

August 25, 2022

War Room/DailyClout Pfizer Research Volunteers

Consolidated Reports and Op-Eds

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Highlights

1. There were four different Pfizer doses: 3 mcg, 10 mcg, and 30 mcg. 100 mcg for Moderna. The three for Pfizer were for, in order, kids 5-11, teens 12-17, and adults ages 18 and over. This means that a 90-lb., 12-year-old girl got the same dose as a 200-lb., 17-year-old male athlete, and that an 11-year-old on the last day of this 11th year would get a dose that would more than triple one day later on his 12th birthday. Many teens died. Were they smaller?
2. The ingredients included spike protein, lipid nanoparticles (LNPs), and mRNA. Lipid nano particles are hard, fatty casings that cross the blood-brain barrier. Cholesterol is also an ingredient. The government agencies and paid influencers claim that the injection material stays in the arm, but the documents show that, within 24-48 hours, it's in the bloodstream and ends up in the liver, spleen, ovaries, lymph nodes, and other organs.
3. The 100-mcg dose shows much higher adverse events than the 30-mcg dose, and the 30-mcg dose show higher adverse events than the 10-mcg dose. But recipients of Moderna's first vaccine, all of whom received 100-mcg doses, were not told this. The 100-mcg dose was dropped internally by Pfizer's study due to its 'reactogenicity.'
4. There was such a flood of adverse events that Pfizer boasted to the FDA that they were hiring 2400 new, full-time staffers to deal with the paperwork.
5. There was a huge imbalance of women subjects vs. men in Pfizer's internal trials: 76% to 22% with 2% that had no gender noted. This is a flaw due to the higher rates of myocarditis among men.
6. Pfizer knew by December 2020 that the vaccine did not work or that it failed. One side effect noted post-vaccination is 'COVID.' Dr. Fauci and Dr. Collins knew in 2020/early 2021 that the vaccines had durability or that they failed, but the general public was not informed about that until late Spring 2021 after an Israeli study confirmed waning efficacy. Only then were 'boosters' announced, but millions of healthy people had gotten vaccinated between December 2020 and April 2021 believing they'd be done.
7. Pfizer and FDA knew in May 2021 that 35 kids had heart damage a week after vaccination per peer-reviewed study, but FDA authorized teen EUA in June of 2021 and did not announce myocarditis risk to teens and young men until August 2021. (A video of the FDA meeting about EUA cannot be played now in the section where a dissident is trying to point this out.)
8. About 22% of the subjects are missing after the study began, and there is no record of what became of them. Did they decline the second dose?
9. Parts of the study were unblinded which in normal science would invalidate the results.
10. Polyethylene glycol (PEG) is a petroleum-based product which is not used for injections but topical applications such as Crest Whitestrips. It's a known allergen that can cause anaphylactic shock. People allergic to PEG were not warned about this, and four of the study subjects died shortly after the injection from anaphylaxis.
11. Over 3% of the study subjects died, but since the total figure of those who received the injections is redacted, we can't know if this can be extrapolated to the general population.
12. Pregnant women were excluded from the study, though VAERS reports show high rates of neonatal death in babies nursing vaccinated mothers.
13. The injections suppress leukocytes, which are a key part of a human's immune response.
14. Myocarditis, neurological problems, muscle pain, and joint pain were the top categories of side effects in the Pfizer internal documents though the spokespeople listed fatigue, headache, and chills as the top side effects.
15. Moderna contains SM 102 which is an OSHA hazardous substance and a carcinogen.

16. No in the documents but in a contracting letter from the FDA: the active ingredients were manufactured in Belgium and Germany and only put in solution and packaged in Andover, Massachusetts, and Kansas. Why were we importing ingredients from overseas to inject into Americans, and can the FDA even check on the safety of manufacturing facilities in Belgium and Germany?
17. Polyethylene glycol (PEG) allergies cause horrible hives and rashes which are being reported by recipients of vaccines, though doctors say they have no idea what's causing these symptoms. (<https://pubmed.ncbi.nlm.nih.gov/10594300/>).
18. The FDA criticized the Kansas facility packaging the mRNA vaccine ingredients in 2019 and 2020 for mold and bacteria and released drugs without quality inspection. Also, they 'neglected to properly sample drugs for excessive levels of certain toxins.' 'The 2019-20 inspection found that the plant had released drugs without reviewing quality issues flagged during routine testing. Inspectors also turned up mold and bacteria in areas that were meant to be sterile and said the plant neglected to properly sample drugs for excessive levels of certain toxins, Bloomberg reported. Specifically, the McPherson [Kansas] plant failed to adequately test for endotoxins – which are created by bacteria like Escherichia coli or botulism – in drugs such as morphine and the cancer medication, Nivestym. Meanwhile, an FDA visit in 2018 found Pfizer had identified mold at McPherson linked to product residue on machinery. The company said inadequate cleaning was to blame but discovered residue in the area months later. As of the latest inspection, Pfizer "continues to recover bacterial and/or mold isolates from critical zones," according to the FDA.

Report 1: “What Happened to Pfizer’s Missing Patients?” Team 5.

Key intelligence question (KIQ) 0022203:

Within this document

(<https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>), there appears to be a large number of "not recovered at the time of report" and "unknown" case outcomes. As shown in Table 1, these numbers are significant, adding up to 20,761 out of 42,086 "relevant cases." Do we know what happened to them? Has this large number of unknown outcomes and patients who had not recovered at the time of this report been reported anywhere in the press, on the [HHS.gov](https://www.hhs.gov) website (FDA, CDC, etc.), or on the Pfizer main website? This number dwarfs the reported deaths number so finding out the eventual outcome is vitally important.

What Happened to Pfizer’s Missing Patients?

A great deal of data are missing from Pfizer’s analysis of adverse events that were reported after the Pfizer mRNA vaccine was approved by the US Food and Drug Administration (“5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021,”

<https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). From the data that are provided, many more questions arise.

- Of the 42,086 cases that Pfizer analyzed, 32,686 (78%) have known outcomes. The outcomes of almost one-quarter (22%) are not known (Table 1, p. 7, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). Why are these case reports incomplete?
- Nearly three-quarters (71%) of the 42,086 patients are female; 22% of the patients are male; another 7% have no sex identified (Table 1, p. 7, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). Why are so few male patients included in the Pfizer report? This is especially worrying, since the Centers for Disease Control states that it is in male adolescents and young adults that most cases of myocarditis and pericarditis have been reported (<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>). Does this explain why Pfizer does not include myocarditis or pericarditis among the cardiovascular adverse events (Table 7, p. 16, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>)? Instead, Pfizer buried the myocarditis and pericarditis cases in its review of immune-mediated/autoimmune adverse events (Table 7, p. 20, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>).

- Sadly, 1,223 (3.7%) of the 32,686 patients with known outcomes died (Table 1, p. 7, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). Thus, in 3.7% of the adverse event cases with known outcomes, the Pfizer mRNA vaccine proved fatal. If we knew the number of doses that were shipped worldwide, we could determine the actual mortality rate; unfortunately, Pfizer has redacted that information (p. 6, Section 3.1.1, paragraph 1, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). The Centers for Disease Control suggests that the number of deaths should be much less, around 0.003% (paragraph 2, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm>). What is the actual mortality rate for the injection?
- Four (0.3%) of the 1,223 deaths occurred on the same day the patients received the mRNA vaccine. These patients died of anaphylaxis, although “they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia” (Table 4, footnote b, p. 10, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). Nonetheless, the Centers for Disease Control advises that “staying up to date with COVID-19 vaccines (getting primary series and booster) . . . is especially important if you are older or have severe health conditions or more than one health condition . . .” (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>). Is this advice consistent with the deaths from anaphylaxis?
- Pfizer’s 3.7% fatality rate for the adverse event cases with known outcomes doesn’t include patients that Pfizer said had not recovered at the time of the report (30 April 2021). Of the 32,686 patients with known outcomes, 11,361 (35%) of the patients are listed as not recovered (Table 1, p. 7, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). Did those 11,361 patients survive the Pfizer mRNA vaccine?
- Of the 32,686 patients with known outcomes, 19,582 (60%) of the patients are lumped together as recovered/recovering (Table 1, p. 7, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). We can assume that recovered cases are free from residual adverse events, but what was the outcome of recovering cases—did they ultimately get well? In reality, recovered and recovering cases should not be combined; instead, coupling not recovered and recovering cases is a more honest way to present the data. By combining recovered and recovering cases, is Pfizer attempting to overcount the number of cases in which the adverse events were resolved?
- Clearly, patients who received the mRNA vaccine weren't adequately tracked, possibly because of the way the mRNA vaccine was named. Pfizer requested a waiver of the standard method for assigning a unique name to the vaccine (p. 4,

https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). The purpose of the unique name is to “secure pharmacovigilance so that the FDA can effectively monitor all biological products in the post market” and to “aid in adverse event report tracking” (paragraph 5, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-steps-naming-biological-medicines-balance>). Pfizer’s waiver request notes that the standard naming method “would be burdensome and redundant” (p. 3, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M1_waiver-req-designated-suffix.pdf). Did Pfizer request the waiver knowing it would be more difficult to track and report adverse events experienced by patients?

