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Misapplication of the Precautionary Principle has Misplaced the Burden of Proof of Vaccine Safety

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Abstract
Vaccination is a medical intervention that comes with a risk for some people. In the expression of infectious diseases, it is known that the pathogen alone does not cause disease: it is a combination of the pathogen, environment, and genetic factors that determines expression and severity of the disease in individuals. In 1960 Macfarlane Burnet, Nobel Prize laureate for immunology, stated that genetics, nutrition, psychological and environmental factors may play a more important role in resistance to disease than the assumed benefits of artificial immunity induced by vaccination. He considered that genetic deterioration of the population may be a consequence of universal mass vaccination and he postulated that in the long-term vaccination may be against the best interests of the state. The current belief that much of the burden of infectious diseases can be alleviated if every child, in every geographical location, has access to multiple vaccines, does not consider the influence of genetics and environment on the health of populations. The historical record shows that deaths and illnesses to infectious diseases fell due to public health reforms – and prior to the introduction of most vaccines. Since 1990 there has been a 5-fold increase in chronic illness in children in developed countries and an exponential increase in autism that correlates directly with the expansion of government vaccination programs. Many individuals are genetically predisposed to the chronic illnesses that are increasing in the population and since 1995 governments have not used mortality or morbidity to assess outcomes of vaccination programs. Human health can be protected in government policies if the precautionary principle is used in the correct format that puts the onus of proof of harmlessness on the government and pharmaceutical industry, and not the general public. This has not been done in current vaccination programs and we cannot rule out the possibility that the increased use of vaccines is destroying the genetic fabric of society as MacFarlane Burnet postulated.

Keywords
vaccine safety, comorbidity, fatality, impact, regulation

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Editor-in-Chief, **James Lyons-Weiler**

1. Introduction

The focus of this paper is to examine the historical evidence for the control of infectious diseases and to describe the changes in health outcomes that have occurred in all populations concurrent with the increased use of vaccines. The decline in health that is being observed is discussed with respect to governments' use of the precautionary principle to show that its use in the correct format is critical to protecting public health.

2. Causality Inference Unsupported

When the World Health Organisation (WHO) and governments claim that vaccines are 'safe and effective' this claim is based on a lack of scientific evidence because they have never performed the empirical causal study that would prove or disprove the direct link that we are observing, in all countries, between the significant increase in chronic illness in children and the expanding vaccination program [1][2][3]. This causal study would use an inert placebo in the unvaccinated group to provide empirical evidence of the effects of the vaccine /combination of vaccines on the human infant, but such a study has never been conducted [4]. This evidence could also be collected from active surveillance systems that monitor adverse health events of all vaccinated individuals for 5-10 years. But these monitoring systems have also never been implemented [4]. Further, the WHO and national governments have never tested vaccines, even the vaccines with a long history of use, in formal controlled clinical trials to demonstrate with empirical evidence that the vaccine can prevent the vaccine-targeted disease [5]. This is significant because governments routinely use the term 'vaccine-preventable diseases' to imply that vaccines can prevent disease.

3. Reliance on Proxy Outcome Measure

Instead of studying the effects of vaccines on detectable infection rates, studies use the surrogate of seroconversion (antibody titre) to claim that vaccines can prevent infectious diseases. Titres are known to not be a reliable indicator of protection from the disease [5][6][7]. This does not suggest that vaccines do not have any benefit in reducing the transmission of the disease in the community, only that it is not accurate to describe these diseases as "vaccine-preventable diseases" when this criteria has not been proven by governments.

Stanley Plotkin described as the 'father of world vaccinology', states that it is not possible to rely on the antibody titre that is considered suitable to confer immunity for measles because it is not known [8]. He also states that antibody titre is not a reliable indicator because we do not know precisely how antibodies work. In other words, without the empirical clinical evidence from controlled clinical trials to demonstrate that *vaccine-induced* (artificial) antibody titre is *protective* against each infection, we cannot claim that vaccines are effective in preventing them.

It is known that antibody sero-conversion is achieved by natural exposure to the infectious agent, with or without clinical symptoms. Cases without symptoms are referred to as asymptomatic infections (sub-clinical infections) and they result in long-term immunity in contrast to the short-term immunity obtained after a vaccine [6][8][9]. Plotkin also admits that some vaccinated individuals are still being diagnosed with vaccine-targeted diseases after they are vaccinated and they can spread these diseases even if asymptomatic - *'The possibility that a subclinical infection or paucisymptomatic infection (a few symptoms) with measles virus occurs in vaccinees must be considered'* [8].

