Citizens' Group Query and Notice on Informed Consent and the Safety Risks of the COVID-19 Genetic Vaccines

- To: Jean-Yves Duclos, Minister of Health Theresa Tam, Chief Public Health Officer of Canada
- CC: Mary Simon, Governor General of Canada

Dear Minister Duclos and Dr. Tam:

We are writing to you as citizen stakeholders in decisions you have made that have impacted millions of Canadians. We represent a broad crosssection of public interest groups that have both the ethical and judicial standing to request your response to the following:

We are submitting for your review and comment the attached **Proposed Government Safety Risk Statement on COVID-19 mRNA Vaccines** (attached hereto as Appendix A, and hereinafter referred to as "the Safety Risk Statement"). We would like you to affirm this statement as being both scientifically accurate and in accordance with the *Charter of Rights and Freedoms* and generally accepted principles on informed and *voluntary* consent that are the foundations of biomedical ethics.

If you dispute any assertion or principle contained in this Safety Risk Statement, then we respectfully ask that you provide a substantive response and comment so that members of the public may properly understand your position on the matters put forward in this document.

We have copied the Governor General on this communication to you, in recognition of the fact that the Governor General is His Majesty's personal representative in Canada, with a constitutional role as the ultimate guarantor and protector of Charter rights that have been impacted by the decisions, judgments - and yes, political biases - of His Majesty's advisory Privy Council, which includes the Prime Minister and the Cabinet.

We consider the adoption of the proposed Safety Risk Statement to be a matter of urgent necessity. Both of you have recently gone on record alerting Canadians to your view that citizens may not be considered "fully

vaccinated" against COVID-19 unless they are repeatedly "updated" with a booster injection every nine months.

In our view, you have not, to date, properly informed Canadian citizens as to the material risks and scientific uncertainties related to the previously authorized lipid nanoparticle COVID-19 mRNA or adenoviral DNA vaccines, which are commonly referred to hereafter as COVID-19 genetic vaccines.

Your public communications have been vague, internally inconsistent, and are riddled with material omissions that have the effect – if not intent – of misleading millions of Canadians about the health risks they face and how they might go about personally managing and mitigating those risks in accordance with long-standing common law principles of informed consent.

There must be clearly defined limits to the authority that you purport to exercise under the veil of a declared and ongoing public health emergency.

We respectfully remind you that, at all material times, your public health judgments are subject to cross-examination and scrutiny by the courts, health experts, and other members of the public.

As you know, or ought to know, public health decisions seldom, if ever, unfold in a purely science-guided vacuum. All public health decisions are accompanied by a reasonably foreseeable prospect of *legal hazard* - the extent to which bias, conflict, error, negligence, groupthink, politics, and/or regulatory capture may influence or impair the judgments of public health officials.

But just as crucially, we wish to put you on notice that, when you prescribe a specified medical treatment under threat – whether direct or indirect – of loss of employment, and access to services and education, while at the same time restricting the rights of millions of Canadians to travel or leave the country unless they take your prescribed treatment, you cannot justly do so without guaranteeing *full*, unrestricted public access and transparency to *all* your regulatory and public health data.

Your comment and response to the proposed Safety Risk Statement will therefore need to be examined against a fully accessible public review of the reporting and sampling protocols that authorities such as the Public Health Agency of Canada (PHAC) apply in collecting, tabulating, and reporting SARS-CoV-2 infection and COVID-19 vaccine injury risks to the public.

As you know or ought to know, your public health and regulatory clinical trial data should be subject to fully transparent public scrutiny, query, and comment. Under the *Public Health Act*, you have a duty to account to Canadians, to respond to citizen queries - such as those herein - and to disclose financial conflicts of interest related to a therapeutic product where public health is at stake.

