Canadian Covid Care Alliance
Alliance canadienne pour la prévention et prise-en-charge de la covid

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To: The Honourable Jean-Yves Duclos, MP

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Date: September 30, 2022

Re: OPEN LETTER – To the Health Minister regarding Health Canada's use of the mRNA vaccines

cc.: The International Criminal Court (The Hague) – Reference: OTP-CR-465/21

Dear Minister,

We ask that you, as Minister of Health overseeing the activities of Health Canada, seriously review and consider the contents of this letter. We are aware that medical and scientific issues are not your area of expertise, and therefore we expect that you will forward our letter to the appropriate persons. In short, we have analyzed several of Pfizer's COVID-19 vaccine reports, and noted several fundamental flaws that were not identified by Health Canada when the submissions were reviewed, and subsequently accepted for use in healthy Canadians. This correspondence concentrates on just one of these issues, which should have resulted in the rejection of Pfizer's submissions. Our objective in writing this letter is to have a face-to-face meeting between your scientists from Health Canada and our scientists. Only then will the Canadian people know the truth regarding the efficacy and safety of these COVID-19 genetic vaccines.

Respectfully submitted by:

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Executive Summary

- The mRNA COVID-19 vaccines are using gene therapy technology in which the active product, the encoded spike protein, is not actually part of the formulation.
- Health Canada has used an inappropriate guidance document for the regulatory review, contrary to Good Scientific Practice, effectively compromising the safety of Canadians.
- Pharmacokinetics, and distribution studies of the encoded spike protein in various tissues were not performed in any of the Pfizer's studies. Therefore, off-target effects and the safety of the product were based purely upon assumptions.
- Genotoxicity studies were not performed.
- Carcinogenicity studies were not performed.
- An inappropriate rodent species (*i.e.,* Wistar Han rat) was used to generate nonclinical toxicology data; a species such as the Chinese Golden hamster, in which the ACE2 receptor behaves more like that of humans, would have been appropriate. This effectively compromised the safety toxicology, developmental and reproductive studies.
- Developmental and reproductive studies were inadequate. Concentrations of the encoded spike protein were not determined in the pups or in maternal milk. Therefore, it cannot be said that the mRNA COVID-19 vaccines are suitable to administer to pregnant women and mothers who are breast feeding.
- A second species (non-rodent) should have been used to generate nonclinical toxicology data, as per standard procedure. This was not done!
- Full histopathology investigations should have been performed plus immunostaining for the encoded spike protein to evaluate its biodistribution in tissue and organs. This was not done.
- An ascending dose Phase 1 clinical study should have been performed to include pharmacokinetics of the encoded spike protein, as well as synthetic cationic lipids. This was not done.
- Analysis of post-authorization adverse event report data showed high mortality following mRNA vaccine administration. This should have resulted in the immediate and full withdrawal of the product from the market. This did not happen.
- Health Canada must give an account for its actions with full transparency. The mRNA vaccines are known not to be as safe and effective, as the Canadian public have been led to believe. Furthermore, the long-term adverse effects of the mRNA vaccines are not known, since the studies required to ascertain this were never performed.
- From all the above, Health Canada and the Government of Canada are guilty of spreading misinformation among the Canadian public through heavy advertising in the media without a formal risk-benefit analysis, putting countless lives needlessly at risk.

All of the Pfizer data or lack thereof were provided by the United States FDA by court order. Although the FDA Biologic's Application License (BLA) is cited, note that Health Canada had reviewed, and accepted the same flawed data.

Introduction

Traditional vaccines contain a known amount of the target antigens or proteins of the pathogen to create an immune response. They do not require a person's cells to manufacture and present them on their membrane surface at an uncontrolled rate and level. It is this very difference that has been overlooked when assessing the safety, dosage, and pharmacokinetics of BNT162b2 (Pfizer-BioNTech mRNA Vaccine) and its components/mRNA encoded product.

Therefore, BNT162b2 is not like any other vaccine that has ever been used successfully in the past as the innate immune response is initially targeted directly against one's own cells rather than against the invading pathogen.

Unlike traditional vaccines, in which the formulation contains a known concentration of viral antigen, BNT162b2 does not contain the viral antigen that triggers the immune response. Instead, the mRNA directs the body's cells to manufacture the viral spike protein *in vivo* at levels that may vary over 100-fold amongst vaccinees, and it is that very difference that has been overlooked when assessing the safety and pharmacokinetics of BNT162b2 and its components/mRNA encoded product. Individuals produce variable amounts of spike protein due to their genetics, age, hormonal, and nutritional status, batch of vaccine they receive, and so on. This problem was further exacerbated by the arbitrary decision to mix different vaccine products from various manufacturers (including adenoviral DNA biologics no longer permitted for use) assuming that they were simply interchangeable.

The concentration and exact composition of the encoded viral spike protein was never determined in any of the Pfizer's studies as required for other biologics. Therefore, the distribution of the encoded spike protein, and the safety of BNT162b2 was based upon assumptions. This product should never have gone into clinical trials, let alone on the market as COMIRNATY.

