Fundamental Flaws in Pfizer's COVID-19 Biologics License Application Submission, and the Implications to the Safety and Effectiveness of these Novel Gene Therapy Vaccines

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.
- Chemistry, manufacturing and control processes were substandard resulting a product with varying amounts of intact mRNA and wide margins for safety and purity of the final product were accepted that may affect safety and efficacy.
- The basic pharmacology of the mRNA and the resulting spike remains unknown such as the fidelity of the translation of the mRNA, quantity of spike protein produced and the metabolism of the cationic and pegylated lipids.
- Pharmacokinetics, and distribution studies of the resultant spike protein from the mRNA in the lipid nanoparticles 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 as is typical in the past. This did not happen.

- Health Canada must give an account for its actions with full transparency. The mRNA vaccines are now 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.

Introduction

Developed by Pfizer and BioNTech, BNT162b2 is a novel gene therapy vaccine, formulated as an RNA-lipid nanoparticle of nucleoside-modified mRNA that encodes for the spike protein of the SARS-CoV-2 virus. Encapsulation into lipid nanoparticles enables transfection of the mRNA into host cells after intramuscular injection. The lipid nanoparticles are taken up by the cells, and the RNA is released into the cytoplasm. In the cytoplasm, the RNA is translated into the encoded viral protein. The spike protein antigen is believed to induce an adaptive immune response through creation of protective antibodies. The intervening steps for this remain sketchy. One theory is that the expressed spike protein is degraded intracellularly, and the resulting peptides presented on an immune cell surface with major histocompatibility antigens, triggering a specific T cell-mediated immune response with activity against the virus and infected cells. However, most of the vaccine is taken up by muscle cells, and the spike protein is believed to be presented at the surface of these cells as an anchored, intact trimer of the spike protein. However, antigen presenting immune cells have to consume the spike protein expressed on muscle cells, and then present the digested pieces of the spike protein on their own surfaces to T cells in the lymph nodes. It is hard to envision this process without an immune attack on the spike protein presenting cells.

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 byproducts, including the mRNA-encoded spike protein.

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. Moreover, with the bivalent COVID-19 vaccines that mix mRNA for the spike protein from the original Wuhan strain with that from the Omicron variants, novel, hybrid complexes of the spike protein trimers are produced that have not been fully examined for their safety.

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 or bivalent version that target spike protein variants that are no longer in circulation.

What is a vaccine?

Until recently the CDC's definition of a vaccine was: **"A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease"** (1).

In September of 2021 this definition was changed to: "**A preparation that is used to stimulate the body's immune response against diseases"** (2).

Please note that the Biologics License Application (BLA) submission (3) was approved on August, 23, 2021, prior to the date that the definition of a vaccine was changed.

Why is that important? It means that these so-called mRNA COVID-19 vaccines when the BLA was approved did not actually qualify as vaccines by definition; they are in actual fact gene therapy products. The safety assessments at the time should have fulfilled the requirements for gene therapy product, and not that of a traditional vaccine. As such they were sub-standard and inappropriate. BNT162b2 itself is unable to stimulate a person's immune system. According to the latest definition of a vaccine is, one can only conclude that such products are unlikely to protect a person against COVID-19, otherwise it would have said so. Instead of advising the public of this gross and dangerous inaccuracy, the CDC simply changed the definition of what could be considered a vaccine. No notice was provided to the public or health professionals that the approved products were unlikely to provide immunity from COVID-19. Which can only be considered as being unethical and fraudulent. By changing the definition to **"a preparation that is used to stimulate the body's immune system…"** these products could then be called vaccines, leading most health professionals to think of these like any other vaccines, they're not! **So, the question is: which definition is true?**

Flaws in Health Canada's review process

Nonclinical safety / toxicology studies

On page 17 of Pfizer's Nonclinical Overview document (4), it states, based upon two World Health Organization (WHO) documents: **"Pharmacokinetic studies have not been conducted with BNT162b2 and are generally not considered necessary to support the development and licensure of vaccine products for infectious diseases" (5-6)"** As we will see later, by not performing pharmacokinetic studies of the viral spike protein, which was already known to be toxic, 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 scope of the WHO 2005 document (5) states: "For the purposes of this document, vaccines are considered to be a heterogeneous class of medicinal products containing immunogenic substances capable of inducing specific, active and protective host immunity against infectious disease." BNT162b2 does not contain **immunogenic substances capable of inducing specific, active and protective host immunity against infectious disease**. The scope of the WHO 2014 (6) states: "This document addresses regulatory considerations related to the nonclinical and initial clinical evaluation of adjuvanted vaccines." BNT162b2 does not contain an adjuvant, although the lipid nanoparticles do cause inflammation. Essentially, the WHO publications are only applicable to traditional vaccines, and not vaccines using gene therapy technology.

