Ministers and Deputy Ministers of Health
Ministers and Deputy Ministers of Education
Ministers and Deputy Ministers of Justice and Attorneys General
Provincial Public Health Officers and Chief Medical Officers of Health
Chief Science Advisors

December 14, 2021

Dear Sir or Madam,

We are writing to you to *plead that you oppose or suspend authorizing COVID-19 Injectable Biological Products* (hereafter "COVID products") *for children*. Such authorization is likely to result in a public health disaster lasting many years, and of a magnitude that is hard to anticipate.

We represent scientists, health, and other professionals, and academics from various disciplines who have followed, evaluated, and reported on the handling of COVID-19 for over a year.

We draw your attention to the safety risks revealed in Pfizer/BioNTech's BNT162b2 mRNA **Phase III trials**, published November 4, 2021 in the *New England Journal of Medicine* (footnote #23), in which:

The risk of **adverse effects** for the vaccinated was <u>298%</u> greater than in the control group; The risk of **severe adverse** effects was <u>71%</u> greater for the vaccinated; and, The risk of **death** was found to be <u>36%</u> greater.

We cannot agree that these vaccines are "safe and effective" based on the clinical data provided by Pfizer itself.

We ask you to review the Pfizer data and study, and reconsider any authorization, pending authorization or roll-out of these vaccines, especially for children.

To set the record straight, allow us to present an overview of the science underlying COVID products, especially as they concern children:

# 1) Risk of death of COVID-19 for children is statistically zero.

The major risk factor for serious COVID-19 is age. For ages 0 to 19, the death rate is statistically zero.<sup>3</sup> COVID-19 is mostly mild in this age range and long-term sequelae are rare.<sup>4</sup> In Sweden, with a population of 10 million, no children died of COVID-19 even though there were no lockdowns, no masks, and hardly any school closures<sup>5</sup>. A recent, widely circulated New York Times article falsely claimed that over 900,000 children in the USA had been hospitalized

due to COVID-19, overestimating the real number of 63,000 hospitalized children by a factor of 14. Even the lower number of 63,000 has been questioned, with some estimates of 39% to 48% of children originally admitted to hospital for unrelated illness but acquiring COVID-19 in the hospital. The roughly 300 deaths of children in the USA were among children with multiple comorbidities who were not offered early treatment. However, by the time the paper retracted its error the false information had already impacted public opinion.

#### 2) Children pose no risk to adults

A peer reviewed article in the prestigious journal *Pediatrics* found that most studies indicate that children are very unlikely to transmit the infection to adults in the household or at school, and when they develop COVID-19 it is generally a very mild form, one that elicits durable, comprehensive, and strong natural immunity. These data, combined with the Swedish data showing that leaving schools open did not lead to higher rates of COVID-19 among teachers, should reassure policymakers that children pose no risk to adults – grandparents, parents, or teachers. Moreover, it would be unprecedented in a democratic society like Canada if children were used as a means to an end – subjected to an experimental medical treatment, as these COVID products are, to shield adults or the elderly. As Dr. Peter Doshi, Associate Editor of the British Medical Journal, has pointed out, "even if we were to assume [protection against COVID-19 with vaccines], the number of children who would need to be vaccinated to protect just one adult from a bout of severe COVID-19 [...] would be extraordinarily high [and] would compare unfavorably to the number of children that would be harmed, including for rare serious events."

### 3) Children who develop COVID-19 can be treated with safe and effective drugs

There exist multiple safe, effective, and inexpensive, generic drugs to treat COVID-19 – for the rare cases when treatment is necessary, i.e., among children with multiple comorbidities – that have been used in all age groups, even young children 10. A systematic review of 15 clinical trials indicated that the Nobel Prize winning antiparasitic drug Ivermectin (IVM) can be successfully applied to the treatment of viral diseases, including COVID-19, and reduces infection by an average of 86%. <sup>11</sup> A more recent report of 64 clinical trials, 30 of them randomized and controlled, indicated 67% effectiveness in prophylaxis, 84% in early treatment, and 20% in late treatment using protocols that include IVM at different doses and for different periods of time.  $^{12}$ Another meta-analysis of 18 Randomized Controlled Trials of IVM in COVID-19 found large, statistically and clinically significant, reductions in mortality, time to clinical recovery, and time to viral clearance. <sup>13</sup> Finally, many examples of IVM distribution campaigns – in Mexico City, several states in India, and several Argentinian provinces – leading to rapid population-wide decreases in morbidity and mortality among all age groups, indicate the safety and effectiveness of this oral medication in all phases of COVID-19. <sup>14</sup> In light of the wealth of data supporting treatment modalities that can help to overcome the current public health, social, and economic crisis in Canada, the suppression and gross misrepresentation – by leading regulatory agencies

and mainstream media<sup>15</sup> – and the efforts of medical colleges to criminalize doctors who treat COVID-19 patients with IVM and other repurposed drugs, <sup>16</sup> is unjustified and nothing short of scandalous. It is also unjustifiable to risk the health of young Canadians by subjecting them to unnecessary medical experiments when safe and effective alternatives exist.