Among the information we need unrestricted access to as a *minimum* precondition for offering our informed, voluntary consent:

- Whether there exist clinical trial or post-roll-out studies tracking the biodistribution of the COVID-19 genetic vaccines (and not a proxy formulation) in those who have taken them. We need to know how much of these genetic vaccines distribute throughout the body, past the site of injection, and how long the expressed SARS-CoV-2 spike protein that is produced, as a consequence, persists.
- Whether or not there are data that the biosynthetic mRNA or DNA is translated with fidelity in our cells, and exactly what alternative protein forms are being produced in a representative cohort of Canadians. We need to know if sequence verification of the spike protein produced by our cells has been performed and compared to the original Wuhan viral spike protein strain, and if not, why not.
- Whether the mRNA or adenoviral DNA genetic vaccines necessitate the damage and/or destruction of those cells, tissues, and organs that express an anchored spike protein after coming into contact with these vaccines. This includes an assessment of the risk of reverse transcription of vaccine spike mRNA to DNA and its potential incorporation into the human genome.
- A transparent record of all communications and directives from the Canadian Institute for Health Information (CIHI) to data analysts in hospitals across Canada, directing the coding of COVID-19 hospitalization and vaccine injury cases. We need to ensure that your public health data is not tainted by reporting and sampling biases.

- A conflict of interest check of the experts that you rely on for your COVID-19 health advisories. A disproportionate number of your expert advisers, panelists, and research grantees, for instance, are affiliated with the Canadian Immunization Research Network (CIRN), an organization that has partnered with Pfizer, and among whose senior researchers sit on Pfizer and Moderna boards and committees or serve as paid consultants.
- Access to the proprietary information related to Pfizer's (ALC-0315) and Moderna's (SM-102) lipid nanoparticle technology. These employ cationic lipids, which are generally known to be toxic and are for "research use only". as stated by their manufacturers. We are not in a position to make an informed decision about these treatments so long as the companies that offer them prevent unrestricted public access to investigate their novel technologies and formulations.
- The chemical composition of representative COVID-19 vaccine vials from different lots need to be thoroughly analyzed and validated by independent experts who are free of any conflicts of interest.

To be clear, our queries should not be dismissed by you as a narrow issue of concern by the remaining population of unvaccinated Canadians. To the contrary, millions of *vaccinated* Canadians have an urgent stake in understanding the material risks that they have taken on in response to the policies, prescriptions, and assurances that *you* communicated to them throughout the course of this declared public health emergency.

As you know or ought to know, millions of Canadians took on those risks for reasons other than health, in an atmosphere of sustained coercion – so that they could secure freedom of movement and employment security that would otherwise be denied to them.

Millions of other Canadians, however, undertook to take an innovative, experimental vaccine on your blanket assurance – and trusted word of authority - that such genetic vaccines were both "safe and effective."

However, in the absence of reliable biomarker and tissue sampling data, the mantra "safe and effective" is little more than a bald assertion, lulling and soothing those Canadians who trust in your assertions that you have placed their safety interests above all other interests and agendas.

As you know or ought to know, a vaccine's effectiveness has traditionally been measured by the degree to which it prevents infectious spread among the population. Well over a year out from the initial roll-out, it can no longer be denied that the authorized COVID-19 genetic vaccines are an unmitigated failure when evaluated against this metric.

However, after the mass roll-out, you shifted the goal posts and pointed to your own public health data as proof of the proposition that, at the very least, the COVID-19 vaccines have been effective in keeping Canadians safe from severe hospitalization and death. The extent and influence of natural immunity from asymptomatic and symptomatic SARS-CoV-2 infections has been completely ignored in these metrics, as well as the more benign nature of the Omicron variants, in making these assessments.

Moreover, we have concerns about the circumstances under which your public health data has been compiled and collected. It was sourced from hospitals and a medical community that were operating under a severe climate of censorship, fear, bias, and groupthink. Most concerning is the evidence that your public health data may have been tainted by biased reporting and sampling protocols.

Hospitals across the country were directed to apply maximal *inclusion* criteria in counting deaths and hospitalizations as related to SARS-CoV-2 infection. Your data made no distinction among those who tested positive *in* hospital after being admitted for health conditions unrelated to SARS-CoV-2 infection. More recently, in 2022, it has come to light that over half of COVID-19 attributed deaths in BC and Ontario, for example, were not directly due to COVID-19, but still linked to SARS-CoV-2 in public health office statistical reports.