So, what should have been done? Well, there is an FDA document finalized on November 2013, Guidance for Industry - "Preclinical Assessment of Investigational Cellular and Gene Therapy Products" (7), which is directly applicable to therapeutic vaccines. The introduction to this guidance reads: "The Center for Biologics Evaluation and Research (CBER)/Office of Cellular, Tissue and Gene Therapies (OCTGT) is issuing this guidance to provide sponsors and individuals that design and implement preclinical (animal) studies with recommendations on the substance and scope of preclinical information needed to support clinical trials for investigational cellular therapies, gene therapies, **therapeutic vaccines**, xenotransplantation, and certain biologic-device combination products which OCTGT reviews (hereinafter referred to as CGT products)."

This guidance, which is applicable to BNT162b2, recognizes the requirement to perform distribution pharmacokinetics of the spike protein (*i.e.*, where the active viral antigen component is produced in the body) in reproduction, and safety toxicology studies. **These studies were never performed, and is a fundamental flaw, totally invalidating their regulatory submission.** If these studies were performed, BNT162b2 would never have gone into clinical trials, as we now know, based on the serious adverse effects on humans, that the encoded spike protein is widely distributed in other tissues having detrimental off-target effects. However, what happened instead was that Pfizer had used a more recent guidance, FDA June 2020 Guidance for Industry - "Development and Licensure of Vaccines to Prevent COVID-19" (8). This 2020 Guidance for Industry focused solely on evaluating the platform technology and not the encoded spike protein (viral antigen) itself. In addition, the 2020 Guidance for Industry was not open for discussion prior to being issued. In the introduction, it states: "this guidance is being implemented without prior

public comment, because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), (21 U.S.C. 371(h)(1)(C)), and 21 CFR 10.115(g)(2)).” The 2020 Guidance for Industry also states, “However, FDA expects that the recommendations set forth in this revised guidance will continue to apply outside the context of the current public health emergency.” The FDA’s 2020 Guidance for Industry is dangerously inadequate, since it deals only with the safety of the contents of the injected material and not its final generated products, *i.e.*, the spike protein.

On February 8, 2021 when Pfizer’s Nonclinical Overview was approved, the definition of a vaccine was: “**A product that stimulates** a person’s immune system to produce immunity to a specific disease, protecting the person from that disease.” However, BNT162b2 does not directly stimulate the immune system, but the mRNA-encoded spike protein product does. Therefore, BNT162b2 should at the least be considered as a gene therapy product that codes for the spike protein. The spike protein in the body then becomes the antigen that is recognized by the immune system. Note that the BLA was accepted before, and not after the change in definition of what a vaccine is. Yet, the regulatory authorities did not pick up on that at the time when reviewing the raw data and associated reports. Instead, the definition was changed retrospectively to accommodate the pharmaceutical industry.

Table 1. List of Toxicology Studies as Provided on Page 17 of Pfizer’s Nonclinical Overview.

