VACCINE CHOICE CANADA
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Position Paper
COVID Vaccine Injury Accountability and Compensation

Overview

In response to the public's legitimate concerns pertaining to the safety of the rushed-to-market COVID vaccines and the 'interim use' authorization granted by Health Canada prior to the completion of Phase III safety trials, the Government of Canada announced its intention to create a national vaccine injury compensation program.

While the members of Vaccine Choice Canada fully support and have long advocated for a system of compensation for Canadians injured and killed by vaccine products, we declare that we have significant reservations with a system of compensation that is not also a system of accountability.

With regards to facilitating compensation for vaccine injuries and deaths, Canada is more than three decades behind other countries. Of the G20 Nations, there are only two nations remaining who fail to ensure compensation for vaccine injury - Canada and Russia.

These programs, however, are fraught with difficulties, inadequacies, limitations, are often funded by taxpayers rather than the industry, and fall far short of being fair, just, accessible and accountable. In fact, there is evidence that these programs which fail to hold industry accountable for harm caused by their products have resulted in decreased public health protection.

While compensation for the unintended consequences of vaccination is necessary and appropriate in a just and compassionate society, it is our hope that higher goals would be achieved by the implementation of a national vaccine injury accountability and compensation program. These goals include:

1. **Improved Professional development** of healthcare providers
2. **Transparency**
3. **Rigorous safety testing**
4. **Timely removal** of unsafe products.

Sincerely,

Vaccine Choice Canada

Purpose

- To identify principles and goals that ought to guide the development of a vaccine injury accountability and compensation program in Canada.
- To identify potential negative consequences of a national vaccine injury compensation program and offer recommendations to mitigate negative consequences.
- To help ensure Canadians are appropriately and fairly compensated for vaccine injury.
- To ensure manufacturers are held accountable when producing unsafe products

Preamble

In response to the public's legitimate concerns pertaining to the safety of the rushed-to-market COVID vaccines and the 'interim use' authorization granted by Health Canada prior to the completion of Phase III safety trials, the Government of Canada announced its intention to create a national vaccine injury compensation program.

The purpose of the announced, but undefined program, is to assure Canadians should they or a family member become severely injured or killed by the COVID vaccine, that they will be financially compensated. One can assume that the unstated intention of the proposed vaccine injury compensation program is to increase COVID vaccine uptake.

At Vaccine Choice Canada, we know the risk of vaccine injury. Many, if not most of our members and supporters have personally experienced injury or the death of a family member due to vaccination. While compensation for the unintended consequences of vaccination is necessary and appropriate in a just and compassionate society, we hold that higher goals ought to be achieved by the implementation of a national vaccine injury accountability and compensation program. These goals include:

1. **Professional development** of healthcare providers in the areas of:

    a) the ethical requirement of complete patient history, knowledge of pre-existing individual and familial contraindications to vaccination, and fully informed and non-coercive consent pre-vaccination

    b) knowledge of COVID vaccine ingredients and associated risks

    c) clinical recognition of vaccine injury and the mandated requirement to report injuries

    d) treatment of vaccine injury

2. **Transparency** in reporting to the Canadian public and health care providers COVID vaccine injury/death statistics and subsequent details of compensation.

3. **Rigorous and transparent testing** by Health Canada of COVID vaccine industry products.

4. **Timely removal** of COVID vaccine industry products shown to cause serious harm and/or death.

Most Canadians are unaware that vaccines do not undergo the same level of safety testing as is required for every other pharmaceutical product. Vaccines are classified as 'biologics' and permitted to be licensed for use in the general population with less rigorous safety testing, shorter clinical trials, and the absence of a neutral control group to scientifically verify vaccine safety and efficacy. As evidence of this fact, none of the childhood vaccine products recommended by Health Canada have been tested against a neutral placebo.

This acceptance of a lower standard of safety and efficacy testing is no more evident than with the COVID vaccines currently authorized for 'interim use' in Canada. None of the COVID vaccine products given 'interim use' authorization by Heath Canada have met the most basic standards of medical product testing. Those currently choosing to receive a COVID vaccine are participating in human experimentation with unknown consequences.

