July 7, 2025

Dear Board of Health:

HL26.2 - Toronto Public Health's Strategic Plan 2024-2028: 2025 Annual Progress Report

I would like to address Priority 1.a. of the Toronto Public Health's Strategic Plan 2024-2028: "Prepare for and respond to outbreaks and public health emergencies informed by best evidence and lessons learned from previous responses."

I agree with the statement, but am concerned about what Toronto Public Health will consider as "best evidence" and as the "lessons learned" because the COVID-19 mRNA vaccines, which I and many others consider unacceptably harmful and questionably effective, continue to be offered.

I would like to use my time today to quickly introduce two excellent documents prepared by Canadian scientists, that should be included in your review of "best evidence":

- A 2024 paper in the Journal of American Physicians and Surgeons by mostly Canadian scientists summarizing issues with the Pfizer COVID-19 mRNA vaccine (poor testing, inefficacy, vaccine adverse events, etc.) The paper concludes that the Pfizer vaccines "should be removed from the market and their use in humans … stopped."[1]
- A 2025 Open Letter of Concern authored by Canadian scientists & clinicians calling for an immediate halt to the COVID-19 mRNA vaccines, citing DNA contamination, SV40 DNA sequence in the Pfizer vaccine, batch inconsistencies, ribosomal frameshifting, and shift to IgG4 antibodies. http://www.call2halt19.ca

I picked these two documents because they are both summaries. The first one covers earlier discovered issues. The second one covers more recently discovered issues. Together they cover most of the known issues. Both are attached.

As for "lessons learned," the full extent of vaccine injuries needs to be acknowledged. This recent July 2, 2025 Global News investigative report called "Immunized Injured Incenced" https://globalnews.ca/news/11247648/covid-vaccine-injury-program-visp-oxaro-workplace-phac-2/ says the people they highlight in their article are some of the thousands of seriously vaccine-injured Canadians. The number is likely many times higher. If we turn a blind eye and don't look into this properly, the future will be more of the same.

Regards,

Mariko Uda, Toronto resident (2 attachments)

[1] Oldfield, P. R.; Gutschi, L. M.; McCullough, P. A.; Speicher, D. J. Pfizer/BioNTech's COVID-19 modRNA vaccines: Dangerous genetic mechanism of action released before sufficient preclinical testing. Journal of American Physicians and Surgeons 2024, 29(4), 118-126. https://jpands.org/vol29no4/oldfield.pdf

Pfizer/BioNTech's COVID-19 modRNA Vaccines: Dangerous Genetic Mechanism of Action Released before Sufficient Preclinical Testing

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Introduction

Independent scientists and medical doctors jointly with the Public Health and Medical Professionals for Transparency filed a Freedom of Information Act (FOIA) request for data and reports reviewed by the U.S. Food and Drug Administration (FDA) to license Pfizer/BioNTech's COVID-19 modified mRNA (modRNA) vaccine (BNT162b2). This resulted in a court order to release a trove of documents that Pfizer/BioNTech submitted to the FDA for regulatory approval to be released in 8 months rather than 75 years.[1,2] Pfizer/BioNTech's regulatory submission must be reviewed independently to determine whether the COVID-19 modRNA vaccines were established as safe and effective products, as the public is led to believe by mainstream media and governmental authorities. This commentary provides a brief overview of the safety and efficacy of the Pfizer/BioNTech COVID-19 modRNA vaccines.

Regulatory Guidelines for RNA Therapeutics

The recent rise of mRNA therapeutics has resulted in a breakdown of the regulatory framework, where even definitions are vague. For example, the COVID-19 modRNA vaccines are not classified as gene therapy products, whereas an mRNA vaccine against a non-infectious disease such as cancer is not classified as a mRNA vaccine, but as a gene therapy product.[3] Therefore, nucleic acid vaccines against infectious diseases were specifically excluded from regulatory guidelines for gene therapy products.[4] This has caused the WHO 2005 guidelines to be used for the nonclinical assessment of the COVID-19 modRNA vaccines.[5] It is a regulatory requirement for manufacturers of a gene therapy product to determine the structure, concentration, and biodistribution of the protein that has been coded for produced in-vivo.[6] However, that was not the case for Pfizer/BioNTech's BNT162b2, as it was misclassified as a traditional vaccine.

How much spike protein antigen is being produced by the BNT162b2? Does the amount vary between individuals? What is the full mechanism of how these modRNA vaccines work within the human body? Both the immunization process and the pathogenesis of vaccine injury syndromes must be delineated. The spike protein is toxic and can have serious immune consequences.[7] However, the modRNA and spike protein pharmacokinetics and pharmacodynamics need to be fully understood to analyze off-target effects. For example, in the case of BNT162b2, the spike protein is produced in human cells transfected by the modRNA encapsulated in lipid nanoparticles (LNPs). The modRNA then instructs the ribosomes how to create the spike protein. This spike protein then subsequently binds to the cell membrane, and is released into the bloodstream.[8] Pfizer/BioNTech BNT162b2 was misclassified as a traditional vaccine, and therefore these assessments were never performed or submitted as part of the regulatory submission.

To determine what should have been the regulatory requirements for safety and efficacy for these modRNA vaccines, we need to understand the fundamental differences between the traditional vaccines, i.e. the inactivated and/or attenuated vaccines that have been used for more than 100 years, and the new COVID-19 modRNA vaccines using gene transfer technology that have received emergency use, and subsequent authorization by the FDA and other national regulatory agencies.