4. Precautionary Principle Misapplied and Burden of Proof

Government vaccination programs are now recommending up to 16 vaccines for children (>52 doses from 0-14 years old). Yet the claims made by the WHO and governments about the safety and efficacy of the program are not evidence-based due to a lack of sufficient empirical evidence. It is incumbent on the proponent of this medical procedure, *the WHO and governments*, to provide the evidence that this program is safe and effective, not the general public upon whom the policies are enforced. This is because governments have a duty of care to promote healthy outcomes in government health policies and this can only be done if a medical procedure is proven not to cause significant harm in the population before it is implemented [10] .

This is implied in the precautionary principle (pp) when it is used in the correct format in decisions for government health policies. The risk to human health that current vaccination programs represent has arisen because the precautionary principle has not been applied in a manner that would protect human health in the design of government vaccination policies. In order to protect human health, the PP should be used in the format that states that the onus of proof of harmlessness of any medical intervention is on vaccine proponents, and *not the general public* [10]. When used in this format the PP will protect human health in government policy. This is because the government is required to provide sufficient evidence to make causal inference on the question of whether the combined schedule of 16+ vaccines is, or is not causing the chronic illness that we are seeing escalate in children *before* they recommend or mandate this program for children. Instead, safety is presumed, out of concern for instilling doubt in the publics' mind about vaccines, and retrospective studies are used to assess safety *after* the vaccines are unleashed upon the public. The reversal of the PP in the design of these programs places the burden of proof of harm, in individual instances, *on the general public*. This is logically equivalent to placing the burden of proof of harmlessness on the public. In this format it allows public health authorities and doctors to ignore the empirical evidence of chronic illness that is *increasing* in children in direct correlation to the increased use of vaccines.

Governments and doctors today claim this association is a 'coincidence' and that vaccines are 'safe and effective' by ignoring evidence supportive of plausibility of a causal relationship between vaccination and chronic illness in children and by not investigating this relationship in controlled clinical trials.

When the precautionary principle is reversed to put the burden of proof of harmlessness on the general public, instead of the pharmaceutical companies and governments, then it can be used to protect the vested interests of industry in government vaccination policies and not the health of the general public.

The current alignment in misuse of the precautionary principle can be expected to lead to the perceived need for enforced policy due to the reliance on uninformed or misinformed regulation of vaccines (Figure 1). An appropriate application of the precautionary principle could be expected to reduce resistance to vaccination due to transparency, informed regulation and respect for informed consent (Figure 1).

Vaccination is a medical intervention that comes with a risk for some people. When adopting a strategy to prevent infectious diseases it is important to choose the preventative measure that best addresses the causal mechanisms for the disease. In the expression of infectious diseases in humans it is a combination of the agent, environment, lifestyle and genetic factors that determines the severity of the disease. There is a wealth of data showing that environmental factors are the primary determinants of health and infectious disease [7][9][11][12].