Many individuals eager to receive a COVID vaccine are under the mistaken notion that the vaccine will protect them from infection. The fact is that the Pfizer and Moderna vaccines are not designed to prevent infection, and no data exists to conclude that COVID vaccines prevent transmission of the SARS-CoV-2 virus. Further, vaccine manufacturers are not required to demonstrate that COVID vaccines result in a reduction in severe illness, hospitalization, or death. [i] [ii] [iii] [iv]

With regards to facilitating compensation for vaccine injuries and deaths, Canada is more than three decades behind other countries. Of the G20 Nations, there are only two nations remaining who fail to ensure compensation for vaccine injury - Canada and Russia. The province of Quebec has had a vaccine injury compensation program since 1985. However, these programs are fraught with difficulties, inadequacies and limitations, are funded by taxpayers rather than the industry, and fall far short of being fair, just, accessible and ensuring accountability. In fact, there is evidence that these programs which failed to hold industry accountable for harms caused by their products have resulted in decreased health protection for the public.

Reservations

While the members of Vaccine Choice Canada, fully support and have long advocated for a system of compensation for Canadians injured and killed by vaccine products, we declare that we have significant reservations with a system of compensation that is government-managed and taxpayer funded rather than industry funded.

Experience in other countries reveals that vaccine injury compensation programs that eliminate or severely restrict manufacturer liability for injury or death result in an ever-expanding market of poorly tested vaccine products. A 2017 study investigated the consequences in the United States of removing litigation risk related to vaccines. The researchers concluded that vaccines that were licensed after legislation that pre-empted most product liability lawsuits are associated with a significantly higher incidence of adverse events than were vaccines that were licensed under a previous regime that permitted consumers to sue. [v]

In short, a government vaccine injury compensation program that removes the risk of manufacturer liability would permit the unethical and dangerous sale of an unaccountable industrial product – the only product (medical or otherwise) that has this status in Canada.

A further concern is that governments are conflicted with competing agendas with regards to vaccination. Governments have gotten into 'the practice of medicine', promoting and even mandating vaccine products, while at the same time holding responsibility for determining the level of compensation for those injured and killed by their policies and practices. Metaphorically, it means that we are relying on "the fox to guard the hen house." Unless there is a robust system of manufacturer accountability when they produce unsafe products and measures to address government conflicts, a vaccine injury compensation program has the potential to do more harm than good and put more Canadians at risk of vaccine injury.

Clearly Defined Goals

As with the creation of any program, clearly defined goals must be identified, and include mechanisms to measure the success or failure of such a program. The rule of accountability is that if you don't measure it, it's not important.

The following outlines what must be developed and administered by a non-governmental independent third-party that includes stakeholder involvement of citizens, medical and allied health professionals, as well as legal counsel specializing in injury compensation and Canadian charter rights.

- **Manufacturer Accountability** - A transparent and accountable system of fair compensation for vaccine injury and death that is solely funded by the manufacturer and is easily accessed by both the Canadian public and by medical providers who report vaccine injury. The requirement of the manufacturer to provide, with integrity and transparency, adequately tested and safe vaccination products. The vaccine injury accountability and compensation program would have the authority to remove from the marketplace inadequately tested vaccine products that injure and kill.

- **Education - Voluntary Informed Consent / Vaccine Risk / Injury Reporting** – An education and training program designed for both vaccine administrators and the Canadian public, that ethically informs of risk and identification of vaccine injury.

- **Manufacturer Requirements for Product Safety** – The requirement for transparent Canadian-based robust safety testing that is publicized and easily accessed by health care providers and the Canadian public at large.

- **Compensation** - A system of parliamentary oversight which financially supports and implements the recommendations of this non-governmental independent third party.

Mechanisms to measure these goals much be established. In a national vaccine injury accountability and compensation program, several principles must be considered to ensure the program puts the interests of Canadians negatively impacted by vaccination ahead of political or corporate interests. These principles include:

A. Manufacturer Accountability

One of the goals of a national vaccine injury accountability and compensation program ought to be to ensure that the vaccines offered to Canadians are the safest products possible. One way to ensure a high standard of safety is to hold vaccine manufacturers accountable when their products cause injury and death. This legal and financial accountability incentivizes vaccine manufacturers to ensure they produce the safest products possible.

