Human Papillomavirus (HPV) vaccine in chapter 9 and the 'Swine Flu' 2009 vaccine in chapter 10. An investigation of these vaccination programs demonstrates the political and economic environment in which vaccines are being produced in the globalization era and the effect this has on the research that is produced in academic institutions. Chapter 11 provides the conclusions drawn about the Australian government's claim that vaccines are a safe and effective prevention for many infectious diseases.

Chapter 3 Conclusion
Chapter Title: Global Health Policy and Australia's National Immunisation Program (NIP)
Chapter pages:68-86

3.18 Conclusion

The Australian government's NIP has been set within the framework and directives of the WHO's global health policy. It has not been developed within the specific environmental context of the Australian community but to comply with directives from the WHO on global vaccination policies. These policies have been developed by WHO/UNICEF since the 1970's and inspired by the campaign to eradicate smallpox. Although there was disagreement at this time about the value of vaccination in eradicating diseases, WHO/UNICEF decided to expand the program to many other infectious diseases. This was initiated as the Expanded Program on Immunisation (EPI) and since the 1970's has developed through many phases in all WHO member countries, both developing and developed. The campaign has been promoted on the moral principle of 'saving the world's children with life-saving vaccines'. During the 1980's the influence of neoliberalism resulted in economic and political experts dominating the development of global health policies. Mixed health messages began to be presented through WHO directives as neoliberalism focused public health policies on technology-based interventions such as vaccination. This was done in many developing countries at the expense of primary healthcare programs that targeted the social and environmental determinants of health. In the 1990's the World Bank, the International Monetary Fund and the Rockefeller and Gates Foundations became partners with the WHO/UNICEF to sponsor global vaccination programs. A shortage of funding in the 1990's for the research and development of vaccines led to the development of public-private partnerships that were influential in the direction of global health policies in WHO member countries.

Economics and politics began to dominate the design of public health policies from this time, with health statistics obtained from non-governmental economic models of the cost-effectiveness of implementing vaccination programs. Global health directives were based on industry modeling for global communities instead of the specific ecological conditions of each country. In 2000 the direction of global public health policies changed with the establishment of the Global Alliance for Vaccines and Immunisation (GAVI), a body that consists of public-private partnerships with governments and corporations jointly influencing global health policy decisions. At this time vaccines became the sole focus of global policy: GAVI promoted vaccines to WHO member nations using financial incentives as well as by controlling the supply of vaccines to these countries. This resulted in the 'vaccine paradox' where governments, in alliance with corporations, control the supply and demand of vaccines. This represents a clear conflict of interest that is not transparent to the public. Since 2000 global public health policies have protected industry interests through the sole focus on vaccination programs and many authorities within the WHO, and developed nations, have expressed concern at these technology-based health programs. This has been at the expense of broader primary healthcare needs.

Australia's NIP expanded in the 1980's and 1990's according to WHO goals for achieving high participation rates for all the recommended vaccines. The goals were set to increase childhood vaccination rates to ninety percent for all the vaccines in Australia even though there was no significant threat to the majority of the population from the targeted infectious diseases. The decision to use vaccines for many diseases was a universal directive to both the developed and the developing countries, without risk/benefit assessments for the use of each vaccine in specific countries and populations. In addition, national governments did not provide an adequate surveillance system for the accurate determination of the frequency of causally related adverse events from vaccines. The harm caused by vaccines, either individually or in the combined schedule, has not been included in the economic modeling for the cost-effectiveness of vaccination programs. These programs have been based on the assumption that vaccine-created herd immunity can prevent infectious diseases, if enough people participate in these programs, without causing significant harm to the population. The lack of empirical evidence for these assumptions is discussed in chapters 4 and 7.