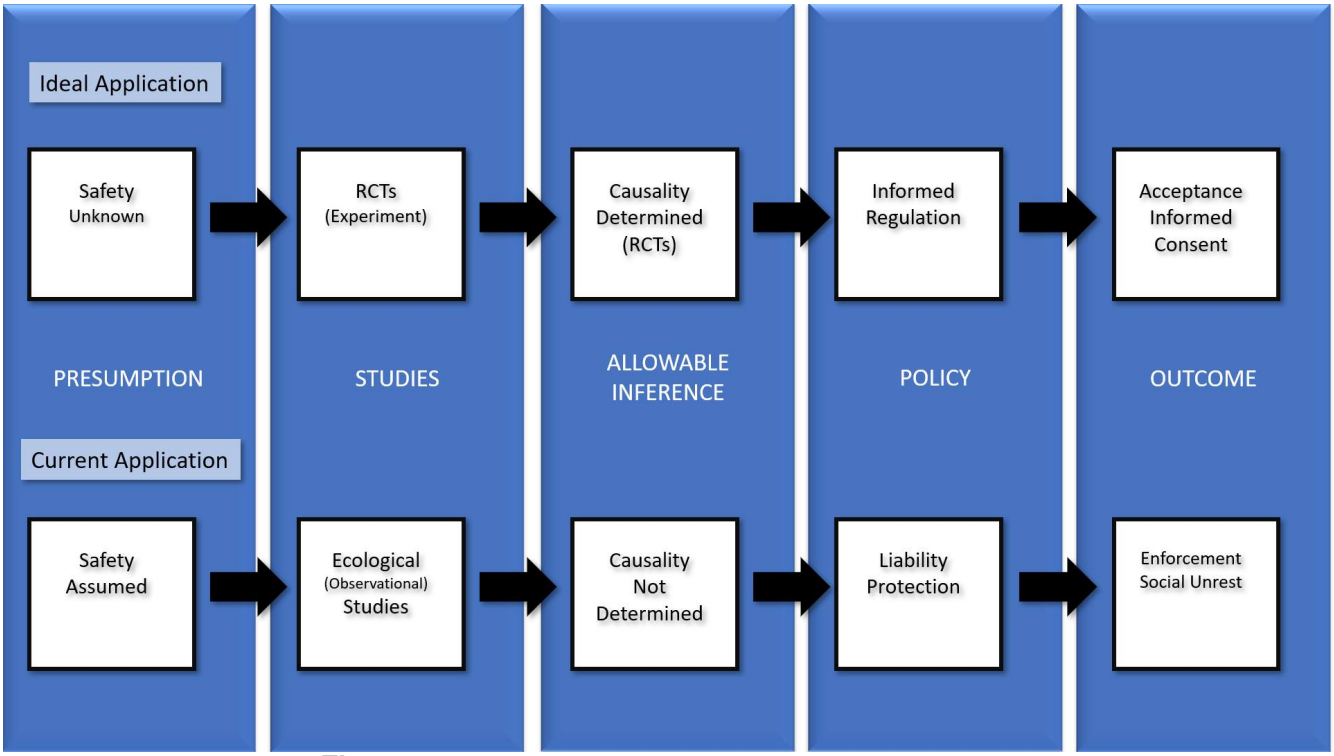

Figure 1. Ideal and Current Regulatory Process Flows

A public health policy that does not include these causal factors in the solution, and relies solely on vaccination that does not address these causal factors, will not produce healthy outcomes in communities.

5. Complex Causality

In 1960 Frank Macfarlane Burnet received the Nobel Prize for immunology. He stated that genetics, nutrition, psychological and environmental factors may play a more important role in resistance to disease than the assumed benefits of artificial immunity induced by vaccination [13]. He considered that genetic deterioration of the population may be a consequence of universal mass vaccination and he postulated that in the long-term vaccination may be against the best interests of the state. The current belief stated by the Global Alliance for Vaccines and Immunisation (GAVI), an alliance that advises the WHO on global vaccination programs, is that much of the burden of infectious diseases can be alleviated if every child, in every geographical location, has access to multiple vaccines [12].

However, this claim does not consider the influence of synergistic toxicity of vaccines, genetics, lifestyle and environment on the health of populations. Since 1990 there has been a 5-fold increase in chronic illness in children/adults in highly vaccinated populations and an exponential increase in autism that correlates directly with the expansion of government vaccination programs [1][2][3][4]. This chronic illness includes childhood cancer, autism, autoimmune diseases, hypersensitivity (allergies), anaphylaxis, seizures, and behavioural and learning difficulties. Is this the genetic deterioration of the population that Macfarlane Burnet predicted in 1952? Vaccines contain foreign DNA from the attenuated/inactivated or genetically engineered pathogens (virus-like particles) plus foreign animal and/or human DNA derived from the manufacturing process. There are two well established pathologies that can potentially develop from injecting children with DNA contaminants such as human foetal cells in the MMR vaccine or animal DNA, such as calf, chicken or monkey, in other vaccines [14]. These mechanisms include insertional mutagenesis in which the human foetal DNA inserts

into the child DNA causing mutations that can lead to cancer and other diseases, and autoimmune diseases that are triggered by the human foetal DNA used in the manufacturing process of vaccines.

Autoimmune diseases cause the child's immune system to attack his or her own body. This leads to diseases such as childhood rheumatoid arthritis, diabetes, hypersensitivity, allergies, anaphylaxis, autism, Crohn's disease etc – all of which are escalating in children in countries with high vaccination rates. These are diseases that are also listed by the pharmaceutical companies as being associated with vaccines for decades [4]. There is also significant research linking vaccines as a plausible cause of this chronic illness [4][14][15][16]. All of these chronic illnesses have escalated in children since the expansion of the vaccination programs in 1990, and even though vaccines are demonstrated to be a plausible cause of this decline in health governments have not investigated this correlation to the childhood vaccination program with causal science.