A vaccine injury accountability and compensation program that shifts the responsibility of compensation from the manufacturer to the taxpayer is unacceptable for the following reasons:

i. Without legal accountability, there is no financial incentive for manufacturers to make the safest vaccines possible.

ii. Manufacturers retain all the profits while taxpayers pay for the consequences of unsafe products. This places the responsibility of compensation on the wrong party.

iii. Legal and financial indemnity does not exist with any other product licensed for sale in Canada. It should be no different with vaccine products.

Presently, the Government of Canada has granted COVID vaccine manufacturers indemnity when producing unsafe products. Federal procurement minister Anita Anand justified the indemnity in the following statement - *"All countries, generally speaking, are faced with the issue of indemnification of companies, especially in cases of novel technologies like this."* [vi]

One would think that a 'novel technology' would demand a higher level of oversight and accountability, not less. This legal immunity is not intended to protect citizens, but rather to protect the pharmaceutical industry. This blanket indemnity of vaccine manufacturers by the Canadian government increases the risk of vaccine injury and cannot be allowed to continue.

iv. The Department of Justice Must be Neutral

In any claims against a vaccine manufacturer for injury or harm, the Government of Canada must be neutral and unbiased. Any vaccine injury accountability and compensation program that forces citizens to defend their claim for compensation against the government, as occurs in the United States, is unacceptable.

Plaintiffs injured by a COVID vaccine should have available a system to appeal a decision in a court of law should the plaintiff deem the level of compensation offered through a vaccine injury accountability and compensation program inadequate or unfair. Plaintiffs must also have available to them medical experts to help evaluate the injury, provide information to support the argument of harm, and provide a course of medical treatment for future needs. As well, plaintiffs require reasonable access to legal experts to assist in guiding petitioners through the administrative process given most of the injured will not have the resources or knowledge to assemble their case.

B. Voluntary and Informed Consent

The promise of financial compensation for injury and death from a COVID vaccine must not negate the responsibility of health professionals administering vaccines to ensure that consent is voluntary and informed. This voluntary and fully-informed consent must be free of any form of disadvantage or coercion.

Those accepting a COVID-19 vaccine under the 'interim order' must clearly understand that they are partaking in a clinical trial with an experimental product where the risks and benefits have not been established.

Any consideration that a vaccine can be made mandatory because a system of compensation exists is unacceptable in a free and democratic society. In no way should a system of compensation for those injured and killed by unsafe products undermine the right of citizens to voluntary informed consent; nor the responsibility of health care professionals to obtain informed consent from patients or caregivers.

A COVID vaccine injury accountability and compensation program presents the opportunity to improve and standardize the informed consent process in Canada. Currently, fully informed consent is not the standard of care exercised by health professionals when administering vaccines. For example, rarely are those receiving vaccines provided with the product information insert/product monograph available for all pharmaceutical products.

The introduction of a vaccine injury accountability and compensation program is an opportunity to develop robust informed consent protocols that ensure patients are given all available information to enable fully informed consent. For consent to be informed, patients must be provided with the following information:

i. evidenced-based benefits of the vaccine

ii. the risks of the vaccine, both known and suspected

iii. the benefits of natural immunity

iv. the risks of natural immunity, both known and suspected

v. alternative treatments to vaccination

Specifically, with regards to the COVID vaccines currently available to Canadians on an 'interim approval' basis, it is imperative that those partaking in these medical products be made fully aware of:

- the experimental status of the product
- that Phase III safety trials have not been completed
- that interim approval was granted based upon only two months of safety data
- that the Pfizer and Moderna products are utilizing synthetic genetic technology never before approved for use as a vaccine
- that the Pfizer and Moderna products include ingredients never before used in a vaccine, making these products highly experimental
- the risk of antibody-dependent enhancement (ADE)
- effective prophylactic and treatment options are available

The specific and significant risk of ADE should be prominently and independently disclosed to all research subjects currently in clinical trials, as well as those being recruited for the trials and future patients after product approval, to meet the medical ethics standard of patient comprehension for informed consent." [vii]

The undermining of informed consent is no more evident than in the administration of vaccines to minors as young as nine years of age under the Mature Minor Doctrine, and to our seniors in extended care facilities without the knowledge or consent of the Power of Attorney. Health authorities routinely use the Mature Minor doctrine to vaccinate children without the knowledge or consent of their parents. This violation of a parent's right and responsibility to make medical decisions for their dependent children must no longer be tolerated. The right and responsibility of parents to make medical decisions for their children must be respected and protected.