During the 1990's government's re-labeled infectious diseases as *vaccine-preventable diseases*, a label that implies vaccines can prevent infectious diseases. The public has been informed through the mainstream media that high participation rates in vaccination campaigns are needed to *prevent* infectious diseases but the empirical evidence to support this claim has not been provided. The evidence the Australian government provides to support vaccination policies is discussed in Chapter 7. The government has introduced many new vaccines since the 1990's and emphasised the need for high vaccination rates for all infectious diseases for which there is a vaccine. New vaccines are continually added to the national recommended schedule. Each vaccine carries a risk to some individuals yet the Australian government does not provide a separate risk/benefit assessment for each disease and vaccine, nor for the combination of vaccines that are recommended in the children's schedule. The vaccines have been added to the recommended schedule without public consultation or participation in policy development, and without informing the public of the ingredients of vaccines. Financial incentives have been used to pressure parents and doctors to use all the recommended vaccines and to assist the government to track the vaccination status of children. These strategies were implemented in 1993 and formalized in 1997 as the Immunise Australia Program (IAP). These coercive practices have increased in 2015 with many employees now being required or expected to vaccinate even though the government continues to claim that vaccination in Australia is not compulsory.

The Australian Government's program does not make any reference to the historical evidence of the control of infectious diseases in Australia or the risk/benefit of using an increasing number of vaccines in children/adults. Mainstream media has been used since the 1990's to influence public behaviour by informing the public that high participation rates in vaccination programs are important in controlling infectious diseases without providing evidence for this claim. In contrast, the media was used in the early 20th century to successfully promote social (ecological) medicine to the public to reduce the threat of infectious diseases through environmental and lifestyle changes. The media message changed in the second half of the century when the focus of public health was directed to vaccination policies. Since this time the mainstream Australian media has emphasised the benefits of vaccines, without providing empirical evidence, and without informing the public of the known risks associated with each vaccine or the long-term health effects of the combined schedule of vaccines.

Chapter 4 Conclusion
Chapter Title: Implementation of the Australian Government's Vaccination Policies
Chapter pages: 87-117

4.11 Conclusion

Australia's National Immunisation Program (NIP) has been developed by the Federal government as a recommendation to the states and territories under the Public Health Acts. The public health laws were reformed in 1999 and the regulation of infectious diseases was placed under infectious disease law and separated from other public health issues - sanitation and environmental control – that were traditionally associated with infectious disease control. This resulted in the use of different methodologies for determining the health risk for infectious diseases and many other environmental health hazards. Risk assessment for infectious diseases is performed by computer modeling however for many other environmental health hazards, including the microbiological risk from food pathogens, it is determined using the Environmental Health Risk Assessment (EHRA) Guidelines. See Appendix 6. This framework for risk assessment is believed by environmental health practitioners to represent the most systematic and transparent method for assessing health risks for environmental hazards in genetically diverse communities.

Risk assessment for environmental hazards must include both technical and non-technical information. This is to address the limitations and uncertainty in the science. Gaps in scientific knowledge result in incorrect value judgments about safety and this can be countered with caution and non-technical input if the gaps in the science are acknowledged. The EHRA framework also ensures that the community is consulted regarding their perceptions of the risk of a hazard. A rigorous risk assessment can stand up to scrutiny by all stakeholders and the public must be encouraged to openly debate vaccination policies to maintain population health. The public perception of risk is essential to policy development to ensure that *health* is the primary focus of the policy. There are many variables and assumptions in computer modeling that are not made transparent to the public or government ministers. In addition, the precautionary principle (PP), with the onus of proof

on the proponent and not the general public, has not been adopted in infectious disease law. When the PP is not implemented with the onus of proof of harm on the proponent instead of the general public, it is possible for governments to claim there is no evidence of harm therefore no action needs to be taken, based on a lack of scientific evidence due to appropriate studies not being funded. The public cannot be provided with definitive evidence if the studies have not been funded.