This is despite the strength of an association, such as, in individual cases, satisfaction of all of Hill's causality conditions possible given the setting and additional strong evidence such as a linear dose-response relationship [9], being consistent with cause and effect. Further, if vaccination policies are to truly protect human health, governments would be promoting vaccination programs on studies that demonstrate an improvement in children's health outcomes. But they cannot do this because children's health has significantly declined with the expansion of this program. How can this be called a 'health policy' when children's health is declining?

6. Inconsistent Evidence on Efficacy

It is also noted that developing countries have had mass vaccination programs for many decades, yet infectious diseases are still predominant [12]. In addition, individuals are not equally susceptible to all diseases or infectious agents [9][13][17] and there is a range of outcomes that can occur after infection. These include no symptoms at all (subclinical infections that are asymptomatic), mild, severe or death. Focusing on the overall incidence of infectious diseases, such as whooping cough and measles, by publicising every case, does not inform the public of the risk of the disease in the community. That is, the deaths and serious illnesses occurring due to these infections. In all developed countries public health reforms, nutrition and smaller family sizes resulted in mostly non-serious cases of measles after 1950 even when measles infection rates were high [13][18][19][20]. Death and serious disease from measles infection were extremely rare after this time. Measles has not been a significant risk to children in Australia since 1950 and this cannot be due to vaccination because a vaccine was not introduced into voluntary vaccination programs in Australia until after 1969 [21] [22]. The Commonwealth of Australia Director General of Health (1913-1945) stated the decline of infectious diseases in Australia occurred at the same time as the period of sanitary reform and prior to the introduction of most vaccines [23]. Another prominent public health authority claimed in 1956 that *'pertussis (whooping cough) was an uncommon cause of death for children and there is a significant decline in mortality if the age of infection increases'* [24][25]. Whooping cough was removed from Australia's national notifiable disease list (with measles and influenza) in 1950 and its decline cannot be due to a vaccine because it was not introduced into voluntary vaccination programs until 1952 in Australia [21]. It is also observed that whooping cough, measles and mumps are common in highly vaccinated populations [22].

Many infections from an agent (virus/bacteria) are subclinical which means they do not produce any signs or symptoms, but they still confer immunity to future infection [9] The vast majority of cases of measles and whooping cough, in infants over the age of one year, in developed countries are non-serious cases of disease. They are self-limiting and the child will receive long-term immunity from this natural infection. This is how herd immunity was originally established [9]. Stewart confirms that notifications are an incomplete indicator of prevalence and they are not an indication of the severity of the disease in the population [26]. Hence, publi-

cising each case of these diseases in the media as if every case is a public health emergency is not informing the public of the lack of severity of *most of these cases* in developed countries. This is the reason that the Australian government took whooping cough, measles and influenza off the national notifiable disease list in 1950 and there was no vaccine for these diseases at this time. These diseases were no longer considered of serious concern in the majority of cases in developed countries after this time even though they were still present.

Burnet stated that the risk of infections such as pertussis (whooping cough) and measles to the community can only be determined by examining the age-incidence of death and illness, not the overall incidence of the disease in the population. This is because these diseases are mainly severe in children less than one year of age [13]. It is also recognised that case-fatality rates will vary greatly in different investigations because of the different criteria that can be used in diagnosing and reporting diseases and death [13]. This information is not made transparent in the statistics that are used by health departments and the media to promote vaccines to the public in 2020.

Currently media reports of cases of whooping cough, measles and other infectious diseases are being used to encourage the *assumption* that a high incidence of these cases results in high mortality and morbidity in the community. This assumption is incorrect. Most cases (99%) of these diseases in developed countries are *non-serious cases* and would otherwise go unnoticed and provide long-term immunity in the individuals if they were not reported. Media articles that report these non-serious cases of disease without reporting the vaccination status (or severity) leave the public to *assume* that the cases are all occurring in unvaccinated people. This assumption is also incorrect. Many vaccinated children/adults are still getting these infectious diseases [7][8]. This contradicts the claim that vaccine-created herd immunity can prevent infectious diseases. Significant outbreaks of infectious diseases in highly vaccinated populations are evidence that vaccine-created herd immunity is not supported by the evidence.

