January 3, 2024

EXPERT REPORT

of

Jessica Rose, PhD

As per your request to engage me to obtain my independent professional opinion concerning Dr. Charles Hoffe with respect to a citation that has been issued against him by the College of Physicians and Surgeons of British Columbia, Canada (the "College"), and the opinion of Dr. Trevor Corneil, please find my professional opinion as they relate to public statements made by Dr. Hoffe and the opinion of Dr. Corneil on these public statements.

Qualifications

I am a Canadian researcher with advanced degrees in **Applied Mathematics** (Bachelor of Science focusing on mathematical modeling of viral kinetics from Memorial University of Newfoundland), **Immunology** (Master of Science in Medicine focusing on HIV immunopathogenesis from Memorial University of Newfoundland), **Computational Biology** (Doctor of Philosophy focusing on cytomegalovirus and hepatitis B viral kinetics from Bar Ilan University), **Molecular Biology** (Post-doctoral project focusing on geolocation of pathogenic Rickettsial species in Ixodes ticks at the Hebrew University of Jerusalem) and **Biochemistry** (Post-doctoral project focusing on allosteric interactions of membrane-bound receptors using molecular dynamics at the Technion Institute of Technology).

For the past four years, I have been using my training in computational analysis and data science, and experience in the fields of immunology, biochemistry and molecular biology to independently analyze the SARS-CoV-2 virus and the syndrome known as CoronaVirus Disease (COVID)-19. I have more recently turned my attention toward the COVID-19 injectable products (IP) based on their novelty, and the speed at which they were administered to such a large number of people, repeatedly, as a solution to COVID-19. Concurrent to the roll-out of these products, incredible numbers of side effects have been reported to a number of pharmacovigilance databases around the world, including the Center for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) database. Due to the rate of accumulation of data in the context of the COVID-19 IP in VAERS, it was necessary for me to teach myself to work with R[1]: a powerful statistical programming language, due to its efficiency in handling large datasets.

I have spent years analyzing VAERS data in the context of the COVID-19 injectable products (IP) - from death reports to myocarditis in children - and have also performed causality and Proportional Reporting Ratio (PRR)[2] assessments of the signals emergent therein in order to make determinations of the safety of the COVID-19 IP. I have read thousands of peer reviewed studies on SARS-CoV-2, COVID-19, vaccine development, epidemiological spread of viruses, gene therapy, lipid nanoparticles (LNPs), mRNA technology and chemical

[1]https://cran.r-project.org/

[2]Evans SJ, Waller PC, Davis S. Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiol Drug Saf. 2001 Oct-Nov;10(6):483-6. doi: 10.1002/pds.677. PMID: 11828828.

modifications of messenger RNA for use in human therapeutics. My conclusion is that in addition to the lack of efficacy of the COVID-19 IP, they do not qualify as safe based on a surplus of coherent data indicating harms, and plausibility based on the experimental nature of these products.

I have become a prolific and well-known science writer, presenter and spokeswoman for individuals suffering adverse events (AEs) in the context of the COVID-19 IP and support the work of such organizations as Science and Solidarity (Dr. Geert Vanden Bossche – formerly WHO), React19 (Brianne Dressen – Astrazeneca clinical trial participant), The World Council for Health (Dr. Tess Lawrie) and the Front Line COVID Critical Care Alliance (FLCCC) (Drs Pierre Kory and Paul E. Marik).

I have presented my work to European and local Parliament members in Belgium, Romania and Croatia, at three FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings, and at many international medical and science conferences. I was also invited twice to provide expert testimony at United States Senate hearings. I have earned the ears of many American senators, American presidential candidates, Canadian leaders, medical doctors, health professionals, scientists, researchers and political leaders from all over the world due to both my expertise and professionalism.

I have written chapters in three upcoming books on COVID-19 subject matter, and participated in many video documentaries, and hundreds of podcasts and interviews in order to bring scientific information to the public. I have authored articles - both in preprint/review and published peer-reviewed - in indexed academic medical journals.[3,4,5,6,7,8,9]

My primary task is to decipher scientific data and information in science and medical journals, and pharmacovigilance databases, in order to make these available to the general public: I want to help individuals who may be suffering harms from the COVID-19 countermeasures. There is zero liability for the manufacturers in the case where an individual *is* harmed by their product so at the very least, I want others to be informed on the potential harms and educated in the subject matters herein.
I speak and write for myself and do not/did not retain services from others and have no conflicts of interest.

[3]Determinants of COVID-19 Vaccine-Induced Myocarditis. Jessica Rose, Nicolas Hulscher, Peter A. McCullough. Therapeutic Advances in Drug Safety. January 2024. Accepted.
[4]The Novelty of mRNA Viral Vaccines and Potential Harms: A Scoping Review. (2023) Halma MTJ, Rose J, Lawrie T. J. 6(2):220-235. https://doi.org/10.3390/j6020017
[5]Determinants of COVID-19 vaccine-induced myocarditis. Jessica Rose, Nicolas Hulscher, & Peter A. McCullough. (2023). Zenodo. https://doi.org/10.5281/zenodo.8356800
[6]Ribosomal frameshifting and misreading of mRNA in COVID-19 vaccines produces “off-target” proteins and immune responses eliciting safety concerns: Comment on UK study by Mulroney et al. Wiseman, D. M., Gutschi, L. M., Speicher, D. J., Rose, J., McKernan, K. (2023, December 6). https://doi.org/10.31219/osf.io/nt8jh
[7]DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events. Speicher, D. J., Rose, J., Gutschi, L. M., Wiseman, D. M., McKernan, K. (2023, October 19). https://doi.org/10.31219/osf.io/mjc97
[8]Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? (2021). J. Rose. Science, Public Health Policy and the Law (2021)
[9]A Report on the US Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. (2021). Rose, J. Sci Publ Health Pol & Law 2:59-80

Goal

I am providing my expertise and opinion on the alleged safety of the COVID-19 IP based on assessments of safety signals emergent from the pharmacovigilance database 'VAERS'. I will also provide my opinion on the nature of these products from the perspective of being experimental based on the novel platform and mechanism of action used, and the lack of true safety testing as per the conventional vaccine track to get from concept to arm. I will also counter some of Dr. Trevor Corneil's claims referenced from his Opinion Letter (Dr. Corneil CPSBC re: Dr. Charles Hoffe (IC File Nos. 2021-0481 and 2021-0535) addressed to Ms. Fong on September 26, 2022).

Professional Opinion

I do not believe the COVID-19 IP to be safe or effective based on peer-reviewed literature studies, clinical and pharmacovigilance data examined over a period of four years. Specifically, I believe that the modified mRNA products to be particularly potentially harmful. I also believe that Dr. Charles Hoffe was doing acting in the interest of *his* patients, as a physician, and that he was simply applying the Hippocratic Oath: to DO NO HARM – and adhering to the British Columbia (BC) Reporting Information Affecting Public Health Regulation under the Public Health Act, Part 2, Division 1, Section 5, in his actions to submit adverse event reports and to care for his patients.

Documents reviewed

Opinion letter of Dr. Corneil CPSBC re: Dr. Charles Hoffe (IC File Nos. 2021-0481 and 2021-0535) addressed to Ms. Fong on September 26, 2022

Video material expressing opinions of Dr. Charles Hoffe.

Objective opinion

The following are extractions, and in some cases extensions, of definitions from the 'objective opinion' section of the opinion letter of Dr. Corneil CPSBC re: Dr. Charles Hoffe (IC File Nos. 2021-0481 and 2021-0535) addressed to Ms. Fong on September 26, 2022, for use in this, my own, opinion letter. In some cases, I extend the definition with additional information for context. Additional definitions follow that will be useful for understanding some of the references, analysis and data herein.

1. Section 5.0 - Objective opinion; subsection 5.2 "Other Definitions"; subsection 11 c) - **Published Peer Reviewed Medical Literature**

Due to its relevance: "Published Peer Reviewed Medical Literature is the full body of international scientific papers reviewed by peers in that same or comparable discipline or specialty of medicine for accuracy, validity, and reasonableness prior to its publication by an organization or editor in a journal or other accessible format."

"It is important to acknowledge the role of pre-peer review pre-published original academic articles submitted to an academic medical journal and made available to their academic peers through a recognized clearing house (e.g., MedRxiv [OSF Preprints]) prior to their publication. While they are useful for the rapid dissemination of new and original information and analysis amongst academic peers in the same or comparable discipline or specialty, they are not considered accurate, or valid, or reasonable without further scrutiny and must be interpreted with this in mind."

Extension: I would like to emphasize the relevance of pre-peer review pre-published original academic articles (preprint studies) within the community of academic peers for promotion and dissemination of ideas to propel general understanding of complex subject matter to solve global problems. It is also notable that inherent problems in the peer review system do exist, including very long time-delays to publication, and inefficiency to publish potentially vital data when it is needed, such as during a 'pandemic'. Preprint studies have been vital during the past four years to those of us in both the academic and the scientific communities who review the scientific literature on the daily, and they have indeed served to propagate transparency in science when read in combination with the peer-reviewed literature.

2. Section 5.0 - Objective opinion; subsection 5.2 "Other Definitions"; subsection 11 d) – **Clinical Practice Standards from outside Canadian jurisdictions**

Dr. Corneil writes: "it is important to acknowledge the role of Clinical Practice Standards from outside Canadian jurisdictions by the same or comparable physician specialties as informative sources of information".

Extension: Not only do I agree with this sentiment but considering that the COVID-19 IP are imported into Canadian jurisdictions including into British Columbia (BC), and that the original Emergency Use Authorization (EUA) order was decided by the American agency CDC (Centers for Disease Control and Prevention), it is necessary to acknowledge the roles of not only Clinical Practice Standards, but people and agencies outside of Canadian jurisdictions on this matter.

3. Section 5.0 - Objective opinion; subsection 5.2 "Other Definitions"; subsection 11 e) - **Misleading**

The definition therein states that the word "Misleading" is defined as something "that leads someone astray or causes someone to have an incorrect impression or belief".

Extension: I believe that all individuals are entitled to **all** pertinent and relevant information such that they can decide for themselves (once having been provided **informed consent**) what a best course of action may be, medically. Individuals also have the right to choose their own doctor and doctors have the right to their own professional medical opinions shaped over much time and observation. Most patient-doctor relationships are formed over years, sometimes even decades, and this relationship is based on trust in the medical opinion of the doctor. If a doctor is up-to-date on the scientific literature and drug facts, and confronts a patient with information about the potential harms of a product, then it is well within the rights of the patient to confirm or

deny this information. But the patient cannot do this if risk potential is hidden. It is the duty in doing no harm of the medical professional to stay up-to-date with relevant peer-reviewed and case studies so as to impart vital information pertaining to risk and benefit to patients prior to taking therapeutic measures. If there is a departure from being current with regard to real risk, then there is indeed potential for Misleading.

4. Section 5.0 - Objective opinion; subsection 5.2 "Other Definitions"; subsection 11 f) - **Incorrect**

The definition therein states that the word "Incorrect" is defined as "of a statement, not in accordance with fact; erroneous, inaccurate."

Extension: If a statement contradicts the peer-reviewed literature or a well-accepted foundational guideline, for example, it can be considered Incorrect.

5. Section 5.0 - Objective opinion; subsection 5.2 "Other Definitions"; subsection 11 h) – **Cause and Causality**

The definition therein states that the word "Cause" and "Causality" is defined as "a specific disease event an as antecedent event, condition, or characteristic that was necessary for the occurrence of the disease at the moment it occurred, given that other conditions are fixed. Sufficient Cause is defined as a set of minimal conditions and events that inevitably produce disease. In the context of a Medical Opinion, Causality is generally assessed using Bradford Hill criteria or viewpoints adapted using reasoned methods and models to fit the causal question. The criteria or viewpoints and reasoned methods and models used to assess the strength of Causality include strength of association, **consistency**, **specificity**, **temporality**, **dose-response**, **plausibility**, coherence, experiment, analogy and **reversibility**. (See Exhibit A)

1. **Consistency** - Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
2. **Specificity** - Causation is likely if there is a very specific population at a specific site and disease with no other likely explanation. The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship.
3. **Temporality** - The effect has to occur after the cause (and if there is an expected delay between the cause and expected effect, then the effect must occur after that delay).
4. **Dose-response** - Greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.
5. **Plausibility** - A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism is limited by current knowledge).
6. **Reversibility** - If the cause is deleted then the effect should disappear as well.

6. Section 5.0 - Objective opinion; subsection 5.3 "Harms of COVID-19 relative to Influenza disease"; subsection 14: "**Benefits of COVID-19 vaccine in preventing serious illness and death**"

Extension: Regardless of the potential risk of developing COVID-19 for which there are many treatments following four years of successful clinical use[10] (hundreds of studies have been Referenced in Front Line COVID-19 Critical Care (FLCCC) Alliance Protocols), the risk of severe adverse events with the use of the COVID-19 IP as a prophylactic in healthy young individuals is too high to dismiss, especially with regard to cardiac issues such as myocarditis.

7. Section 5.0 - Objective opinion; subsection 5.5: "COVID-19 vaccine safety surveillance"; subsection 20: "**Post-market surveillance in Canada**"

"While pre-market studies are large enough to detect efficacy and common adverse events, they cannot reliably detect an increased incidence of adverse events or events with significant latency thus phase IV studies and post-marketing surveillance are required." He is absolutely correct.

Extension using Section 6.8 subsection 49:

It is unclear why Dr. Corneil states the following in Section 6.8 subsection 49: "VAERS is a post-market vaccine safety reporting system in the United States, therefore is not applicable to Canada."

These two statements are contradictory. Canadian and American citizens alike received the Pfizer/BioNTech, Moderna and Janssen COVID-19 IP and there is no reason to assume that they would affect Canadian and American people differently.