Pfizer/BioNTech's COVID-19 Vaccine

Traditional vaccines contain a target antigen at known concentrations from the pathogen (which can be live attenuated, inactivated, or a subunit of the pathogen) in conjunction with an adjuvant. Together the antigen and adjuvant produce an immune response. This is not the case with the COVID-19 modRNA (e.g. Pfizer/BioNTech and Moderna), and the adenovirus vector (e.g. Astra Zeneca) vaccines. These newer "vaccines" are similar to a "prodrug" as they use the body's own cells to produce the viral spike protein in vivo at levels that vary greatly.[9]

Prodrugs have no intrinsic activity to elicit a pharmacological response (in this case formation of antibodies) on their own, but give instructions to the ribosomes on how to produce the "active drug" (i.e., spike protein). Pfizer/BioNTech's modRNA vaccines have a pronounced pharmacological phase that is then followed by an immunological phase to produce the immune response. This difference has been ignored when assessing the safety and pharmacokinetics of Pfizer/BioNTech's BNT162b2 COVID-19 modRNA vaccine and its components. Injected individuals may produce variable amounts of spike protein for variable durations of time based on their genetics, age, hormonal and nutritional state, athletic condition, and batch of vaccine they receive.[10] Studies to investigate these factors were never performed in the preclinical and clinical phases of development. Therefore, BNT162b2 is not like any other vaccine that has ever been used successfully. The innate immune response is initially targeted against the spike protein, which is bound to the vaccinee's own cells rather than to the invading pathogen. The fundamental differences are summarized in Table 1.

Table 1. Fundamental Differences Between Traditional and modRNA Vaccines

Product Characteristics	Traditional vaccines	mRNA vaccines
Contains the antigen	Yes	No
Contains adjuvant	Yes	No/Yes*
Enters human cells (*i.e.,* transfect)	No	Yes
Remains at the injection site	Yes	No
Antigen binds to the cell surface	No	Yes
Mechanism of action adequately understood	Yes	No

*Lipid nanoparticles have intrinsic adjuvant properties, as do impurities such as endotoxin or dsRNA

The characterization and structure of the resultant spike protein or its trimerized state in the prefusion conformation was never determined in any of Pfizer/BioNTech's studies. The distribution of the encoded spike protein, the protein sequence itself, and the safety of BNT162b2 was based purely upon assumptions from traditional vaccine regulatory reviews.

A Review of Pfizer/BioNTech COVID-19 modRNA Vaccine Submission Data

Nonclinical Safety / Toxicology Studies

By not performing pharmacokinetic and pharmacodynamic studies of the encoded spike protein produced from the modRNA, which was already known to be toxic via natural SARS-CoV-2 infection,[11,12] the regulatory submission is incomplete. Pfizer/BioNTech's BNT162b2 Module 2.4. Nonclinical Overview,[8, p 17] states:

> 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 (WHO, 2005; WHO, 2014).[5,13]

Thus, the nonclinical safety studies were designed to provide data that was insufficient for such a new type of "vaccine." The World Health Organisation (WHO) guidance documents were only applicable to traditional vaccines, and as a result the pharmacological, pharmacodynamic characteristics, and safety risks unique to nucleic acid medicinal products were not assessed.[4] In brief, the WHO's regulatory body guidelines allowance for DNA in the vaccines is 10 ng/dose.[14] These guidelines are for naked DNA fragments that are smaller than 200 bp and not for DNA being transfected inside LNPs. The guidelines also do not account for multiple dosing of the same vaccine or platform, the risk of regulatory sequences, integration of small DNA fragments (7 bp to 200 bp), or nuclear entry/integration.

The mRNA in the vaccine is extensively modified to improve its stability and efficiency at producing spike protein,[15] as well as making the modRNA "immunologically silent."[16] The modRNA used in the LNPs is not naturally occurring mRNA but bioengineered modRNA in which all the uridines have been replaced with synthetic N1-methylpseudouridine.[17] In addition, the mRNA is also codon optimized and contains human sequences in the 5-UTR and 3-UTR as well as a bioengineered segmented poly(A) tail.

The problem with modifying mRNA by replacing all the uridines with N1-methylpseudouridine is that it produces a "slippery sequence" (UUUs or ΨΨΨs) that causes problems for the tRNA binding to the modRNA during translation from RNA to amino acid production in the ribosome. This slippery sequence causes the ribosomes to "skip" during translation (i.e., ribosomal frameshifting) and produces a wide range of aberrant and degenerate spike proteins. This is a safety concern as the production of various-sized spike protein can cause variable, underperforming, and/or altered immune responses as well as the potential for prion-like illness, especially if the spike proteins are not attached to a cell membrane.[18] The "error prone" code is also a safety concern with a significant potential to be harmful leading to autoimmune responses and other unknown toxicological effects.[19]

The Pfizer/BioNTech toxicology studies are listed in Table 2.

Table 2. Toxicology Studies Extracted from Pfizer/BioNTech's BNT162b2 Module 2.4. Nonclinical Overview.[8, p 9]

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

Pfizer/BioNTech's toxicology studies were performed using Wistar Han™ rats. This approach is unusual for two reasons. First, the standard procedure for toxicology studies is to use two species (one rodent and one non-rodent species); in this case the second species would have been Macaques primates. Secondly, although not as obvious, 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 can pass onto humans; SARS-CoV-2 is not one of them. Therefore, like mice to which they are closely related genetically, their ACE2 receptor does not bind to the SARS-CoV-2 spike protein.[20] While rats would be expected to produce neutralizing antibodies against the encoded spike protein, any potential toxicity effects noted would likely be due primarily to the LNPs only, not to unbound spike protein. Specifically, they would not be expected to exhibit adverse effects associated with the spike protein, as it does not bind to its ACE2 target. The most relevant rodent species would have been the Chinese golden hamster.[21,22] Studies following the 2003-2004 SARS-CoV-1 outbreak determined that the viral spike protein binding to the ACE2 receptor is toxic to humans.[11,12] However, as studies performed on the SARS-CoV-2 spike protein used the incorrect animal model, toxicity due to the spike proteins off-target effects could not be determined.