A universal management strategy that carries a risk to sub-groups in the population needs to be openly debated by the community. The dominance of scientific experts in vaccination policy is questionable because of the increasing gaps in scientific knowledge due to undone science. This can synchronise with a lack of transparency in risk assessment to compromise health management strategies. A dependency on scientific experts and elite knowledge from computer models results in the exclusion of public participation in policy debate. Yet the existence of unfunded research in the underpinning knowledge (see Chapter 6) needs to be debated and addressed with non-technical information in policy decisions. The corporate model of health that was adopted by the states and territories in the 1990's allows corporations to fund health promotion programs, such as vaccination, to the public in media campaigns. If industry funding is involved in health promotion campaigns it is possible for vaccine manufacturers to influence public behavior through the selection or framing of information. The case study of the *Swine Flu Pandemic* in 2009 illustrates how the framing of disease statistics in the media can misrepresent risk and influence public behavior regarding the use of vaccines.

Surveillance statistics can be misrepresented to the public by changing the definition of the disease or changing the surveillance of the disease without publicising the changes. This information can then be promoted to the public in health promotion campaigns in the media that are funded by corporate partnerships. The media is not accountable for the information it provides to the public and the community is expected to *trust* that the information provided is in the public's best interest. This situation can compromise public health because industry promotes industry interests which are not always compatible with the public interest. Industry became more involved in health research and promotion in the latter part of the twentieth century with the development of the medical-industrial

partnership in institutions and public-private partnerships to sponsor health programs. These have been discussed in Part 2 of the thesis: Corporate Influence and Undone Science in Public Policy.

Chapter Overview

Chapter 5 describes the scientific medical model of health and the ethical values inherent in health promotion and chapter 6 discusses the influence of corporations in the production of scientific knowledge. In chapter 7 I discuss the information the government provides to the public to support its claims about vaccines. Chapter 8 introduces the concept of undone science and the political framework that leads to its existence. Examples of undone science and industry influence in government vaccination polices are provided in case studies in chapters 9 and 10. Chapter 11 presents the conclusions drawn from this investigation.

Chapter 5 Conclusion
Chapter Title: Public Health Policy and Health Promotion Ethics
Chapter pages:118-136

5.8 Conclusion

In the mid-20th century there was a change in focus in Australia's public health policies from the social and environmental determinants of health to the use of vaccines, a medical intervention, as the main focus for disease prevention. This was in line with progress in scientific (western) medicine that considers most causes of infectious disease to be biological and initiated from within the individual. Consequently it has a narrower focus on etiology that discounts the influence of environmental, political and social causes of disease. The central aim of the scientific medical model of health is to reduce morbidity and mortality in the population by increasing the use of medical interventions. This is evidenced in the development of Australia's vaccination policies which show an increase in the number of vaccines recommended by the government, and an increase in coercive measures, as the threat from infectious diseases declined. When powerful associations

shape medical knowledge they can influence the behaviour of individuals in society through public health policies. In Australia the medical profession and the pharmaceutical industry have a major role in determining areas of health policy with limited input from other interest groups, particularly the public on whom this policy is enforced. This situation can result in the appearance of a scientific consensus on vaccination because these professional bodies can choose the research topics that will be funded. When evidence is selected to support a desired outcome in a health policy the status quo can be maintained. The political framework that enables evidence to be selected for government policies is described in chapter 8. This outcome is also achieved by the professional medical associations through the regulation of doctors' education and by the standards set through the *Good Medical Practice g*uidelines. Medical practitioners in Australia can be de-registered from the profession if they do not comply with the standards and regulations set by the Medical Board of Australia (MBA). This means doctors are not free to present their personal assessment of the risks and benefits of vaccination because their professional regulations require them to support government vaccination policies.

Vaccines were adopted as the primary preventative strategy for infectious diseases from the 1950's onwards. The sales of drugs and vaccines increased in the 1980's when the free market economic model was adopted in Australia even though the safety of many of these products had not been established in properly designed clinical trials. In this political model industry can provide financial incentives to doctors to increase the sales of their products. They can also provide sponsorship for doctors' education. When financial incentives are provided to enhance a doctor's livelihood the ethical guidelines for health promotion can be overlooked and this puts patient health at risk. Gaps may exist in the scientific knowledge that are essential to predicting health outcomes, yet these can be ignored if information is presented to doctors and patients in a selective manner or if conflicts of interest exist in decision-making boards. Doctors trust that they are getting a balanced education and in general patients trust the advice provided to them by doctors. Patients and doctors are dependent upon the information they receive to make an informed decision on a medical procedure. Consequently, maintaining patient autonomy and informed choice regarding medical interventions is fundamental to maintaining the health of populations. This is particularly important when the integrity of medical science, and sponsorship of education,

can be influenced by political and cultural factors. A policy that removes these values contravenes the guiding principles stated in the Seedhouse Ethical Grid for the promotion of health in the population.