8. Pharmacovigilance

Pharmacovigilance is the act of monitoring databases for signals that represent a signal for harm in the context of a particular product. This includes science and activities relating to the detection, assessment, understanding and prevention of adverse events. This applies throughout the life cycle of a product and implies on-going monitoring from pre to post-approval of a product.

9. Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)

The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is a federal, provincial and territorial (FPT) public health post-market vaccine safety surveillance system. CAEFISS is managed by PHAC and is unique in that it includes both passive (spontaneous reports from FPTs) and active surveillance.[11]

10. Vaccine Adverse Event Reporting System (VAERS)

[10] https://covid19criticalcare.com/studies/

[11]https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

The pharmacovigilance data used herein is downloaded from the CDC website for VAERS data.[12] VAERS was created in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports of adverse events that may be associated with vaccines. The primary purpose for maintaining the database is to serve as an early warning or signaling system for adverse events not detected during pre-market testing and clinical trials. VAERS is highly under-reported as it is a passive reporting system, irrespective of the duty of medical professionals to report adverse events.[13] VAERS is the most prolifically-utilized and acknowledged pharmacovigilance database of all of CAEFISS, YellowCard,[14] and European Union Drug Regulatory Authorities (Eudra) EudraVigilance[15] and Database of Adverse Event Notifications (DAEN)[16] systems, as demonstrated by the sheer number of reports and prevalence of use by the United States government owning bodies CDC, Health and Human Services (HHS) and the United States Food and Drug Administration (FDA)[17], and thus **well represents** AE reporting and AE distribution as per product world-wide. (See Exhibit B)

N.B. Only ***domestic*** VAERS data (data reported within the United States) will be referenced herein. As part of some Exhibits, both the domestic and foreign data may be referenced in some cases.

11. Adverse Events Following Immunization (AEFI)

An adverse event following immunization (AEFI) is any untoward medical occurrence in a vaccinee that follows immunization. It does not necessarily have a causal relationship with the vaccine or the immunization process.[18]

12. Adverse Event (AE)

An adverse event is any undesirable experience associated with the use of a medical product in a patient.[19] (Rather, a person.)

13. Serious Adverse Event (SAE)

[An adverse] event is serious and should be reported to FDA when the patient outcome is death, hospitalization, emergency room requirement, disability, birth defect or if a life-threatening situation ensues.[20]

[12]https://vaers.hhs.gov
[13]Lazarus, Ross et al. Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Submitted to The Agency for Healthcare Research and Quality (AHRQ)
[14]https://yellowcard.ukcolumn.org/
[15]https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance- research-and-development/good-manufacturing-practice/eudragmdp-database
[16]https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen
[17]VAERS is co-sponsored by the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), agencies of the U.S. Department of Health and Human Services (HHS); https://vaers.hhs.gov
[18]http://www.bccdc.ca/health-professionals/clinical-resources/adverse-events-following-immunization
[19]https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event
[20]https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

14. Under-reporting

Passive pharmacovigilance surveillance systems such as CAEFISS[21] and VAERS suffer from under-reporting – a failure in data reporting - since it is up to individuals, including health care professionals, to report adverse events to the system. In the case of VAERS, most individuals submit reports online as part of a 30-minute multiple-page electronic filing system. Following successful electronic submission, reports *may* be assigned permanent VAERS ID depending on the number of reports filed, and the designated validity of the report.[22] As was pointed out in the definition of VAERS, the under-reporting of VAERS has been estimated to capture approximately 1% of all incidents. Using the Pfizer phase III clinical trial data estimate of serious adverse event (SAE) rate of 0.7%, I calculated the under-reporting factor (URF) for SAEs to be 31 times.[23]

Professional opinion and evidences

Efficacy

Based on a recent peer-reviewed publication in Open Forum Infectious Diseases, a study in the Cleveland Clinic of employees showed that "the higher the number of vaccines previously received, the higher the risk of contracting COVID-19**.**"[24] This lack of efficacy to prevent COVID-19 and harms associated is clearly demonstrated in Figure 1.

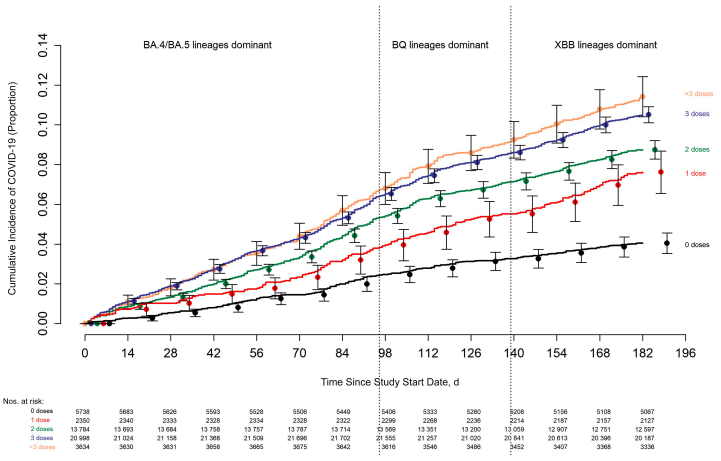


Figure 1: Cumulative incidence of coronavirus disease 2019 (COVID-19) for study participants stratified by the number of COVID-19 vaccine doses previously received. Source: Shrestha *et al.* 2023

[21]https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html

[22]VAERS Team: Immunization Safety Office, Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases and Centers for Disease Control and Prevention. 2021. Vaccine Adverse Event Reporting System (VAERS), Standard Operating Procedures for COVID-19 (as of 29 January 2021). https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

[23]Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? (2021). J. Rose. Science, Public Health Policy and the Law (2021)

[24]Nabin K Shrestha, Patrick C Burke, Amy S Nowacki, James F Simon, Amanda Hagen, Steven M Gordon, Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine, Open Forum Infectious Diseases, Volume 10, Issue 6, June 2023, ofad209, https://doi.org/10.1093/ofid/ofad209

General Information pertaining to pharmacovigilance

"In BC, a health professional who is aware of an AEFI must report the event to the Medical Health Officer as per the Reporting Information Affecting Public Health Regulation under the Public Health Act, Part 2, Division 1, Section 5."

Dr. Hoffe, in reporting 11 AEFIs (review of Schedule "C" Document 8) to Interior Health in 2021, acted in accordance with the Public Health Act, Part 2, Division 1, Section 5 as a practicing clinician.

As of August 19, 2022, in Canada, health professionals have reported AEFIs in the context of the COVID-19 IP at a rate 0.06%.[25] (88,237,534 doses of COVID-19 IP administered). The numerator (50,545) - representative of the absolute number of reports that qualified as AEFIs representative of the number of Canadian citizens who suffered AEs and SAEs in the context of the COVID-19 injections - does not take under-reporting into account, so this rate is lower minimum.

As of August 27, 2022, in British Columbia (BC), health professionals reported AEFIs in the context of the COVID-19 IP at a rate of 0.05%[26] (12,249,299 doses of COVID-19 IP administered). The numerator (5,853) - representative of the absolute number of reports that qualified as AEFIs representative of the number of Canadian citizens who suffered AEs and SAEs in the context of the COVID-19 injections - does not take under-reporting into account, so this rate is lower minimum. It is notable that the reporting rate for BC is 1.2 times lower of that of the country. It is also notable that the reporting rate for SAEs in BC (0.0037%)[27] is 3.2 times lower that the reporting rate for SAEs in Canada (0.012%)[28]. It is arguable that fewer people suffered SAEs in BC but it is far more likely that this discrepancy represents a reporting anomaly.

Note: COVID-19 injection metrics in the United States as of May 11, 2023 are no longer being updated.[29]

As of May 11, 2023 in the United States, 976,270 VAERS IDs have been successfully assigned (reports for individuals filed) in the context of the COVID-19 IP[30] despite issues with filing due to documented increases in the numbers of reports being made. "The CDC and the FDA had a requirement for technical and programmatic support related to the VAERS SARS-CoV-2 Vaccines" due to an inability to maintain standard operating

[25]Reported side effects following COVID-19 vaccination in Canada. Health Canada. August 19, 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/

[26]Adverse Events Following Immunization with COVID-19 Vaccines, December 13, 2020, to August 27, 2022. BCCDC. http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/AEFI_reports/COVID19_AEFI_Monthly_Report_2022-09-01.pdf

[27]Reported side effects following COVID-19 vaccination in Canada. Health Canada. August 19, 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/

[28]Reported side effects following COVID-19 vaccination in Canada. Health Canada. August 19, 2022. https://health-infobase.canada.ca/covid-19/vaccine-safety/

[29]https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions

[30]This includes the modified mRNA (Pfizer/BioNTech/Moderna), Novavax and Janssen products(Janssen Jcovden Product Description and Resources. https://covid-vaccine.canada.ca/jcovden/product-details);Pfizer BioNTech Comirnaty Product Description and Resources. https://covid- vaccine.canada.ca/comirnaty/product-details;Moderna Spikevax Product Description and Resources.: https://covid-vaccine.canada.ca/covid-19-vaccine-moderna/product-details

procedures[31,32] and thus subsequently contracted out this need[33] to keep up with the increases in reporting. It is noteworthy that even if the CDC were able to catch up, under-reporting is still an issue with VAERS. In spite of these factors, almost 1 million people in the United States had successfully filed AE reports to VAERS in the context of the COVID-19 IP (Moderna, Pfizer/BioNTech, Janssen and Novavax) by May 2023, whereby the majority (72%) of these reports were filed in 2021 when the roll-out and reception of the COVID-19 IP was highest. This represents an AE reporting rate of 0.36% by U.S. citizens who received at least one dose of COVID-19 injectable product as May 11, 2023 (270,227,181 total vaccinated with at least one dose).[34] This reporting rate, even in the context of known under-reporting in VAERS, is 7.2 times higher than the reporting rate in BC (and 6 times higher than in Canada in general), thus this could be construed as evidence of severe under-reporting of AEFIs in BC by Canadian health professionals. The discrepancy warrants investigation and although reporting inadequacies is likely the reason, it could also be due to differences in product use and distribution. Astrazeneca was administered in Canada but not in the United States, for example.

It is also noteworthy that the SAE rate in the United States (not considering under-reporting) is 0.07% (191,161) individuals reported SAEs as of May 2023) and that this rate is 19 times higher than the reporting rate for SAEs in BC, and 5.8 times higher than for Canada. I would also like to emphasize that each report is a person who suffered an injury in the context of an expedited medical product designed as a prophylactic. Whether considering the 191,161, the 10,194 or the 456 reports of SAEs in the United States, Canada or BC, respectively, this is an unacceptable rate of SAE reporting, let alone occurrence, in the context of what is deemed a 'safe' product. Statistics can be useful, yes, but we must not forget that these are our fellow Canadian countrymen and women whom, in some cases, unwillingly were administered these products due to mandates: they are *not* numbers and their suffering should not be dismissed and qualified as collateral damage or low statistical values.

Absolute counts

Since VAERS was incepted in 1990, we can examine trends in AEs, including SAEs, from the past 30 years in the context of other vaccines, and compare the rate of AE occurrence according to the number of injections administered in order to determine if a particular product is associated with clusters of reports of AEs, and/or a broader range of AE types. A broader range of AE types suggests more comprehensive physiological implications. The average absolute number of VAERS reports for all vaccines combined for the past 30 years per year is approximately 39,000, and the total number of reports in 2020 was 38,560 - which does not include the additional 10,852 reports that were filed in the final two weeks of December 2020 in the context of the COVID-19 IP. This 2020 sum is in stark contrast to the absolute number of VAERS IDs reported to VAERS in the context

[31]VAERS Team: Immunization Safety Office, Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases and Centers for Disease Control and Prevention. 2021. Vaccine Adverse Event Reporting System (VAERS), Standard Operating Procedures for COVID-19 (as of 29 January 2021). https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf
[32]https://www.documentcloud.org/documents/22278999-vaers-sop-2022
[33]https://researchrebel.substack.com/p/foiad-contracts-show-cdc-expected
[34]https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions (270,227,181 total vaccinated with at least one dose)

of the COVID-19 IP alone in 2021 (702,466). In fact, it is a 1,722% increase in the absolute number of VAERS IDs filed successfully between 2020 (all vaccines less COVID products) and 2021 (only COVID products).

Rates of reporting

In addition to absolute numbers, it is important to examine ***rates*** of reporting in the context of the number of injections administered, for example, the number of AEs reported per million doses. It is also important to compare these rates to other vaccine data – such as Influenza vaccine data – prior to the roll-out of the COVID-19 IP for comparison. The CDC fastidiously reports the number of doses of all vaccines administered per year, including Influenza vaccines and COVID-19 IP.[35] We can thus **determine the rate of AE occurrence per million doses** administered to the American public in the context of a selected vaccine - such as the Influenza vaccine and COVID-19 IP - within specific timeframes, and compare these to determine if one is more highly-associated with general AEs, or specific SAEs like death.[36,37] If the COVID-19 IP have the same pharmacovigilance safety profile as the Influenza vaccines, then we would expect these rates to be equal. Figure 2 (left) shows the number of AEs reported per million Influenza vaccines in 2020 (cyan), and COVID-19 products in 2021 (yellow) by the CDC. Figure 2 (right) also shows the number of deaths reported per million Influenza vaccines in 2020 (blue), and COVID-19 products in 2021 (red) by the CDC.