Biodistribution Studies

Pfizer/BioNTech's BNT162b2 Module 2.5 Clinical Overview, section 2.5.2.2, Biopharmaceutical Studies,[23, p 27] states:

> Bioavailability and bioequivalence assessments are not relevant to vaccine antigenicity and have not been measured. The major pharmacodynamic effect of a vaccine, unlike a drug, is to elicit an immune response to the antigens included in the vaccine. Vaccine induced activation of antigen presenting cells takes place at the site of injection (i.e., muscle) which is rapidly followed by antigen-presenting cell migration via lymphatic vessels towards the draining lymph node where vaccine antigens activate specific B and T cells. There is no specific vaccine antigen blood level required to elicit the immune response.

Since the antigen (encoded spike protein) is not included in the modRNA vaccine, the statements made in this clinical overview are misleading. Pfizer/BioNTech had no idea how much of the spike protein is generated in vivo, or where it subsequently distributes within the human body. Moreover, Pfizer/BioNTech assumed that the modRNA vaccine resides at the injection site, concluding there is no need to measure the spike protein in the blood. This conclusion is incorrect based upon Pfizer/BioNTech's own biodistribution study data that appeared following the FDA emergency use authorization, in which it was demonstrated that LNPs were distributed to a variety of tissues likely mediated via LNPs entering the blood stream.[8, p 17]

Although no traditional pharmacokinetic or biodistribution studies were performed with BNT162b2 specifically, or the final modRNA/LNP formulation used clinically, Pfizer/BioNTech did conduct a nonclinical study in which biodistribution was assessed using luciferase as a surrogate marker protein, since it was assumed that changing the coding sequence of the mRNA was unlikely to affect its biodistribution or physicochemical properties. However, differences between the luciferase reporter RNA and BNT162b2 nucleosides (i.e., modRNA) could potentially affect stability or persistence of the measured signal since spike protein has a longer half-life than luciferase.[24] Furthermore, no duration was specified for biodistribution studies for vaccines.[5] Using RNA encoding luciferase formulated like the BNT162b2 "pro-vaccine," with an identical lipid composition, the Pfizer/BioNTech's BNT162b2 Module 2.4. Nonclinical Overview, Section 2.4.3.4., Distribution,[8, p 17] states:

> In an in-vivo study (R-20-0072; Tabulated Summary 2.6.5.5A), biodistribution was assessed using luciferase as

a surrogate marker protein, with RNA encoding luciferase formulated like BNT162b2, with the identical lipid composition. The LNP-formulated luciferase-encoding modRNA was administered to BALB/c mice by IM injection of 1µg each in the right and left hind leg (for a total of 2µg). Using in vivo bioluminescence after injection of luciferin substrate, luciferase protein expression was detected at different timepoints at the site of injection and to a lesser extent, and more transiently, in the liver (Figure 2.4.3-2). Distribution to the liver is likely mediated by LNPs entering the blood stream. The luciferase expression at the injection sites dropped to background levels after 9 days….

The biodistribution of the antigen encoded by the RNA component of BNT162b2 is expected to be dependent on the LNP distribution and the results presented should be representative for the vaccine RNA platform, as the LNP-formulated luciferase-encoding modRNA had the same lipid composition.

Note that in the nonclinical overview it is stated that: "Distribution to the liver is likely mediated by LNPs entering the blood stream." Therefore, both Pfizer/BioNTech and the FDA knew in advance that it was incorrect to assume that in vivo generation of spike protein would be restricted to the deltoid muscle. This was confirmed in a subsequent tissue distribution study in Wistar Han™ rats using an LNP-formulated luciferase-encoding modRNA with the exact same lipid composition as BNT162b2 (Study 185350; Tabulated Summary 2.6.5.5B).[25,26] The cholesterol in the LNP was radiolabelled and the signal measured by Quantitative Whole-Body Autoradiography (QWBA), considered the industry standard for RNA therapeutics.[3]

Based upon the biodistribution results above, it can be concluded that if BNT162b2 instead of the surrogate were to be administered, in vivo production of spike protein would also likely occur in the liver, adrenal glands, spleen, ovaries, and elsewhere. Although the distribution of the spike protein itself was not examined, it is expected to be extensive since the spike protein has easy access to the blood stream. LNPs have selectivity for certain tissue types and transportation into the cell, which necessitates measuring the actions of the LNPs, the modRNA, and the spike protein separately. Therefore, biodistribution studies should measure the distribution of each of these components separately and simultaneously since there is not always a correlation between where the LNPs are found in the body and where and how much spike protein is produced.[3] These studies were not done.

Since the LNPs have adjuvant-like activities,[27] a thorough safety and immunological assessment and a potentially longer follow-up for adverse events was indicated compared to what was required under the WHO 2005 vaccine guidelines. Furthermore, only about 1–2% of the LNPs result in successful transfection leading to spike protein production, and the disposition of the remaining LNPs is not fully known.[28] Because the rate-limiting step for protein production is release from endosomes after transfection, toxicity from stored LNPs in endosomes has been proposed.[29] No assessments of these risks from LNPs have been performed.

Other Toxicology Studies

Pfizer/BioNTech's Nonclinical Overview document, section 2.4.4.4., Genotoxicity,[8, p 29] 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, the document 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 expected to have genotoxic or carcinogenic potential, the encoded spike protein that is produced does.[30] Therefore, these studies should have been performed. They were not. Also, Section 2.4.4.6. Reproductive and Developmental Toxicity shows that these studies were performed using Wistar Han™ rats, a rodent species that is totally inappropriate for toxicology studies. A more relevant species should have been chosen for the toxicity studies on the developing pups. In addition, the distribution of the spike protein in the tissues of both the mother and pups would have provided much needed information as to whether BNT162b2 is suitable to administer to pregnant women and mothers who are breast feeding. Furthermore, male rats were not studied, and data on male fertility is unknown. Moreover, it has recently been documented that the modRNA may predispose otherwise healthy individuals to cancer.[31]

Clinical Studies

Pfizer/BioNTech's BNT162b2 Module 2.5, Clinical Overview section 2.5.3, Overview of Clinical Pharmacology,[23, p 27] states: "Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible."