Estimating the risk from an infectious agent depends upon the method of measuring disease burden in the community – case-fatality or incidence of the disease (see chapter 4). These methods are value-based and ethical guidelines imply that governments should seek the consent of the community before value-based interventions are implemented in public policy. When policies are presented in a benevolent manner, infringements on human rights can be overlooked if the community places unwarranted trust in the medical profession and the government. The public's interest in these policies should not be compromised by the economic or political interests of special groups. The Australian government has not provided adequate evidence for coercive measures in vaccination policies or that the recommended actions are proportionate to the risk of infectious diseases in Australia. These actions are also not included in any laws under Australian health acts. In addition, they are being implemented whilst the government states that vaccination in Australia is not compulsory. When certain political structures exist, governments can claim a procedure is safe simply because there is a *lack of evidence* for the public to prove otherwise. This is termed 'undone science' and the political structures that lead to areas of unfunded research relevant to public health policy are described in Part 2 of this thesis 'Corporate Influence and Undone Science in Public Policy'.

Part 2 Chapter Overview

The influence of corporations in the production and promotion of science is described in chapter 6 and a discussion of the government's claims about the safety and efficacy of vaccines is provided in chapter 7. In chapter 8 I describe the political framework that allows increasing areas of undone science to exist in the design of public health policy. Chapters 9 and 10 provide case studies of the HPV vaccine and the 'Swine Flu' 2009 vaccine to illustrate the influence of politics and corporations in the development of global and national vaccination policies. Chapter 11 provides the conclusions to this investigation.

Chapter 6 Conclusion
Chapter Title: Industry Influence in Research and Policy
Chapter pages:137-163

6.9 Conclusion

In the 21st century universities and research institutions are operating in partnerships with industry and directing research into profitable technology. Universities receive large amounts of money from industry that are not transparent to the public. COI are ubiquitous in financial relationships involving researchers in university faculties. Consequently industry has unprecedented influence over the type of research that is performed and the outcomes achieved. COI also exist in relationships involving the medical profession, media and government. These relationships play a significant role in the way drugs/vaccines are promoted to the community. When industry funds the research it leads to less public

interest science being investigated because it might not serve industry interests. This is termed ‘undone science’ and the political framework for this practice is described in chapter 8. Vaccines/drugs are being approved for the market without properly designed clinical trials. The side-effects of drugs are being down-played to doctors and consumers and the benefits are over-emphasised. Many peer-review journals now depend upon industry funding for their profits and this increases the publication bias towards positive trial results and the suppression of negative results. Pharmaceutical companies are also sponsoring lobby groups that appear to be advocating for consumer interests but in fact are fronts for drug companies. This influence synchronises with pharmaceutical marketing to doctors which is presented as ‘education’ and the media promotion of vaccines influenced by corporations. Consequently there is a systematic bias towards industry interests in medical research and public health policy and promotion.

A lack of acknowledgment by governments of an important area of research is easier to maintain if the stakeholder whose interests are affected is removed from the political decision-making process. This is observed in the development of Australia’s vaccination policies as the community is not consulted or encouraged to participate in public debate on vaccination and there is only one consumer representative on the government vaccine advisory committee (ATAGI). In addition, pharmaceutical representatives can be invited to ATAGI committee meetings to provide information but these meetings are not open to the public and the information is not available for public scrutiny before vaccines are approved. A lack of political power and financial support also has the effect of reducing the consumer voice in the mainstream media. These factors are synchronising to remove an independent consumer perspective from the risk assessment process of policy development. They are also resulting in non-transparent policy decisions being made by ATAGI/NCIRS members in an unsystematic assessment of the risks.