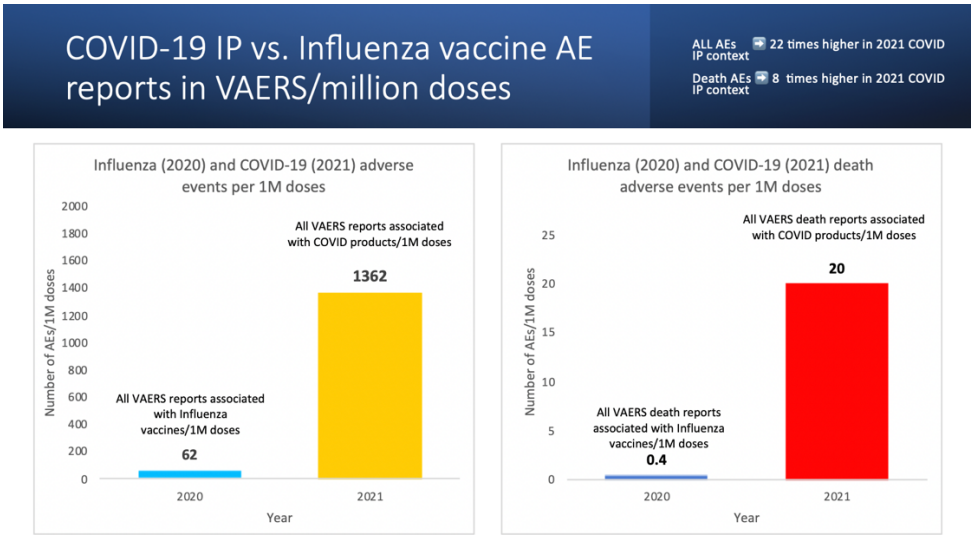


Figure 2: Number of VAERS reports filed in the context of Influenza vaccines reported in 2020, per million doses administered, compared with the number of reports filed in the context of COVID-19 injections reported in 2021, per million doses administered. Sources: https://vaers.hhs.gov; https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm#anchor_1627000360838; https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-boost

[35]https://www.cdc.gov/vaccines/adults/vaccination-records.html
[36]https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm#anchor_1627000360838
[37]https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-boost

It is clear that the reporting rates for Influenza and COVID-19 vaccines are very different both in general, and in the context of death reports. The reporting rate is 22 times higher for general AEs and 50 times higher for death in the context of the COVID-19 IP. Even if there was an increase in reporting to VAERS in 2021 in the context of the COVID-19 IP, this government data indicates that there was a greater than 2,000% increase in general reporting from 2020 to 2021. I would argue that this is highly unlikely and that this increase represents and validates a true increase in adverse event reporting, occurrence and cause.

It is also notable that the **range in AEs has increased 6-fold with regard to Influenza and COVID- 19 products**. According to the CDC, 193.8 million doses of Influenza vaccine were administered in the United States as of February 26, 2021 (for the 2020-2021 flu season): "the highest number of doses in a single flu season".[38] 558 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 21, 2022.[39] This is 462 days. An Influenza season is a year (365 days), thus it is fair to assume that if 193.8 million doses of Influenza vaccine were administered in 365 days, then ~245 million doses were administered in 462 days.

If we assume then that 2.3 times more doses of COVID-19 IP were administered than for Influenza vaccines for the same time period of 462 days, then it would make sense that the rate of reporting in VAERS should be about twice for COVID-19 IP than for Influenza vaccines. Twice as many doses, combined with a proportional reporting rate would result in twice as many reports.

As of March 25, 2022, according to the WONDER/CDC system[40], there were 1,696 different types of AEs and 45,650 total AEs reported to VAERS in the context of the 14 variations of Influenza vaccines. Also according to the WONDER/CDC system, there were 10,526 different types of AEs and 5,368,444 total AEs reported to VAERS in the context of the 3 variations of the COVID-19 products used in the United States at that time. Therefore, given that there were 2.3 as many COVID-19 shots administered than Influenza shots in the same time frame, it is quite astonishing that there were 6.2 times as many types of AEs and **117.6 times** as many total AEs reported in the context of the COVID-19 IP. As previously noted, if the Influenza vaccines and the COVID-19 IP have equal pharmacovigilance safety profiles, then what explains this massive discrepancy between absolute numbers of reports of AEs and types of AEs, that is **not** the by-product of the number of shots administered?

Even though all the other vaccines were omitted in the previous example (there are 82 other types), there is still no comparison with regard to the number of injections administered and the relationship to the number of AEs reported, and we certainly do not see the expected doubling of the reports if the injection to AE ratio *was* proportional for Influenza and COVID-19 IP. What this means is that ***the products are different*** in terms of AE

[38]https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm
[39]https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
[40]https://wonder.cdc.gov/controller/datarequest/D8

profile – COVID-19 IP are much more highly-associated with a broad range of AE type and high numbers of reports of AEs.

SAE occurrence is prevalent at 19% in the VAERS data. Again, a serious or severe adverse event (SAE) is defined as any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires, or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects or is another condition which investigators judge to represent significant hazards.[41,42] These classifications are based on the Code of Federal Regulations. The VAERS handbook states that 10-15% of reported AEs are classified as severe for any given set of data thus since SAE occurrence exceeds the upper limit by 4% this requires investigation.

Put simply, if the COVID-19 IP are **not** inducing more AEs in people, then we would not see this profile emerge. Similarly, If the COVID-19 IP are **not** inducing broad ranging reports with higher frequency reporting, then what explains this data?

Dr. Corneil makes the following statement: "While there is no evidence that COVID-19 vaccines or the spike-like proteins they produce cause adverse effects on the brain…" Dr. Corneil is incorrect in this statement.[43,44,45,46,47,48,49] Referenced are 7 of the 195 results returned for a query in PubMed using keywords "neurological adverse events covid vaccine".[50] Some quotes from these peer-reviewed articles of note include: "There is a greater than expected occurrence of severe neurological adverse events such as cortical sinus venous thrombosis, Bell's palsy, transverse myelitis, and Guillain-Barré syndromes along with other common effects such as headaches following different kinds of COVID-19 vaccination." [Chatterjee & Chakravarty, 2022] and "The production of 'safe and effective' vaccines was a key public health target. Sadly, unprecedented high rates of adverse events have overshadowed the benefits." [Parry *et al.* 2023]

[41]https://vaers.hhs.gov/docs/VAERSDataUseGuide_November2020.pdf

[42]NIA Adverse Event and Serious Adverse Event Guidelines [Internet]. [cited 2023 Aug 24]. Available from: https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf

[43]Garg RK, Paliwal VK. Spectrum of neurological complications following COVID-19 vaccination. Neurol Sci. 2022 Jan;43(1):3-40. doi: 10.1007/s10072-021-05662-9. Epub 2021 Oct 31. PMID: 34719776; PMCID: PMC8557950.

[44]Samim MM, Dhar D, Arshad F, Anudeep DDS, Patel VG, Neeharika SR, Dhamija K, Ravindranath CM, Yadav R, Raja P, Netravathi M, Menon D, Holla VV, Kamble NL, Pal PK, Nalini A, Vengalil S. Co-VAN study: COVID-19 vaccine associated neurological diseases- an experience from an apex neurosciences centre and review of the literature. J Clin Neurosci. 2023 Feb;108:37-75. doi: 10.1016/j.jocn.2022.12.015. Epub 2022 Dec 23. PMID: 36586226; PMCID: PMC9780646.

[45]Chatterjee A, Chakravarty A. Neurological Complications Following COVID-19 Vaccination. Curr Neurol Neurosci Rep. 2023 Jan;23(1):1-14. doi: 10.1007/s11910-022-01247-x. Epub 2022 Nov 29. PMID: 36445631; PMCID: PMC9707152.

[46]Toljan K, Amin M, Kunchok A, Ontaneda D. New diagnosis of multiple sclerosis in the setting of mRNA COVID-19 vaccine exposure. J Neuroimmunol. 2022 Jan 15;362:577785. doi: 10.1016/j.jneuroim.2021.577785. Epub 2021 Dec 9. PMID: 34922126; PMCID: PMC8656147.

[47]Waheed W, Carey ME, Tandan SR, Tandan R. Post COVID-19 vaccine small fiber neuropathy. Muscle Nerve. 2021 Jul;64(1):E1-E2. doi: 10.1002/mus.27251. Epub 2021 Apr 28. PMID: 33851437; PMCID: PMC8250971.

[48]Patone M, Handunnetthi L, Saatci D, Pan J, Katikireddi SV, Razvi S, Hunt D, Mei XW, Dixon S, Zaccardi F, Khunti K, Watkinson P, Coupland CAC, Doidge J, Harrison DA, Ravanan R, Sheikh A, Robertson C, Hippisley-Cox J. Neurological complications after first dose of COVID-19 vaccines and SARS-CoV-2 infection. Nat Med. 2021 Dec;27(12):2144-2153. doi: 10.1038/s41591-021-01556-7. Epub 2021 Oct 25. Erratum in: Nat Med. 2021 Nov 29; PMID: 34697502; PMCID: PMC8629105.

[49]Parry PI, Lefringhausen A, Turni C, Neil CJ, Cosford R, Hudson NJ, Gillespie J. 'Spikeopathy': COVID-19 Spike Protein Is Pathogenic, from Both Virus and Vaccine mRNA. Biomedicines. 2023 Aug 17;11(8):2287. doi: 10.3390/biomedicines11082287. PMID: 37626783; PMCID: PMC10452662.

[50]https://pubmed.ncbi.nlm.nih.gov/?term=neurological+adverse+events+covid+vaccine

It is imperative that doctors like Dr. Corneil keep up-to-date with the literature, otherwise, they run the risk of Misinforming patients and health authorities and making Incorrect statements.

Consistency in observed findings – Bradford Hill Criterion #1

It has also been shown in a peer-reviewed article published in *Pathology - Research and Practice* (Available online December 12, 2023) that there is a striking difference between the COVID-19 IP and other vaccines - in addition to, but primarily Influenza vaccines), in the context of deaths reported per million doses of vaccine as shown in Figure 3.[51] Using their calculated rates, the fold increase in reporting of death in the context of the COVID-19 IP is very similar to the one calculated from independent analysis at 74 times higher reporting rate for COVID-19 IP than for Influenza. The reason for the difference between the fold increases reported in this article and independently is due to the differences in timeframes for COVID-19 IP deaths. The authors reported COVID-19 IP death rates from 2020 onward, whereas I examined only 2021. If all deaths are considered from 2020 onward, by my calculation, the fold increase in death reporting rate is 74 times, as documented by the authors.

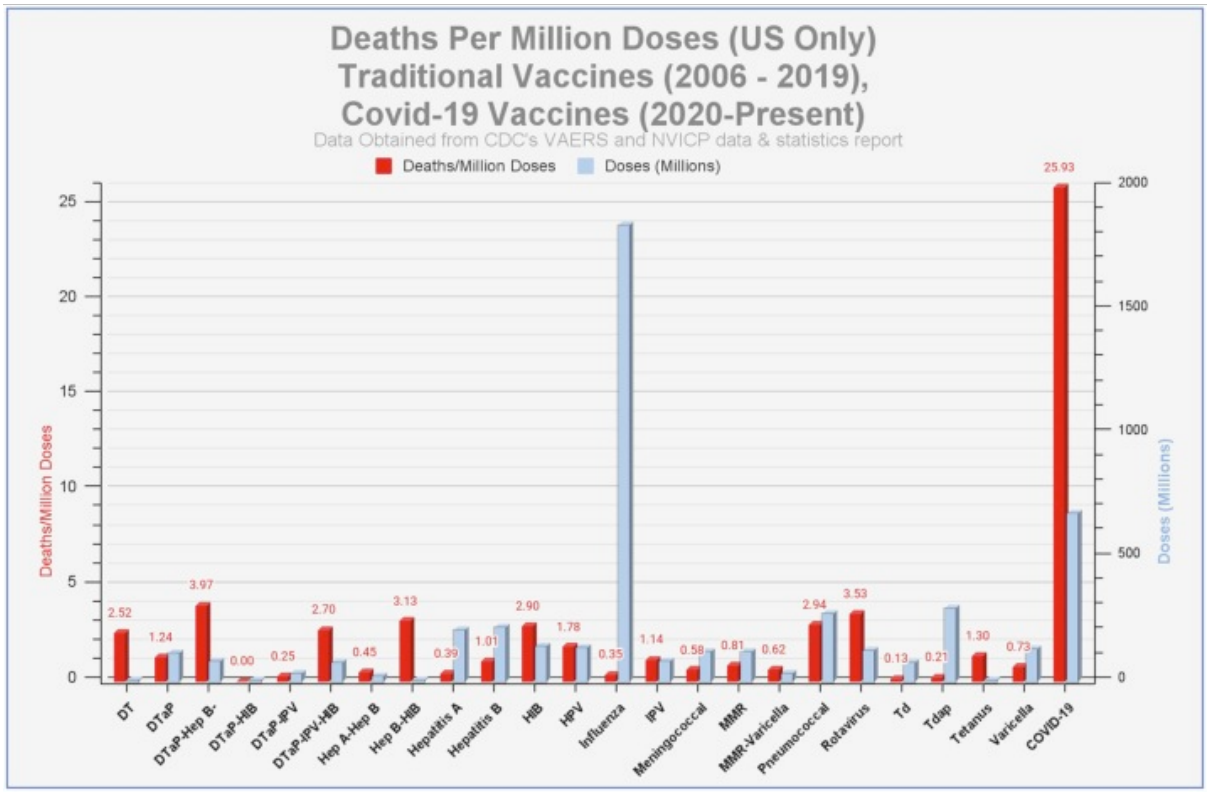


Figure 3: Deaths per million doses in US only for traditional vaccines versus COVID-19 IP. Source: Figure 4 from https://doi.org/10.1016/j.prp.2023.155030

The number of deaths per million doses is ~2,000% higher (Rhodes & Parry, 2024) (Figure 3) and this is corroborated by independent analysis of VAERS. When expanding the timeframe to three years (2018-2020 –

[51]Peter Rhodes, Peter Parry, Gene-based COVID-19 vaccines: Australian perspectives in a corporate and global context, Pathology - Research and Practice, Volume 253, 2024, 155030, ISSN 0344-0338, https://doi.org/10.1016/j.prp.2023.155030

Influenza & 2021-2023 for COVID-19 IP), the COVID-19 IP are associated with a 2,816% increase in reporting rate of death (per million doses) when compared to Influenza vaccines as shown in Figure 4.