Since BNT162b2 is not a traditional vaccine, the pharmacokinetics of the encoded spike protein (i.e., the viral antigen) should have been determined as part of an ascending dose Phase I clinical trials. This was never studied. A full pharmacokinetic profile would show the variability in levels of spike protein produced between individuals. Unfortunately, the variability remains unknown. Furthermore, adverse effects could have been collated with the spike protein concentrations in the blood. In a meeting on June 15, 2022, Dr. Portnoy, a member of the FDA's Vaccines and Related Biologics Advisory Committee (VRBAC) asked Dr. W. Gruber from Pfizer what cells produce spike protein, how much do they produce, and for how long? Dr. Gruber dismissed this question as academic.[32] Understanding these basic questions is essential to understanding modRNA vaccine safety. To date these questions have yet to be answered. In fact, a study by Stanford researchers demonstrated persistence of both the modRNA and the spike protein for up to 60 days.[33]

Safety Profile

Pfizer/BioNTech's Module Section 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports,[34] Table 1 on page 7 of their report (included here as Table 3 below), shows 1,223 deaths

Table 3. 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.

Extracted from: https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

over a 3-month period (Dec 1, 2020, to Feb 28, 2021). Such a high mortality rate following medical intervention would have resulted in having any other medicinal product taken off the market immediately. Therefore, the question must be asked: Why were the modRNA vaccines allowed to remain in use?

The case outcomes of 9,400 people are classified as "unknown." How many of them died? Also, from Table 3 there were 6,876 people whose age could not be determined. Of the 11,361 that had not recovered at the time of this initial report, how many of them subsequently died? Was this simply poor documentation or is there another explanation? Either way, such flaws in documentation of a regulated study should have been further investigated and the findings documented.

Implications of Approving Pfizer/BioNTech's COVID-19 modRNA Vaccine Based on Flawed and Incomplete Data

Safety

The VAERS (Vaccine Adverse Event Reporting System) is a database maintained by the FDA/CDC of reports of injury post vaccination designed for signal detection of a potential safety problem with a vaccine. OpenVAERS is a publicly available overlay that allows browsing and searching of VAERS reports without the need to compose an advanced search.[35] It is quite laborious and time-consuming to submit a report to VAERS, but a report can be submitted by either a medical professional or a member of the public with detailed information about the injury. Physicians and other medical professionals usually submit reports when they have suspected the vaccine has caused the adverse event. Filing a false claim risks hefty federal fines or imprisonment. The reporting system itself is transparent and highly detailed, and as a result, many professionals do not file reports, even for serious adverse events, because of the time required, the fact that reporting may be discouraged, or other systemic factors.[36] This lack of reporting has resulted in VAERS underestimating the actual numbers of adverse events,[37] as is typical for passive pharmacovigilance systems.[38] Since the rollout of the COVID-19 modRNA vaccines, there has been a huge jump in the number of serious adverse events, including deaths (Figure 1). There is a stark contrast between the response to rotavirus vaccine (Rotashield®), in which 15 cases of intussusception led to the rapid removal of this vaccine from the market,[39] and that to Pfizer/BioNTech BNT162b2. Due to the huge increase in serious adverse events and death, one must ask: What does it take before corrective action is taken?

To answer that question, if this level of injury had occurred in the aviation industry, every aircraft of that make and model would be grounded until the fault was located and fixed.[40] However, for the BNT162b2 vaccines no such action was taken. Apart from