Medical professionals administering vaccines without obtaining informed consent of the individual, caregiver or Power of Attorney must be held personally and jointly liable for injury or death caused by vaccination, as well as held to account by their professional bodies for ethical standards violations. This liability is separate and distinct from liability of manufacturers for producing unsafe products.

vi. Education and Training

One of the most significant limitations to the creation of a fair and effective vaccine injury accountability and compensation program is that medical professionals, including doctors and nurses, receive no formal training on how to recognize and diagnose vaccine injury. Absent from

current medical school curriculum is complete and up-to-date information about vaccine ingredients, diagnosis and treatment of vaccine injury, adverse events reporting, and individual genetic susceptibilities to vaccine injury.

Medical professionals must be trained in recognizing and diagnosing vaccine injury and susceptibility to vaccine injury. The failure of medical professionals to recognize and report vaccine injury puts patients at risk. Their failure to acknowledge vaccine injury also impedes the removal of unsafe products, the development of safer vaccine products, and the development of alternative methods of immune support and disease prevention.

To ensure medical professionals receive a curriculum independent of industry bias, an independent, public oversight mechanism must be included in the development of the curriculum.

vii. Prior Testing for Genetic Pre-disposition

There are several known risk factors which increase an individual's susceptibility to suffering vaccine reactions that may lead to permanent injury or even death. This rapidly growing body of knowledge is referred to as adversomics. These high-risk factors must be identified prior to vaccination.

Where genetic susceptibility to vaccine injury is known and where appropriate testing is available, those administering vaccines without proper pre-screening must be held personally responsible for vaccine injury.

This growing body of information must be constantly update as more data becomes available.

C. Manufacturer Requirements for Product Safety

i. Conduct Robust Safety Testing

The technology used in the current COVID vaccines is new and highly experimental, the safety profile of which is still not fully known. An ongoing priority will be to maintain a robust data base of continuously updated possible and confirmed vaccine injuries – forming the vaccine injury table (VIT) to be used as the basis from which compensation is awarded.

With multiple COVID vaccines approved for 'interim' use, using different technologies and containing different ingredients, it will be necessary to develop distinct vaccine injury profiles for each vaccine product. These profiles ought to recognize differences due to age, gender, and co-morbidities.

A vaccine injury compensation program must not be used as justification to accept less than robust safety testing.

Those accepting a COVID vaccine under the 'interim order' must clearly understand that they are partaking in a clinical trial with an experimental product where the risks and benefits have not been established. Consent to acceptance of an experimental product does not negate the responsibility of the manufacturer for compensation for injury and death.

The federal government must fund and support a robust post-market vaccine surveillance system to understand the efficacy of vaccines in the real world (e.g., on populations not included in the

trials), case severity and adverse events, and they must support research on the impact of vaccines on transmission.

The government of Canada must also support research to determine the impact of adding a COVID vaccine to the vaccine schedule in its entirety.

COVID vaccine producers must be required to conduct vaccinated vs. unvaccinated studies as part of their clinical trials to prove that vaccines are both safe and effective. The unvaccinated control group must include an inert placebo and be preserved for a minimum of five years to ensure the integrity of the vaccinated vs. unvaccinated study. Permitting the unvaccinated control group to receive a COVID vaccine undermines the integrity of the safety testing.

For final approval, COVID vaccine producers must submit their products to the same level of safety testing and oversight as is required with all other pharmaceutical drugs, or higher given that these drugs are given as prophylactics to healthy children and adults.

Given that adequate safety testing has not been conducted to prove the safety of COVID vaccine products[viii] the government must not assume this experimental product is safe and instead err on the side that the vaccine product is unsafe until proven safe. It is incumbent upon vaccine makers to prove safety, not upon citizens to prove that vaccines are unsafe.