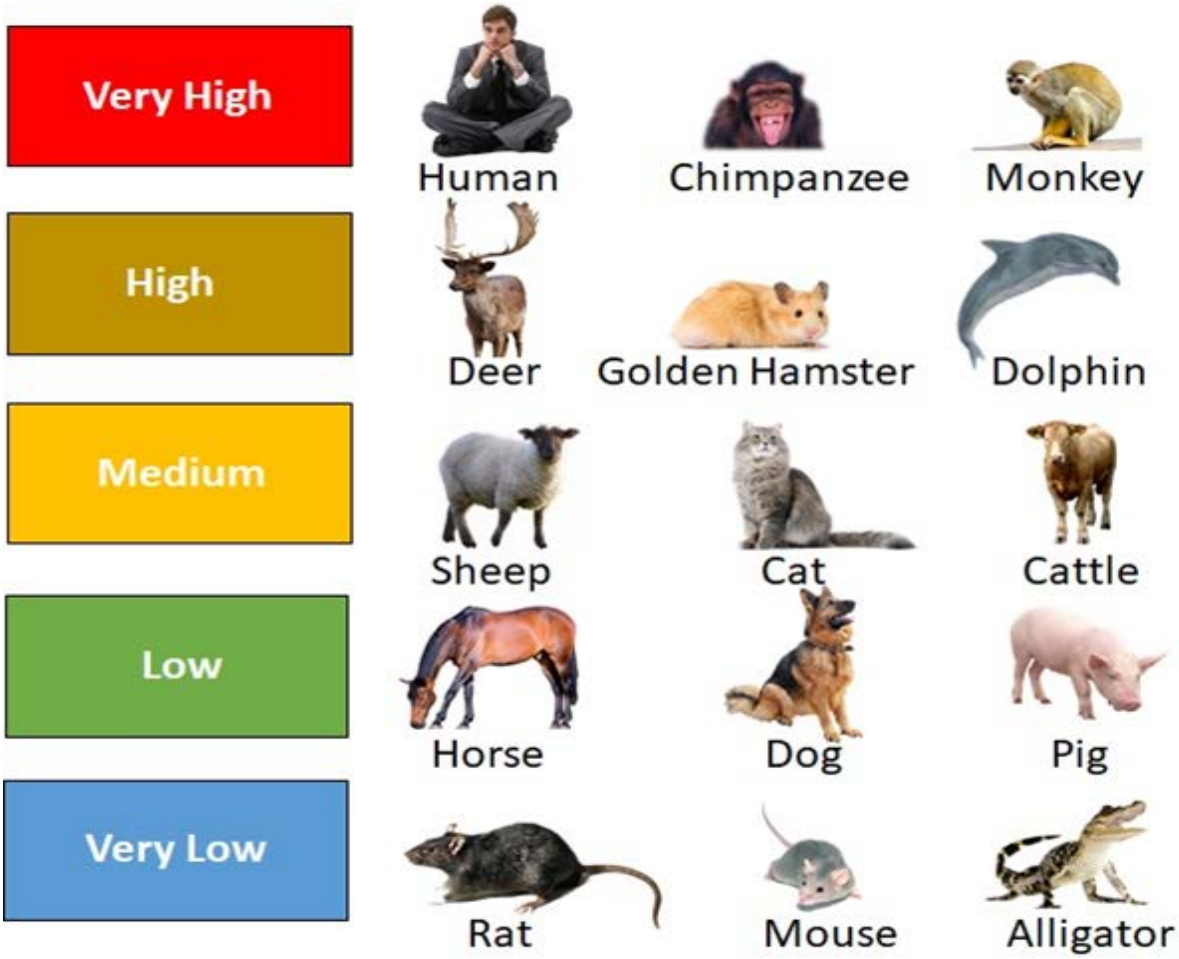
Toxicology – Studies with BNT162b2 variants					
38166	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V8)	100 µg	Section 2.4.4.3
20GR142	Repeat-dose toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section 2.4.4.3
20256434	Development and Reproductive Toxicity	Wistar Han Rats	BNT162b2 (V9)	30 µg	Section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

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**.

Figure 1. Genomic Study of SARS-CoV2 Risk



So, what types of studies should have been performed? For that we must use the FDA 2013 Guidance for Industry (7). First, there has to be an acute ascending dose study, followed by the pivotal non-clinical safety study using 3 dose levels selected based upon the acute study including pharmacokinetics of the spike protein and full histopathology. The dose regimen to mimic that of the intended use in the clinic setting. These studies

were not adequately performed by Pfizer to assess the safety of BNT162b2. The following is a brief outline on what should have been done, not to be considered as a definitive list:

1. **The ascending dose acute study**
    i. Two relevant species, rodent and non-rodent.
    ii. Multiple BNT162b2 dose groups, and three control groups (ALC-0315, ALC-0159, and saline).
    iii. Endpoints: BNT162b2 lowest dose to produce little or no toxicity, whereas the highest dose is there to demonstrate server toxicity. Compared with the controls.
    iv. Pathological examination as required.
    v. From this study, the dose levels to be used for the non-clinical pivotal study will be selected to bracket the anticipate dose to be used for humans.