Pfizer’s report raises more questions than it answers. Yet in Pfizer’s review of adverse events reported after the Pfizer mRNA vaccine was approved by the FDA, they conclude that their review “confirms a favorable benefit:risk balance” for the mRNA vaccine (p. 29, <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>). With 22% of patients having unknown outcomes, 35% not recovered at the time of the review, and 3.7% dead, Pfizer concludes that the benefits of taking their mRNA vaccine outweigh the risks. So another question arises: how can that conclusion be true?

Even without knowing what happened to the missing patients, the data in Pfizer’s analysis of adverse events raise important warning flags. Consider the absolute number of major adverse cardiac events that Pfizer reviewed. In the period from 24 hours to 21 days after receiving Pfizer’s mRNA vaccine, there were 394 total cases that included the following.

- Arrhythmia: 102 cases
- Myocardial infarction: 89 cases
- Acute myocardial infarction: 41 cases
- Cardiac failure: 80 cases
- Acute cardiac failure: 11 cases
- Cardiogenic shock: 7 cases
- Orthostatic tachycardia syndrome: 7
- Pericarditis: 32 cases
- Myocarditis: 25 cases

Are nearly 400 major adverse cardiac events enough to pause or stop the widespread use of Pfizer’s mRNA vaccine?

Report 2: “PFIZER’S 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENTS REPORTS ON VACCINE EFFICACY AND NEW REPORTS/STUDIES RAISE CONCERNS OF VACCINE INEFFECTIVENESS, VACCINE FAILURE, AND THE LIMITED DURABILITY OF THE VACCINE.” Team 1.

Astonishingly, Pfizer’s internal documents that were recently released by court order revealed that beginning on December 1, 2020, Pfizer was aware that the vaccine that was pushed upon the American people had limited efficacy.

For the next 3 months, from 12/1/2020-2/28/2021, Pfizer’s 5.3.6 cumulative analysis of post authorization adverse events reports indicate that Pfizer received multiple reports of both vaccine failure and vaccine ineffectiveness.

According to Pfizer’s cumulative analysis, there were 16 serious cases of vaccine failure and 1,625 serious cases of vaccine ineffectiveness reported. (Page 14). In the same Pfizer document, Covid-19 is identified as an adverse event special interest (AESI), with 3,067 cases of Covid-19 reported after receiving the vaccine. From that number, there were 2,585 serious relevant events, including Covid pneumonia, and 136 people died. (Page 17)

Pfizer excluded cases from analysis, including 546 cases in which SARS-CoV-2 infection was developed between days 1-13 from the first dose. (Page 15). After allowing for Pfizer’s exclusion of some cases, this data still reveals multiple serious cases, including fatalities, indicating there is vaccine failure and vaccine ineffectiveness with Pfizer’s vaccine. And worse, Pfizer, which is responsible for the post authorization analysis, admits that there are limitations in the reporting and that “the magnitude of underreporting is unknown.” (Page 5).

Even though there were multiple reports of lack of vaccine efficacy, Pfizer stated in the confidential document that “no new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.” (Page 15)

However, just as Dr. Fauci anticipated in 2020, the duration of vaccine protection is limited. Dr. Fauci stated that “if Covid-19 acts like other coronaviruses, it likely isn't going to be a long duration of immunity,”
(<https://www.cnn.com/2020/06/02/dr-anthony-fauci-says-theres-a-chance-coronavirus-vaccine-may-not-provide-immunity-for-very-long.html>)

Dr. Fauci told Dr. Collins in 2020 regarding the Covid vaccines that “we’re going to assume that there’s a degree of protection, but we have to assume that it's going to be finite. It’s not going to be like a measles vaccine. So there’s going to be follow-up in those cases to see if we need a boost. We may need a boost to continue the protection.”

Excerpts from NIH Director Dr. Collins’s conversation with NIAID Director Dr. Fauci
<https://newsinhealth.nih.gov/2020/08/dr-anthony-fauci-covid-19-vaccines>

The findings from a Swedish study from 12/28/2020 to 10/4/2021 “show there was a progressive waning of vaccine effectiveness of BNT162b2 (Pfizer) against SARS-CoV-2 infection of any severity, with no vaccine effectiveness detected from 7 months onwards.”

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00089-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00089-7/fulltext)

The study found that **“unlike natural immunity, which appears robust with little waning for a year following infection, there is a gradual but relatively rapid waning in vaccine immunity against infection following the second dose.”**

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00277-X/fulltext?rss%3Dyes](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00277-X/fulltext?rss%3Dyes)
(emphasis added)

“Waning immunity (is) also known as secondary vaccine failure”. Israel attributed an increase in infections and hospitalizations of vaccinated persons due to a “combination of waning vaccine immunity... and from potentially reduced effectiveness of the (Pfizer) vaccine against the delta variant.”

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02249-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02249-2/fulltext)

A report from the FDA indicates that the efficacy of Pfizer’s vaccine wanes.

Immunogenicity (measures how well a vaccine is working) of the original strain of SARS-CoV2, was identified in a study as follows:

Neutralizing antibody titers against original strain: **762** 1 month post 2nd dose.

Neutralizing antibody titers decreased to **136** prior to first booster.

The antibody titers increased to **2374.2** 1 month post booster

<https://www.fda.gov/media/152239/download>

Now there are reports that the efficacy of the booster is waning after 3-6 months.

“Emerging evidence, including data from Kaiser Permanente Southern California (KPSC), suggests that effectiveness against both symptomatic COVID-19 and severe disease caused by Omicron wanes 3 to 6 months after receipt of an initial booster (third dose). Thus, additional booster doses may be needed to ensure individuals remain adequately protected.” <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-us-emergency-use-authorization>

On March 15, 2022, Pfizer submitted an application for EUA of an additional booster dose for older adults who have received an initial booster. On March 29, 2022, the FDA authorized a second Pfizer Covid-19 vaccine booster in persons aged 50 years and older in addition to immunocompromised persons aged 12 years and older.

In support of yet another booster, Dr. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, stated that **“current evidence suggests some waning of protection over time against serious outcomes from Covid-19....and a second booster dose.... could help increase protection levels for ...higher-risk individuals.”** (emphasis original).

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>

There is an abundance of evidence that the Pfizer vaccine has a serious durability problem, resulting in waning protection and vaccine failure.

In a risk/benefit analysis, the risk of known serious adverse events, including death, from the vaccine, outweighs the possible benefit of a vaccine that we know will fail.

The vaccine program must stop. We need to focus on early treatment and natural immunity.

Vicki Goldstein, RN, JD

Report 3: “Phase 1 /2 Study of COVID-19 RNA Vaccine BNT162b1 in Adults:
Key Processes Missing.” Team 5.

Review and Comments: Team 5, Tranche 2

Phase 1 / 2 study of Covid-19 RNA vaccine BNT162b1 in Adults

Mulligan, Lyke et. al. Nature Published online 8/12/2020.

Cite this article as: Mulligan, M. J. et al.
Phase 1/2 study of COVID-19 RNA vaccine
BNT162b1 in adults. Nature <https://doi.org/10.1038/s41586-020-2639-4> (2020).

P1 p2: The authors' put forth the argument that mRNA in BNT162b1 (Note this series used **BNT162b1** not **BNT162b2**) briefly expresses the encoded protein and then is metabolized without being incorporated into the host genome.

“RNA is required for protein synthesis, **does not integrate into the genome, is transiently expressed, and is metabolized and is eliminated by the body's natural mechanisms and, therefore is considered safe.**^{4, 7}”

⁴Alberer, M. et al. *Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomized, prospective, first-in-human phase 1 clinical trial. Lancet* 90, 1511-1520 (2017).

⁷Sahin, U. e al. *Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer. Nature* 547, 222-226 (2017).

However, Zhang et. al. working at MIT demonstrated fragments of SARS-CoV-2 integrated in host DNA in a paper published in 2021, *PNAS* vol. 118, no. 21.

It will be important, in follow-up studies, to demonstrate the presence of SARS-CoV-2 sequences integrated into the host genome in patient tissues. However, this will be technically challenging because **only a small fraction of cells in any patient tissues are expected to be positive for viral sequences** (61). Consistent with this notion, it has been estimated that only between 1 in 1,000 and 1 in 100,000 mouse cells infected with LCMV either in culture or in the animal carried viral DNA copies integrated into the genome (30). In addition, only a fraction of patients may carry SARS-CoV-2 sequences integrated in the DNA of some cells. However, **with more than 140 million humans infected with SARS-CoV-2 worldwide (as of April, 2021), even a rare event could be of significant clinical relevance.** It is also challenging to estimate the frequency of retro-integration events in cell culture assays since infected cells usually die and are lost before sample collection. For the same reason, no clonal expansion of integrated cells is expected in acute infection experiments. Moreover, **the chance of integration at the same genomic locus in different patients/tissues may be low, due to a random integration process.**

Alden, et. al. reporting in *Current Issues in Molecular Biology* 2022, 44, 1115-1126 found BNT162b2 mRNA is reverse transcribed into host DNA beginning 6 hours after contact with BNT162b2.