The lack of independent regulation of the global vaccine market is resulting in sub-standard vaccines. Vaccines are a global production and they can be automatically approved in many countries based on clinical trials that were performed in another country. Manufacturers in the US have less incentive to develop safe and effective vaccines because they are exempt from liability when harm is caused. This legislation ensures that there is a stable vaccine

market but it does not provide incentives to protect the health of the population. Government regulators in most countries are 100% funded by industry under a Cost-Recovery (User-Pay) system. This means they approve their sponsor's vaccines/drugs for the market and monitor these same products for safety and efficacy. In effect they are indirectly monitoring their own products. Large political donations from pharmaceutical companies are also being allowed to influence government policy. Funded lobby groups are targeting policy decision-makers, medical practitioners, educational boards and mainstream media with selective information. Vaccine advisory boards are rife with conflicts of interest, enabling industry to influence the direction of government funding in health policy research and policy decision-making. National vaccine advisory committees such as ATAGI have been established in many WHO member countries and they receive advice and financial support from the WHO in the development of national vaccination programs. Recommendations for new vaccines are not always founded on local data and cost-effectiveness is being determined using economic models that rely on non-transparent assumptions about the safety and efficacy of vaccines. Although the importance of vaccine-created herd immunity is used to promote vaccines to the community, the chairman of ATAGI for the last decade states that the implications for herd immunity for new vaccines are 'neither necessary nor sufficient for a positive recommendation for NIP suitability' (Nolan 2010 A79). This indicates that vaccines are being promoted to the community on a false premise that has serious implications for population health. Further, the cost-effectiveness of vaccines is being determined on evidence produced in clinical trials that are funded by pharmaceutical companies and carried out by researchers/chief investigators who are representatives on government vaccine advisory boards such as ATAGI and the NCIRS.

This arrangement is very profitable for universities, governments, researchers and representatives on vaccine advisory boards but it is extremely costly to public taxpayers and to population health. In 2008-2009 the cost of providing vaccines 'free' to Australians was well above $AU400 million (Nolan 2010 A76). However, the actual cost of these programs is unknown because the figures are not released to the public (even when requested) and they do not include the cost to the community of the deaths and disability that are a known side-effect of vaccines. This cost to the community is unknown because

the TGA has not established an active surveillance system that can make causal relationships to vaccines. A regulator that is 100% funded by industry has no incentive to accurately monitor the adverse events from its own products. This demonstrates the need for vaccination policies to be independent from commercial and political interference in order to protect public health. In Australia policy decisions for vaccination programs are based on research (often unpublished) that is performed by government representatives on vaccine advisory boards who receive honoraria and funding for their clinical trials from pharmaceutical companies. The findings from such research are being used in policy decisions for vaccination programs without public scrutiny or assessment by independent researchers.

In chapter 7 I discuss the evidence the Australian government is providing to the public to support the claims about vaccine safety and efficacy. Chapter 8 presents a description of undone science and the political framework that leads to a lack of integrity and rigour in medical science. Chapters 9 and 10 are case studies of the HPV vaccine and 'Swine Flu' 2009 vaccine, showing the influence of corporations in the development of global vaccination policies. Chapter 11 presents the conclusions for this investigation.

Chapter 7 Conclusion
Chapter Title: The Evidence Underpinning Claims about Vaccines
Chapter pages: 164-194

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 polices even though the underpinning science is incomplete. Chapter 11 presents the conclusions to this investigation.