The ascending dose acute study was deemed unnecessary by Pfizer and was never apparently performed.

2. **The nonclinical pivotal safety study**
    i. Two relevant species, rodent and non-rodent.
    ii. Three BNT162b2 dose groups, and three control groups (ALC-0315, ALC-0159, and saline).
    iii. Dosing regimen to mimic that of the intended use in the clinic.
    iv. Full toxicokinetic analysis of the spike protein using a fully validated method.
    v. Determination of the immunogenicity against the spike protein ideally using a bridging assay so that the analyses is independent of the isotype (with the exception of IgG4).
    vi. Appropriate biomarkers to assess toxicity.
    vii. Macro and micro pathology and should include immuno-staining for the spike protein.

For the nonclinical pivotal safety study, the major items that are missing from the BLA submission are highlighted in **bold**.

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 (9) 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." At the time that Pfizer's Nonclinical Overview was approved the definition of a vaccine was: "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease." As the product did not meet the definition of a vaccine, it therefore, it goes without saying that pharmacokinetics of the encoded spike protein (*i.e.,* the viral antigen) should have been determined in an ascending dose Phase I clinical trials along with the appropriate biomarkers (*e.g.,* troponin-I as an indicator for heart damage) associated with possible vaccine adverse effects as determined in the nonclinical studies in the relevant species as previously discussed. The other advantage for having a full pharmacokinetic profile would be to determine variability in levels of spike protein production between individuals which so far is not known. Also, adverse effects can be collated with the spike protein concentration in the blood. At present, we have no idea what type of kinetic profile, for example, is the concentration of the spike protein proportional to the amount of BNT162b2 given?

Chemistry, Manufacturing, and Controls

To ensure that the product is safe and effective, and consistent between batches, manufacturing processes, product characteristics and product testing must be defined prior to manufacturing. The physiochemical properties of the product must be established so that it can be scaled up from a small bench chemistry method to manufacturing on a commercial scale. These activities are known at Chemistry, Manufacturing and Control (CMC). Since this product was not only a new biological (mRNA), it was a new platform for a vaccine and established testing, assays and standards were not available. As part of the EUA process, the standards for CMC were to be considered "adequate" as there was no regulatory guidance to support the assessment of these products. As a result, serious

flaws in the manufacturing of these products were accepted based on the "adequate" standard. This included, but is not limited to:

- Basic pharmacology of the mRNA remains unknown
- Quantity of spike protein production is unknown
- Quality and reproducibility of the commercial batches were and are poor
- Lipids used in the product were considered laboratory grade and identity not fully disclosed
- Steps in the chemical manufacturing were not fully described or known
- The process for encapsulation of the mRNA was proprietary and poorly described
- The pharmacology, pharmacodynamics, and pharmacokinetics of the mRNA/LNP product was unknown and partially based on another approved product with a different composition of lipids
- Quality control was based on in-house tests and not on compendial standards used for drug manufacturing

While some of these manufacturing issues have improved over the last 18 months, there remains a lack of clarity on the pharmacology and action of the spike protein produced by the BNT162b2 mRNA. It remains unknown if the mRNA is translated with fidelity and if the spike protein produced is equivalent or even bioequivalent to the canonical Wuhan spike protein. It is still unknown how the mRNA is metabolized or broken down, for how long the spike protein is produced and how much, how the lipids are metabolized, and what specific toxicology they may exhibit.

Wide margins of safety and purity were accepted for vaccine product based on this adequate standard resulting in poor batch reproducibility, so much so that stainless steel particles found in the Moderna vaccine was not identified prior to distribution to clinics. This new vaccine platform is also plagued by the fact there are limited validated assays used for critical quality acceptance criteria, and that impurities may present but not identified as the appropriate assays have not been established and validated.