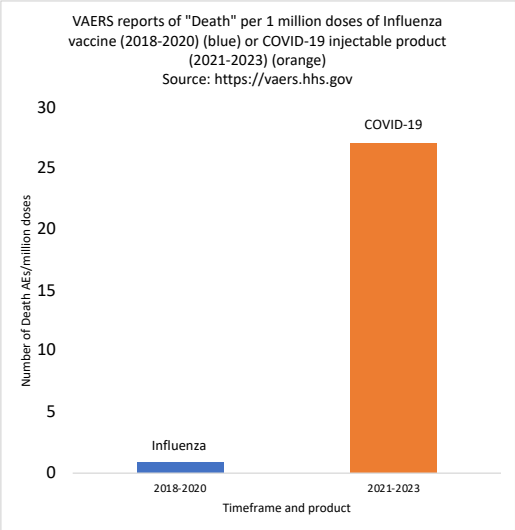


Figure 4: VAERS reports of Death per 1 million doses of Influenza vaccines or COVID-19 IP for the timeframes 2018-2020 and 2021-2023, respectively. Source: https://vaers.hhs.gov

Historically, a threshold of people 'permitted to die' in the context of a prophylactic product would *not* permit persistence of administration of these particular products based on these data, and this is only data for death. There are a staggering 17,481 reports of disability in VAERS as of November 2023, without considering under-reporting. VAERS IDs represent people. Death reports in VAERS in the context of the COVID-19 IP represent people who died following administration, and disability reports represent people who may be immobilized and unable to participate in day-to-day life anymore. **These people were under the impression that the COVID-19 IP were safe because they were told that they were by agencies that they trusted.** At the very least, it should be made public that the data clearly indicate a minimum 1 in 14,674[52] chance of dying (or 1/15,458 chance of becoming disabled) following administration of these prophylactic products without considering under-reporting. With an under-reporting factor of just 10, these chances become 1/1,467 and 1/1,545. Most people, I suspect, if they were aware of these risks, would depend on natural immunity - which has certainly already assured mass protection.[53] With risk, should come caution. It would be prudent to stratify these risks based on age and moribundity when determining who is legitimately at risk of increased hospitalization and death from the pathogen and thus who may benefit from injection in spite of the risks associated with them. Above all else, **informed consent is necessary**.

[52]Based on 18,416 deaths from January 2021 through to May 2023 and 270,227,181 total vaccinated with at least one dose https://covid.cdc.gov/covid-data-tracker/#vaccination-states-jurisdictions (N.B. A total of 676,728,782 doses have been administered in the United States according to https://covid.cdc.gov/covid-data-tracker/?ref=dailybrief.net#vaccinations_vacc-people-booster-percent-pop5

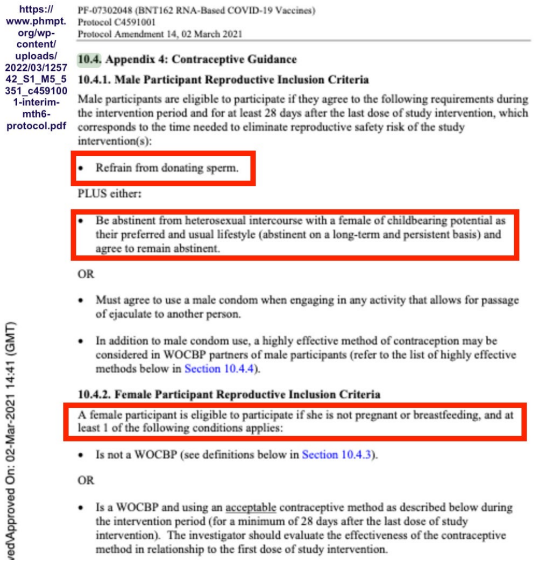
[53]Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Esma Herzel, Hillel Alapi, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study, Clinical Infectious Diseases, Volume 75, Issue 1, 1 July 2022, Pages e545–e551, https://doi.org/10.1093/cid/ciac262

N.B. Anyone with even a slight background in immunology knows that intramuscular injection (IM) is not the optimal way to confer immunity to a coronavirus, since the mucosal route is the means to achieve this goal.[54,55] Exposure to a low dose wild-type virus is the best way to obtain long-lasting and complete immunity.

Specificity – Bradford Hill Criterion #2

Dr. Corneil quotes a study that determined that COVID-19 vaccines have a "*good safety profile in pregnancy with low risk of serious adverse effects*."

Again, this statement is in opposition to both clinical and pharmacovigilance data. As part of the original Pfizer clinical trial protocol, it was imperative that women and men refrain from exposure to the COVID-19 products as part of the exclusion criteria as shown in Figure 5. It is imperative to prevent harms to pregnant women at all cost, especially in the context of clinical trials. There are MedDRA codes for exposure to vaccines, including the COVID-19 IP, that include: 'Accidental exposure to product', 'Maternal exposure during pregnancy', 'Exposure during pregnancy', 'Maternal exposure before pregnancy' and 'Exposure via skin contact'.


https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf

PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines)
Protocol C4591001
Protocol Amendment 14, 02 March 2021

10.4. Appendix 4: Contraceptive Guidance

10.4.1. Male Participant Reproductive Inclusion Criteria

Male participants are eligible to participate if they agree to the following requirements during the intervention period and for at least 28 days after the last dose of study intervention, which corresponds to the time needed to eliminate reproductive safety risk of the study intervention(s):

- Refrain from donating sperm.

PLUS either:

- Be abstinent from heterosexual intercourse with a female of childbearing potential as their preferred and usual lifestyle (abstinent on a long-term and persistent basis) and agree to remain abstinent.

OR

- Must agree to use a male condom when engaging in any activity that allows for passage of ejaculate to another person.
- In addition to male condom use, a highly effective method of contraception may be considered in WOCBP partners of male participants (refer to the list of highly effective methods below in Section 10.4.4).

10.4.2. Female Participant Reproductive Inclusion Criteria

A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least 1 of the following conditions applies:

- Is not a WOCBP (see definitions below in Section 10.4.3).

OR

- Is a WOCBP and using an acceptable contraceptive method as described below during the intervention period (for a minimum of 28 days after the last dose of study intervention). The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study intervention.

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Figure 5: Exclusion criteria for interim protocol PF-07302048 (BNT162b2 RNA-based COVID-19 Vaccines) Protocol C4591001 Appendix 10.4 Appendix 4: Contraceptive Guidance

In a peer-reviewed publication by Zauche *et al.*, they write "Miscarriage typically occurs in about 11-16% of pregnancies, and this study found miscarriage rates after receiving a COVID-19 vaccine were around 13%, similar

[54]Matuchansky C. Mucosal immunity to SARS-CoV-2: a clinically relevant key to deciphering natural and vaccine-induced defences. Clin Microbiol Infect. 2021 Dec;27(12):1724-1726. doi: 10.1016/j.cmi.2021.08.008. Epub 2021 Aug 12. PMID: 34391929; PMCID: PMC8358136.
[55]Ahmed O. Hassan et al, A Single-Dose Intranasal ChAd Vaccine Protects Upper and Lower Respiratory Tracts against SARS-CoV-2, Cell, Volume 183, Issue 1, 2020, Pages 169-184.e13, ISSN 0092-8674, https://doi.org/10.1016/j.cell.2020.08.026

to the expected rate of miscarriage in the general population."[56] Naert *et al.* put this figure closer to 5.4% in the context of the first trimester of pregnancy.[57] They estimated a range "from 0.8% in women at 13 weeks of gestation with no prior miscarriages to 33.7% in women at six weeks of gestation with three or more prior miscarriages".

In a recent analysis of women exposed to the COVID-19 IP just *prior to* pregnancy from VAERS reports, it was discovered that 32% of these women also suffered a miscarriage. This is twice as high as the upper end of the miscarriage rate according to Zauche *et al.*, and the absolute extreme of the subset of women at six weeks of gestation with three or more prior miscarriages. This requires explanation and investigation. If nothing else, it indicates that women are reporting high frequencies of miscarriages in the context of these particular products. During the years spanning 2018 through 2020, the percentage of women exposed to Influenza vaccines during their pregnancy who also experienced and reported a miscarriage to VAERS is 8.8%. This is in stark contrast to the percentage of women exposed to COVID-19 IP during their pregnancies who also experienced and reported a miscarriage to VAERS (32%). The reason for this discrepancy requires investigation.

Myocarditis is inflammation of the myocardium or 'musculature' of the heart.[58,59] The myocardium is made up of many cell types however the greatest mass of tissue is accounted for by cardiomyocytes.[60,61] Cardiomyocytes are the principal contractile cells and are supported by specialized conduction and stromal cell types including cardiac pericytes.[62] All of these cell types can be damaged by inflammation.[63]

There are 1,077 published papers found when querying "myocarditis covid vaccine" in PubMed as of Thursday December 28, 2023. It is well-established that the COVID-19 IP induce myocarditis in young males.[64,65] Figure 6 shows the reports of myocarditis in VAERS following dose 1 and 2 and clearly demonstrates the discrepancy

[56]Lauren Head Zauche, Bailey Wallace, Ashley N. Smoots et al. Receipt of mRNA COVID-19 vaccines preconception and during pregnancy and risk of self-reported spontaneous abortions, CDC v-safe COVID-19 Vaccine Pregnancy Registry 2020-21, 09 August 2021, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-798175/v1]

[57]Mackenzie N. Naert, Hanaa Khadraoui, Alberto Muniz Rodriguez & Nathan S. Fox (2022) Stratified risk of pregnancy loss for women with a viable singleton pregnancy in the first trimester, The Journal of Maternal-Fetal & Neonatal Medicine, 35:23, 4491-4495, DOI: 10.1080/14767058.2020.1852212

[58]Cooper LT Jr. Myocarditis. N Engl J Med. 2009 Apr 9;360(15):1526-38. doi: 10.1056/NEJMra0800028. PMID: 19357408; PMCID: PMC5814110.

[59]Camm, A. John and others (eds), The ESC Textbook of Cardiovascular Medicine, 3 edn, The European Society of Cardiology Series (Oxford, 2018; online edn, ESC Publications, 1 July 2018), https://doi.org/10.1093/med/9780198784906.001.0001, accessed 15 Aug. 2023.

[60]Libby P, Swirski FK, Nahrendorf M. The Myocardium: More Than Myocytes. J Am Coll Cardiol. 2019 Dec 24;74(25):3136-3138. doi: 10.1016/j.jacc.2019.10.031. PMID: 31856970.

[61]Banerjee I, Fuseler JW, Price RL, Borg TK, Baudino TA. Determination of cell types and numbers during cardiac development in the neonatal and adult rat and mouse. Am J Physiol Heart Circ Physiol. 2007 Sep;293(3):H1883-91. doi: 10.1152/ajpheart.00514.2007. Epub 2007 Jun 29. PMID: 17604329

[62]Weinhaus A.J., Roberts K.P. (2009) Anatomy of the Human Heart. In: Iaizzo P. (eds) Handbook of Cardiac Anatomy, Physiology, and Devices. Humana Press. https://doi.org/10.1007/978-1-60327372-5_5

[63]Avolio E, Carrabba M, Milligan R, Kavanagh Williamson M, Beltrami AP, Gupta K, Elvers KT, Gamez M, Foster RR, Gillespie K, Hamilton F, Arnold D, Berger I, Davidson AD, Hill D, Caputo M, Madeddu P. The SARS-CoV-2 Spike protein disrupts human cardiac pericytes function through CD147 receptor-mediated signalling: a potential non-infective mechanism of COVID-19 microvascular disease. Clin Sci (Lond). 2021 Dec 22;135(24):2667-2689. doi: 10.1042/CS20210735. PMID: 34807265; PMCID: PMC8674568

[64]https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf

[65]https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/03-COVID-Su-508.pdf

between reporting between the first and second doses in 15-year-olds. This trend of COVID-19 injection-induced myocarditis continues to be revealed in the literature.[66,67] This is also demonstrative of a type of dose response.

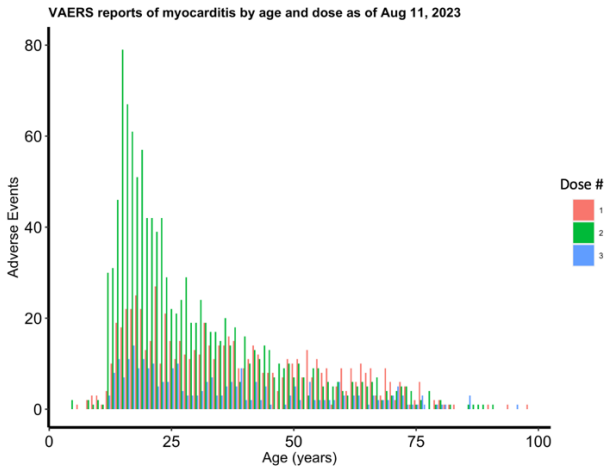

Figure 6: VAERS reports of myocarditis by age and dose as of August 11, 2023.