In the BNT162b2 toxicity report, no genotoxicity nor carcinogenicity studies have been provided [26]. Our study shows that BNT162b2 can be reverse transcribed to DNA in liver cell line Huh7, and **this may give rise to the concern if BNT162b2-derived DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects. At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome.** Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination.

Other studies have shown mRNA from BNT162b2 circulates then may reside longer in host cells. This enhanced stability is the result of N1-methyl-Pseudouridine incorporation into the mRNA.

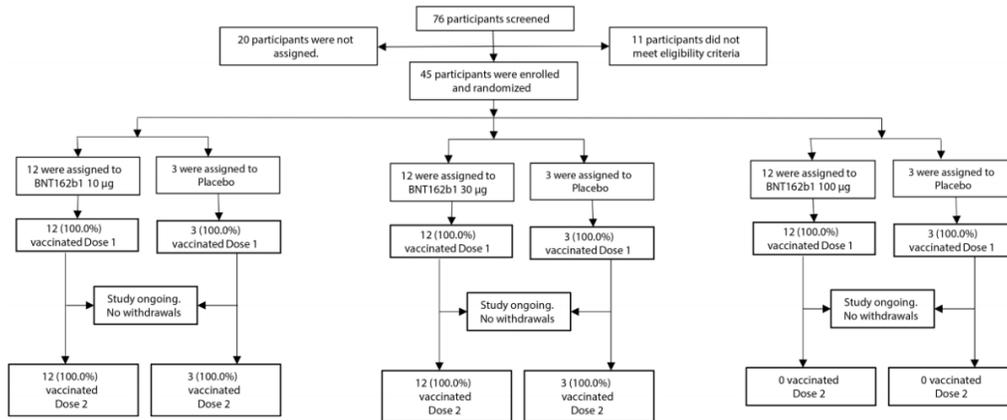
In 2009, Kariko et. al. reported that addition of N1-methyl-Pseudouridine to mRNA “...not only suppresses RNA-mediated immune activation in vitro and in vivo, but also enhances the translational capacity of the RNA.”

¹¹Kariko, K. et al. Incorporation of pseudouridine into mRNA yields superior nonimmunogenic vector with increased translational capacity and biological stability. Mol. Ther. 16, 1833-1840 (2008).

P 1 p3: BNT162b1 was formulated to use N1-methyl-Pseudouridine to stabilize and improve translation. “Vaccine RNA can be modified by incorporating N1-methyl-Pseudouridine which dampens innate immune sensing and increases mRNA translation in vivo.¹¹”

“Here, we present available data, through 14 days after a second dose in adults 18 to 55 years of age, from an ongoing Phase I/II vaccine study with **BNT162b1**, which is **also enrolling adults 65 to 85 years of age** (Clinical Trials.gov identifier: NCT04368128).” P2 p1.

Study Design:



- 76 participants screened
- 45 healthy participants randomized into three groups of 12 with 3 placebo groups.
- Mean age 35.4 years, 19-85.
- 51% Male, 49% female.
- Dose levels: 10-µg, 30-µ, 100µ **BNT162b1**.

Page 8 p1: “This study was conducted in healthy men and nonpregnant women 18 to 55 years of age to assess the safety, tolerability, and immunogenicity of ascending dose levels of various BNT162 mRNA vaccine candidates. **In the part of the study reported here, assessment of three dose levels (10-µg, 30-µg, or 100-µg) of the BNT162b1 candidate was conducted at two sites in the United States.** This study utilized a sentinel cohort design with progression and dose escalation taking place after review of data from the sentinel cohort at each dose level.”

Endpoints:

- Reporting of solicited local reactions,
- Systemic events,
- Use of antipyretic and/or pain medication within 7 days after vaccination,
- AEs and SAEs (available through up to~45 days after Dose 1)
- Proportion of participants with clinical laboratory abnormalities 1 and 7 days after vaccination
- Shifts in laboratory assessments between baseline and 1 and 7 days after Dose 1 and between Dose 2 and 7 days after Dose 2
- SARS-CoV-2 neutralizing GMT,
- SARS CoV-2 RBD-binding IgG GMCs 7 and 21 days after Dose 1 and 7 and 14 days after Dose 2.

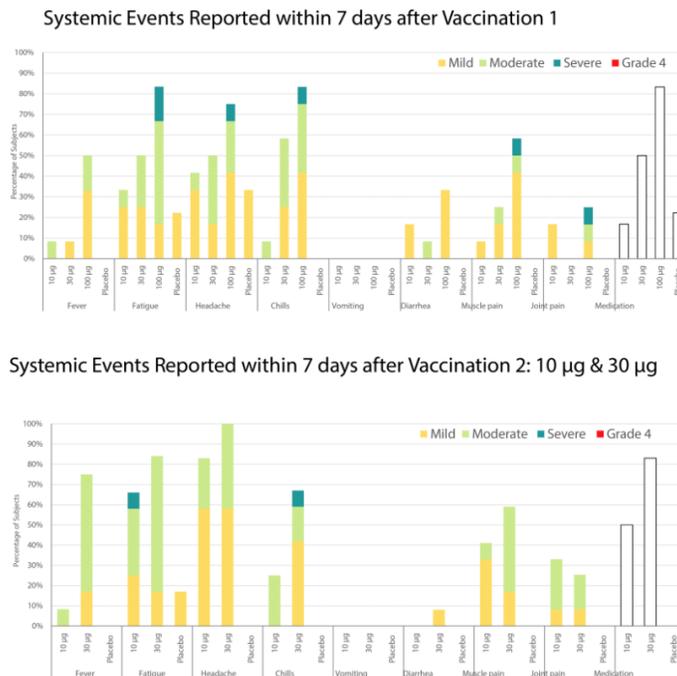
“Hematology and chemistry assessments were conducted at screening, 1 and 7 days after Dose 1, and 7 days after Dose 2.” These data are not reported other than “No Grade 1 or greater change in routine clinical laboratory abnormalities were observed for most participants after either of the BNT162b1 vaccinations. Of those with laboratory changes, the largest changes were decreases in lymphocyte count after Dose 1 in 8.3% (1/12), 45.5% (5/11?), and 50.0% (6/12) of 10 µg, 30 µg and 100 µg BNT162b1 recipients, respectively.” P2 p6.

Upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions, and exceptions, Pfizer may also provide access to the related individual anonymized participant data. See <https://www.pfizer.com/science/clinical-trials/trial-data-and-results> for more information. These data are interim data from an ongoing study, with the database not locked. Data have not yet been source verified or subjected to standard quality check procedures that would occur at the time of database lock and may therefore be subject to change.

Note: No data such are immediately available on web site 4/6/2022. (see <https://www.pfizer.com/science/clinical-trials/trial-data-and-results/data-requests>). What studies were performed? Did they measure d-dimer, il-6, troponin, as well as a complete blood count, electrolytes, renal and hepatic function test? Where are the raw data?

Adverse Event Report:

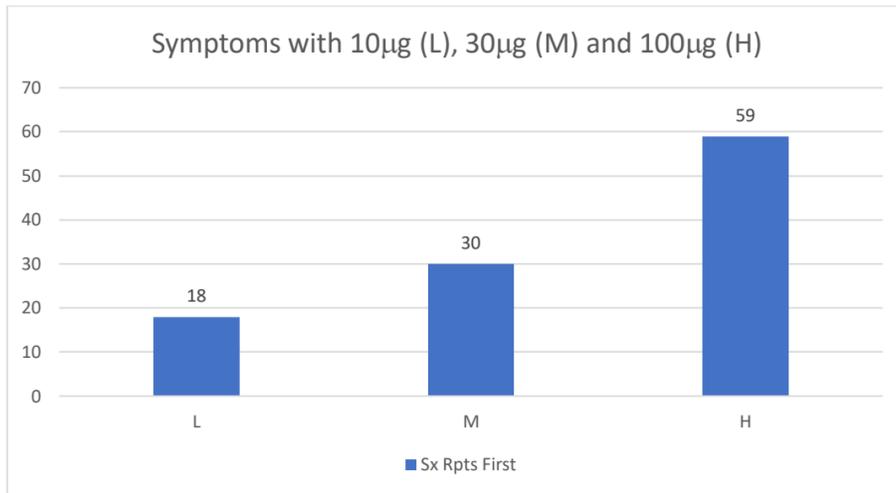
Figure 3:



In these two histogram charts, the x axis reports symptoms, other than the last column, medications. These are subjective complaints, not objective findings. Each active group consists of only 12 subjects, yet the reporting stratifies the data into four different levels of complaints and uses percent rather than raw numbers.