#### 4) COVID-19 products are not like traditional vaccines

Traditional vaccines, involving inactivated or attenuated viral particles have decades of research supporting their safety and effectiveness, i.e., their ability to stop transmission in the real world and not only in randomized controlled trials, with no major adverse effects. Still, vaccination is not mandatory in Canada<sup>17</sup>, so mandating COVID products in schools – as they currently are in post-secondary educational establishments – would be unprecedented in Canadian history. Such mandates are also a major violation of the right to informed consent, which by definition must be free from coercion. <sup>18</sup> In the case of the very young, it is also a major violation of the right of parents to decide on the medical procedures performed on their children.

## 5) COVID-19 vaccine products are not safe – for adults or children

Several countries have stopped using COVID products in the young. Finland, Sweden and Denmark no longer use them in the population under 30 years of age due to concerns about myocarditis. <sup>19</sup> A retrospective assessment of reports filed to the US Vaccine Adverse Event Reporting System (VAERS) between January 1, 2021, and June 18, 2021, among healthy adolescents ages 12-17 who received COVID products, identified that this age group was up to six times more likely to be diagnosed with myocarditis than to be hospitalized for COVID-19. <sup>20</sup>

In Canada, a recent SickKids report notes that heart disease among the young – myocarditis and pericarditis – have risen since the launch of the vaccination campaign, and instructs clinicians on treatment of adverse events post injection – abdominal pain, vomiting, encephalopathy, and in some severe cases, hypertension and shock among others. Considering that only 16 of 1,129 participants in the control group of the Pfizer trial tested positive for COVID-19<sup>22</sup> – of note, a positive test is not necessarily illness – whereas in the treatment group 3 in 4 participants experienced fatigue and headaches, around half muscle pain, and 1 in 4 joint pain, the relative benefits of the COVID-19 products remain at best dubious.

Additionally, phase III trials are the highest level of evidence and our best tool for ascertaining the risks and benefits of a treatment. Results from the phase III trial of the Pfizer/BioNTech BNT162b2 mRNA product through 6 months were recently reported by Thomas *et al.* in the New England Journal of Medicine. <sup>23</sup> The study, which compared the mRNA COVID-19 vaccine to placebo in healthy adults, showed an absolute risk reduction (ARR) in symptomatic and PCR- confirmed COVID-19 cases among fully vaccinated individuals of 3.7%, *but an absolute risk increase (ARI) of 17.9% in treatment-related adverse effects in that same group.* As well, the study reported an ARR in severe COVID-19 cases of 0.1% among the fully

vaccinated, but also an ARI in serious adverse events among vaccine recipients of 0.5%. While deaths were relatively comparable across arms initially (15 vs 14 deaths, vaccine vs placebo, respectively), 5 additional deaths were reported in vaccine recipients after cross over, bringing the total death count after vaccination to 20. (Table 1). Of note, there were nearly twice as many deaths due to cardiac events in the vaccine arm compared to the placebo arm (7 vs 4 deaths). Results of the BNT162b2 mRNA COVID-19 phase III clinical trial clearly demonstrate at the highest level of evidence that the risks associated with the BNT162b2 mRNA COVID-19 vaccine outweigh the risks of COVID-19 in healthy adults, and do not support claims about the safety of these products, in this or any other population, and regardless of antibody levels.

Finally, vaccine safety reporting systems are revealing a record number of injuries. As of October 15, 2021, reported adverse events worldwide had surpassed 2,344,240 in the WHO reporting system Vigiaccess. <sup>24</sup> VAERS recorded 122,833 serious adverse events, 17,128 of which ended in death, post administration of COVID products. For context, the *combined* serious adverse events, including deaths upon administering *all* (around 70) vaccines, except for COVID products, that have been reported to VAERS since 1990 when the system was established, was 103,767 and 9,054, respectively. <sup>25</sup> *Put another way, about 50% of serious adverse events ever recorded in the over 30 years of the existence of VAERS were associated with three COVID products* (AstraZeneca's product was not approved in the USA) within *less than one year*. Even these staggering numbers *underreport* the true adverse events post COVID products by a factor of at least 10<sup>26</sup> and likely as high as 41. <sup>27</sup>

VAERS data from October 22, 2021, for 12- to 17-year-olds specifically revealed:

- 22,212 total adverse events, including 1,348 rated as serious and 25 reported deaths (2 were suicides).
- 58 reports of anaphylaxis among 12- to 17-year-olds where the reaction was lifethreatening, required treatment, or resulted in death.<sup>3</sup>
- 539 reports of myocarditis and pericarditis (heart inflammation).
- 125 reports of blood clotting disorders.<sup>5</sup>