Below in Figure 7 are images from a case study of a 15-year-old boy with COVID-19 IP-induced myocarditis published in *Radiology* in August 2021.[68]

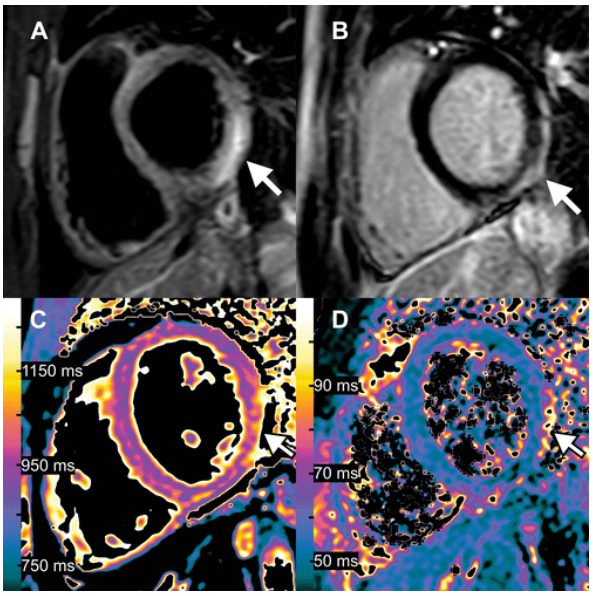

Figure 7: Images in 15-year-old boy with myocarditis after COVID-19 vaccination. One day after receiving his second vaccination dose, he developed fever, myalgia, and intermittent tachycardia. Source: https://pubs.rsna.org/doi/full/10.1148/radiol.2021211766

[66]Bozkurt B, Kamat I, Hotez PJ. Myocarditis With COVID-19 mRNA Vaccines. Circulation. 2021 Aug 10;144(6):471-484. doi: 10.1161/CIRCULATIONAHA.121.056135. Epub 2021 Jul 20. PMID: 34281357; PMCID: PMC8340726.
[67]Yonker LM, Swank Z, Bartsch YC, Burns MD, Kane A, Boribong BP, Davis JP, Loiselle M, Novak T, Senussi Y, Cheng CA, Burgess E, Edlow AG, Chou J, Dionne A, Balaguru D, Lahoud-Rahme M, Arditi M, Julg B, Randolph AG, Alter G, Fasano A, Walt DR. Circulating Spike Protein Detected in Post-COVID-19 mRNA Vaccine Myocarditis. Circulation. 2023 Mar 14;147(11):867-876. doi: 10.1161/CIRCULATIONAHA.122.061025. Epub 2023 Jan 4. PMID: 36597886; PMCID: PMC10010667.
[68]Myocarditis Following COVID-19 Vaccination. Alexander Isaak, Andreas Feisst, and Julian A. Luetkens. Radiology 2021 301:1, E378-E379

69% of reports of myocarditis filed between 2021 and 2023 in the context of the COVID-19 IP were filed within 7 days of injection. 58% were filed within 3 days of injection, and 28% were filed within 48 hours.

Children

Children were never at risk of hospitalization or death from SARS-CoV-2 as repeatedly published in the literature[69,70,71,72,73,74,75,76] (summary of literature: children and young people remain at low risk of COVID-19 mortality due to mucosal immunity as based upon multiple multinational cohort studies and reports) and therefore it was never necessary to recommend injections with the COVID-19 IP. Well into 2021, the risk to children remained low.[77] As Dr. Marty Makary, a professor at Johns Hopkins University School of Medicine and editor-in chief of MedPage Today, pointed out in early 2021: "In the United States, a total of 335 children under 18 have died with a COVID-19 diagnosis on their death certificate."[78] He goes onto say that "***no one at Johns Hopkins has systematically investigated the cause of each child's death, in an effort to determine if COVID was actually involved or if the death was the result of a preexisting condition***". Figure 8 demonstrates just a few of these earlier studies and statistics.[79,80] These studies combined clearly indicate(d) that children develop robust and long-lasting immunity via mucosal immunity routes.[81] It is also documented that by injecting children with the COVID-19 IP, that immune pressure towards escape variants is exerted and perpetuation of the problem.[82,83] It has also been documented in the peer-reviewed literature that children can shed infectious SARS-CoV-2 despite being injected with the COVID-19 IP.[84] It is therefore unacceptable that 65,961 reports of AEs have been

[69]Martins MM, Prata-Barbosa A, da Cunha AJLA. Update on SARS-CoV-2 infection in children. Paediatr Int Child Health. 2021 Feb;41(1):56-64. doi: 10.1080/20469047.2021.1888026. Epub 2021 Feb 22. PMID: 33616026

[70] Gudbjartsson DF et al. Spread of SARS-CoV-2 in the Icelandic Population. *New England Journal of Medicine* 382, 2302–2315 (2020)

[71]Pan X et al. Asymptomatic cases in a family cluster with SARS-CoV-2 infection. *The Lancet Infectious Diseases* 20, 410–411 (2020).

[72]Jiehao C et al. A Case Series of Children With 2019 Novel Coronavirus Infection: Clinical and Epidemiological Features. *Clin Infect Dis* 71, 1547–1551 (2020)

[73]Lu X et al. SARS-CoV-2 Infection in Children. *N Engl J Med* 382, 1663–1665 (2020)

[74]Grasselli G et al. Baseline Characteristics and Outcomes of 1591 Patients Infected With SARS-CoV-2 Admitted to ICUs of the Lombardy Region, *Italy. JAMA* 323, 1574–1581 (2020)

[75]Götzinger F et al. COVID-19 in children and adolescents in Europe: a multinational, multicentre cohort study. *The Lancet Child & Adolescent Health* 4, 653–661 (2020)

[76]Saatci D et al. Association Between Race and COVID-19 Outcomes Among 2.6 Million Children in England. *JAMA Pediatrics* 175, 928–938 (2021)

[77]S. Bhopal et al. Children and young people remain at low risk of COVID-19 mortality. March 10, 2021 https://doi.org/10.1016/ S2352-4642(21)00066-3

[78]O'Driscoll, M., Ribeiro Dos Santos, G., Wang, L. *et al.* Age-specific mortality and immunity patterns of SARS-CoV-2. *Nature* **590,** 140–145 (2021). https://doi.org/10.1038/s41586-020-2918-0

[79]Sunil S Bhopal, Jayshree Bagaria, Bayanne Olabi, Raj Bhopal. Children and young people remain at low risk of COVID-19 mortality. The Lancet/Child and Adolescent Health. Correspondence| Volume 5, ISSUE 5, e12-e13, May 01, 2021. Published:March 10, 2021. DOI:https://doi.org/10.1016/S2352-4642(21)00066-3

[80]O'Driscoll, M., Ribeiro Dos Santos, G., Wang, L. *et al.* Age-specific mortality and immunity patterns of SARS-CoV-2. *Nature* **590,** 140–145 (2021). https://doi.org/10.1038/s41586-020-2918-0

[81]Pierce CA, Sy S, Galen B, Goldstein DY, Orner E, Keller MJ, Herold KC, Herold BC. Natural mucosal barriers and COVID-19 in children. JCI Insight. 2021 May 10;6(9):e148694. doi: 10.1172/jci.insight.148694. PMID: 33822777; PMCID: PMC8262299

[82]Frost SDW, Magalis BR, Kosakovsky Pond SL. Neutral Theory and Rapidly Evolving Viral Pathogens. Mol Biol Evol. 2018 Jun 1;35(6):1348-1354. doi: 10.1093/molbev/msy088. PMID: 29688481; PMCID: PMC6279309

[83]Martin DP et al. The emergence and ongoing convergent evolution of the SARS-CoV-2 N501Y lineages. Cell. 2021 Sep 30;184(20):5189-5200.e7. doi: 10.1016/j.cell.2021.09.003. Epub 2021 Sep 7. PMID: 34537136; PMCID: PMC8421097

[84]Riemersma KK, Haddock LA III, Wilson NA, Minor N, Eickhoff J, Grogan BE, et al. (2022) Shedding of infectious SARS-CoV-2 despite vaccination. PLoS Pathog 18(9): e1010876. https://doi.org/10.1371/journal.ppat.1010876

filed in VAERS as of November 2023, including deaths (95) and now well-known, myocarditis (706). The average age of the children who died is 13 and the average age of the children diagnosed with myocarditis is 15.

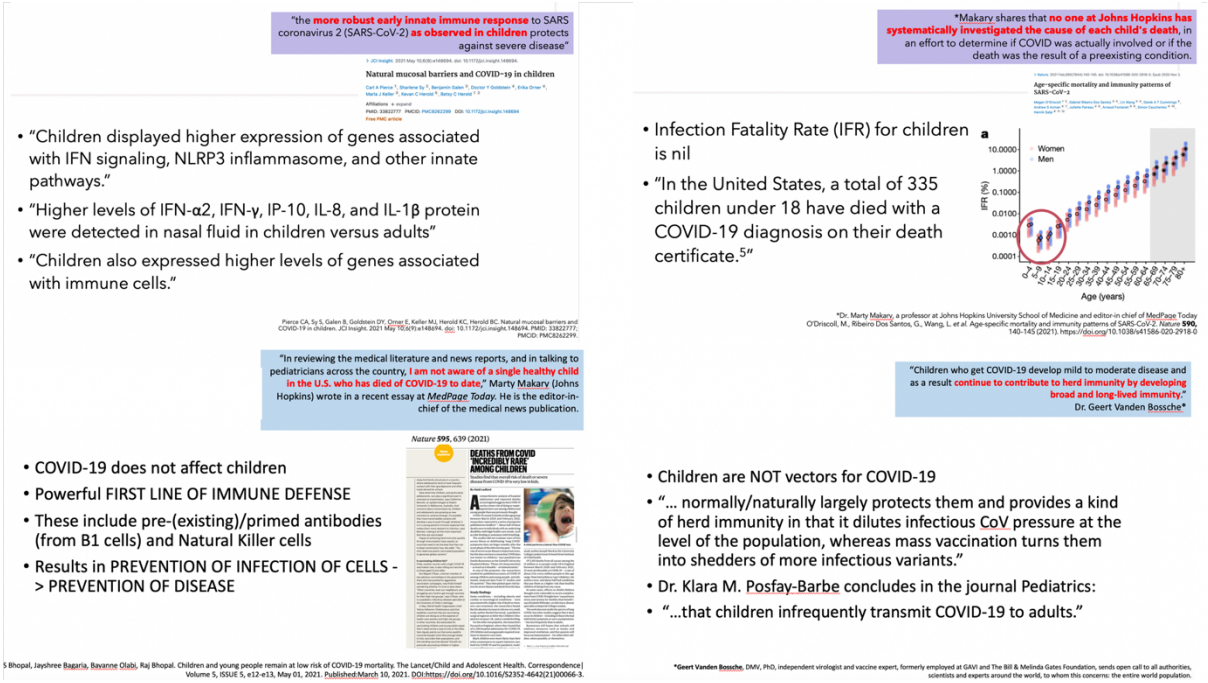

Figure 8: Evidences in the peer-reviewed literature that children required no intervention or countermeasures in the context of SARS-CoV-2 and that accounts of death due to COVID-19 were not confirmed.

Age-specific data collected from official government sources for seven countries (including the United States) up to May 2020 was examined in the context of deaths associated with COVID-19.[85, 86] Examination revealed an estimated 0.3% of individuals who died with SARS-CoV-2 were under 20 years of age. In the context of the total population of people who filed death AE reports following injection with COVID-19 IP, 0.6% were under 20 years of age, according to CDC data.[87,88] In other words, twice as many young adults and children are estimated to have died in association with the COVID-19 IP when compared to COVID-19. 23.3% of these death reports were filed within 48 hours of injection with the COVID-19 IP. (See Exhibit C)

Fertility

On the subject matter of fertility issues associated with the COVID-19 IP, there is evidence beyond what has already been presented herein that provides reasons for concern. Figure 9 (left) demonstrates how reports of miscarriages from VAERS track the roll-out of the COVID-19 IP. The fact that the monthly total of reports of miscarriage maps very well to the monthly toll of new injections is disturbing. A full causality assessment is

[85]Bhopal S, Bagaria J, Bhopal R. Children's mortality from COVID-19 compared with all-deaths and other relevant causes of death: epidemiological information for decision-making by parents, teachers, clinicians and policymakers. *Public Health*. 2020;185:19-20. doi:10.1016/j.puhe.2020.05.047

[86]https://data.unicef.org/topic/child-survival/covid-19/

[87]https://vaers.hhs.gov

[88]The number of children under 18 who received at least one dose of COVID-19 IP (Vaccination Trends by Age) is 31,779,895 as of May 11, 2023. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

required to secure a diagnosis of cause. Nonetheless, it is indeed compelling that in addition to the high covariance (V_{co}=26) and correlation (R = 0.81) (Figure 8 - left), there has been a 1,075% increase in miscarriage (MedDRA code: "Abortion spontaneous") reporting rates (per million doses) when comparing Influenza (2018-2020) and COVID-19 IP (2021-2023) (Figure 9 - right).

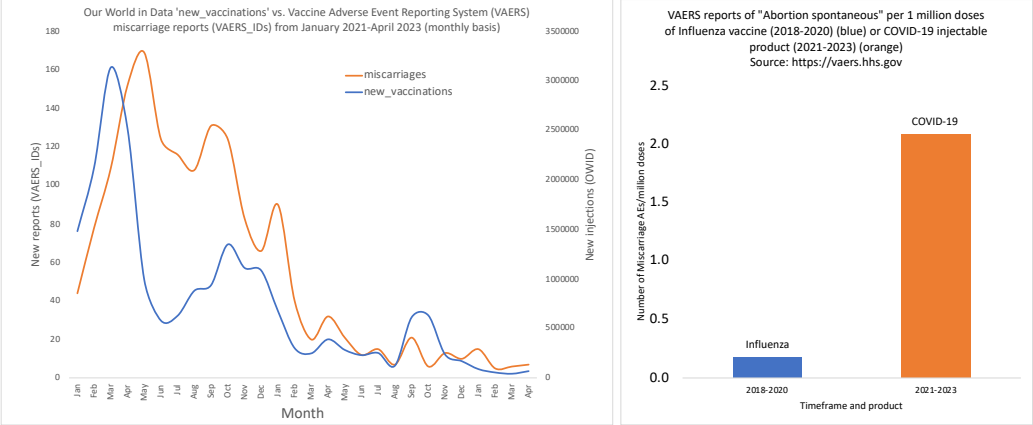

Figure 9: Our world in data 'new_vaccinations' versus VAERS miscarriage reports (VAERS_IDs) from January 2021 through April 2023 (left). Abortion spontaneous reporting rates per million doses for Influenza (2018-2020) and COVID-19 IP (2021-2023) (right).