Identification of, and improvement in, manufacturing defects are required in order to ensure a safe and effective product. The Pfizer/BioNTech product does not meet the robust requirements of a pharmaceutical grade product given to billions of people, contains potentially significant amounts of impurities, has wide margins for quality, and lacks transparency on the structure of the protein produced. Because of the EUA standard of "adequate safety," **these products would normally have been considered adulterated and would have been suspended pending quality control assessment. So why aren't the mRNA vaccines taken off the market until the problem is fixed?**

Safety

Traditionally the FDA has always been data driven, and focuses on Good Scientific Practice, taking precedence over what any Guidance for Industry may recommend. It is very disappointed that the FDA would accept such a submission. If we had evidence from properly designed and executed nonclinical studies that the encoded spike protein following vaccination was distributed in various tissue including the brain and reproductive organs, that would have been enough to have rejected the BLA submission. In short, the locations and levels encoded spike protein was never determined in any of Pfizer's studies. Therefore, the safety of BNT162b2 was based upon assumptions. This product should never have gone into clinical trials, let alone on the market. What were the safety issues post-authorization?

Drawing our 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 only 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 would have been 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 we already know that it is not safe.

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

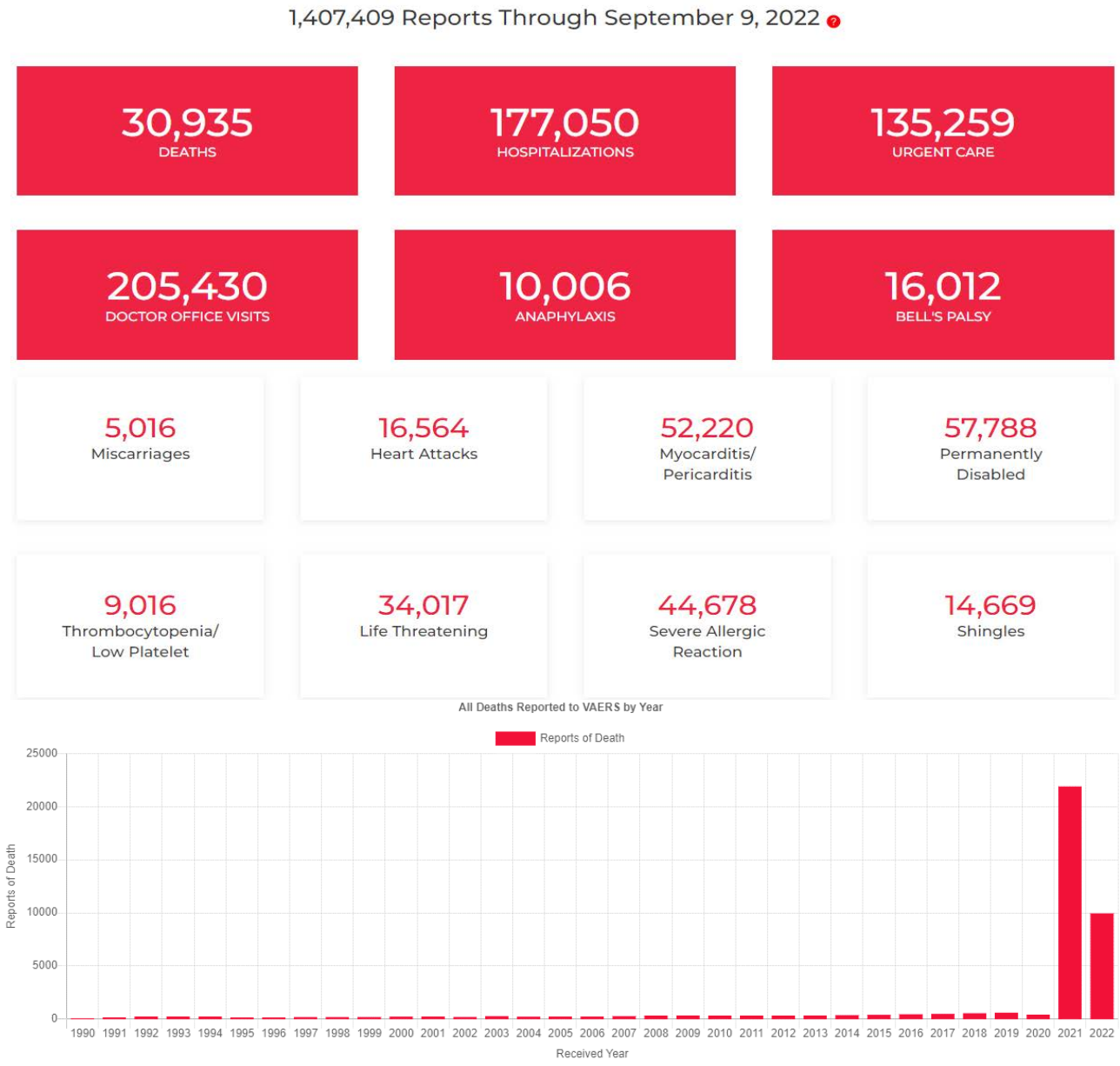
Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	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.