Chapter 8 Conclusion
Chapter Title: Politics and Undone Science in Public Policy
Chapter pages: 195-216

8.11 Conclusion

Undone science is the research that is not carried out because the likely results would be unwelcome to powerful groups. When areas of science are not funded, policies can be designed on incomplete knowledge and result in unpredictable health outcomes in the population. This is because there are gaps in the scientific knowledge that underpins the value judgments that are made in policy decisions. Government policies that are designed on incomplete scientific knowledge may not protect the public interest. Areas of undone science have expanded in the era of globalization because industry is influencing the research agendas of both governments and research institutions. This is a consequence of industry being in partnership with universities and being the main sponsor for many private research institutions. In addition, government funding agendas have aligned with industry goals because the dominant network of scientists is influential on government advisory boards. A shift to industrial sources of funding for scientific research is also achieved when there is increased scope for the patenting and licensing of scientific discoveries. These developments lead to increased conflicts of interest in the production of scientific knowledge and in the design of public health policy, along with a lack of transparency. They also have the effect of reducing government emphasis on public interest research and increasing the pockets of undone science in different fields of science.

In Australia the federal health minister receives advice on vaccination policies from technical experts without consultation with the community. The institutional barriers that exist in the Australian political system and in academic and media organizations have resulted in the marginalisation of the public's contribution to vaccination policy, even though the public is a main stakeholder in these policies. The Australian government justifies current vaccination policies by claiming, in effect, there is no evidence of harm so therefore no action is required. However, this claim ignores the lack of evidence due to research that has not been funded. The undone science in Australia's vaccination policies includes comprehensive RCT's for the efficacy and safety of vaccines, either singly or in the combined schedule of vaccines in animals and humans. In this situation it becomes necessary for the public to have influence in the decision-making process to ensure that all relevant research is undertaken and accounted for in policy decisions.

The lack of integrity and rigour in the clinical trials and scientific research that is being sponsored by industry for global health policies was discussed in chapters 6 and 7. In chapters 9 and 10, I have provided case studies illustrating the undone science and industry influence in the promotion of global HPV vaccination programs and the pandemic 'Swine Flu' 2009 vaccine. These case studies illustrate how vaccines can be developed and policies implemented on incomplete science due to the political framework that results in undone science.

Chapter 9 Conclusion
Chapter Title: Case Study: The Human Papillomavirus Vaccine (HPV)
Part 1 HPV and Cervical Cancer Pathogenesis
Chapter pages: 217-257

9.15 Conclusion to Part 1

The promotional campaigns for HPV vaccine misrepresented the risk of HPV infections and cervical cancer to women in different countries. This was done in order to create a market for the vaccine. Currently the benefit of HPV vaccines against the burden of cervical cancer is unknown and the risk of injury or death associated with the vaccines has not been accurately determined in different populations. Universal HPV vaccination programs that target infection from HPV 16 and 18 are not beneficial to the majority of women in developed countries because these infections will not progress to cancer without specific environmental and genetic factors (risk factors) also being present. HPV infections do not progress to carcinoma in the majority of cases and there are currently 13+ oncogenic strains of HPV that the vaccine does not protect against.

HPV vaccines are not demonstrated to be safer or more effective than Pap screening combined with surgical procedures. Hence it follows that implementing broad HPV vaccination programs is not necessary or cost-effective because Pap screening programs

combined with surgery are the most effective prevention and are still required by vaccinated women. HPV vaccines are offering uncertain benefits in reducing the burden of cervical cancer and may cause more harm than good due to the lack of investigation of their long-term safety.

Chapter 9 Conclusion
Chapter Title: Case Study: The Human Papillomavirus Vaccine (HPV) Part 2 Undone Science in HPV Vaccination Programs
Chapter pages: 258-268

9.20 Conclusion to Part 2

It is important that comprehensive research on the safety and efficacy of drugs is completed prior to their implementation. When crucial research is left unfunded, policy decisions are founded on incomplete evidence (selective science). In addition, it is essential that any research that is performed and funded by industry is open to assessment by independent scientists before the conclusions are accepted in public health policies. Research that is performed by scientists with ties to industry may result

in biased results and this has significant implications for population health when the findings are recommended to policy advisors by representatives who also have financial ties to industry.