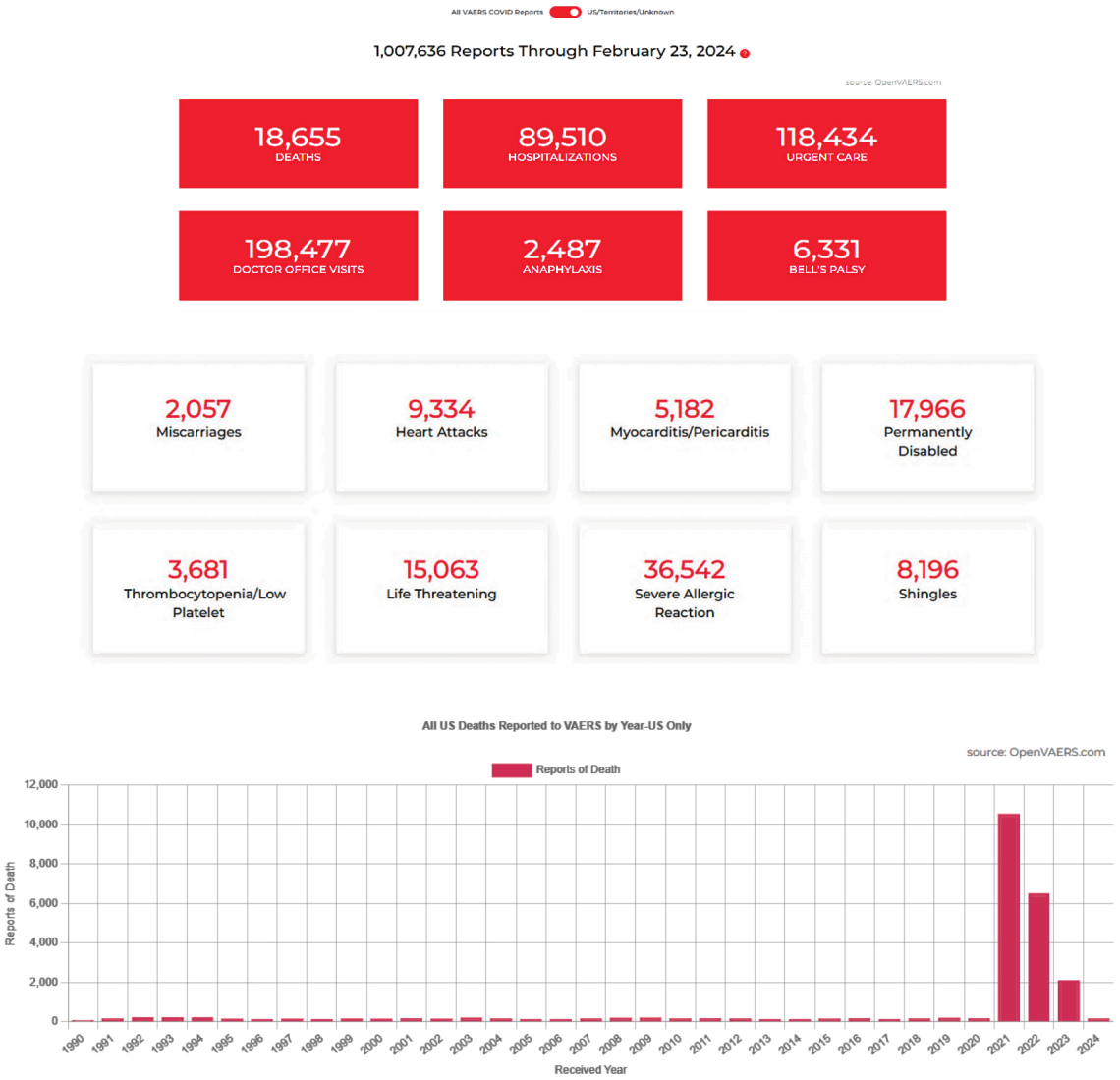

Figure 1. Red Box Summaries from the VAERS database, showing reported COVID-19 vaccine adverse events up to Feb 23, 2024 (U.S./domestic only), from openVAERS.com

Florida Health,[41] the COVID-19 modRNA vaccines continue to be aggressively promoted by government officials to the population as being "safe and effective" despite "the science" showing the complete opposite.

By February 2021, both Pfizer/BioNTech and the FDA were already aware that the product carried significant hazards. Vaccine-related adverse effects were being documented in VAERS. However, COVID-19 modRNA vaccines are still touted as highly effective by government authorities, who are promoting vaccination with the latest booster shots for as many people as possible. Meanwhile, these authorities accept a higher death toll than would otherwise be tolerated by another vaccine or medication. This death rate is accepted as "collateral damage" for the greater good. However, is the assumption that the COVID-19 modRNA vaccines are highly effective even accurate? There are two points to consider.

1. Is there definitive proof that the COVID-19 modRNA vaccines stopped the spread of infection and saved lives, i.e., do the potential benefits outweigh the known risks?
2. Were there alternative medications that are safe and effective, and readily available for the treatment of patients infected with COVID-19?

Effectiveness

The initial trials were all stopped early and severely flawed by offering the control group the vaccine after only a few months.[42] The unblinding of placebo patients to receive the vaccine was criticized by researchers due to the loss of future reliable data, especially in the elderly. This unblinding "will set a de facto standard for all vaccine trials to come."[43] Therefore, in the absence of properly powered randomized clinical trials, it is impossible to definitively demonstrate that the COVID-19 modRNA vaccines are effective in reducing the binary endpoint of mild COVID-19 illness. There has been no prospective double-blind randomized placebo-controlled trial of COVID-19 vaccination that demonstrated reductions in hospitalization and death. Likewise, no valid non-randomized study controlling for early multidrug therapy, natural immunity, and progressively milder strains of SARS-CoV-2 demonstrated that vaccination was associated with reductions in hard endpoints. Additionally, how can the effectiveness be demonstrated, since it is now known that these vaccines do not prevent transmission or occurrence of the disease?[44] Finally, the available studies showed that any theoretical protective effect of vaccination lasted less than six months.[45]

In the place of actual data, models have been used to predict what would have happened if the COVID-19 pandemic had occurred in the absence of vaccines. One such study[46] predicted that the COVID-19 modRNA vaccines and public health measures were responsible for saving up to 800,000 lives in Canada. This model used data collected from Feb 7, 2020, to Mar 31, 2022. The Canadian population during that time was approximately 38 million,[47] and the average death rate for the Wuhan strain was suggested to be 2.3%.[48] It is only by assuming that the subsequent less lethal/more contagious variants had the same death rate as the original Wuhan strain, that naturally acquired immunity did not exist, and that everyone got infected, do we get a number close to that in the predicted model publication, i.e., 38,000,000 (Canadian population) X 2.3% (death rate) = 874,000 lives saved.

As of May 22, 2020, before the roll-out of the COVID-19 modRNA vaccine, the number of deaths in Canada was 2,305 "with" COVID (i.e., COVID might not have been the cause of death).[49] By the same date, the reported number of cases was 80,142,[50] giving a calculated infection fatality rate of 2.9%. Thus, a 2.3% death rate for the Wuhan strain was considered reasonable and was used in the calculation.[48]

Therefore, to say that the publication of this model is biased would be an understatement. The assumptions used were obviously unrealistic.