Converting percent back to raw numbers and using a binary reporting for “Yes” symptom is present and “No” symptom is not present, we can convert percentage to raw numbers. Placebo effects were minor and not addressed here.

First Dose	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Jt. Pain	Meds	Total
10	1	4	5	1	2	1	2	2	18
30	1	6	6	7	1	1	2	6	30
100	6	10	9	10	4	7	3	10	59

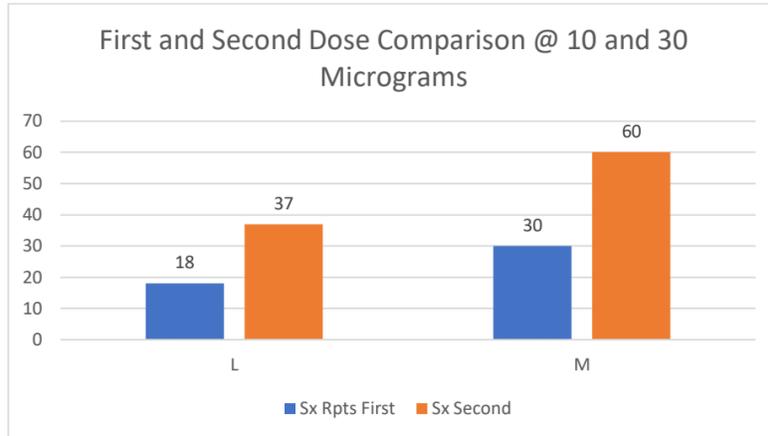


The first dose shows increased symptom reporting associated with increasing dose of mRNA. (L = 10 µg, M = 30 µg and H = 100 µg.) The 100 µg dose was dropped for dose 2.

Comparing 1st and 2nd doses:

30 µg	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
1st	1	6	6	7	1	3	0	6	30
2nd	9	10	12	8	1	7	3	10	60
Incr.	8	4	6	1	-1	6	1	4	29

%
incr. 800% 67% 100% 14% -50% 600% 50% 67% 48%



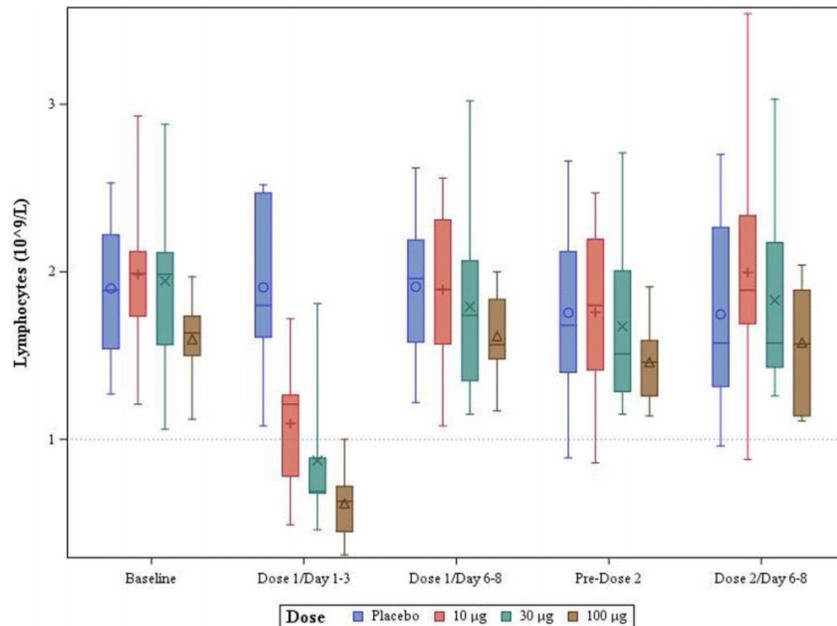
Conclusion: Increased symptoms occur with increased µg dose of BNT162b1. Increased symptoms were reported after the second dose at 10 µg and 30 µg compared with the first dose. The differences in the number of adverse events between different dosages of the "vaccine" other than Placebo versus 10 µg are statistically significant, $p < 0.05$. (See Appendix).

Trial #	1	2	1	2	1
Dose	10	10	30	30	100
Pain	7	10	12	12	12
Redness	0	0	2	2	4
Swelling	0	0	0	2	5

Pain, redness and swelling was reported but was not very useful other than a dose effect may be present for pain at the site of injection. Redness can be very subjective and swelling is very difficult to determine.

Objective findings including blood pressure, heart rate, fever, temperature, respiratory rate, physical examinations and complete laboratory findings were not reported and are not available on the Pfizer web site.

Extended Data Figure 1: Lymphocyte changes following three dosing levels as a function of time



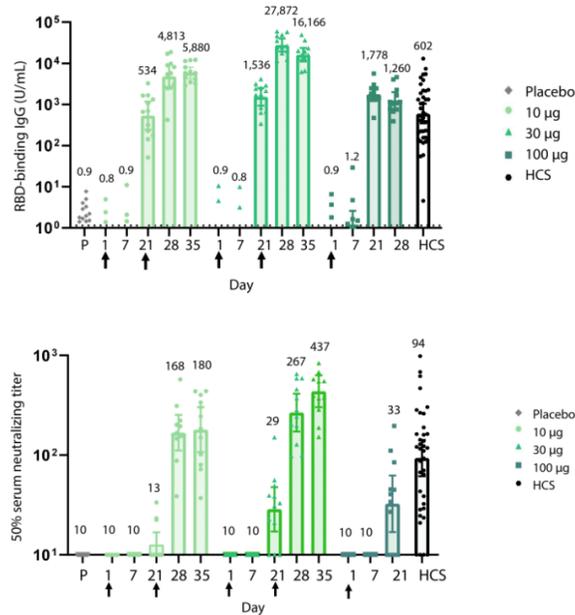
Lymphocytopenia on Days 1-3 after the first dose occurred in 1/12, 5/11, 6/12 for 10 µg, 30 µg and 100 µg respectively. **No lymphocyte reporting is given following the second dose during the comparable interval, Day 1-3, which after the first dose produced substantial drops in lymphocytes.** 1/12 (10 µg), 1/11 (30 µg) and 4/12 (100 µg) had Grade 3 decreases in lymphocytes. Neutropenia occurred in two subjects, one each in the 10 µg and 30 µg groups. No explanation for the decrease in lymphocytes and neutrophils is given. The reporting of raw data is required here, not a verbal description.

There is a lymphocyte measurement for a second dose @100 µg whereas the text “Based on the reactogenicity reported after the first dose of 100 µg and the second dose of 30 µg participants who received an initial 100 µg dose **did not receive a second 100 µg dose.**” P2 p4

The schematic in Figure 1 also indicates no second 100 µg doses were given. Yet, there is a plot of second dose of 100 µg as indicated by the brown data candle plot on the far right. Was a second 100 µg dose given or not?

Finally, the variance in lymphocyte counts in the second dose 30 µg group appears to be very high. Was there a lymphocytosis as well as lymphocytopenia? Why? We need the actual data here. What caused the lymphocytopenia and were these cases associated with lymphadenopathy and or splenomegaly?

Immune Response:



Immune response was assessed using geometric mean titers of RBD-binding IgG concentrations at baseline, 7 and 21 days after dose 1 and at 7 and 14 days after dose two in the 10 and 30 µg groups. The 100 µg dose was given only once according to this chart. A second assessment using neutralizing titers showed increases after the second dose.

Discussion:

“Our study had several limitations. **While we used convalescent sera as a comparator, the kind of immunity (T cells versus B cells or both) and level of immunity needed to protect from COVID-19 are unknown.**”

“Further, this analysis of available **data did not assess immune responses or safety beyond 2 weeks after the second dose of vaccine. Both are important to inform the public health use of this vaccine.**”

“**Follow -up will continue for all participants and will include collection of SAEs for 6 months and COVID-19 infection and multiple additional immunogenicity measurements through up to two years.**”

“The clinical testing of BNT162b1 described here has taken place in the context of a broader, ongoing COVID-19 vaccine development program. That **program includes the clinical testing of three additional vaccine candidates** including candidates encoding the full-length spike, and a parallel trial in Germany, in which additional immune responses including neutralizing

responses against variant strain and cell-mediated responses are being assessed (US manuscript in preparation).²⁴”

“The clinical findings for the BNT162b1 RNA-based vaccine candidate are encouraging and strongly support accelerated vaccine candidate development, including efficacy testing, and at-risk manufacturing to maximize the opportunity for the rapid production of a SARS-CoV-2 vaccine to prevent COVID-19.”

Comments/Questions:

BNT162b1 not BNT162b2 was used in this Phase I/II clinical trial. What are the differences between the two? Was there a Phase I/II trial for BNT162b2? Why was the substitution made?

Was the 100 µg dose repeated or not? Extended Data Figure 1 shows a data plot for the 100 µg dose at Dose 2 Day 6-8.