Hidden COI in all areas of research and policy development are institutional barriers that prevent the government from being accountable to the public. This is because industry agendas influence the research and industry employees double as representatives on government and professional decision-making bodies. Ultimately, the price that is paid for adopting private-public sponsorship of global health policies and the academic-industry model for research institutions is an increased risk to the health of populations because the profit motive contaminates the search for knowledge. This health model is a faith-based system and not an evidence-based system because it is dependent upon trade secrets and political decisions that are based on biases that are not transparent to the public.

10.13 Conclusion

The 'Swine Flu' pandemic of 2009 was declared by a secret WHO committee that had ties to pharmaceutical companies that stood to make excessive profits from the pandemic. This situation was facilitated by the lack of effective regulations and transparency regarding COI, within the WHO and national governments, to prevent pharmaceutical companies from exploiting global health policies to their advantage. The pattern of this pandemic was similar to that of the 'swine' flu pandemic of 1976 which also did not eventuate. Scientists are using industry funded research to predict the occurrence of influenza pandemics and these are based upon questionable premises and assumptions linked to the profits that can be made if a pandemic is declared. Under the influence of GAVI significant changes were made to the governance of global health policies through the implementation of the International Health Regulations (IHR) in 2005. These changes required all WHO member countries to increase surveillance systems for *all* infectious diseases to create extensive national surveillance systems: not just at the entry and exit points for countries. GAVI/WHO also spent 10 years developing Pandemic Preparedness Plans (PPP) with all member countries to ensure that if a global pandemic was declared all countries would be required to buy vaccines at prices that were set in 'silent contracts'. By 2005 nascent technologies had enhanced the surveillance of diseases by enabling greater sub-typing of infectious agents. Whilst increased surveillance of a disease can give the *appearance* of a greater risk due to more cases, this is not always the case. For many diseases, such as influenza, the majority of cases are mild and without complications, and would otherwise have gone unnoticed. This risk assessment of disease incidence and severity needs to be characterised for each disease because it is the *severity* of a disease and not the *incidence* that presents a risk to population health (Burnet 1956; Cumpston 1989). This characteristic of risk assessment for infectious diseases was discussed in chapter 4.

Influenza is a common respiratory virus that mutates regularly. Whilst a new strain of virus *ma*y be more virulent it is important to establish the risk prior to introducing a new vaccine because vaccines themselves produce a risk to individuals and the efficacy and safety of influenza vaccines are still being debated. The interpretation of the PP used in government policies is a political decision that is linked to the desired outcomes of the policy. An interpretation that does

not put the onus of proof on the proponent does not protect the public interest in health policies. The information about the risks of vaccines is significant to public health but it is not communicated to the public by governments or the mass media. In the case of the 2009 ‘Swine Flu’ pandemic, a level 6 pandemic could not have been declared if the WHO secret Emergency Committee had not been given the power to change the definition of a pandemic. This power was given to the EC by the European Scientific Working Group on Influenza that was 100% funded by industry. Public health is at risk if authorities and the media are not accurately informing the public about the risks of both diseases and vaccines. For many diseases increased surveillance results in a large number of identified cases that do not present a greater threat to public health. This was the case for the increased surveillance of ‘Swine Flu’ in 2009 and it resulted in an excessive waste of government funds and endangered public health.

Chapter 10 Conclusion
Chapter Title: Conclusion
Chapter pages: 294-307

11.4 CONCLUSION

In chapter 1 I stated that the aim of this thesis is to examine the following claims made by the Australian government (section 1.3):

1. Vaccines are *proven* to be a safe, effective and necessary management strategy for infectious diseases and
2. The benefits of vaccines to the community far *outweigh* the risks of vaccines to individuals and population health.

This thesis has demonstrated that there is inadequate evidence from independent studies to support these claims about vaccines.

Claim 1: Most mass vaccination campaigns were introduced into developed countries after 1950 in an attempt to *eliminate* infectious diseases, not because infectious diseases were a serious risk to the majority of Australian children. In addition, many vaccines were introduced after 1980 on a directive from the WHO at a time when infant mortality rates and the risk of infectious diseases in Australia were very low. There is a lack of evidence to support the claim that vaccine-induced herd immunity can eliminate infectious diseases. The Australian government has not provided evidence from formal controlled clinical trials that demonstrate the efficacy of vaccines in preventing disease nor has it provided transparent, independent data on the vaccination status, socioeconomic status, and severity of reported cases of disease that would demonstrate the influence of vaccines in preventing disease.