Furthermore, subsequent dominant variants during that period, ending with Omicron, had greater infectivity but much less lethality. In another study, investigators studied the relationship between the percentage of population fully vaccinated and new COVID-19 cases across 68 countries and across 2,947 counties in the U.S. No correlation between the vaccination rate and new cases of COVID-19 was found.[51] Until a proper randomized clinical trial is conducted, any conclusions based upon predictive models are nothing more than conjecture. Therefore, with predictive modelling and population analyses alike, it must be concluded that the potential benefits of the BNT162b2 vaccines are associated with considerable known and unknown risks.[35]

Alternative Safe and Effective Treatments for COVID-19

On Dec 11, 2020, the FDA issued emergency use authorization (EUA) for Pfizer-BioNTech's COVID-19 vaccine to be distributed in the U.S.[52] "For FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition."[53] However, early in the COVID-19 pandemic, there was overwhelming evidence indicating that ivermectin (IVM),[54-60] and hydroxychloroquine (HCQ)[61]-based multidrug protocols were active agents when used early against COVID-19. Yet governmental and medical literature demonized the off-label drug treatment of patients with COVID-19 in favor of the COVID-19 modRNA vaccines.

There were several randomized control trials (RCTs) that were poorly designed and executed, and yet, these results were extensively referenced by the media and government policy recommendations as proof that IVM was ineffective against COVID-19. Notably, the TOGETHER Trial[62] was a high-profile RCT that concluded that IVM was not effective for treating patients with COVID-19. This RCT had several critical shortcomings that effectively invalidated the study.[63] In contrast, a clinical observational study at a long-term care facility in France[64] definitively showed that IVM used to treat patients was safe and effective against COVID-19. The integrity of the data can be easily verified and was never questioned. If the COVID-19 vaccines instead of IVM had given such clear-cut results, the observational study would have gotten worldwide media coverage. Instead, what happened at the long-term care facility in France remains hidden in plain sight. As proof that IVM has saved at least one life is a compelling case study in which a patient was close to death.[65]

IVM has been on the market for more than 40 years with more than 4 billion treatments administered and has been proven to be safe (see Table 4).[66] However, treatments using repurposed drug such as IVM were even banned by governmental authorities for treatment for COVID-19, with more toxic and unproven treatments, such as remdesivir and COVID-19 modRNA vaccines employed under EUA, being promoted instead. There was one notable exception, in which the governmental authorities actually listened to the health professionals on the front-line. Doctors in Zimbabwe formally appealed to the government to use IVM to treat patients with COVID-19, asserting the drug has proved to be "a game-changer" on the ground.[67] In a notice to the Medicines Control Authority of Zimbabwe (MCAZ), Dr. Mudyirandima, Secretary in the Health Ministry, stated:[68]

> In these difficult times of Covid-19 treatment, we have to be careful to protect the patients as well as not to deny them effective treatment regimes. It is in this regard that authority is hereby granted for you to proceed under Section 75 of the Medicines and Allied Substances Control Act to allow importation and use of these medicines under the supervision and guidance you outlined.
>
> Ivermectin can be evaluated for both treatment and prophylaxis.

Subsequently, the MCAZ issued a circular permitting the use of IVM for the prevention and/or treatment of COVID-19.[69]

Table 4. Safety Track Record of Medications Used to Treat COVID-19

Drug	Adverse Events	Deaths	Reported Since Year
Remdesivir*	11,224	746	2020
Paxlovid*	48,718	78	2022
Molnupiravir*	3,009	16	2021
Ivermectin*	7,503	26	1999
Fluvoxamine*	1,008	87	1986
COVID modRNA vaccines**	1,007,636	18,655	2021

* From www.Vigiaccess.org accessed March 2024 (Worldwide)
** From VAERS Feb 23, 2024 (only U.S./Territories/Unknown)

The Current Situation

SARS-CoV-2 and COVID-19 will be with us for years to come with the virus likely appearing seasonally. The lethality of COVID-19 has greatly diminished since the Omicron variant replaced the Delta variant. Nevertheless, people are still being encouraged to keep up to date with their COVID-19 modRNA vaccine booster shots. Another problem is that "long COVID" and "vaccine injuries" have very similar clinical appearances, and the adverse effects of the COVID-19 modRNA vaccines continue to accumulate. Short-term adverse effects associated with the spike protein include but are not limited to: myocarditis and other inflammatory conditions,[70-74] autoimmune disease,[75] blood clots and thrombosis,[76-78] neurological disease,[79,80] multi-organ failure, and vaccine-related cases of long COVID.[81,82]

While the spike protein itself and the LNPs are toxic, they are not the only problem with Pfizer/BioNTech's COVID-19 modRNA vaccine. This vaccine also contains high amounts of residual, fragmented plasmid DNA from the process-2, bait-and-switch manufacturing process.[83-85] While the regulatory bodies allow up to 10 ng/dose in residual DNA,[14,86,87] these guidelines are for naked DNA fragments ≤200 bp and not for protected plasmid DNA inside lipid nanoparticles (LNPs). Data have shown that LNPs are capable of significantly increasing RNA or DNA cell entry.[88] The guidelines also do not account for multiple dosing of the same vaccine or platform, the risk of regulatory sequences, possible integration of small DNA fragments (7 bp to 200 bp), or nuclear entry/integration. In a Canadian study, Speicher et al. found that while the quantity of residual plasmid DNA in the Pfizer vaccines as determined by qPCR was below 10 ng/dose, the total DNA when tested by fluorometry was 1,896 to 3,720 ng/dose.[83] A published German study showed that the total DNA following Triton-X-100 lysis of the LNPs was 3,600 to 5,340 ng/dose.[89]

Since the 2021 COVID-19 vaccine rollout there has been a large increase in morbidity and mortality to malignant neoplasms.[90,91] There are several mechanisms that may account for the observed association of the pro-vaccine and risk for oncogenesis,[30] including the SV40 promoter-enhancer-ori found in the Pfizer/BioNTech COVID-19 modRNA vaccines. This sequence was first identified by McKernan et al. in April 2023, after sequencing the residual DNA in both the Pfizer/BioNTech and Moderna pro-vaccine in the final drug product found in the vials.[84] Shockingly, the analysis identified the SV40 promoter/enhancer/ori sequences, sometimes as an intact 317 base pair sequence. There were no SV40 sequences identified in the Moderna pro-vaccine. Other sequences were also identified including an SV40 poly (A) signal, an AmpR promoter, an HSV-TK poly (A) signal, and a reverse open reading frame (ORF) spanning the entire spike protein sequence.