By contrast, you misleadingly presented Covid-19 vaccine injury data that was compiled under circumstances which encouraged maximal *exclusion*. Reported vaccine injuries were accepted into the official tally only after consideration by registered nurses at the local public health units, whose responsibility it was to put each report through a cursory WHO checklist. A reported adverse injury that could theoretically be attributed to alternative causes might not be accepted, and hence, excluded from the official tally. You then misleadingly presented to the public the resulting tally as a record of reported vaccine injuries when, in fact, you were presenting heavily *adjudicated* vaccine injury data.

Even more egregiously, you undercut your own passive vaccine safety surveillance system by enabling and encouraging colleges of physicians and surgeons across Canada to warn doctors –under threat of reprimand – not to discourage their patients from taking the COVID-19 genetic vaccines you promoted.

Here, too, you effectively tainted the reliability of your public health data, as you *disincentivized* doctors from reporting serious genetic vaccine injuries (in contravention of the *Protecting Canadians from Unsafe Drugs Act*, also known as Vanessa's Law). You *biased* them against serious consideration of patient reports of injury. You placed doctors across the country in the conflicted position of choosing between their fiduciary duty to their patients and the security of their medical license.

From the outset of the roll-out, you encouraged physician groupthink by repeatedly lulling the medical community with your authoritative assurances that the COVID-19 genetic vaccines were both "safe and effective."

But again, these were little more than blanket value judgments that misled the Canadian public by masking the fact that there exist fundamental *inconsistencies* between the pre-roll-out clinical trial data and the post-rollout public health data reported across Canada and worldwide.

As you know or ought to know, you misframed the data in order to present a misleading picture of vaccine safety and efficacy. With the clinical trial data, you sold the Canadian public on the endpoints of generating antibodies and avoiding infectious *cases*. However, you failed to alert the public that, according to the clinical trial data you published, Canadians would have to risk *multiple* serious adverse genetic vaccine injuries in order to avert just *one* excess severe COVID-19 hospitalization.

Repeated injections of non-sterilizing mRNA COVID-19 vaccine products also carry a well-known risk for inducing immune dysfunction, ranging from antibody-dependent enhancement, antigenic imprinting, and immune tolerance. These material long-term risks to human health have not been communicated to the general public. You misleadingly told Canadians that the genetic vaccines were 95% effective in avoiding SARS-CoV-2 *infection* (a *relative* efficacy statistic that no longer remotely applies after three doses in less than a year), and yet you failed to inform them that – according to the clinical trial data – the average member of the public would better their absolute risk odds against being hospitalized *for COVID-19* by less than 1% if they got vaccinated. In short, their *absolute* risk of ending up hospitalized for COVID-19 would barely be affected by a decision to get vaccinated, at least according to the clinical trial data. However, you contradicted the clinical trial data by leading the public to believe otherwise.

But most flagrantly, you put the public focus on just one side of the safety equation – hospitalization from SARS-CoV-2 infection – and steered the public away from weighing the *other* side of the safety ledger: hospitalization from Covid-19 vaccination.

As you know, or ought to know, it is misleading to market a vaccine as "safe and effective" in the absence of ensuring that the public understands the concept of *all-cause hospitalization*. In other words, how many Canadians do you need to put in the hospital on account of vaccine injury in order to avert hospitalization from COVID-19?

As you know or ought to know, public health data is *notoriously* unreliable in answering that question. The fact is, public health data – as with all epidemiological data – can be gamed and massaged and confabulated by any number of confounding variables. With public health data, *everything* hinges on how the reporting and sampling protocols are designed. Depending on their design, the data can reflect either high or low COVID-19 hospitalizations; or a state of high genetic vaccine injury or low genetic vaccine injury.

Without knowing how such protocols are designed and applied at the local hospital level – the source for your aggregated public health data – the average Canadian doctor, immunologist, and health researcher has no assured way of evaluating whether your data presents a true picture of the public health reality, other than by proceeding with an untested presumption that your data *can* be relied on, that it hasn't been distorted or biased in one direction or another.

But here is the problem, at least from our perspective as concerned citizens:

To date, you haven't been open with the public about the protocols you apply in compiling COVID-19 hospitalization and genetic vaccine injury data. Emergency ward doctors, nurses, and hospital data analysts are in a position to inform us as to any irregularities. But as you know or ought to know, many – if not most – are loathe to step forward, out of fear of being blacklisted from ever working in a hospital.