D. Compensation

i. Mandatory and Public Reporting of Vaccine Injury

Currently, the reporting of vaccine injury by health professionals in Canada is passive and voluntary. The passive and voluntary nature of reporting of vaccine injury undermines the integrity of claims of vaccine safety. The reporting of vaccine injury by health professionals must be mandatory with legal consequences for failing to report vaccine injury. There must also be an independent, public oversight mechanism to ensure complete and accurate reporting.

A Harvard Pilgrim Health Care study in the US revealed that less than 1% of vaccine adverse reactions are reported. [ix] There is no reason to assume that the reporting of vaccine injury by Canadian medical professionals is any more accurate. This means that the real number of children and adults who experience injury from vaccination is unknown. This is unacceptable and must be addressed as an essential component of a vaccine injury accountability and compensation program.

Medical professionals have disclosed their reluctance to report adverse events from vaccinations for fear of harassment and disciplinary measures taken against them for reporting vaccine injury. This fear of reporting of vaccine injury impacts the integrity of vaccine injury reporting data. Medical professionals must be safe and free from harassment and disciplinary measures taken against them for reporting vaccine injury.

In addition to the reporting by medical professionals, the federal government must also develop a publicly accessible vaccine adverse events reporting system which allows an individual, parent or guardian to self-report an adverse event. This raw data must be available for public and independent third-party viewing and for raw data on which to monitor vaccine safety. Currently, only medical professionals are permitted to report vaccine injury in Canada. Relying solely on those who may be culpable for vaccine injury to voluntarily self-report vaccine injury fails to meet the most basic test of integrity.

ii. Stakeholder Involvement

Any committee overseeing the provisions of vaccine injury accountability and compensation in Canada must include public representatives or stakeholders, including individuals or parents of children who have been affected by vaccine injury. All committee members must be without intellectual, financial or political ties to government agencies or the pharmaceutical industry. Adjudicators of the vaccine injury compensation plan must be approved by all public stakeholders who are part of the committee.

Further, the reality must be acknowledged that the medical industry has significant financial and intellectual conflicts of interest in matters related to vaccination. These conflicts of interest bias medical professionals to assume vaccine safety in the absence of robust scientific evidence. These biases and conflicts of interest must not be permitted to influence the decisions of a vaccine injury accountability and compensation program.

ii. Compensation should be fair, just, and accessible

Any vaccine injury compensation program must be fair, just, timely and accessible. Current vaccine injury compensation programs in other countries reveal a reluctance to acknowledge and compensate for vaccine injury due to an intellectual and/or financial conflict of interest on behalf of the adjudicators, and the desire of governments to maintain public confidence in the safety of a vaccine program whether the safety is legitimate or not. In the US, for example, the vaccine injury compensation program compensated less than 6% of the claims filed in the last decade. [x] These conflicts of interest impact the ability of a program to recognize and fairly award compensation for vaccine injury.

Further, compensation must be provided in a timely manner. Established timelines must be implemented to reduce the negative consequences of delays in compensation for vaccine injury including incremental penalties for failing to meet established timelines.

There must be no arbitrary cap on the monetary settlement for vaccine injury and death.

The level of compensation for vaccine injury must include a ‘medical inflation index’ that annually adjusts the level of compensation to reflect increases in costs of care and inflation.

Any compensation must be open and transparent. Non-disclosure agreements must not be permitted. Transparency increases the accountability and oversight to ensure the highest level of safety possible and assist in enabling informed consent.

There must be no statute of limitations for reporting a vaccine injury given that the consequences and impact of the novel COVID technology is unknown. Further, it may take years or decades for those who sustain vaccine injuries to identify the connection between the vaccine and the injury, as some injuries, such as auto-immunity illnesses and neurological disorders, manifest themselves over time. In the case of the experimental COVID vaccines, it is impossible to know the adverse effects of a COVID vaccine in the few months the product has existed.

iii. Parliamentary Oversight

Any vaccine injury accountability and compensation plan must include regular and robust reporting to a parliamentary accountability committee, with a minimum of annual public reports including a comprehensive overview of the program.