VAERS (Vaccine Adverse Event Reporting System) database maintained by the FDA/CDC Red Box Summaries (11), show reported COVID-19 vaccine adverse reactions up to the September 9, 2022 (Figure 2).

Figure 2. Vaccine Adverse Event Reports Through to September 9, 2022



A general question comes to mind: **How many people must die before corrective action is taken?** To answer that question, at least in part, let us look at the aviation industry.

Figure 3. Photograph of a Boeing 737 Max

On October 29, 2018, a Lion Air Flight 610 was a scheduled domestic passenger flight from Soekarno–Hatta International Airport, Jakarta to Depati Amir Airport, Pangkal Pinang in Indonesia. The Boeing 737 MAX 8 operating the route crashed into the Java Sea 13 minutes after takeoff, killing all 189 passengers and crew. Approximately 5 months later, on March 10, 2019, an Ethiopian Airlines Flight 302 was on a scheduled international passenger flight from Addis Ababa Bole International Airport in Ethiopia to Jomo Kenyatta International Airport in Nairobi, Kenya. The Boeing 737 MAX 8 aircraft used in this flight crashed near the town of Bishoftu 6 minutes after takeoff, killing all 157 people aboard.

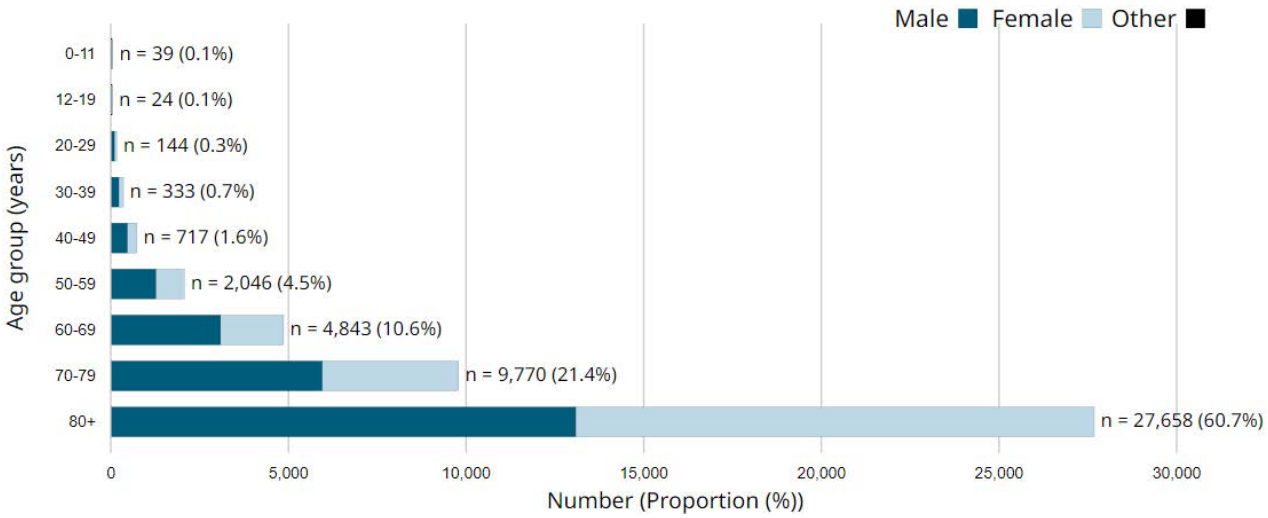
There were significant similarities between Ethiopian Airlines and Lion Air crashes. Within 3 days of the Ethiopian Airlines crash all Boeing 737 MAX 8 aircraft worldwide were grounded (12). The preliminary report implicated a problem with the plane's computer system pushing the nose down four times into a steep 40-degree dive, which had to be fixed before the Boeing 737 MAX 8 aircraft was considered to be airworthy again.