If the public is to cross-examine and test the reliability of your public health data, it absolutely *must* have free and open access to the source of your data – the front-line hospital and clinic witnesses who might personally attest to how your data is compiled in the field.

We are therefore putting you on notice that where you insist on restricting *Charter* rights on the basis of the public health data you put forward, we absolutely insist on the right of Canadian citizens to cross-examine and freely question the reliability of your data, to ensure it isn't unduly biased in one direction.

We are putting you on notice that, whenever you purport to restrict rights of movement and employment based on your public health value judgments, you immediately engage a statutory and constitutional duty to allow full, unrestricted public access to all your clinical trial and public health data. You must publicly *account* for the basis of your value judgments, not simply demand that we accept those judgments on the prestige and authority of your appointed positions.

Where you restrict access to data and claim that certain information pertinent to your prescribed medical treatment is both proprietary and privileged, you therefore cannot restrict rights based on a refusal to take your prescribed medical treatment, particularly where such refusal arises out of a sincerely held concern for safety and bodily integrity.

Under the veil of a declared public health emergency, you have distorted and undermined the law on informed consent and bodily autonomy. Though you are free to *recommend* and *authorize* a permitted medical treatment for those who wish to take it, it is wholly inappropriate for a public health officer to prescribe a specified medical treatment while at the same time specifying the permissible conditions under which such treatment may attract an exemption.

The doctrine of informed consent was enunciated in the Ontario Court of Appeal decision of Fleming v. Reid (and is included in the Safety Risk Statement):

With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the physician, who ultimately must decide if treatment — any treatment — is to be administered.

The attached Safety Risk Statement contains informed consent content that was adopted from the Canadian Medical Protective Association (CMPA), which in turn, based its content from long-standing common law principles and cases. CMPA statements on informed consent may be found at the following link: <u>https://www.cmpa-acpm.ca/en/advice-publications/</u>handbooks/consent-a-guide-for-canadian-physicians).

According to the principles affirmed by the CMPA (and established in our common law):

Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated.

As you know, or ought to know, vaccine mandates – combined with a restriction on the scope of permissible exemptions - were a key factor in coercing millions of Canadians to take an otherwise unwanted medical intervention, under threat of loss of employment, movement, and access to services and education.

By any measure, you moved forward with a policy to vitiate the informed consent and violate the bodily autonomy of millions of Canadians. Dr. Tam, you made no secret that you were alive and alert to the coercive effect of such policies on those who were otherwise reluctant to take the medication you prescribed.

In a video interview reported on September 10, 2021, you acknowledged that provincial ministers across Canada were moving forward with vaccine mandates, and asserted that such measures were "one way of encouraging vaccine uptake...it's something that we should pay close attention to and study." (https://globalnews.ca/video/8181658/canadas-top-doctor-says-vaccine-mandates-helping-uptake-impact-on-spread-of-covid-19-remains-to-be-seen)

It remains to be seen whether you had proceeded with the best of intentions. However, it is worrisome that you did not appreciate the extent to which your policies and judgments significantly undermined long-standing legal principles on informed and *voluntary* consent.

More to the point, you exposed millions of Canadians to multiple legal hazards that may have to ultimately be adjudicated on by our courts and the Governor General (in her role as His Majesty's public safeguard against Charter breaches by her advisory Privy Council).

As you are contemplating to exert pressure yet again on the medical decisions of millions of Canadians this coming Fall, we are putting you on notice that those legal hazards are active and ongoing as of this date.

Canadian Charter rights cannot be subject to your biased and selective reading of medical evidence. Though you may have the statutory authority to declare a public health emergency and to advise on mitigation strategies applicable to all, it is *beyond* the scope of your statutory authority to prescribe medical treatments to Canadians under circumstances of third party coercion and duress, particularly when your value judgments on the medical evidence are hotly disputed by millions of citizens and thousands of medical experts. As you know or ought to know, every citizen has a different threshold as to the scope and quality of information they require in order to make what they consider to be an informed and personal medical decision. Your statutory responsibility was to ensure that Canadian citizens have the necessary and accurate information they need in order to make an informed and voluntary decision in consultation with their doctor, secure from any outside factors of coercion, duress and enticements.