Flaws in Health Canada's review process

Nonclinical safety / Toxicology studies

By not performing pharmacokinetic studies of the encoded spike protein, which was already known to be toxic and bioactive, the regulatory submission is incomplete. From the very start, the nonclinical safety studies were designed in order to provide data that would put their product in a "good light." The critical flaw here, was that the guidance documents used by Health Canada were only applicable to traditional vaccines, and not vaccines using gene therapy technology.

Table 1. List of Toxicology Studies as Provided on Page 17 of Pfizer's Nonclinical Overview[(a)].

Toxicology – Studies with BNT162b2 variants					
38166	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V8)	100 µg	Section 2.4.4.3
20GR142	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.3
20256434	Development and Reproductive Toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.6

(a) FDA. BLA (STN: BL 125742/0) Summary Basis for Regulatory Action. [Online] August 23, 2021. https://www.fda.gov/media/151733/download

The first thing to notice from Table 1 is that all these studies are performed using Wistar Han rats. This approach is rather unusual on two accounts. Firstly, it is standard procedure to perform toxicology studies using two species (rodent and non-rodent species), in this case the second species would have been Macaques. Secondly, although not as obvious, was the selection of the species used for these studies, does not correlate with human physiology. Rats in the wild are associated with at least 55 different pathogens that they can pass onto humans, SARS-CoV-2 is not one of them. Therefore, we suspect that like mice to whom they are genetically closely related, their ACE2 receptor does not bind to the SARS-CoV-2 spike protein. So, although rats would be expected to produce antibodies against the encoded spike protein, they would not properly demonstrate adverse effects (toxicology), since the spike protein is not expected to bind its ACE2 target in this species. The most relevant rodent species would be the Chinese Golden Hamster. Therefore, this needs to be considered when interpreting the results from such studies. **In any case, two relevant species should have been used in toxicology studies.**

As these studies stand, the direct adverse effects of the encoded spike protein would never have been detected. During these past 19 years since the initial SARS outbreak, the toxic effects of the viral spike protein binding to the ACE2 receptor in humans have been elucidated. **The fact that the appropriate rodent species was not used, means that the results of the repeat dose, and reproductive toxicology studies would be misleading to say the least**.

Other toxicology studies

On page 29 of Pfizer's Nonclinical Overview document section 2.4.4.4. Genotoxicity, it states: "*No genotoxicity studies are planned for BNT162b2 as the components of the vaccine construct are lipids and RNA and are not expected to have genotoxic potential*." And again, in section 2.4.4.5. Carcinogenicity, it states:

"*Carcinogenicity studies with BNT162b2 have not been conducted as the components of the vaccine construct are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential. Carcinogenicity testing is generally not considered necessary to support the development and licensure of vaccine products for infectious diseases*."

Although BNT162b2 might not be expected to have genotoxic or carcinogenic potential, the encoded spike protein that is produced does. Therefore, these studies should have been performed. Also, in section 2.4.4.6. Reproductive and Developmental Toxicity, it should be noted that these studies were performed using Wistar Han rats, a rodent species that is totally inappropriate for toxicology studies as mentioned earlier. A more relevant species such as the Chinese golden hamster should be used to focus on the toxicity of the spike protein and how it affects the offspring. In addition, the distribution of the spike protein in the tissues in both the mother and the pups would have provided much needed information as to whether BNT162b2 is suitable to administer to pregnant women and mothers who are breast feeding.

Clinical studies

On page 27 of Pfizer's Clinical Overview document [(b)] section 2.5.3. Overview of Clinical Pharmacology, it states: "*Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible*." Drawing our

(b) Pfizer, Inc. BLA Submission for BNT162b2 Module 2.4. Clinical Overview. Public Health and Medical Professionals for Transparency Documents. [Online] April 30, 2021. https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf

attention to safety, Section 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports submitted by Pfizer, on Table 1 of their report, denoted here as Table 2 (see below) there were 1223 deaths over a 3-month period from December 1, 2020 until February 28, 2021. Such a high mortality rate following drug administration would have resulted in any other medicinal product being taken off the market immediately. Therefore, the question should be asked, why aren't the mRNA vaccines taken off the market? From Pfizer's own data, Health Canada must have already known that it is not safe.

Table 2. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

In addition, what about the case outcomes of 9400 people classified as "unknown" along with 6876 people whose age could not be determined? Was that a result of poor documentation, or is there something else going on? Either way, such a flaw in the documentation of a regulated study should have been further investigated, and the findings documented.

Conclusion

The fundamental flaw was that Pfizer failed to determine the concentration and distribution of the encoded spike protein in their nonclinical and clinical studies. They had also failed to perform a Phase 1 ascending dose clinical study, which would have provided important information regarding the amount of encoded spike protein produced. With the knowledge that is already known regarding the spike protein's toxicity, any safety conclusions of the mRNA vaccines that have been offered are purely speculative and unsupported by the evidence, and are therefore invalid. In addition, genotoxicity and carcinogenicity studies were not performed. It can only be assumed that the incorrect guidance document (*i.e.,* that for a traditional vaccine) was used, instead of one more applicable to a gene therapy product. Good science should always supersede an inappropriate regulatory guidance document.