In total, 346 passengers and crew members died. In the case of these novel gene therapy vaccines, the numbers are far greater, and are being deliberately under reported, not fully investigated, and to date, no action has been taken. Of course, it goes without saying that one has to weigh up the risk/benefit.

A question that constantly comes up: Is there any need for children to receive the COVID-19 mRNA vaccines?

To answer this question, we need to look at a histogram (Figure 4) from the Government of Canada website (13) (shown as Table 7 on their website).

Figure 4. Age and gender distribution of COVID-19 cases deceased in Canada as of September 16, 2022. 7 am ET (n=45,574)



Since the start of the pandemic, there were only 63 COVID-19 cases deceased recorded in the 0- to 19-year-old age-group (Figure 4). Just to provide a perspective, compare that with approximately 10 people committing suicide every day in Canada (14). Note that the title says "distribution of COVID-19 cases deceased in Canada." Although implied, that does not mean that all of these people died as a direct result of COVID-19. Many of these children had co-morbidities or died of other causes such as leukemia while showing a positive test result for COVID-19. Over, 90% of deaths occurred in people over 60 years of age. Therefore, there is no need for children to receive the COVID-19 mRNA vaccines using novel gene therapy technology.

Effectiveness

So, the question must be asked: How effective are these novel gene therapy vaccines of which BNT162b2 is just one of them? For this we need to take another look at the definition of a vaccine and how that was changed to accommodate these novel gene therapy vaccines.

Until recently the CDC's definition of a vaccine was: **"A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease"** (1).

In September of 2021 this definition was changed to: "**A preparation that is used to stimulate the body's immune response against diseases"** (2). Here is a question: which of the two definitions of a vaccine would you feel safe with, the original or the revised?

A few years ago, I helped with a humanitarian project for which I had to receive vaccinations for yellow fever, typhoid, and cholera in addition to a few others. My expectations were that these vaccines would stimulate my own immune system so that I would be protected from those specific diseases, irrespective of other people's vaccine

status. Based upon my expectations of what a vaccine must do to qualify. We must conclude that the September 2021 definition is misleading and therefore, false!

I can only assume that the Development and Licensure of Vaccines to Prevent COVID-19 - Guidance for Industry – 2020 as well as the subsequent change in definition of a vaccine was politically motivated, since a more applicable Guidance for Industry was already issued in 2013. The revised definition of a vaccine gives no mention of protecting a person against becoming infected from a specific pathogen (virus/bacteria), which also means that a vaccinated person can transmit that pathogen to other people. Therefore, one has to conclude that these novel gene therapy vaccines offer no protection from SARS-CoV-2 infection or from being contagious.

It started off with two, now currently going up to four/five shots, within a very short period, atypical for a normal vaccine. Where is it going to end? Therefore, why is there such a need to discriminate against the unvaccinated, unless of course there is a financial incentive to certain individuals. **Please note that Health Canada had reviewed, and accepted the same flawed data.** It is also noteworthy that when a vaccine product is approved in the US, there is much less liability to the manufacturer for vaccine injury than an adverse result from a drug product.

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. Proper science should always supersede an inappropriate regulatory guidance document.

Another question is: Now we have the Omicron variant, is there any need for a vaccine? According to the World Health Organization (WHO) there is. Their mantra is the same "you need to continue with your booster shots if you want to avoid serious illness and death from Omicron (15)." But is that true? I know two people in their 30's who have had three shots of the "so-called" vaccine and have had the COVID-19 three times, the last time was with the Omicron variant and it was serious, or may be a vaccine injury? I also know of a lot more unvaccinated people who have had COVID-19 (Delta/Omicron variant) just once, and recovered perfectly well within a few days. By the way, I am one of them, and I am in my 60's. However, having said that, people who have co-morbidities and have susceptibilities also die of the flu. So, is Omicron any different from a bad cold or flu? Therefore, all that I am asking is that you use your eyes, speak to friends and family, and determine what is true for yourself.