You violated *multiple* biomedical ethic principles in this regard.

One particular example of concern is that the Ministry may have communicated misleading information to the public as to the unique scope and nature of the COVID-19 mRNA vaccination platform – in particular, the mechanism by which it stimulates an immune response.

The proposed Safety Risk Statement is intended to rectify that oversight, to ensure that Canadians fully appreciate the unique design and mechanism by which these genetic vaccines stimulate an immune response:

All authorized COVID-19 mRNA vaccines work by instructing your cells to express a spike protein that is anchored to that cell.

To stimulate an immune response, your immune system initially attacks, damages, and/or destroys that cell. Though the vaccine is administered in your arm, a certain portion of your vaccine (currently unknown) goes beyond your arm and travels throughout your body, where it may penetrate liver, spleen, adrenal, ovarian, heart or brain cells. The extent of cell and/or tissue damage in your body, beyond your arm, may differ significantly from person to person.

Health Canada currently has no conclusive data to determine the extent to which you may experience cell and tissue damage that may impact your health, either in the short-term or long-term.

It is possible that you may incur such damage without necessarily experiencing it as an adverse event related to the time of vaccination.

If you have any evidence to show that the mechanism of immune response in the COVID-19 mRNA vaccines does not work in the above-noted manner, then please extend us the courtesy of knowing what portion of that statement is incorrect and why. Otherwise, you have an urgent moral and legal duty to

ensure that Canadians fully understand the material risks to which these vaccines expose them.

For young and healthy Canadians, such genetic vaccines might be considered an unacceptable trade-off of risks for protection against a disease that has killed less than 55 children and youth between the ages of 0-19 across Canada since the start of the pandemic.

As you know or ought to know, young and healthy Canadians may be better placed to ward off a SARS-CoV-2 infection via safer alternative prophylaxis measures - such as vitamin D supplementation and povidone-iodine antiseptic nasal rinses - without any consequent cell or tissue damage. By contrast, a strong immune response to the genetic vaccine – aggravated by repeated boosting on this vaccine platform - might expose them to cumulative cell loss, tissue inflammation and organ damage, the long-term effects of which - for example, on immune function and fertility - are currently unknown.

As you know or ought to know, a material omission of safety risks under these circumstances may operate to vitiate the informed consent of millions of Canadians who might have otherwise refrained from taking these medications if they had been sufficiently alerted to the precise mechanism of immune response with this novel vaccine platform.

Sweeping value judgments based on potentially biased epidemiological data cannot be taken as adequate disclosure for a genetic vaccine that foreseeably damages cells, tissues, and organs, depending where in the body the genetic vaccine circulates.

Many of us require more than epidemiological data in order to make an informed health decision, particularly where such data may have been compiled and reported under circumstances of legal hazard.

To make an informed health decision, we need to first assure ourselves that *your* value judgments were not tainted by the legal hazards of bias, conflict, negligence, error, groupthink, and regulatory capture.

To date, your conduct has raised a number of serious red flags of concern with us. You have not been open, candid, and transparent with your clinical trial and public health data. You have made it exceedingly difficult for us to get a clear medical opinion from our doctors, many of whom are too scared to express any safety concerns they might have, under threat of being reprimanded by their disciplinary college. In essence, you presided over a climate of coercion and intimidation that has interfered with the doctor/ patient relationship, undermining our ability to make an informed health decision in consultation with an un-conflicted physician.

We have no faith in your epidemiological data until such time as you ensure a free and secure atmosphere for frontline health care workers to come forward and publicly share information on hospital reporting protocols with the public without fear of reprisal.

In the meantime, we would much rather rely on the kind of multiple biomarker and tissue sampling tests that you *ought* to have insisted on as a condition for interim use regulatory approval. These are the kind of tests that would have given us a much more robust picture of the material risks that we face, telling us the extent to which the genetic vaccines might travel beyond the site of injection (the pharmacokinetic data); and whether there are deleterious biomarkers in the blood and tissue samples of the vaccinated when compared to a clinical trial placebo group.