The researchers erroneously believed that the mRNA in BNT162b1 would be transient, briefly producing spike protein then being metabolized and gone with no translation into host DNA. There is now concern that BNT162b2 mRNA code may be incorporated into the host genome based on a study by Alden, et. al. (See page 1 for the citation). Similar concerns were raised by Zhang, et. al. with regard to SC2 viral mRNA.

Clinical findings reported in this paper are deficient in presenting adequate detailed findings and should have body weight changes, appetite, and symptom changes during the reporting intervals, vital signs, physical findings and complete laboratory results.

This study was published in August 2020. Where are the reports noted as pending in the paper?

What role did N1-methyl-Pseudouridine (1MP) have in the unexpectedly long bioavailability of mRNA products? If not, what is the mRNA longevity attributable to? Does this enhanced stability have anything to do with dropping the lymphocyte counts noted in the Pre Clinical studies?

The 100 µg dose not only suppressed lymphocytes, but had a marked decline in immune response compared with immune sera and lower doses of BNT162b1. How and why did this happen? Is BNT162b1/BNT162b2 toxic to lymphocytes?

The objective of the vaccine was to prevent COVID-19. This product failed to prevent COVID-19. This product failed to prevent illness, hospitalization and death from COVID-19.

Was a risk benefit analysis performed? If so, where can the document be found?

Appendix: Statistical Analysis

How to interpret results:

The first two tests are Chi Square test. The left most numbers are:

- 1 10 µg Yes (number of adverse events)
- 2 10 µg No (number of without adverse events)
- 3 30 µg Yes
- 4 30 µg No
- 5 100 µg Yes
- 6 100 µg no

A simple data transformation was required to use the Chi Square test. All numbers were multiplied by 10.

The first number under each AE category is the number of events (X10)

The second number under each AE category is the expected number of events

The third number is the Chi Square statistic.

The larger the Chi Square statistic, the more unusual the event.

The p values of both dose 1 and dose 2 Chi Square test are less than 0.05 and therefore the test is statistically significant.

The six other tests are Test of Proportions. It is the total number of all categories of AE divided by the total number of events.

All but the first (10 µg vs. placebo), are statically significant.

Chi-Square Test: Fever, Fatigue, Headache, Chills, Diarrhea, Muscle Pain, Joint

1st Dose without placebo X 10

Expected counts are printed below observed counts

Chi-Square contributions are printed below expected counts

	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain
1	10 22.50 6.944	40 22.50 13.611	50 22.50 33.611	10 22.50 6.944	20 22.50 0.278	10 22.50 6.944	20 22.50 0.278
2	110 97.50 1.603	80 97.50 3.141	70 97.50 7.756	110 97.50 1.603	100 97.50 0.064	110 97.50 1.603	100 97.50 0.064
3	10 37.50 20.167	60 37.50 13.500	60 37.50 13.500	70 37.50 28.167	10 37.50 20.167	30 37.50 1.500	0 37.50 37.500
4	110 82.50 9.167	60 82.50 6.136	60 82.50 6.136	50 82.50 12.803	110 82.50 9.167	90 82.50 0.682	120 82.50 17.045
5	60 73.75 2.564	100 73.75 9.343	90 73.75 3.581	100 73.75 9.343	40 73.75 15.445	70 73.75 0.191	30 73.75 25.953
6	60 46.25 4.088	20 46.25 14.899	30 46.25 5.709	20 46.25 14.899	80 46.25 24.628	50 46.25 0.304	90 46.25 41.385
Total	360	360	360	360	360	360	360

	Medication	Total
1	20	180
	22.50	
	0.278	
2	100	780
	97.50	
	0.064	
3	60	300
	37.50	
	13.500	
4	60	660
	82.50	
	6.136	
5	100	590
	73.75	
	9.343	
6	20	370
	46.25	
	14.899	
Total	360	2880

Chi-Sq = 496.633, DF = 35, P-Value = 0.000

Results for: 2nd Dose wo placebo x 10

Chi-Square Test: Fever, Fatigue, Headache, Chills, Diarrhea, Muscle Pain, Joint

Expected counts are printed below observed counts
 Chi-Square contributions are printed below expected counts

	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain
1	10	80	100	30	0	50	40
	46.25	46.25	46.25	46.25	46.25	46.25	46.25
	28.412	24.628	62.466	5.709	46.250	0.304	0.845
2	110	40	20	90	120	70	80
	73.75	73.75	73.75	73.75	73.75	73.75	73.75
	17.818	15.445	39.174	3.581	29.004	0.191	0.530
3	90	100	120	80	10	70	30
	75.00	75.00	75.00	75.00	75.00	75.00	75.00
	3.000	8.333	27.000	0.333	56.333	0.333	27.000
4	30	20	0	40	110	50	90
	45.00	45.00	45.00	45.00	45.00	45.00	45.00
	5.000	13.889	45.000	0.556	93.889	0.556	45.000
Total	240	240	240	240	240	240	240

	Medication	Total
1	60 46.25 4.088	370
2	60 73.75 2.564	590
3	100 75.00 8.333	600
4	20 45.00 13.889	360
Total	240	1920

Chi-Sq = 629.452, DF = 21, P-Value = 0.000

Test and CI for Two Proportions 10 µg vs p

Sample	X	N	Sample p
1	18	96	0.187500
2	7	72	0.097222

Difference = p (1) - p (2)
 Estimate for difference: 0.0902778
 95% CI for difference: (-0.0135438, 0.194099)
 Test for difference = 0 (vs not = 0): Z = 1.70 P-Value = 0.088

Test and CI for Two Proportions 30 µg vs p

Sample	X	N	Sample p
1	30	96	0.312500
2	7	72	0.097222

Difference = p (1) - p (2)
 Estimate for difference: 0.215278
 95% CI for difference: (0.100039, 0.330516)
 Test for difference = 0 (vs not = 0): Z = 3.66 P-Value = 0.000

Test and CI for Two Proportions 100 µg vs p

Sample	X	N	Sample p
1	59	96	0.614583
2	7	72	0.097222

Difference = p (1) - p (2)
 Estimate for difference: 0.517361
 95% CI for difference: (0.398360, 0.636362)
 Test for difference = 0 (vs not = 0): Z = 8.52 P-Value = 0.000

Test and CI for Two Proportions 30 µg vs 10 µg

Sample	X	N	Sample p
1	30	96	0.312500
2	18	96	0.187500

Difference = $p(1) - p(2)$
Estimate for difference: 0.125
95% CI for difference: (0.00378499, 0.246215)
Test for difference = 0 (vs not = 0): $Z = 2.02$ P-Value = 0.043

Test and CI for Two Proportions 100 μg vs 10 μg

Sample	X	N	Sample p
1	59	96	0.614583
2	18	96	0.187500

Difference = $p(1) - p(2)$
Estimate for difference: 0.427083
95% CI for difference: (0.302286, 0.551881)
Test for difference = 0 (vs not = 0): $Z = 6.71$ P-Value = 0.000

Test and CI for Two Proportions 100 μg vs 30 μg

Sample	X	N	Sample p
1	59	96	0.614583
2	30	96	0.312500

Difference = $p(1) - p(2)$
Estimate for difference: 0.302083
95% CI for difference: (0.167638, 0.436528)
Test for difference = 0 (vs not = 0): $Z = 4.40$ P-Value = 0.000

Dose 1:

Dosage - Reaction	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
10 µg Yes	1	4	5	1	2	1	2	2	18
10 µg No	11	8	7	11	10	11	10	10	78
30 µg Yes	1	6	6	7	1	3	0	6	30
30 µg No	11	6	6	5	11	9	12	6	66
100 µg Yes	6	10	9	10	4	7	3	10	59
100 µg No	6	2	3	2	8	5	9	2	37
p Yes	0	2	3	0	0	0	0	2	7
p No	9	7	6	9	9	9	9	7	65
Total	45	45	45	45	45	45	45	45	360

Dose 2:

Dosage - Reaction	Fever	Fatigue	Headache	Chills	Diarrhea	Muscle Pain	Joint Pain	Meds	Total
10 µg Yes	1	8	10	3	0	5	4	6	37
10 µg No	11	4	2	9	12	7	8	6	59
30 µg Yes	9	10	12	8	1	7	3	10	60
30 µg No	3	2	0	4	11	5	9	2	36
p Yes	0	2	0	0	0	0	0	0	2
p No	6	4	6	6	6	6	6	6	46
Total	30	30	30	30	30	30	30	30	240

Team Five: Review of Polack with comments and questions.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Perez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Satrajit Roychoudhury, Ph.D., Kenneth Koury, Ph.D., Ping Li, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Robert W. Frenck, Jr., M.D., Laura L. Hammitt, M.D., Ozlem Türeci, M.D., Haylene Nell, M.D., Axel Schaefer, M.D., Serhat Unal, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

NEJM 383:27 12/31/2020.