The Pfizer-BioNTech COVID-19 modRNA vaccines used a gene therapy plasmid,[92] which contained an SV40 enhancer-promoter-ori cassette[83] that was not disclosed to the regulators,[93,94] contrary to regulatory guidelines.[95, p 95-96]

The fact that the SV40 enhancer regulatory element promotes nuclear localization and host genomic integration when fragments containing the SV40 enhancer are inserted cytoplasmically is not new. A 1999 study by David Dean et al. showed that as few as 3 to 10 copies of DNA fragments with a 72 bp SV40 enhancer injected cytoplasmically into non-dividing cells greatly increases their ability to be transported into the nucleus.[96] (This is how the DNA fragments inside the LNPs in the COVID modRNA vaccines are inserted into the cells.) This is not merely speculation. Preliminary work conducted in Germany has found evidence of genomic integration of the whole COVID-19 vaccine spike DNA open reading frame. After human ovarian cancer cells (OVCAR-3) were exposed in cell culture overnight to the Pfizer modRNA vaccine, the whole SARS-CoV-2 spike DNA as sequenced in the Pfizer vaccine was found to have integrated into the genome at chromosomes 9 and 12.[97] Therefore, integration into the human genome is possible, and integration may well be found in the primary cells of a vaccinated person. Furthermore, the SV40 promoter can bind to the p53 tumor suppressor gene (i.e., the guardian of the genome), and potentially inactivate the p53, providing another mechanism to drive oncogenesis.[96,98,99]

Some scientific publications are now linking cancer and other diseases to COVID-19 infection only.[100,101] In these publications, the authors had not considered the possibility that the vaccines could also be responsible for these pathologies, since the presence of spike protein is common to both. Because of incomplete data from randomized studies and reliance on data from observational studies lacking good comparators, it can be difficult to differentiate between adverse effects of the COVID-19 modRNA vaccines and the complications and comorbidities of a disease whose natural history is not yet fully understood. However, since it is possible the spike protein produced by both the virus and the vaccine is responsible for these pathologies, it is prudent to accept that both SARS-CoV-2 and the spike proteins generated from the COVID-19 modRNA vaccines are potentially responsible for these increases in cancer.[102]

In order to determine the extent to which the modRNA vaccines may contribute to the risk of cancer, epidemiological studies should include a full medical history, considering not only the infection, but also the modRNA vaccine status and the number of boosters administered. Moreover, certain variants of SARS-CoV-2 seem to have caused serious disease in the younger population.[103-105] Immune tolerance to SARS-CoV-2 infection occurs when an individual has been exposed to the spike protein over an extended period following several COVID-19 modRNA vaccine booster shots.[106] The consequences of this are repeated and more serious SARS-CoV-2 infections. Moreover, because the modRNA employed in these vaccines is modified to enhance mRNA stability,[107] this allows the spike protein to be generated over an extended period of time,[108] with serious consequences, especially if a person is immune-compromised or immune tolerant.

Circulating vaccine-generated spike protein could cause a variety of vaccine-related injuries. These well-documented injuries[35,37] are consistent with the spike protein's mode of action as previously referenced. A recent review delineates the unique concerns with the modRNA vaccines including both immune stimulating and inhibiting effects.[109]

Discussion

The studies provided by Pfizer/BioNTech to the FDA and other regulatory authorities were fundamentally flawed and insufficient

to prove safety and efficacy. Pfizer/BioNTech failed to determine the concentrations and structure of the encoded spike protein in their nonclinical and clinical studies. Such studies are fundamental to determine the pharmacology, pharmacodynamics and pharmacokinetics of a "pro-drug" as represented by the Pfizer/BioNTech vaccines. Pfizer/BioNTech did perform a biodistribution study using a surrogate mRNA coding for luciferase instead of the spike protein. The study demonstrated that the LNPs were distributed to a variety of different tissues including the liver, spleen, adrenals, reproductive organs, and the brain. The assumption that the modRNA vaccine would reside at the injection site, i.e., the deltoid muscle, was known to be false. Pfizer/BioNTech's own data showed the spike protein would also be expressed in these distal tissues. This data helps to explain the extent and variety of serious adverse effects to the modRNA vaccine observed in humans.[7,35,110]

Pfizer/BioNTech also failed to perform adequate Phase 1 ascending dose clinical studies, which would have provided important information regarding the amount of encoded spike protein produced and how widespread it varies between individuals. The cumulative effect of continued dosing beyond the primary series of up to 12 injections for the immunocompromised has not been studied. Given that the spike protein was known to be toxic, using Pfizer/BioNTech's own data, the claim that the modRNA vaccine is safe is dubious. Additionally, the modRNA vaccine's short-term safety, genotoxicity, carcinogenicity or excretion characteristics were not ascertained since vaccine regulatory guidance's did not require it, and the long-term adverse effects such as cancer, neurological, or autoimmune diseases have yet to be determined.

Finally, Pfizer/BioNTech could not adequately establish the short-term or long-term safety of the modRNA vaccines. The rolling review process used by regulatory authorities worldwide, including the FDA, the European Medical Agency, and Health Canada, revealed issues of concern, which were either ignored or downgraded in the published assessments of the COVID-19 vaccines, raising questions of effectiveness, veracity, and reliability of our regulatory agencies.[111]

Conclusion

For any other medicinal product, the regulatory submission would have been considered incomplete and most probably rejected. Therefore, a moratorium on the use of Pfizer/BioNTech COVID-19 vaccines and boosters should be enacted at minimum, but ideally, they should be removed from the market and their use in humans should be stopped. It should be the responsibility of the pharmaceutical industry, not independent scientists, to determine whether a medical intervention is safe. Based upon Pfizer/BioNTech's data, safety of their COVID-19 modRNA vaccine has not been proven.