The GAVI alliance that advises the World Health Organization (WHO) on which vaccines to recommend in government programs, has been criticised for focusing on vaccination to control infectious diseases. This focus has been described as a major flaw in public health policy because it is driven by major financial inducements and not the evidence of healthier outcomes in communities [27], This focus by GAVI for public health policy is in contrast to the focus of field workers, European donors and governments of developing countries. These groups do not prioritise vaccines in public health policy because they do not believe that this is the best strategy for achieving healthy outcomes in the developing world [27]. Chronic illness in all countries is increasing with the increased use of vaccines and there are still outbreaks of infectious diseases even in highly vaccinated populations. The risk of death from infectious diseases was reduced in developed countries *before* the vaccines were introduced and therefore it is necessary for governments to provide the annual statistics of the number of these cases that are occurring in vaccinated people to demonstrate the claim that vaccines *can prevent* these diseases in the majority of cases.

7. Herd Immunity

Vaccine manufacturers and governments also do not provide sufficient evidence that vaccines can create herd immunity in the population. Yet they are promoting infectious diseases as 'vaccine-preventable' diseases and claiming that the vaccines create 'herd immunity'. Governments are recommending vaccines in coercive and mandatory programs without providing sufficient empirical evidence [28], a result of the misapplication of the precautionary principle (Figure 1). Mandatory vaccination policies are being promoted to the public based on the concept of creating herd immunity without any evidence to support this theory. The term 'herd immunity' was first used with respect to the creation of immunity by natural exposure in communities through asymptomatic and mild infections [9][29][30].Health departments and the GAVI/WHO are only theorising that vaccines can also create herd immunity because

vaccine manufacturers have not provided this evidence.

There are several reasons why vaccines may not be able to achieve herd immunity. Firstly, there can be more than one strain of an organism that causes the disease which may not be included in the vaccine [8][29][31]. These strains also mutate from year to year, or the vaccine may select for strains not adequately targeted by the antigen source in the vaccine. Secondly, humans may not be the only reservoir for the disease. The virus/bacteria may be found in other animals therefore transmission is not always interrupted by vaccination programs [9]. For example, strains of whooping cough (pertussis) are also found in dogs. These criteria contradict the government's claim that all vaccines can create herd immunity. This is significant because the government uses the claim of 'vaccine-created herd immunity' to promote vaccines and to state that it is everyone's responsibility to vaccinate to protect the community. Further, vaccines are not protective for a proportion of the population due to their genetics. Many people are pre-disposed to chronic illnesses due to the influence of vaccine components on their genetic make-up. Hence, vaccines will cause an unknown number of adverse health outcomes in the population because governments are ignoring the science of epigenetics and are not systematically monitoring the health outcomes of vaccination programs to determine the frequency of adverse events to vaccines.

The claim that vaccines can produce herd immunity in populations is only an *assumption* by the GAVI alliance: an alliance that includes the Federation of Pharmaceutical Companies and many other corporations that profit from vaccines [32]. When health needs are determined by outside experts, they do not always fulfill the needs of the community [33]. The targeted vaccination levels of 80-90% that governments are recommending are also assumptions that have been accepted by the community on faith and not empirical evidence [29] (p158). Further the duration of immunity should also be considered in the decision to mandate vaccines in the community. Natural infection with measles and whooping cough produces long-term immunity [8][34] and the risk of death and serious illness from these diseases were reduced in developed countries by 1950/60, before vaccines were introduced. This was a result of the improvements to the environment and lifestyle from political and economic decisions that reduced the virulence of these infectious agents:

8. Risk Due to Population-Wide Vaccination Strategy

It is unnecessary and harmful to vaccinate every individual because not everyone has the same risk of getting these infectious diseases even if they are infected by the agent [34][9]. This is a key factor to consider when the vaccines that are being used to mitigate the risk also carry a serious risk of death or chronic illness for many people due to their genetics. This fact will undermine the genetic fabric of society if all individuals are vaccinated. This is a form of artificial selection on humans with unknown consequences. Further, natural infections in children over one year of age are essential for priming all parts of the immune system to function properly and to provide better community protection through long-term immunity [13][29].

In addition to the foreign animal and human DNA there are many chemicals in the vaccine carrier that the public is not informed about. These chemicals are referred to as 'excipients' because they are not active components of vaccines in inducing immunity. Whilst an excipient is defined as a 'non-active component' the chemicals in the vaccine carrier do react in the human body and they are a plausible cause of the chronic illnesses that we are seeing increase in populations.