Abstract:

BNT162b2: full length spike protein, nucleoside modified

21,720 BNT162b2 21728 Placebo

Severe covid after first dose:

- 9 in Placebo group
- 1 in BNT162b2

Cases of covid onset after at least 7 days after second dose:

- 8 cases in BNT162b2
- 162 cases in Placebo:

“The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of adverse events was low and was similar in the vaccine and placebo groups.” P2603 p3.

Main Body of Paper:

“A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728)”, P2603 p4.

“Safe and effective prophylactic vaccines are urgently needed to contain the pandemic, which has had devastating medical, economic, and social consequences.” P2604 p 1.

“Findings from studies conducted in the United States and Germany among healthy men and women showed that two 30 mg doses of BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers and robust antigen-specific CD8+ and Th1-type CD4+ cell responses.”

“Here we report safety and efficacy findings from the phase 2/3 part of a global phase 1/2/3 trial evaluating the safety, immunogenicity, and efficacy of 30 mg of BNT162b2 in preventing Covid-19 in persons 16 years of age or older.” P2604 p3.

“Collection of phase data on vaccine immunogenicity of phase 2/3 data on vaccine immunogenicity and the durability of the immune response to immunization is ongoing, and those data are not reported here.” P 2604 p 3.

Study group included HIV, hep B or C patients.

Exclusion: Prior history of covid-19, immunosuppression. P. 2604 p 5.

Pfizer conducted trial, collected the data, performed the data analysis, data interpretation, and the writing of the manuscript. “This data set and these trial results are the basis for an application for emergency use authorization.” P2604 p 3.

Study Design:

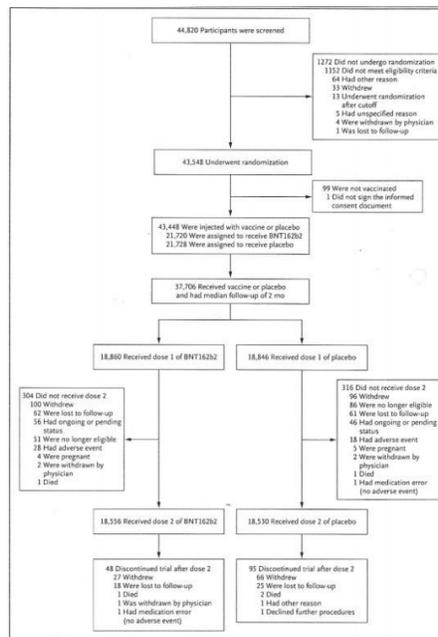


Table S1, Online Supplementary Appendix: Explanation of the various denominator values for use in assessing the results (available NEJM.org)

Figure/Table Number	Figure/Table Title	Population(s)/Sample Size	Explanation
Figure 1	Disposition of participants (CONSORT)	All enrolled population N=37,706 "main safety subset"	All randomized ≥16 years of age, N=43,548 <ul style="list-style-type: none"> [minus 99 non-vaccinated, 1 no ICD] Vaccinated N=43,448 Main safety subset (N=37,706) needed to have been enrolled by October 9, 2020 for EUA application
Figure 2	Local and Systemic Reactions Reported within 7 Days after Receipt of 30 µg BNT162b2 or Placebo by Age Group	Reactogenicity subset of ≥16 years old N=8,183	Per protocol
Figure 3	Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1	N=43,355 (modified intention-to-treat)	All randomized ≥=12 years of age N= 43,651 <ul style="list-style-type: none"> [minus 99 non-vaccinated, 1 no ICD] Vaccinated (dose 1 efficacy) N=43,551 <ul style="list-style-type: none"> [minus 196 HIV+] All efficacy N=43,355
Table 1	Demographics	N=37,706 main safety subset	As above
Table 2	Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 [Primary Endpoints]	1st primary efficacy endpoint: Includes those without evidence of prior infection (N=36,523) 2nd primary efficacy endpoint: Includes those with and without evidence of prior infection (N=40,137)	Evaluable population: <ul style="list-style-type: none"> received 2 vaccinations as randomized no major protocol deviations Excludes HIV+
Table 3	Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection Prior to 7 Days After Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S2	Baseline Comorbidities	N=37,706 main safety subset	
Table S3	Participants Reporting at Least 1 Adverse Event From Dose 1 (All Enrolled Participants)	N=43,252	Vaccinated N=43,448 minus 196 HIV+
Table S4	Vaccine Efficacy from 7 Days After Dose 2 by Underlying Comorbidities among Participants without Evidence of Infection Prior to 7 Days after Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S5	Vaccine Efficacy of Severe COVID-19 Occurrence after Dose 1 (Modified Intention-to-Treat)	N=43,355 (modified intention-to-treat)	See comments to Figure 3

Table S1 | Explanation of the Changes in Denominator Numbers in Various Analyses.

7

- 44,820 subjects screened & 43,448 participants injected:
 - BNT162b2
 - 18,860 dose 1: 28 withdrew after adverse reaction.
 - 18,556 dose 1 & 2: 48 discontinued after second

- 18,435 dose 1 & 2: completed 2-month follow-up
- Placebo
 - 18,846 dose 1: 18 withdrew after adverse reaction.
 - 18,530 dose 1 & dose 2: 95 discontinued after 2nd
 - 18,435 dose 1 & dose 2 completed 2-month follow-up.
- 43,355 subjects Modified intention-to-treat (mITT) efficacy population.
 - All age groups 12 years of age or older.
 - 100 participants who were 12 to 15 years of age “...contributed to person time years but included no cases.” P2605 p5.
- 40,137 subjects evaluated 7days after the second dose “with or without evidence of prior infection”.
- 37,706 subjects “**Safety population**” (defined by the FDA):
 - Persons 16 years of age or older.
 - Median of 2 months of follow-up as of October 9, 2020.
- 36,523 subjects evaluated for efficacy 7 days after the second dose and “who had no evidence of prior infection”.
- 8183 subjects = Reactogenicity Subset

Methods:

“Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle.” P2604 p6. **Aspiration not mentioned.**

Adults 16 years of age or older who were:

- Healthy or had
- Stable chronic medical conditions, including but not limited to
 - Human immunodeficiency virus (HIV),
 - Hepatitis B virus, or
 - Hepatitis C virus infection

Division of work:

- Pfizer:
 1. Design and conduct of the trial,
 2. Data collection,

3. Data analysis and interpretation
 4. Writing of the manuscript.
- BioNTech:
 - Trial sponsor
 - Manufactured BNT162b2
 - Contributed: interpretation of the data and the writing of the manuscript.
 - **All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. This data was not on the web site 4/13/2022.**
 - An independent data and safety monitoring board reviewed efficacy and unblinded safety data.

Safety:

- Observation for 30 minutes after injection.
- Solicited data:
 1. End points.
 2. Specific local or systemic adverse events.
 3. Use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset)
- Unsolicited: Unsolicited serious adverse events through 6 months after the second dose.
- Adverse event data through approximately 14 weeks after the second dose are included.
- Safety data are reported for all participants who provided informed consent and received at least one dose of vaccine or placebo.
- Per protocol, safety results for participants infected with HIV (196 patients) will be analyzed separately and are not included here.
- A stopping rule for the theoretical concern of vaccine-enhanced disease was to be triggered if the one-sided probability of observing the same or a more unfavorable adverse severe case split (a split with a greater proportion of severe cases in vaccine recipients) was 5% or less, given the same true incidence for vaccine and placebo recipients. Alert criteria were to be triggered if this probability was less than 11%.

Efficacy:

Efficacy of BNT162b2 against **confirmed Covid-19**:

- **First Primary End Point**: Onset of confirmed Covid-19 at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose. P. 2604

Restated: Confirmed Covid-19 after 28 days following the initial dose. Covid-19 positives prior to 28 days were considered unvaccinated. P2605 p 3.

- Confirmed Covid Diagnosis: FDA criteria. (No reference provided).
 - **One** of the following Symptoms:
 - Fever
 - Chills
 - Diarrhea
 - Vomiting
 - Loss of Taste
 - Loss of smell
 - New or increased:
 - Cough
 - SOB
 - Muscle pain
 - **Plus**: a respiratory specimen in suspected SC2 + by NAAT obtained during symptomatic period +/- four days before.
- **Second Primary End Point**: was “efficacy in participants with and without evidence of prior infection.” P2605 p 3.
- **Major secondary end points**: Efficacy against severe covid. “Details are provided in the protocol.” P2605 p4.
 - Confirmed covid.
 - One of the following:
 - Respiratory failure.
 - Acute neurologic event.
 - Renal dysfunction.
 - Hepatic dysfunction.
 - ICU Admission.
 - Death.

Results:

Reactogenicity: n = 8183.