Figure 5. Photograph of Freedom Truckers Convoy Protest

Figure 5 Shows a scene taken in Ottawa not so long ago, during the peaceful "Freedom Truckers Convoy." Although as you can see, it was more than just truckers. There must be at least several thousand people in that photograph alone. During approximately a three-week period, no one was wearing a mask, and as you can see, no social distancing during the Omicron out-break, and yet, the hospitals were not filled with COVID-19 patients. There was no mention of a COVID-19 out-break in Ottawa during that time. We have already concluded that the novel gene therapy vaccines are harmful and known to kill people, offering little to no benefit. Therefore, the photograph illustrates that for most people, Omicron is mild, and that lasting herd immunity from COVID-19 can only be obtained by recovering from the illness itself.

However, there is a world-wide pandemic, but it is of misinformation. Whoever controls the media, controls the culture.

Tell a lie loud and often enough, and people will believe it as being true. When such lies are readily accepted, it results in fear, hatred, division, and constant insecurity; and people suffer as a result of those lies.

During this COVID-19 pandemic in Canada, not only are people needlessly suffering from these so-call vaccines, but they are also having their civil rights taken away, resulting in an apartheid system for the unvaccinated.

Figure 6. Front page from the Toronto Star newspaper on August 26th, 2021.

Try this: Substitute the word "**Unvaccinated**" with "**Jewish** or **Jews**". Now you get:

"I have no empathy left for the Jews. Let them die."

"Jewish patients do not deserve ICU beds."

"At this point, who cares, Stick the Jews in a tent outside and tend to them when the staff has time."

Figure 6 shows the headline from the front page of the Toronto Star last year. Back in the fall of 2019, it would have been inconceivable to believe that ordinary people in Canada would state in such a public manner rhetoric reminiscent of Nazi Germany during the late 1930's - 1945.

Today, people in Canada are being persecuted simply for choosing not to be vaccinated. More importantly, people are also suffering because they are vaccinated.

I am very concerned that misinformation is being emanated from the World Health Organization (WHO), regulatory authorities, and governments, who we are supposed to put our trust in. What may happen next is nothing less than disturbing.

The International Health Regulations (IHR) was adopted by 194 member states (Canada being one of them) of the WHO in 2005 (16). They enable the WHO to declare a Public Health Emergency of International Concern (PHEIC) if it decides that an infectious disease outbreak has occurred in a member state, but with the consent of the member state. I for one acknowledge this aspect of the current regulations, because it recognizes the sovereignty of nations that adopted the IHR. But that is about to change. The WHO is working towards amendments to the International Health Regulations May 22-24, 2022, and simultaneously, a new pandemic treaty to be finalized by 2024.

The WHO intends to amend 13 IHR articles (17): 5, 6, 9, 10, 11, 12, 13, 15, 18, 48, 49, 53, 59. It would be worth your while to read through the changes for yourself, and see what is happening behind our backs. But wait, it gets even worse. The WHO aims to also confirm the pandemic agreement (18) in the 77th World Health Assembly in 2024, but it could happen much sooner. The proposed WHO agreement is unnecessary, and is a threat to our sovereignty and inalienable rights. It increases the WHO's suffocating power to declare unjustified pandemics (*e.g.,* seasonal colds and flu), impose dehumanizing lockdowns, and enforce expensive, unsafe, and ineffective treatments against the will of people. Moreover, it is evident with the Monkey Pox scare, how easily the checks and balances within the WHO can be abused. The president of WHO, Dr. Tedros Adhanom Ghebreyesus recently overruled his advisory committee to declare the Monkey Pox pandemic, when there had only been five deaths world-wide (19).

Historically, the WHO leadership has failed the people. Among many examples, it approved the injurious H1N1 (swine flu) vaccine for a controversially declared pandemic. Equally, the WHO failed during the COVID-19 chapter as it encouraged lockdowns, suppressed early preventive treatments, and recommended product interventions, which have not been proven to be safe or effective. **The question is: How many people have needlessly died because of the spread of misinformation by the WHO, mainstream media, and government health authorities?**

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