Examples of these chemicals are the neurotoxins, aluminium and mercury. Mercury is present in some vaccines in the form of thimerosal and it has not been removed from all childhood vaccines [35][36]. Genetic predisposition alone should prevent any vaccine from being coerced or mandated in genetically diverse populations. When the mitigating preventative measure involves a medical intervention that is associated with serious adverse health outcomes in some people, including death,

it is against the tenets of good medical practice and ethics to provide financial incentives to medicate healthy people with this intervention [37][38]. The guiding principles set by the Australian Medical Association (AMA) state that doctors must put their patient's best interest first and that they will not use their medical knowledge to breach human rights [39]. These principles have been set by the World Medical Association (WMA). Health is not promoted in communities when doctors and health professionals do not have autonomy in the medical advice that they provide to patients [40]. Governments claim current vaccination policies promote 'health' in the community, but they do not evaluate or promote these policies on evidence of *improved health outcomes* in the population. Prior to 1995 the surrogate of age standardised infant mortality rates was used as an indicator of the health status of communities. This was an inadequate way of determining the health of communities as there are many aspects of health that are difficult to measure. This includes disability, pain, chronic illness and mental well-being. However, it was a useful measure of health in the first part of the twentieth century when infectious diseases were prevalent, and children were dying from these infectious diseases. After the risk from infectious diseases had declined by 1950/60, infant mortality rates were no longer the best measure of the health of communities. By the 1990's it was observed that infant mortality rates in countries that use the highest number of doses of vaccines were increasing in a direct dose-response correlation with the expanding vaccination program. For example, the US specified 26 doses of vaccine for infants less than one year of age in 2011 yet 33 developed nations had lower infant mortality rates than the US and they used less doses of vaccine. Linear regression analysis showed a high statistically significant correlation between increasing number of vaccine doses and increasing infant mortality rates, particularly between nations giving 12-14 vaccines (Japan and Sweden) and those like the US and Australia who give 24-26 vaccines in the first year of life [40]. Miller also found a dose-dependent association between the number of vaccines administered simultaneously in one visit and the likelihood of hospitalisation or death from an adverse event (AE): the younger the age the more likely the occurrence of a significant AE [41]. Governments have not used infant mortality rates to assess the outcomes of vaccination programs since 1995 [42] (p11). After this time, vaccines were promoted on the need to raise the vaccination rate to 95% to establish vaccine-created herd immunity. However, governments do not have to provide evidence that a vaccine can create herd immunity to get it listed on the government recommended program [28]. Consequently, many vaccines have been mandated for children in Australia that have never been used by adults and were clearly not responsible for controlling the diseases with a 95% uptake by 1950/60.

9. Back to Evidence (3)

The fact that governments have never used health outcomes of children to evaluate and promote vaccination programs means there is no causal-level evidence to support claims that vaccination programs are promoting health in the community. These programs are not being evaluated or promoted on health outcomes. They are being promoted on the *assumption* that a 95% uptake rate of each vaccine results in healthier communities. There is no scientific justification for this uptake rate or evidence that communities are healthier when it is achieved. The evidence of children's health since 1990 in all countries demonstrates health is declining in direct correlation to the government's expanding vaccination program. A government that does not investigate this direct dose-response correlation, a significant indicator of causality, and other evidence consistent with causality, before claiming the vaccination program is safe is experimenting on the entire population without informed consent, and is committing a crime against the population.

10. Conclusion

The deterioration of the health of populations is not being associated with the increased use of vaccines because governments do not systematically

monitor vaccinated populations with active surveillance systems for 5-10 years. They also do not use: i) inert placebos in the clinical trials for safety ii) acknowledge the mechanisms by which vaccines can cause these chronic illnesses iii) investigate the direct-dose response correlation to chronic illnesses or iv) acknowledge parents' evidence of vaccine injury. Many of these illnesses/deaths have been linked as being associated with vaccines for over six decades, as reported on pharmaceutical package inserts. Government policies that allow unsupported claims of the benefits and risks of vaccines due to a lack of scientific evidence are unfounded. Coercive and mandatory vaccination policies may be a threat to the genetic fabric of human populations due to our genetic diversity. Human health is at serious risk whilst ever governments do not apply the precautionary principle in a manner that renders public health programs capable of protecting human health. The proper application would cause the burden of proof of harmlessness to rest with pharmaceutical companies and governments, not the general public. This will result in the protection of human health in government policy and not the vested interests of pharmaceutical companies and others with a financial interest in promoting vaccines.

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