As health needs, vaccine technology, and demographics change, the plan must be updated every five years at a minimum.

iv. Comprehensive Compensation Coverage

Compensation for vaccine injury, similar to an insurance award, must include, but is not limited to:

a) Income replacement
b) Bodily injury
c) Ongoing home care and long-term care costs as needed
d) Death benefits including funeral expenses
e) Reimbursement of medical expenses including alternative treatments of the patient's choosing
f) Rehabilitation including physical, social and occupational aspects.

Indemnities are indexed to the cost of living every year to protect beneficiaries against cost-of-living increases.

v. Federal and Provincial Funding and Cost Sharing

Given that health care is a provincial responsibility and given that Health Canada and regulatory agencies are a federal responsibility, the ultimate responsibility for compensation costs due to inadequately tested and poorly regulated medical products must rest with the Federal government. Provincial governments must be fully compensated for any expenses incurred as a result of vaccine injury and deaths.

Appendix 1: Limitations to Informed Consent

i. Health Canada does not conduct its own clinical trials to determine the safety and efficacy of a vaccine. Instead, Health Canada relies on the data provided by the vaccine manufacturers.
ii. Vaccine producers such as Pfizer, Merck and GlaxoSmithKline have paid billions in criminal penalties and settlements for research fraud, faking drug safety studies, failing to report safety problems, bribery, kickbacks, and false advertising. [xi] [xii] In 2009, Pfizer paid $2.3 billion to resolve criminal and civil allegations in what was then the largest health care fraud settlement in history. [xiii]
iii. Health Canada does not require that vaccine makers test their products against a neutral placebo, a requirement for all other drugs and pharmaceutical products. The safety profile of a vaccine cannot be established without testing it against a neutral placebo.
iv. The vaccine injury reporting system in Canada is voluntary and therefore unreliable as a measure of vaccine injury. There are no consequences for the failure of professionals to report vaccine injury.
v. According to a US 2017 study, less than 1% of vaccine injury is reported.

Appendix 2: Specific to the COVID vaccine:

i. The Pfizer and Moderna vaccines granted 'interim approval' by Health Canada have not been adequately tested for either safety or efficacy. This means that the use of the COVID vaccine is **human experimentation**.

ii. The normal development timeline of a vaccine product is 5 - 10 years. It is impossible to identify the adverse effects of a COVID vaccine in the few months the product has existed.

iii. The Pfizer and Moderna COVID vaccine utilize messenger RNA/DNA technology. This genetic modification technology has never before been used as a vaccine in the general population. The consequences of introducing genetic altering technology into a human body is unknown.

iv. Moderna vaccine maker admits that these vaccines *"have a risk of permanently changing a person's DNA."* [xiv] The potential exists for catastrophic consequences, not only for the person receiving the vaccine, but for all future generations.

v. Normal protocols to test the safety of vaccines include testing in animals prior to testing in human subjects. This protocol is even more necessary for a coronavirus vaccine given that all previous efforts to develop a coronavirus vaccine over the last two decades have failed because the vaccine caused an exaggerated immune response in lab animals upon re-exposure to the virus. [xv] This exaggerated immune response resulted in severe injury and death. In the rush to develop a COVID vaccine, Health Canada has permitted vaccine makers move directly to testing on humans.

vi. Health Canada has deemed it appropriate to grant Pfizer 'interim approval' for deployment of their vaccine in the general population WITHOUT completing phase three trials. This is unprecedented in vaccine development. Health Canada admits that long-term safety data does not exist for the vaccine. [xvi] There is no data that defines the vaccine's interaction with other vaccines or prescription medications. [xvii]

vii. COVID vaccines have not been tested for their ability to cause cancer, damage an organism, change the genetic information of an organism, impact the foetus of a pregnant woman, or to impair fertility.

viii. COVID vaccine makers are not required to demonstrate that their product prevents either infection or transmission of the virus.

ix. Vaccine manufacturers are not required to demonstrate that the vaccine will result in a reduction in severe illness, hospitalization, or death.

x. According to a report in the British Medical Journal, *"Hospital admissions and deaths from COVID are simply too uncommon in the population being studied for an effective vaccine to demonstrate statistically significant differences in a trial of 30 000 people. The same is true of its ability to save lives or prevent transmission: the trials are not designed to find out."* [xviii]

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