Local:

- Younger recipients reported symptoms more often than older >55

Local Pain	< 55	>= 55
First Dose	83%	71%
Second Dose	78%	66%

- **Systemic:** More reports after second dose than first:

- Fatigue: 59% <55, 51% => 55, placebo 23%
- Headache: 51% < 55, 39% =>55, placebo 24%
- Temperature > 38 Deg C after second dose:
 - 16% < 55, 11% => 55
 - 38.9-40 deg C: 0.2% after 1st dose, 0.8% after 2nd dose; 0.1% placebo 1st and 2nd.
 - > 40 deg C: 2 subjects one in injected and placebo.
- Antipyretic/analgesic:
 - < 55: dose 1 = 28% & dose 2 = 45%.
 - => 55: dose 1 = 20% & dose 2 = 38%.
 - Placebo: dose 1 = 10 % & dose 2 = 14%.

Adverse Events: Table S3 (available online): No deaths were related to vaccine, placebo or Covid-19.

Adverse Event	BNT162b2 (30 µg) (N=21621) n ^a (%)	Placebo (N=21631) n ^b (%)
Any event	5770 (26.7)	2638 (12.2)
Related ^c	4484 (20.7)	1095 (5.1)
Severe	240 (1.1)	139 (0.6)
Life-threatening	21 (0.1)	24 (0.1)
Any serious adverse event	126 (0.6)	111 (0.5)
Related ^c	4 (0.0)	0
Severe	71 (0.3)	68 (0.3)
Life-threatening	21 (0.1)	23 (0.1)
Any adverse event leading to withdrawal	37 (0.2)	30 (0.1)
Related ^c	16 (0.1)	9 (0.0)
Severe	13 (0.1)	9 (0.0)
Life-threatening	3 (0.0)	6 (0.0)
Death ^a	2 (0.0)	4 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 (All Enrolled Participants). The 'all enrolled' population included all participants who received at least 1 dose of vaccine irrespective of follow-up time. a. N = number of participants in the specified group. This value is the denominator for the percentage calculations. b. n = Number of participants reporting at least 1 occurrence of the specified event category. For 'any event', n = the number of participants reporting at least 1 occurrence of any event. c. Assessed by the investigator as related to investigational product.

n = 43,253 according to published article. P2608 p 3.

n = 36,523 according to online Table S1 P 7. "Same as primary endpoint."

n = 43,252 according to online Table S3 P 9. "All enrolled." At least 1 dose.

	BNT162b2	Placebo
n =	21621	21631
All events	5770	2638
Related	4484	1095
% AE React	69%	31%
% All AE		
Total	27%	12%
% Rel. AE		
Total	21%	5%

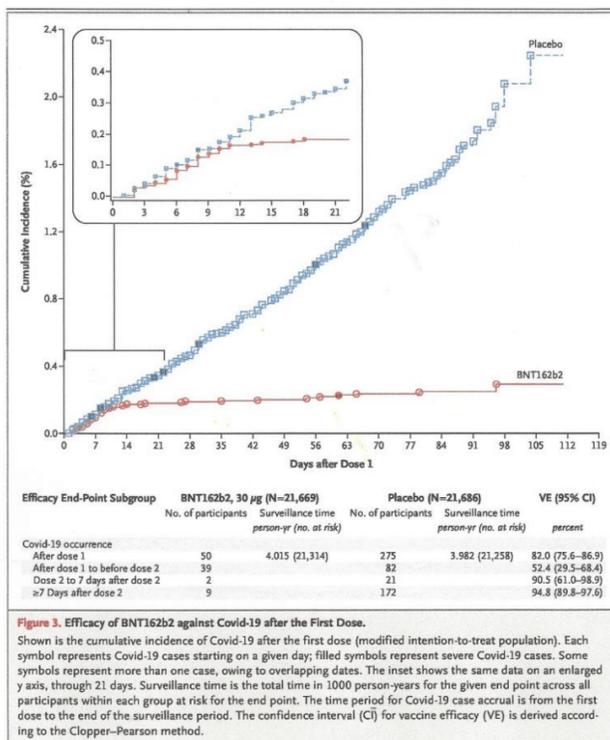
Rel = Related AE; P = Placebo

	BNT162b2	Placebo
Lymphadenopathy	64	6

Efficacy:

	BNT162b2	Placebo	VE*
n =	18198	18325	
Surveillance Time	2.214	2.222	
Covid-19: >= 28 days after dose 2	8	80	
Covid-19: <28 days after dose 2+			
Placebo	39	82	52%
All	47	162	
Study comparison	8	162	95%

*VE = Vaccine Efficacy



Discussion:

“A two-dose regimen of BNT162b2 (30 µg per dose, given 21 days apart) was found to be safe and 95% effective against Covid-19.”

“The vaccine met both primary efficacy end points, with more than a 99.99% probability of a true vaccine efficacy greater than 30%.”

“These results met our prespecified success criteria, which were to establish a probability above 98.6% of true vaccine efficacy being greater than 30%, and greatly exceeded the minimum FDA criteria for authorization.9”

“...in the interval between the first and second doses, the observed vaccine efficacy against Covid-19 was 52%, and in the first 7 days after dose 2, it was 91%, reaching full efficacy against disease with onset at least 7 days after dose 2.”

“Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group. This finding is consistent with overall high efficacy against all Covid-19 cases.”

“The severe case split provides preliminary evidence of vaccine mediated protection against severe disease, alleviating many of the theoretical concerns over vaccine-mediated disease enhancement.¹¹”

“Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities.”

Comments/Questions:

1. Diagnosis of covid-19 required only one symptom and a positive NAAT test. Why was only one symptom + a positive NAAT rather than an actual clinical diagnosis based upon symptoms, signs, and supportive laboratory data?
2. NAAT have proven unreliable leaving only one symptom as the basis to diagnose covid-19. Are there any other studies of experimental gene therapy that are dependent upon a single symptom to diagnose a disease? How can this be adequate?
3. What NAAT was used and what are the statistics for false negatives and positives? Was the same test used throughout the study?
4. Aspiration was not reported as the technique for injection of the BNT162b2.
5. “All the trial data”, reported to have been available to all the authors, is no longer available with the full text of the article at NEJM.org as reported in the text. Why not?
6. Participants received “informed consent”. Where can the consent documenting risks, benefits and alternative be found?
7. Were participants with prior infection with SC2 included or not?
8. Where is the raw data for reactogenicity?
9. Complete reporting of symptoms, signs, laboratory and diagnostic studies are not provided.
10. Table S2 lists 14 disease categories after consolidating All Malignancies, Diabetes, and Liver Disease. The CBC identifies 21 disease categories.¹
 - a. There were 18 subjects with dementia. What legal process was required for each of these individuals?

- b. What was the distribution of co-morbidities the control versus experimental groups given that a major risk factor is clustering of co-morbidities in subjects? Data presented in Table S2 provides no information about clustering of co-morbidities in the study subjects. Some studies have indicated that covid-19 fatalities were associated with multiple co-morbidities average 3.8 per fatality.
 - c. Hypertension is a major risk factor that was not reported.
 - d. Coronary artery disease and arrhythmia are risk factors for covid-19 and Prevalence Data was not reported.
 - e. The number of smokers and drug users was not given.
 - f. Age is a continuous variable. It is also a risk factor. Table 1 gives age data for 16-55 and >55 years. These categories are overly broad. More granular data is required.
11. “The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively).” This data needs to be carefully examined. P2610 p2.
 12. “Lymphadenopathy, which generally resolved within 10 days, is likely to have resulted from a robust vaccine-elicited immune response.” Given that lymphocytopenia is associated with BNT162b2, are there other explanations for lymphadenopathy? Was splenomegaly found in these cases? What were the lymphocyte counts for study subjects?
 13. “...the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain (sic) to be determined.” Shouldn’t a longer follow-up period be required given the experimental nature of this gene therapy?
 14. Physicians look to the NEJM as a trusted source for guiding their recommendations to patients. This publication is quite superficial given the gravity of the pandemic and the implications of administering this drug to a significant portion of the human race.
 15. The medical files of all covid-19 patients should be carefully reviewed as well as random sampling of the study population.

1

Pfizer Co-Morbidities	CDC Co-Morbidities
1 AIDS/HIV	1 Cancer
2 Any Malignancy	2 Chronic Kidney Disease
3 Cerebrovascular Disease	3 Chronic Liver Disease
4 Chronic Pulmonary Disease	4 Chronic Lung Disease
5 Congestive Heart Failure	5 Cystic Fibrosis
6 Dementia Report	6 Dementia
7 Diabetes With Chronic Complication Diabetes Without Chronic Complication	7 Diabetes
8 Hemiplegia or Paraplegia	8 Disabilities
Leukemia	9 Heart Conditions
Lymphoma	10 HIV/AIDS
Metastatic Solid Tumor	11 Immunocompromised
9 Mild Liver Disease	12 Mental Health
Moderate or Severe Liver Disease	13 Obesity
10 Myocardial Infarction	14 Inactivity
11 Peptic Ulcer Disease	14 Pregnancy
12 Peripheral Vascular Disease	16 Sickle Cell Disease
	17 Smoking Solid organ/Stem Cell
13 Renal Disease	18 Transplant
14 Rheumatic Disease	19 Stroke or CVA
	20 Substance Use
	21 Tuberculosis

¹ (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>).