In other words, we wanted the opportunity to evaluate the kind of biochemical data that the FDA and Health Canada might have secured for all if it had not signed off on the policy to dissolve the clinical trial placebo groups after just a few months.

In the absence of a placebo trial group and the required biomarker data, you left us to rely on the very epidemiological data that is most prone to gaming and legal hazard.

At all material times, you knew or ought to have known that your policies and biases therefore compromised our ability to evaluate the material risks posed by this vaccine platform. You have lost our confidence in your judgment, competence, and reliability.

On that basis alone, we justly claim our section 7 Charter rights (liberty and security of person) against you. You subverted the law on informed consent by wrongfully backing a policy designed to coerce the health choices of millions of Canadians. The trusting consent that millions of others gave, in turn, may have been solicited through misrepresentation of information and/

or fraud, contrary to provisions such as the *Health Care Consent Act* (in Ontario, along with similar provisions in other provinces). Millions of Canadians may reserve the right to seek a judicial declaration on that point alone.

Now that you have been duly put on notice, you have an opportunity – going forward – to mitigate some of the legal and moral damages you have inflicted on Canadian citizens.

You can be proactive in opening up all your epidemiological and regulatory data to unrestricted public evaluation and scrutiny. You can start taking the biomarker, blood, and tissue sampling tests that are necessary to look for long-term and subtle risks that would not otherwise be captured by a passive vaccine injury reporting system.

You can work toward making doctors feel comfortable in debating and airing their reasonable safety concerns, secure from any threat of disciplinary censure. You can remove yourself from the untenable business of prescribing, promoting and marketing experimental genetic vaccines with coercive strategies intended to increase mass vaccine uptake irrespective of individual risk-benefit assessments.

You have now been formally put on notice by Canadian citizens represented by the signatory groups to this letter. If you opt to start up a similar campaign of coercion this Fall, we are entitled to seek any and all legal remedies against you to which we are entitled, both domestically and through international courts of law.

All along, you ought to have recognized that the best public health strategy would be to assure us that you were *open* to public debate, and that you were providing unrestricted public access to all your clinical, regulatory, and public health data and protocols.

Until you do so, we are of the opinion that you cannot credibly be seen to be acting in pursuit of safety or the public interest, but rather in pursuit of other agendas influenced by bias and conflicts of interest.

Finally, we respectfully call upon the Governor General to view this document as a petition in the name of millions of Canadians against the unprecedented overreach and multiple Charter breaches of His Majesty's

advisory Privy Council. The Governor General's declaration that our rights have been wrongfully abridged would go a long way toward reining in the harmful and unethical conduct of the current government.

We look forward to you accepting and providing constructive feedback on the proposed Safety Risk Statement, with the hope that you will formally adopt it, so as to give Canadians the accurate information they need to understand the material risks they face with this vaccine platform, along with their legal rights to manage their health choices as they see fit, free from a climate of coercion, duress, and legal hazard.

The scientific content of this letter has been reviewed and affirmed by the following doctors, scientists, and academics:

Philip Britz-McKibbin, PhD, Professor, Dept. of Chemistry and Chemical Biology, McMaster University

Carole Beveridge, BSc Pharm, MSc

Claudia Chaufan, MD, PhD, Associate Professor, Health Policy and Global Health, York University

Maria Gutschi, BSc Pharm, Pharm D (retired)

John Hardie, BDS, MSc, PhD, FRCDC, Oral pathologist (retired)

York Hsiang, MB, MHSc, FRCSC, Professor, Dept. of Surgery, University of B.C.

Niel Karrow, PhD, Professor of Immunology, Dept. of Animal Biosciences, University of Guelph

Bernard Massie, PhD, former Director of Human Health Therapeutics Research Center of the NRC

Kanji Nakatsu, PhD, Professor Emeritus Pharmacology, Queen's University

Susan Natsheh, MD, Pediatrician (retired)

Philip R. Oldfield, DPhil, CSci, CChem, FRSC (UK) (retired)

Eric T. Payne, MD, MPH, FRCPC, Pediatric Neurologist and Clinical Assistant Professor, Univ. of Calgary

Steven Pelech, PhD, Professor, Dept. of Medicine, University of B.C.