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March 31, 2025

Dear Government Representatives and Health Officials:

Canadian Open Letter of Concern Regarding COVID-19 mRNA Vaccines

As qualified Canadian and international researchers and professionals, we are extremely concerned as evidence questioning the quality, efficacy and safety of the COVID-19 mRNA (more precisely, modified mRNA or modRNA) vaccines continues to mount.

Given the accumulating evidence of concern, on behalf of the Canadian public, we call on you, our government representatives and public health officials, for:

- **An immediate halt to the use of and a recall of the COVID-19 mRNA vaccine products.**
- **An independent and transparent public inquiry** into the regulatory processes leading to the approval of these products and their ongoing use.
- **Scientific assessments and analyses of all mRNA products** to determine the health risks to humans from residual plasmid DNA, potential aberrant protein production, and shift to IgG4 antibodies.
- **Access to data and funding for independent research** to assess the potential link between the COVID-19 mRNA vaccines and the recent probable increase in cancer rates and mortality,[1,2] including any association with the SARS-CoV-2 virus itself.

Our plea for your immediate action is based on many scientifically-supported concerns regarding the COVID-19 mRNA products,[3] the latest of which are outlined below:

- **Variable and concerning levels of residual plasmid DNA have been found in the COVID-19 mRNA products** in vials from Canada,[4] the USA,[5] France,[6] Germany,[7,8] and Australia,[9] as well as by independent research conducted at a US Food and Drug Administration (FDA) facility.[10] Residual DNA is undesirable as it has potential oncogenic and infectious risks.[11] This concern is further compounded by the fact that **lipid nanoparticles (LNPs),** in which the COVID-19 mRNA products are encased, **increase the delivery of foreign DNA across cell membranes by 10-100 times.**[12,13] The current regulatory limit of residual DNA does **not** account for this effect.

- **Undisclosed bioactive SV40 promoter-enhancer DNA sequences are used in the production of the Pfizer/BioNTech vaccines.**[4,5] This has been confirmed by Health Canada,[14] the US FDA,[15] and the European Medicines Agency (EMA),[16] and is highly concerning because these SV40 sequences are used in gene therapy to transport foreign DNA into the cell nucleus and facilitate DNA integration into the human

genome.[17] These sequences should not be present in vaccines; as stated by Health Canada scientists, these sequences "serve no purpose in the manufacturing of Pfizer COVID-19 vaccines" and are "not present in any vaccines currently approved in Canada."[18] Irrespective of the potential health risks associated with these sequences, the lack of disclosure to Health Canada[14] and other regulators by the manufacturer *alone* is a violation of World Health Organization (WHO) Guidelines for mRNA vaccines that require *all* sequences in the DNA starting material to be annotated and justified.[19]

- **Numbers of reported vaccine adverse events are batch specific.**[20,21,22,23] Multiple analyses of public data by independent research groups have revealed unacceptable inconsistencies in manufacturing, storage, administration and/or delivery of the COVID-19 mRNA vaccines.

Further issues with these mRNA products that have already been *identified by Health Canada scientists* include:

- **Aberrant unintended proteins may be produced due to ribosomal frameshifting.**[24] Ribosomes carry out the synthesis of proteins from mRNA instructions inside cells. In ribosomal frameshifting the reading of the instructions is shifted resulting in the production of aberrant unintended proteins. Health Canada scientists have considered these aberrant proteins to represent a "high level of impurity" and "cannot absolutely exclude any possible undesirable effects on cell proliferation or toxicity."[25]

- **A shift of individuals' antibody immune responses from the expected antibody types (*e.g.*, IgG1, IgG3, and IgA) to IgG4 antibodies has been observed following repeated COVID-19 vaccinations.**[26] Health Canada scientists have noted that international bodies, including themselves, have identified this shift.[27] IgG4 antibodies are associated with immune tolerance (*i.e.*, more SARS-CoV-2 infection) and serious auto-immune conditions.[26]

Concerns similar to ours have been raised by many other groups both in Canada and around the world who have also asked for a suspension of the COVID-19 mRNA vaccines. For instance:

- Canadian National Citizens' Inquiry, a citizen-led effort to examine Canada's response to COVID-19, which heard 305 expert and lay witnesses in eight cities (2023)[28]
- Australian Member of Parliament Russell Broadbent who, supported by 52 scientists and health care professionals, wrote a letter to Australia's Prime Minister (2024)[29]
- NORTH group, a coalition of scientists, physicians, other professionals, and politicians, who issued letters to the governments of 23 European countries and Canada (2024/25)[30]
- Alberta COVID-19 Pandemic Data Review Task Force, which concluded that "further research to establish the safety and efficacy of COVID-19 vaccines is necessary before widespread use in adults and children" (2025)[31]

- Réinfo Québec, a collective of health professionals, scientists and citizens in Québec, who recently held a press conference on this matter (2025)[32]
- Seventeen other professional public health and physician organizations around the world who have made statements (2021-2024)[33]

In order to protect the health of Canadian citizens, we appeal for an immediate halt to the COVID-19 mRNA vaccines and a redirection of efforts towards much needed inquiry, assessment, and research. We hope for a fulsome discussion of the evidence and welcome the opportunity to contribute to the path forward.

With utmost concern and respect,

Canadian researchers and professionals [in alphabetical order]

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Canadian Citizens Care Alliance
Alliance Canadienne de Soins pour les Citoyens

REINFO QUÉBEC
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