A recent death involved a 12-year-old girl (VAERS I.D. 1784945) who died from a respiratory tract hemorrhage 22 days after receiving her first Pfizer product dose. Another recent death is the case of a 16-year-old girl (VAERS I.D. 1694568) who died of pulmonary embolism 9 days after a Pfizer product dose (whether it was the first or second is unknown). Yet another recent death was that of a 15-year-old boy who died six days after receiving his first dose of Pfizer product. The VAERS report (I.D. 1764974) states that the previously healthy teen "was in his usual state of good health. Five days after the vaccine, he complained of shoulder pain. He was playing with two friends at a community pond, swinging from a rope swing, flipping in the air, and landing in the water feet first. He surfaced, laughed, told his friends 'Wow, that hurt!', then swam toward shore, underwater as was his usual routine. The friends became worried when he

did not re- emerge. His body was retrieved by local authorities more than an hour later." The autopsy revealed "small foci of myocardial inflammation", an adverse effect of these COVID products commonly found among children and youth, particularly young men.

Of note, *none of these reports include long-term adverse events*, critical to assessing the safety of any medical product. If the history of drug development – such as that of thalidomide, dengue vaccine, and swine flu vaccine – teaches us anything, it is that the harm caused by implementing "remedies" that have not been properly tested can be much greater than the harm caused by the "disease" that these remedies are designed to treat. <sup>28–30</sup>

In concluding, we thank you for taking the time to read our analysis, expect it will contribute to your efforts to keep Canadian children safe, and would appreciate the opportunity to engage and collaborate with you and members of your team towards that goal.

## Respectfully,

Claudia Chaufan, MD PhD<sup>1</sup>

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Table 1

Table 1. Differences in efficacy and safety events reported in the 6-month update of the BNT162b2 mRNA Covid-19 Vaccine

Event	BNT162b2 (n)	Placebo (n)	Absolute Difference (p-value)	Absolute Risk Change* (%)	Relative Risk Change* (%)
Total Randomized Adults and Adolescents (n)	23,219	23,210			
Fully Vaccinated Cases Adults and Adolescents <sup>\$</sup> COVID-like symptoms + PCR	77	850	-773 (p<.00001)	-3.7	-90.9
Any Treatment-Related Adverse Event Adults <sup>#</sup>	5,241	1,311	+3,930 (p<.00001)	+17.9	+298.3
Any Severe Event Adults <sup>/</sup>	278	187	+91 (p=.000022)	+0.4	+48.7
Full Vaccinated Severe Cases Adults <sup>&amp;</sup> COVID-like symptoms + PCR	1	23	-22 (p<.00001)	-0.1	-95.6
Severe Adverse Events Adults Prevents daily routine activity or requires intervention or worse	262	150	+112 (p<.00001)	+0.5	+71.4
Deaths during placebo-controlled period [additional deaths during open-label period in vaccine recipients or those that only received placebo] <sup>%</sup>	15 [+5]	14 [NR]	+1 [+5] (p=.853117)	+0.005 [+0.022]	+7.1 [+35.7]
Deaths due to cardiac events^	7	4	+3		

<sup>\*</sup> Significance figures (p-values) estimated using a chi-square calculator available at https://www.socscistatistics.com/tests/chisquare. P-values are without the Yates correction. This procedure was applied following the framework used by Classen (2021) in their analysis of "All Cause Severe Morbidity" based on data from the initial reports of the vaccine Phase III trials.<sup>2</sup>

<sup>\*</sup> Absolute and relative risk change calculations were performed using the common statistical definition, ie. number of events relative to total number of eligible patients for each event analysis reported; 3 vaccine efficacy estimates reported at source used total surveillance time as denominator, however, this value is not available for all the events analyzed

<sup>\$ \</sup>ge 7 Days after dose 2 among participants without evidence of previous infection

<sup>\*</sup> Assessed by the investigator as related to investigational product

In calculations combining efficacy and safety events, the number of patients randomized that received any dose of vaccine or placebo was used as the study population in the statistical calculations, following the framework used by Classen (2021) in their analysis of "All Cause Severe Morbidity". Differences in the total (event-incident) population (ITT vs efficacy vs safety) used as denominator are relatively small and are expected to have minimal impact on the relative differences between arms.

<sup>&</sup>amp; ≥7 Days after dose 2

<sup>&</sup>lt;sup>%</sup> During the open-label period, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died

<sup>^</sup>Those with reported cause of death due to: cardiac arrest, cardiac failure congestive, cardiorespiratory arrest, chronic obstructive pulmonary disease, hypertensive heart disease, or myocardial infarction.

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