There is a lack of evidence to claim that vaccines are a safe and effective management strategy in diverse genetic populations because the appropriate scientific studies have not been funded to determine the types and frequency of adverse events that are occurring in different communities.

Claim 2: The government's claim that the benefits of vaccines to the community far outweigh the risks of vaccines to individuals cannot be sustained because the government has

not established an active surveillance system that can provide data on the long-term health effects of single or multiple vaccines in the Australian population. The correlation between the increased use of vaccines in the NIP and the significant increase in chronic illness in children has not been acknowledged or investigated by the Australian government. Furthermore, the Australian government claims that the benefit of using vaccines is to create herd immunity to protect the community. Yet the criterion for recommending a vaccine for approval in the NIP does not include the necessity to demonstrate that the vaccine has implications for herd immunity in the population (Nolan 2010 A79).

Summary:

The undone science in Australian government vaccination policies results in unpredictable health outcomes in the population. It needs to be acknowledged by the Australian government that increased morbidity in the Australian population is a possible outcome if vaccination policies are being implemented on a lack of comprehensive scientific evidence. Infectious diseases had declined in severity in Australia before most vaccines were introduced. Vaccines were not introduced to reduce the deaths and illness due to infectious diseases but to see if they could be *eliminated.* Infectious diseases were re-labeled *vaccine-preventable diseases* to imply that vaccines are the key to preventing disease, which contradicts the historical decline of infectious diseases. The contribution that vaccines may have made to the decline of infectious diseases is unknown because there has been no systematic assessment of their efficacy in preventing disease. Australian government vaccination policies have been founded on global directives from the WHO/GAVI that were designed by an alliance with industry. They have not been recommended as a result of an independent assessment of the need for vaccines in the ecological context of Australia. This is significant because environmental and host characteristics play a role in disease expression. Infectious agents on their own do not cause disease and this explains why many infectious diseases are not severe in countries with improved environmental and social conditions. The Australian government has not provided a risk/benefit assessment for each vaccine in the Australian context to support the claims that are made in vaccination policies.

Finally it must also be acknowledged that industry influence is pervasive and is affecting research findings as well as the research topics that are being investigated and the decisions being made in policy. Undone research in the government's vaccination policies includes the absence of studies of vaccination by scientists who are completely independent of industry

influence. In addition, decisions are being made by policy decision-makers with COI with industry that are not transparent to the Australian public, even if they are required to be declared before a meeting. The public is also not informed that directives for Australia's public health policies are provided by the WHO/GAVI alliance that includes partnerships with pharmaceutical companies. This synchronises with government vaccine advisory boards that do not have adequate representation of public members to present the public perspective in these policies. In this situation, the public is left to trust that officials are using evidence that is produced with integrity and rigour to develop policies that protect the public interest. Biomedical research produced in academic/industry research institutions contains trade secrets that prevent collaboration and an independent assessment of the science. There is also a lack of independent studies to assess the accuracy of the conclusions that are drawn. This leads to institutional biases in the political decisions that are made in national and global public health policies. Government policies are being promoted to the public in the interests of the community yet they are being designed and driven by industry interests. This misleads the public and endangers public health. Governments are also informing the public that they should seek their advice on vaccination from medical practitioners. Yet health professionals are unable to speak freely about the risks and benefits of vaccines because they are required to support government vaccination polices for their professional registration.

These conclusions emphasise the need for maintaining voluntary participation, without coercion, in public health policies that include a medical intervention. This is particularly the case for preventative health policies that promote a medical intervention to *healthy* individuals. Healthy communities are achieved by increasing individual autonomy, that is, the individual's right to choose how they care for their own bodies in the prevention of disease. This prevents indoctrination and it must be respected and promoted in public health policies to ensure that better health is the primary outcome of these policies.

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