Christopher Pinto, MD, Physician, Independent practice

Patrick Provost, PhD, Professor, Dept. of Microbiology, Immunology and Immune Diseases, Université Laval

Denis Rancourt, PhD, Interdisciplinary research scientist, epidemiologist, former Professor, Physics, University of Ottawa

Wendi Roscoe, MSc, PhD, Professor, Dept. of Health Sciences, Fanshawe College

Christopher A. Shaw, PhD, Professor, Dept. of Ophthalmology, University of B.C.

David Vickers, PhD, Statistical Assoc. & Epidemiologist

Submitted and affirmed by the following public interest groups, representing the voices, concerns, and interests of millions of Canadian citizens, both vaccinated and unvaccinated:

B.C. Public Service Employees for Freedom Canada Rise Canadian Covid Care Alliance Canadian Frontline Nurses Childrens Health Defence Canada Concerned Constituents of Canada Fearless Canada Feds for Freedom Free to Fly Canada Freedom Lovers Canada Georgetown Freedom Group Halton United United Healthcare Workers of B.C. United Health Care Workers of Ontario Mama Bears Project Police for Freedom Police on Guard for Thee Strong and Free Canada Stand up Canada Thunder Bay Freedom Community Uni4 Rights Unifor Labour Union Vaccine Choice Canada

APPENDIX A

Proposed Government Safety Risk Statement on COVID-19 Vaccines

All authorized COVID-19 mRNA vaccines work by instructing your cells to express a spike protein that is anchored to that cell. They represent a complex biologic product under interim use regulatory approval whose mechanisms of action are distinct from traditional vaccine products.

To stimulate an immune response, your immune system initially attacks, damages, and/or destroys that cell. Though the vaccine is administered in your arm, a certain portion of your vaccine (currently unknown) goes beyond your arm and distributes throughout your body, where it may be taken up into various tissues, including liver, spleen, adrenals, ovaries, heart and the brain. The extent of cell and/or tissue damage in your body, beyond your arm, may differ widely from person to person.

Health Canada currently has no conclusive data to determine the extent to which you may experience cell and tissue damage that may impact your health, either in the short-term or long-term.

It is possible that you may incur such damage without necessarily experiencing it as an adverse event related to the time of vaccination.

Moreover, with each successive dose on this platform, the damage may be cumulative. Some types of cells - such as brain neurons and cardiac muscle cells - cannot be regenerated once they die.

The current COVID-19 mRNA and adenoviral DNA vaccines are innovative products that are currently in Phase III clinical trials that have yet to be completed. Under such circumstances, a standard of full disclosure of

material risks may be applicable to, and incumbent upon, any health practitioner administering this therapeutic treatment to you.

With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination and bodily autonomy. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the physician, who ultimately must decide if treatment — any treatment — is to be administered.

For consent to treatment to be considered valid, it must be an "informed" consent. The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its purported benefits as well as the significant risks involved and alternative treatment options available. The information must be such as will allow the patient to reach an informed decision.

Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion by the actions or words of others may be no consent at all and therefore may be successfully repudiated. In this context, physicians must keep clearly in mind there may be circumstances when the initiative to consult a physician was not the patient's, but was rather that of a third party, coercing the patient to seek treatment, for instance, under threat of loss of employment, freedom of movement, or access to services and education.

Your physician owes you a fiduciary duty to speak candidly - free from coercion or duress by third parties – about the material risks pertinent to the COVID-19 mRNA vaccines, both known and unknown.

Lastly, you should appreciate that vaccination against COVID-19 may not necessarily guarantee that you are immune from infection. Conversely, if you are unvaccinated but have previously been infected, it may be possible that you are already immune. Vaccination status may or may not signal immunity, depending on the particular health circumstances of each individual.

Speak to your physician to consider if this vaccine platform is right for you.

This document was prepared under the auspices of the United Health Care Workers of Ontario. We request your immediate attention and look forward to your response. UHCWO@protonmail.com <u>www.UHCWO.com</u>