Temporality – Bradford-Hill Criterion #3

As previously noted, 69% of reports of myocarditis in VAERS filed between 2021 and 2023 in the context of the COVID-19 IP were filed within 7 days of injection. 58% were filed within 3 days of injection, and 27% were filed within 48 hours. This can be applied to all AEs. 44%, 60% and 67% of all reports were filed within 24, 48 or 72 hours. 74% of all reports were filed within 7 days. Anaphylaxis[89] is a good positive control for how readily and quickly reports of these acute reactions to the COVID-19 IP are reported to VAERS. As shown in Figure 10, 80% of anaphylaxis reports were filed immediately (within 24 hours). The remaining 20% are likely not reactions to the COVID-19 injections since they were reported more than 24 hours after the injection took place. It's possible the reporter filed a report in the context of a reaction to a different trigger, or that either the injection or the onset dates were transcribed incorrectly.

[89]Simons FE, Ardusso LR, Bilò MB, Cardona V, Ebisawa M, El-Gamal YM, Lieberman P, Lockey RF, Muraro A, Roberts G, Sanchez-Borges M, Sheikh A, Shek LP, Wallace DV, Worm M. International consensus on (ICON) anaphylaxis. World Allergy Organ J. 2014 May 30;7(1):9. doi: 10.1186/1939-4551-7-9. PMID: 24920969; PMCID: PMC4038846

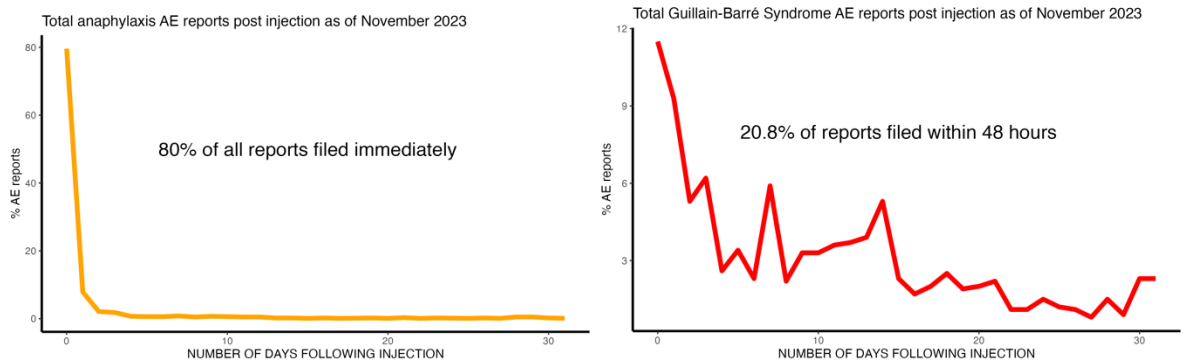

Figure 10: Percentage of VAERS reports of anaphylaxis (orange) and Guillain-Barré Syndrome (red) AEs versus the time from injection to onset of AE. https://vaers.hhs.gov

A high number of neurological AEs and more specifically, Guillain-Barré Syndrome (GBS), have been filed in the context of the COVID-19 IP to VAERS. GBS is a rare disorder in which the body's immune system attacks the nerves to the legs and arms and is one of the leading causes of non-trauma-induced paralysis.[90] There is a variable collected in the VAERS database called 'NUMDAYS' which is a calculation of the timeframe between injection (VAX_DATE) and onset of reported AE (ONSET_DATE). With regard to temporality, 20.8% of the 1,043 GBS reports were filed within 48 hours of onset following injection. The short timeframe between injection and onset makes a great case for causation with regard to temporality in that not only does injection precede onset, but the short timeframe (and its comparability to an acute reaction to a trigger an AE like anaphylaxis) makes it more likely that the injected product is the instigating ***cause*** of the GBS.

Put into question: In the absence of the injection, would the GBS have ensued? It is also noteworthy that almost half (46.5%) of all GBS reports in VAERS were filed within 1 week. It bears repeating that GBS is rare and is a leading cause of non-trauma-induced paralysis.

Most stand-alone of AEs in VAERS reflect this same pattern (not shown).

Dose-response – Bradford Hill Criterion #4

Biological gradient or dose-response relationship implies that greater exposure should generally lead to greater incidence of the effect. However, in some cases, the mere presence of the factor can trigger the effect. In other cases, an inverse proportion is observed: greater exposure leads to lower incidence.

In a recently uploaded preprint, Speicher *et al.* demonstrated an exploratory analysis whereby a dose-response curve may be emergent from the existing data. It is absolutely necessary to acquire more data to determine if a dose-response is applicable in the residual DNA setting. Additionally, VAERS data reveals another type of dose-

[90]https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Safety-Adverse-Events/Adverse-Events-for-Healthcare-Providers/Neurologic-Adverse-Events

response curve as shown in Figure 11. On the left, is an exploratory dose response analysis comparing the concentration of residual DNA measured by qPCR for spike (red) and plasmid ori (blue) found in Pfizer to SAEs/total AEs in VAERS.[91] This plot is very preliminary and extracted from a preprint so it must be interpreted as a *possibility*. But considering that there is an already visible relationship in the exploratory analysis, this is most certainly a point that requires additional data collection. When VAERS reports of cancer are queried per dose from VAERS and subsequently plotted per dose, a dose-response curve emerges as shown in Figure 10 on the right with a high correlation constant (R = 0.9).

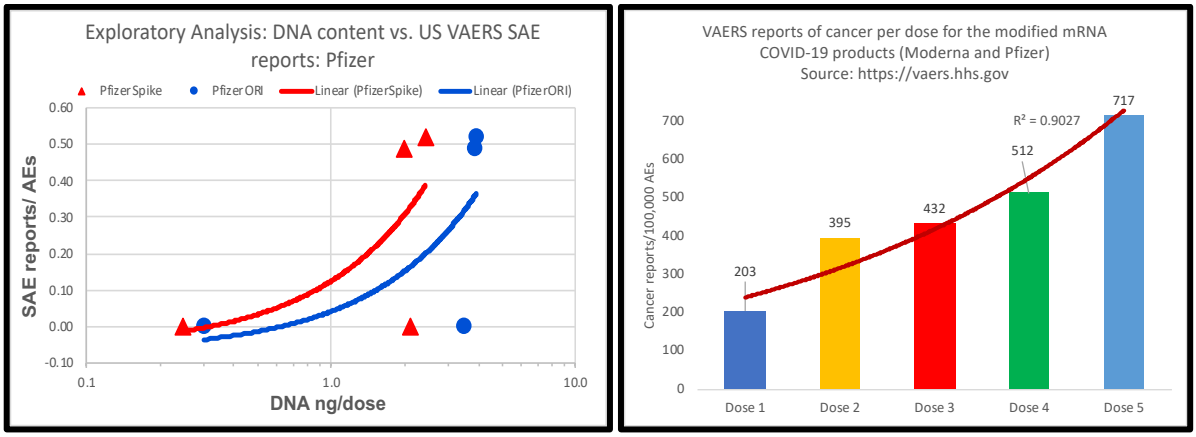

Figure 11: Dose-response relationships are being seen from a variety of sources. On the left is an exploratory dose-response curve between DNA content in modified mRNA COVID-19 product vials and SAEs from VAERS. On the right is the increase in cancer reports according to dose from VAERS.

Plausibility (and experimental nature of the modified mRNA products) – Bradford Hill Criterion #5

Dr. Corneil states: "Health Canada regulates drugs including vaccines that are brought to market for clinical use by: a) evaluating a drug or vaccine for its safety, efficacy and quality based on scientific and clinical evidence", in section 5.4 entitled: "Regulation and Approval of Drugs and Vaccines for the Prevention of COVID-19", subsection 15 as objective opinion.

Health Canada recently admitted (Figure 12) to the presence of a foreign DNA fragment called Simian Virus 40 promoter (SV40 promoter) - which contains a known and well-documented Nuclear Location Sequence (NLS) called the SV40 enhancer[92] - in the Pfizer/BioNTech product.[93] They were prompted to check the product provided to them years ago by the FDA/manufacturer following the publication of the discovery of both Pfizer/BioNTech and Moderna vial contamination with DNA, and an inquiry from journalists at The Epoch

[91]Speicher, D. J., Rose, J., Gutschi, L. M., Wiseman, D. M., PhD, & McKernan, K. (2023, October 19). DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events. OSF preprints. https://doi.org/10.31219/osf.io/mjc97

[92]Strayer DS. Gene therapy using SV40-derived vectors: what does the future hold? J Cell Physiol. 1999 Dec;181(3):375-84. doi: 10.1002/(SICI)1097-4652(199912)181:3<375:AID-JCP1>3.0.CO;2-8. PMID: 10528223.

[93]https://www.theepochtimes.com/world/exclusive-health-canada-confirms-undisclosed-presence-of-dna-sequence-in-pfizer-shot-5513277

Times.[94] The SV40 enhancer has indeed been discovered using various sequencing techniques by at least two independent labs in multiple COVID-19 modified mRNA product vials with appropriate cold chain management, and this is now recognized by Health Canada.

In spite of this recognition, Health Canada maintains that these products are 'safe'. But in light of unknown quantities of DNA as by-products of modified mRNA production that, in some cases exceed European Medical Agency (EMA) standards, being discovered in every vial tested, it would be prudent to withhold this claim and to commence an inquiry into the validity of this claim of safety by Health Canada. DNA fragments of foreign origin transfected into cells in the context of an NLS could result in genomic integration and a plethora of genetic complications including insertional mutagenesis.


THE EPOCH TIMES

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EXCLUSIVE: Health Canada Confirms Undisclosed Presence of DNA Sequence in Pfizer Shot

The health regulator says Pfizer did not disclose the presence of the Simian Virus 40 (SV40) DNA sequence in its mRNA COVID-19 vaccine at the time of filing.

Figure 12: Health Canada confirms undisclosed presence of DNA sequence in Pfizer/BioNTech shot as reported by The Epoch Times on October 19, 2023.

The risks of cancer induction are **not nil** and until proven otherwise, this risk must be addressed properly by Health Canada. The health and well-being of Canadian citizens must be prioritized.

Dr. Corneil states: "… these vaccines are not gene therapy" on page 66 of his opinion letter. In fact, the FDA defines human gene therapy in the following way: "Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. Gene therapy is a technique that modifies a person's genes."[95,96] If there are integration events occurring due to NLS translocation of DNA fragments to the nucleus of cells[97,98] then the COVID-19 IP qualify as gene therapies according to the

[94]Speicher, D. J., Rose, J., Gutschi, L. M., Wiseman, D. M., PhD, & McKernan, K. (2023, October 19). DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events. OSF preprints. https://doi.org/10.31219/osf.io/mjc97

[95]https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

[96]https://www.fda.gov/media/113768/download?attachment

[97]Vera M, Fortes P. Simian virus-40 as a gene therapy vector. DNA Cell Biol. 2004 May;23(5):271-82. doi: 10.1089/104454904323090903. PMID: 15169607

[98]Strayer DS. SV40-based gene therapy vectors: turning an adversary into a friend. Curr Opin Mol Ther. 2000 Oct;2(5):570-8. PMID: 11249759

FDA's definition. The question remains: are integration events ensuing in people's cells transfected with the COVID-19 IP?

The clinical trials as run by Pfizer/BioNTech are moot. The placebo participants were unblinded and subsequently injected with drug product as confirmed by Team Leader and Clinical Review Staff for FDA Dr. Rachel Zhang at the FDA's June 14, 2022 VRBPAC meeting. (See Exhibit D) This effectively destroys the trial as a randomized controlled trial. The products that were administered world-wide made by Pfizer/BioNTech were not produced using the same modified mRNA synthesis procedure as for the products used in the clinical trials as described in the Manufacturing Process from Pfizer's Clinical Protocol Template.[99,100] Figure 13 is a screenshot of Figure 6.1.1. demonstrating the Manufacturing Processes Process 1 – as used in the clinical trial products – and Process 2 as used in the roll-out of commercial products.

6.1.1. Manufacturing Process

The scale of the BNT162b2 manufacturing has been increased to support future supply. BNT162b2 generated using the manufacturing process supporting an increased supply ("Process 2") will be administered to approximately 250 participants 16 to 55 years of age, per lot, in the study. The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with material generated using the existing manufacturing process "Process 1," and with material from lots generated using the manufacturing process supporting increased supply, "Process 2," will be described.

In brief, the process changes relate to the method of production for the DNA template that RNA drug substance is transcribed from, and the RNA drug substance purification method. The BNT162b2 drug product is then produced using a scaled-up LNP manufacturing process.

Figure 13: 6.1.1. Manufacturing Process from Pfizer's Clinical Protocol Template

The modified mRNA used in the Pfizer/BioNTech and Moderna products is synthesized *in vitro* using a five-step synthesis process. It begins with *in silico* design of the DNA template, and subsequent cloning of these templates into DNA plasmids - small circular DNAs - and introduction of these plasmids into *E. coli* bacteria. The bacteria are grown and using specific antibiotic resistance genes built into the DNA plasmids, the bacteria with the plasmids are extracted. Following extraction, the DNA is linearized. *In vitro* transcription follows with addition of N1-methylpseudouridines in place of uridines as per the immune-evading inspiration for COVID-19 vaccine development.[101] The product is then purified and tested for residual DNA left-over from the plasmid template and for potential lipopolysaccharide (LPS) carry-over from the bacteria.

[99]6.1.1. Manufacturing Process: PFIZER CONFIDENTIAL CT02-GSOP Clinical Protocol Template Phase 1,2,3,4 https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf. Page 64

[100]https://factreview.gr/wp-content/uploads/2023/07/Rolling-Review-Report-Quality-COVID-19-mRNA-Vaccine-BioNTech.pdf

[101]Nance KD, Meier JL. Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines. ACS Cent Sci. 2021 May 26;7(5):748-756. doi: 10.1021/acscentsci.1c00197. Epub 2021 Apr 6. PMID: 34075344; PMCID: PMC8043204

The modified mRNA drug substance made for use in the clinical trial was transcribed from DNA templates with entirely different methods of production as shown in Figure 14.[102] Shown on the left is the PCR-produced DNA template used to synthesize modified mRNA for the clinical products. Shown on the right is the plasmid/E coli-produced DNA used to synthesize modified mRNA for the commercial products. It is alarming that safety and immunogenicity of the Process 2 products were only tested on 250 individuals between 16 and 55 years of age.[103,104]

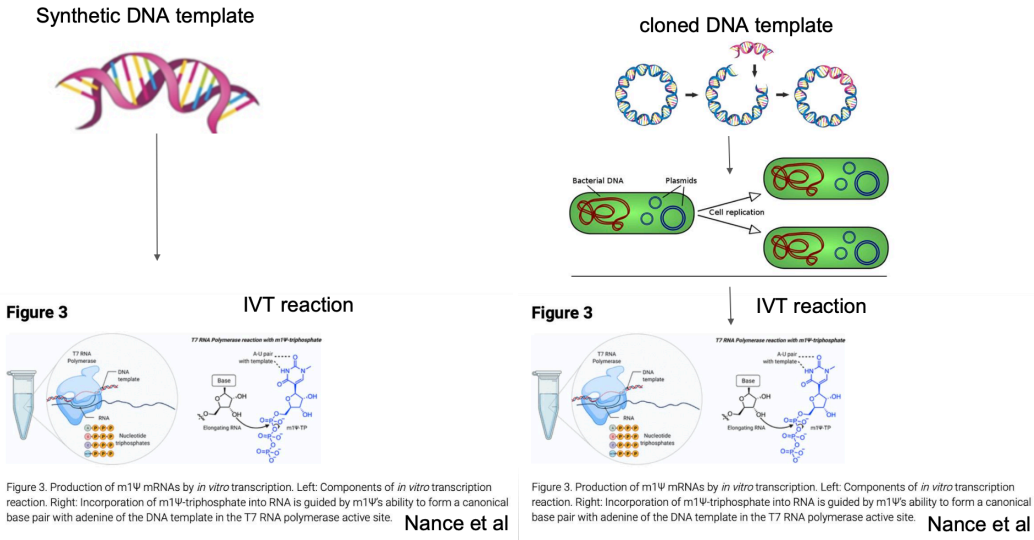

Figure 14: Process 1 and 2 *in vitro* transcription follows production of DNA using two different methods as illustrated by K. McKernan adapted from Nance *et al.* PCR-produced DNA (left) was used in the clinical setting whereby cloned DNA was used in the commercial setting preceding the *in vitro* transcription reactions to produce the modified mRNA.

The COVID-19 IP made by Pfizer/BioNTech[105] and Moderna[106] are based on a novel lipid nanoparticle (LNP) delivery vehicle that contains modified messenger RNA designed to transfect human cells for ribosomal production of foreign spike protein fragments. Never before has this kind of technology or platform been disseminated to the public en-masse in the context of a therapeutic aimed against a virus.[107] These LNPs were not tested as empty vectors prior to output, and therefore we do not know if they have inherent toxicity *in vivo* (in humans). Studies show that the cationic lipids used in the LNP formulation for both Moderna and

[102]Nance KD, Meier JL. Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines. ACS Cent Sci. 2021 May 26;7(5):748-756. doi: 10.1021/acscentsci.1c00197. Epub 2021 Apr 6. PMID: 34075344; PMCID: PMC8043204

[103]Josh A. Geutzkow and Retsef Levi. Effect of mRNA Vaccine Manufacturing Processes on Efficacy and Safety Still an Open Question. BMJ 2022;378:o1731 https://www.bmj.com/content/378/bmj.o1731/rr-2

[104]PFIZER CONFIDENTIAL CT02-GSOP Clinical Protocol Template Phase 1 2 3 4 https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf. Page 46. 6.1.1. Manufacturing Process Page 54

[105]https://www.pfizer.com/science/coronavirus-resources

[106]https://www.modernatx.com/en-US

[107]Halma MTJ, Rose J, Lawrie T. J. The Novelty of mRNA Viral Vaccines and Potential Harms: A Scoping Review. (2023) 6(2):220-235. https://doi.org/10.3390/j6020017

Pfizer/BioNTech LNP production are toxic to human cells.[108,109,110] It is also quite disturbing that the Safety Data Sheets for the specific cationic lipids used in the Moderna and Pfizer/BioNTech formulations, namely SM-102 and ALC-0315, are specifically designated for research use and **are not for human or veterinary diagnostic or therapeutic use**.[111,112]

Based solely on the fact that the modified mRNA COVID-19 products are both novel in platform, concept and production methodology, with regard to the Bradford Hill criterion #5, **Plausibility** is undeniable in the case of these particular products.

In addition, it has been shown in pharmacokinetic studies from Japan that the lipid nanoparticles (LNPs) used in the Moderna and Pfizer/BioNTech formulations biodistribute and bioaccumulate in various organs.[113,114] Figure 15 is a Table extracted from a pharmacokinetic study of the Pfizer/BioNTech LNP components showing which organs these LNP components traffic to and accumulate in and what percentage of the administered dose is found in each of these organs. It should be noted here that the mean total lipid concentration in the ovaries measured 48 hours after injection was one of the highest at 12.3 ug lipid equivalent/g. It should also be pointed out that the concentrations were increasing when the measurements were stopped at 48 hours.

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

Species (Strain):	Rat (Wistar Han)
Sex/Number of Animals:	Male and female/3 animals/sex/timepoint (21 animals/sex total for the 50 µg dose)
Feeding Condition:	Fed ad libitum
Method of Administration:	Intramuscular injection
Dose:	50 µg [^{3}H]-08-A01-C0 (lot # NC-0552-1)
Number of Doses:	1
Detection:	Radioactivity quantitation using liquid scintillation counting
Sampling Time (hour):	0.25, 1, 2, 4, 8, 24, and 48 hours post-injection

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)							% of administered dose (males and females combined)						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181	--	--	--	--	--	--	--
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.8	18.2	0.001	0.007	0.010	0.015	0.035	0.066	0.106
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365	0.000	0.001	0.001	0.001	0.001	0.002	0.002
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687	--	--	--	--	--	--	--
Bone marrow (femur)	0.479	0.960	1.24	1.24	1.84	2.49	3.77	--	--	--	--	--	--	--
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068	0.007	0.013	0.020	0.016	0.011	0.010	0.009
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112	0.000	0.001	0.001	0.002	0.002	0.002	0.003
Heart	0.282	1.03	1.40	0.987	0.790	0.451	0.546	0.018	0.056	0.084	0.060	0.042	0.027	0.030
Injection site	128	394	311	338	213	195	165	19.9	52.6	31.6	28.4	21.9	29.1	24.6
Kidneys	0.391	1.16	2.05	0.924	0.590	0.426	0.425	0.050	0.124	0.211	0.109	0.075	0.054	0.057
Large intestine	0.013	0.048	0.093	0.287	0.649	1.10	1.34	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3	0.602	2.87	7.33	11.9	18.1	15.4	16.2
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09	0.052	0.101	0.178	0.169	0.122	0.101	0.101
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--	--	--	--	--	--	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--	--	--	--	--	--	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--	--	--	--	--	--	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--	--	--	--	--	--	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--	--	--	--	--	--	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--	--	--	--	--	--	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--	--	--	--	--	--	--

Figure 15: Pfizer report of Japanese government – FOIA-requested by Dr. Byram Bridle. 2.6.5.5B. Pharmacokinetics: organ distribution table. Tritium-labelled LNP-mRNA formulation containing ALC-0315 and ALC 0159.

[108]Lv H, Zhang S, Wang B, Cui S, Yan J. Toxicity of cationic lipids and cationic polymers in gene delivery. J Control Release. 2006 Aug 10;114(1):100-9. doi: 10.1016/j.jconrel.2006.04.014. Epub 2006 May 13. PMID: 16831482

[109]Soenen SJ, Brisson AR, De Cuyper M. Addressing the problem of cationic lipid-mediated toxicity: the magnetoliposome model. Biomaterials. 2009 Aug;30(22):3691-701. doi: 10.1016/j.biomaterials.2009.03.040. Epub 2009 Apr 15. PMID: 19371948

[110]Cui S, *et al*., Correlation of the cytotoxic effects of cationic lipids with their headgroups. Toxicol Res (Camb). 2018 Mar 22;7(3):473-479. doi: 10.1039/c8tx00005k. PMID: 30090597; PMCID: PMC6062336

[111]https://cdn.caymanchem.com/cdn/insert/33474.pdf

[112]https://cdn.caymanchem.com/cdn/msds/34337m.pdf

[113]Pfizer/Comirnaty- 125742_S1_M2_24_nonclinical-overview.pdf/125742_S1_M2_26_pharmkin-written/tabulated-summary.pdf; Jan; Feb 2021

[114]JAPANESE FOIA-requested study: https://www.docdroid.net/xq0Z8B0/pfizer-report-japanese-government-pdf#page=16

It is also notable that after 48 hours, the second highest accumulation of 24.3 ug lipid equivalent/g (after the injection site) is found in the liver. Based on a drug named Onpattro[115], it is possible that the mechanism of action for targeting the LNPs to the liver via the apolipoprotein E /apolioprotein E receptor is shared by the LNPs used in the COVID-19 products. (See Exhibit E)

Dr. Corneil states explicitly that "Importantly SARS-CoV-2 mRNA does not enter the cell nucleus, nor does it affect host DNA or RNA." The CDC similarly maintains this position. There is **no** evidence that nuclear import is **not** occurring, and in the face of a known and acknowledged (by Health Canada) NLS in the sequence, Dr. Corneil's statement is not possible to make at this stage. It must be shown by scientific discovery that this is the case. It is not enough to quote the CDC: the CDC have no data to support this statement either.

DNA has been discovered in all vials tested to date (unpublished data). This leaves the door wide open for the possibility of integration events.[116,117] It is vital to acknowledge the possibility of integration events based on the potential harms associated with them. The relevant questions that require answers will involve studies that definitively prove that integration events are **not** ensuing in order to make claims pertaining to risk profiles of these products with regard to DNA contamination or residual amounts that exceed EMA standards. (See Exhibit F)

It has also even more recently been shown in a Nature publication that *in vivo* frameshifting events occur due to the N1-methylpseudourine substitutions producing off-target proteins in the modified mRNA COVID-19 products.[118] Off target proteins are ***unknown proteins***: they are not meant to be produced by the cells of the person. This raises a plethora of questions pertaining to how these potentially aberrant proteins are affecting the cell. They could very well have amyloid or prion-like properties due to the fact that out-of-frame, off-target protein production very likely results in mis-folding of the proteins.[119,120,121,122]

[115]Akinc, A., Maier, M.A., Manoharan, M. et al. The Onpattro story and the clinical translation of nanomedicines containing nucleic acid-based drugs. Nat. Nanotechnol. 14, 1084–1087 (2019). https://doi.org/10.1038/s41565-019-0591-y

[116]McKernan, K., Helbert, Y., Kane, L. T., & McLaughlin, S. (2023, April 10). Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. OSF preprints. https://doi.org/10.31219/osf.io/b9t7m

[117]Speicher, D. J., Rose, J., Gutschi, L. M., Wiseman, D. M., PhD, & McKernan, K. (2023, October 19). DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events. OSF preprints. https://doi.org/10.31219/osf.io/mjc97

[118]Mulroney, T.E., Pöyry, T., Yam-Puc, J.C. et al. N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting. Nature (2023). https://doi.org/10.1038/s41586-023-06800-3

[119]Louros, N., Schymkowitz, J. & Rousseau, F. Mechanisms and pathology of protein misfolding and aggregation. *Nat Rev Mol Cell Biol* **24**, 912–933 (2023). https://doi.org/10.1038/s41580-023-00647-2

[120]McAlary Luke, Plotkin Steven S., Yerbury Justin J., Cashman Neil R. Prion-Like Propagation of Protein Misfolding and Aggregation in Amyotrophic Lateral Sclerosis. Frontiers in Molecular Neuroscience. VOLUME=12. 2019. https://www.frontiersin.org/articles/10.3389/fnmol.2019.00262 DOI=10.3389/fnmol.2019.00262

[121]https://www.nature.com/articles/s41586-023-06800-3 Comment

[122]Wiseman, D. M., PhD, Gutschi, L. M., Speicher, D. J., Rose, J., & McKernan, K. (2023, December 6). Ribosomal frameshifting and misreading of mRNA in COVID-19 vaccines produces "off-target" proteins and immune responses eliciting safety concerns: Comment on UK study by Mulroney et al. https://doi.org/10.31219/osf.io/nt8jh

Off-target protein production also raises issues pertaining to autoimmunity due to cross-reactivity and molecular mimicry. According to a query of the MedDRA code "Autoimmune disorder" in the Vaccine Adverse Events Reporting System (VAERS), there is an 803% increase in reporting rate per million doses administered when comparing Influenza vaccines administered from 2018 through 2020 to COVID-19 modified mRNA injections administered from 2021 through 2023, as shown in Figure 16. It is worth noting that the reports exclude individuals with a history of an autoimmune disorder.

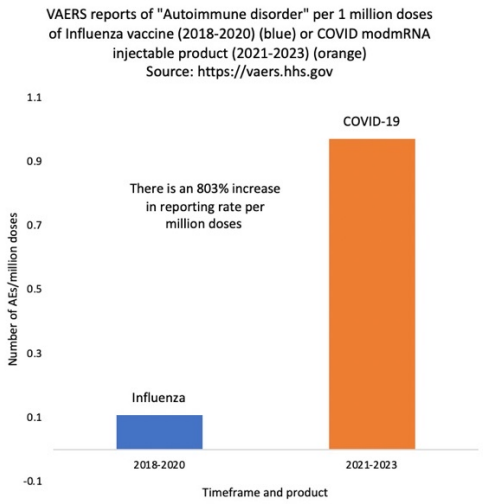

Figure 16: VAERS reports of "Autoimmune disorder" in the context of the Moderna and Pifzer/BioNTech COVID-19 modified mRNA IP.

Reversibility – Bradford Hill Criterion #6

Our World in Data (CDC)[123] 'new_vaccination' data from January 2021 through April 2023 was plotted against VAERS reports of thrombocytopenia, menstrual dysfunction, death, myocarditis, miscarriages and disability. It is striking how reports of thrombocytopenia, menstrual dysfunction and death from VAERS track with the roll-out of the injections as shown in Figure 17. This satisfies the Bradford Hill Criterion **Reversibility** in that when suspected cause is deleted, the effect disappeared as well. These six AE types are just a sample of the multitude of COVID-19 IP-associated AEs reported in VAERS. Currently there are over 14,000 reported AE types by Medical Dictionary for Regulatory Activities (MedDRA) code in VAERS in the context of the COVID-19 IP. It is notable that the disability reports maintain a high peak in reporting for an extended period of time spanning March 2021 through May 2022.

[123]Official data collated by Our World in Data – processed by Our World in Data. "Total vaccinations (per 100)" [dataset]. Official data collated by Our World in Data [original data]

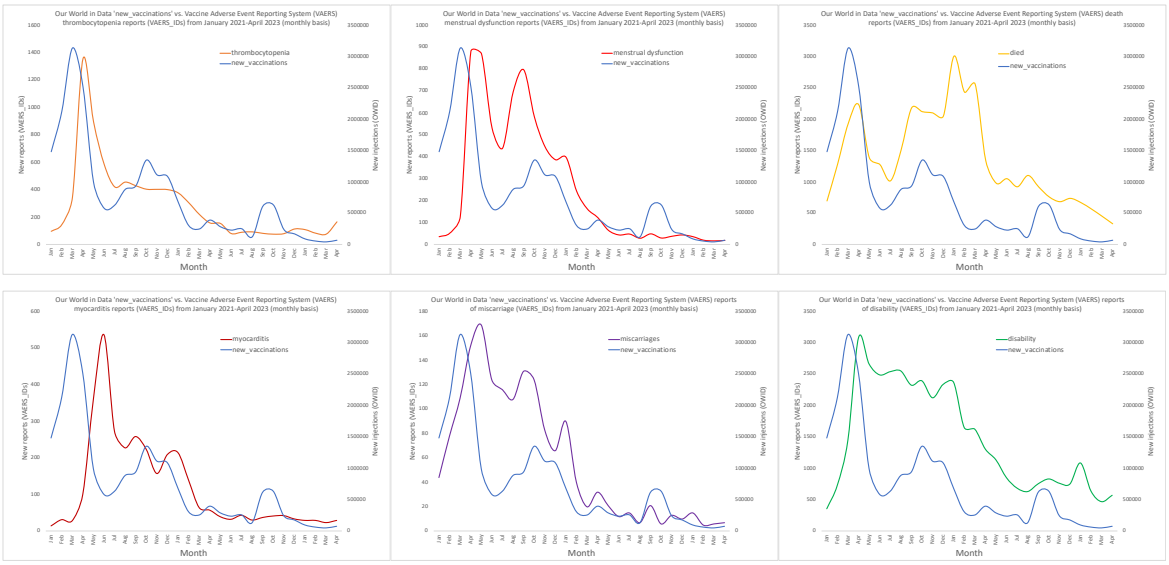

Figure 17: Our World in Data (CDC)[124] 'new_vaccination' data from January 2021 through April 2023 plotted against VAERS reports of thrombocytopenia, menstrual dysfunction, death, myocarditis, miscarriages and disability. Source: https://vaers.hhs.gov; https://ourworldindata.org

Summary

Dr. Corneil wrote: "(iii) is Misleading: a. a person seeking information or receiving information about a personal health or health care matter listening to this statement is likely to believe his Medical Opinion and have the Incorrect impression that COVID-19 vaccines approved for use in Canada cause serious vaccine injury relative to the known harms of COVID-19 disease including death, are experimental and have not undergone sufficient pre-market studies including animal studies, and negatively impact or modify human genes (DNA)."

As a point of note, the macaque animal studies were done after the phase I and II studies, not prior. In addition, the phase III study was unblinded and the placebo participants injected.[125] The manuscript describing these preclinical data is available on a preprint server.[126] The typical timeframe for proper development of a conventional vaccine is approximately 10 years according to FDA guidelines.[127,128] The modified mRNA products went from ionizable cationic lipid concept to arm in 10 months thanks to Operation Warp Speed as shown in Figure 18.[129] It is absolutely remarkable that conventional vaccine development timelines and methodologies were by-passed. As written on the United States Government Accountability Office (GAO) website: "Vaccine companies also took steps, such as **starting large-scale manufacturing during clinical trials** and **combining clinical trial phases** or **running them concurrently**." The Emergency Use Authorizations (EUAs) issued by the

[124]Official data collated by Our World in Data – processed by Our World in Data. "Total vaccinations (per 100)" [dataset]. Official data collated by Our World in Data [original data]
[125]https://www.statnews.com/2021/01/01/pfizer-and-biontech-speed-up-timeline-for-offering-covid-19-to-placebo-volunteers/
[126]Vogel et al., A prefusion SARS-CoV-2 spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primates. bioRxiv 2020.09.08.280818; doi: https://doi.org/10.1101/2020.09.08.280818
[127]https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101
[128]https://www.vumc.org/viiii/immuknow/covid-vaccine-pandemic-speed
[129]https://www.gao.gov/products/gao-21-319

FDA[130] were based on these anemic 'trials' and the approval was based on the EUAs. Freedom of information requested data[131,132,133] and all of the information and data herein reveals - via Pfizer/BioNTech and Moderna's own data - that an evaluation of *safe* in the context of these products is simply Incorrect.

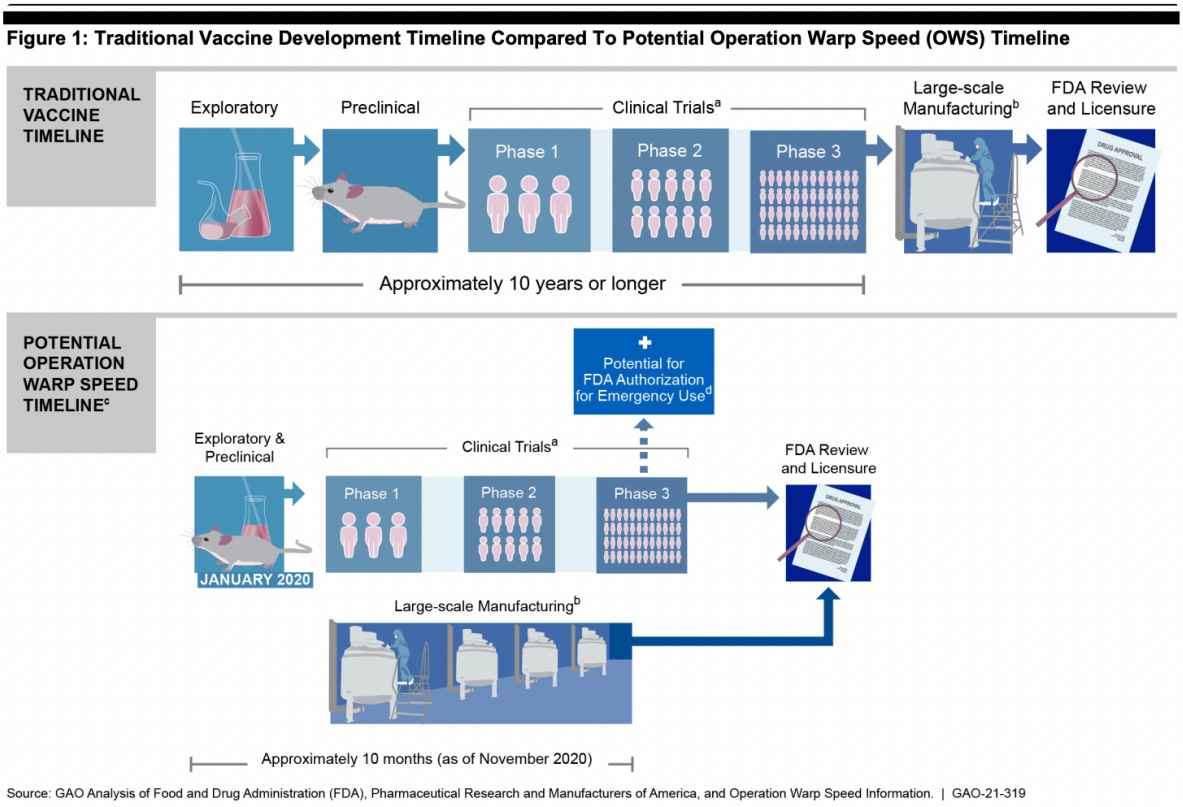

Figure 18: Traditional vaccine development timeline versus Operation Warp Speed timeline for production and administration of the COVID-19 IP

I hope, following careful consideration of the data presented herein, that it is clear that the COVID-19 IP approved for use in Canada 1. can indeed cause SAEs relative to the known harms of COVID-19 disease - including death, 2. are indeed experimental based on the novel platform and mechanism of action, 3. have not undergone sufficient pre-market studies including animal studies, and 4. potentially negatively impact or modify human genes (DNA) by insertional mutagenesis.

It is worth documenting that Dr. Corneil's statement undermines the ability of individuals to make their own judgements as to the necessity of getting vaccinated in lieu of choosing for themselves how to deal with SARS-CoV-2 or any virus for that matter. Natural immunity against SARS-CoV-2 is established following exposure, thus

[130]https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
[131]https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines-4956733
[132]https://phmpt.org/pfizer-16-plus-documents/#
[133]https://phmpt.org/moderna-documents/

there is no need for prophylaxis in the form of an injection of any kind. Long-lived and robust immunity is precisely what inoculation attempts to mimic.[134,135,136,137]

In conclusion, the 'incorrect impression' that Dr. Corneil is concerned was imparted to the public by Dr. Hoffe in the context of the COVID-19 IP involves the following subject matter:

1. serious adverse event (SAE) occurrence, such as death
2. experimental nature
3. insufficient pre-market studies including animal studies
4. negative impact or modification of human genes (DNA)

The definition herein of the word "Incorrect" would seem to apply to the claim that the COVID-19 IP are safe if we adhere to the pharmacovigilance data and the peer-reviewed literature.

Pertaining to professional obligations as they relate to public statements made by Dr. Hoffe, based on the information herein, in my expert opinion, Dr. Hoffe acted in the interest of his patients. In addition, people and patients alike have to the right to know about AEs associated with these products. Full disclosure of potential risks associated with injection with these products must be easily accessible, and for the sake of proper informed consent, must be conveyed by medical practitioners to their patients.

[134]Lingshu Wang et al. Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants.Science373,eabh1766(2021).DOI:10.1126/science.abh1766

[135]Jagannathan, P., Wang, T.T. Immunity after SARS-CoV-2 infections. *Nat Immunol* **22**, 539–540 (2021). https://doi.org/10.1038/s41590-021-00923-3

[136]Frieman M, Heise M, Baric R. SARS coronavirus and innate immunity. Virus Res. 2008 Apr;133(1):101-12. doi: 10.1016/j.virusres.2007.03.015. Epub 2007 Apr 23. PMID: 17451827; PMCID: PMC2292640

[137]Diani S, Leonardi E, Cavezzi A, Ferrari S, Iacono O, Limoli A, Bouslenko Z, Natalini D, Conti S, Mantovani M, Tramonte S, Donzelli A, Serravalle E. SARS-CoV-2-The Role of Natural Immunity: A Narrative Review. J Clin Med. 2022 Oct 25;11(21):6272. doi: 10.3390/jcm11216272. PMID: 36362500; PMCID: PMC9655392

January 3, 2024

Declaration of Responsibilities

I have set out in my report what I understand from those instructing me to be the questions in respect of which my opinion as an expert is required.

I have done my best, in preparing this report, to be accurate and complete. I have mentioned all matters which I regard as relevant to the opinions I have expressed. All of the matters on which I have expressed an opinion lie within my field of expertise.

I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.
I have drawn to the attention of the Court all matters of which I am aware that might adversely affect my opinion.

Wherever I have no personal knowledge I have indicated the source of factual information.

I have not included anything in this report which has been suggested to me by anyone, including lawyers instructing me, without forming an independent view of the matter.

Where, in my view, there is a range of reasonable opinion, I have indicated the extent of that range in the report.

At the time of signing the report I consider it to be complete and accurate. I will notify those instructing me if, for any reason, I subsequently consider that the report requires any correction or qualification.

I understand this report will be the evidence I will give under oath, subject to any correction or qualification I may make before swearing to its veracity.

I believe the facts I have stated in this report are true and that the opinions I have expressed are correct. I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

January 3, 2024

List of documents

1. **Curriculum Vitae**
2. **Exhibit A: Presentation to World Council for Health - ASSESSING CAUSALITY from ADVERSE EVENT DATA (February 5, 2022)**
3. **Exhibit B: Presentation to the National Vaccine Injury Compensation Program – The VAERS system and reporting of vaccine injuries and how to prove causation (November 1, 2023)**
4. **Exhibit C: Presentation to 22nd Public Hearing in Brazil (November 22, 2023)**
5. **Exhibit D: Movie of FDA_VRBPAC_Rachel_Zhang**
6. **Exhibit E: Presentation to Doctors for COVID Ethics (September 7, 2023)**
7. **Exhibit F: Presentation to Croatian Parliament (December 1, 2023)**

Jessica Rose, PhD
January 10, 2023