Report 4: “Pfizer mRNA Construct: Why Spike Protein Causes Disease” Team 5.

By Daniel P Demers, PhD

Daily Clout 4/20/22 Report: Pfizer mRNA Construct
Researcher/Author: Daniel B. Demers, PhD
Reviewed by: Team 5
Team 5 Leader: Linnea Wahl

Introduction

In the first paragraph of Pfizer document 2.4 NONCLINICAL OVERVIEW, Pfizer states that “BNT162b2 is a nucleoside modified mRNA (modRNA) expressing full-length S [spike] with two proline mutations (P2) to lock the transmembrane protein in an antigenically optimal prefusion conformation” (p. 6, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

They list two references (Pallesen et al., 2017; Wrapp et al., 2020) as their justification for this design. That is the end of Pfizer’s discussion on why that particular design was selected, and it appears that Pfizer conducted no further research before selecting this design (or construct) and proceeding with vaccine development. This, as it turns out, is quite important.

Concerns Regarding the Pfizer mRNA Construct

There are three primary concerns regarding the Pfizer approach used to design their mRNA vaccine.

1. The basic Pfizer construct utilizing two proline substitutions to stabilize the spike protein molecule is flawed, and the protein molecule as well as the mRNA itself, remain unstable.
2. The spike protein has been shown to cause disease; therefore, a vaccine based on the spike protein will promote pathogenesis, not prevent it.
3. The S1 subunit of the spike protein has been shown to shed into the circulatory system, thereby furthering disease.

The following discussion expands on these three concerns.

Concern 1: Pfizer selected the Pallesen et al. (2017) construct as the basis for the Pfizer vaccine.

The work described by Pallesen et al. (2017) was performed on the MERS-CoV virus. Pallesen selected proline substitutions based on the work of others (Qiao et al., 1998; Sanders et al., 2002; Krarup, et al., 2015).

Pfizer also references a paper in the journal *Science* authored by Daniel Wrapp (Wrapp et al., 2020). Wrapp cites Pallesen et al. (2017) and the work of Robert Kirchdoerfer et al. (2018) who evaluated the Pallesen-style double proline substitutions (S2P) in the spike protein of SARS-CoV. Wrapp et al. (March 2020) assessed the 2P substitution in the spike protein of SARS-CoV-2, evaluating the construct for its affinity for the host cell receptor ACE2. Wrapp did not evaluate the SARS-CoV-2 S2P antigenicity nor the fate of the S1 subunit that is shed when the spike protein binds to the cell.

Wrapp et al. (March 2020) states that “Knowing the atomic level structure of the SARS-CoV-2 spike will allow for additional protein engineering efforts that **could** [emphasis added] improve antigenicity and protein expression for vaccine development.” It appears that Pfizer took this article and used it as is to create a vaccine without “additional protein engineering efforts” as suggested by Wrapp et al. (2020).

Moreover, the purpose of introducing two proline substitutions into the spike protein as described by Pallesen and Wrapp (Pallesen et al., 2017; Wrapp et al., 2020; Pfizer, p. 6, https://phmpt.org/wp-content/uploads2022/03/125742_S1_M2_24_nonclinical-overview.pdf) was to stabilize the spike protein to improve its thermal **stability, conformation and antigenicity**. But, as stated by Hsieh et al. (2020)

with co-author Daniel Wrapp, “even with these (2P) substitutions the SARS-CoV-2 S-protein remains unstable and difficult to produce reliably in mammalian cells, hampering R&D of subunit vaccines.”

Hsieh and Wrapp (Hsieh et al., July 2020) found that 26 of 100 variants that they created and tested had higher expression than the S-2P substitution that Pfizer selected. One of their variants, labeled Hexa-Pro, contained four proline substitutions in addition to the S-2P substitutions and had nearly 10X greater expression, had improved thermal stability and retained the desired conformation.

Numerous articles since then state that the 2P substitution used by Pallesen/Pfizer is unstable (McCallum et al., 2020, posted on-line Aug. 2020; Xiong et al., 2020; Brun et al., 2020; Juraszek et al., 2021). *Brun et al. (posted November 2020) even made suggestions for improving the Pfizer BNT162b2 vaccine after describing why it was a suboptimal design.*

Why did Pfizer select the Pallesen construct requiring storage in ultra-low-temperature freezers when the HexaPro construct is more stable, can be stored at room temperature and has much greater expression?

Concern 2: Pfizer did not address the well-documented pathogenesis caused by the coronavirus spike protein before release of their vaccine and before FDA approval.

In a 2005 article, Kuba demonstrated that SARS-CoV spike protein injected into mice worsened their lung disease (Kuba, 2005).

In 2008, Wang et al. demonstrated that the receptor binding domain (RBD) of the spike protein of SARS-CoV leads to internalization of ACE2, resulting in downregulation and subsequent lung injury (Wang et al., 2008). *The authors concluded that “because the RBD spike binding to ACE2 contributes to SARS pathogenesis, the use of subunit vaccines based on RBD spike should be considered carefully.”*

Wang et al. (2020) and Semimukai et al. (2020) noted that recombinant spike protein induced antibodies in mice and protected against SARS-CoV infection, but lung eosinophilic immunopathology was observed in the immunized mice after SARS infection.

Elizabeth M. Rhea and her co-authors reported on-line in December 2020 and published in March 2021 (Rhea et al., 2021) that S1 subunit labeled with radioiodine (I-S1) readily crosses the mouse blood-brain-barrier (BBB) and could explain the adverse effects of S1 and/or SARS-CoV-2 such as encephalitis, respiratory difficulties and reduced ability to smell. I-S1 was also detected in kidney, liver and spleen.

In January 2021, Letarov et al. published an article in the journal *Biochemistry (Moscow)*, titled *Free Sars-CoV-2 Spike Protein S1 Particles May Play a Role in the Pathogenesis of COVID-19 Infection* (Letarov et al., 2021). They noted that the upregulation of cell surface expression of ACE1 and/or downregulation of ACE2 can lead to pulmonary damage. This occurs during SARS infection and by recombinant SARS-CoV spike protein. They hypothesize that S1 molecules carry intact RBDs, and their binding to ACE2 may induce ACE2 downregulation and deleterious downstream effects such as increased inflammation, thrombosis, and pulmonary damage.

Letarov et al. (2021) also reference the work of Zhang et al. (2020) who elucidated a spike protein mutation in SARS-CoV-2 (the D614G variant) that is associated with increased infectivity but reduced S1 shedding and mild symptoms. This is further evidence that the spike protein is responsible for pathogenesis.

Nuovo et al. (2021, posted on-line Dec. 2020) reported on the endothelial cell damage caused by the S1 subunit of the spike protein. They reported two main findings: 1) Human COVID-19 cases demonstrated microvessel endothelial damage in the brain and other organs, including the skin, due to circulating spike protein that induces cytokine production resulting in microencephalopathy; and 2) injection of the S1 full-length spike subunit into mice (but not the S2 subunit) induced an equivalent microvascular encephalopathy as seen in

human COVID-19 cases. The authors further note that although their study *“focused on the brain, it should be stressed that there are other sites where there is a rich bed of microvessels with the ACE2 receptor, including skin/subcutaneous fat and the liver. As has been documented in human patients, microvessels at these sites can also display an endothelialitis that, in the skin/fat can induce complement activation/hypercoagulable state and the so called cytokine storm typical of fatal COVID-19.”*

“In sum, the data presented indicates that the full length S1 subunit of the spike protein of SARS-CoV-2 alone is capable, without the infectious virus, of inducing systemic microendothelial cell damage in mice with a cognate pattern of complement activation and increased cytokine expression and the concomitant thrombosis/hypercoagulable state. This disease pattern strongly parallels the extra-pulmonary manifestation of severe human COVID-19 and suggests that the latter may not represent systemic infectious virus. Thus, prevention of the CNS disease so common in severe COVID-19 may require neutralization/removal of the circulating pseudovirus.”

Lei et al. (April 2021) created a pseudovirus exhibiting spike protein but containing no virus inside and concluded that the spike protein alone is sufficient to cause damage to the vascular endothelial cells.

With so much evidence demonstrating a direct link between the presence of the spike protein S1 subunit in the circulatory system and pathogenesis, why would Pfizer create a vaccine that not only injects spike protein into the patient, but converts the cells of the patient into “spike protein factories” that turn out the spike protein S1 subunit, the very molecule that causes illness?

Concern 3: Pfizer did not address the well-documented shedding of the coronavirus spike protein into the circulatory system, where it crosses over to multiple organ systems to cause pathogenesis, before release of their vaccine.

It was shown as early as 1994 (Bullough et al., 1994) that the surface spike protein of an enveloped virus (Influenza) would release a subunit after proteolytic cleavage of the structure upon binding to the host cell surface. Work by Alexandra Walls (2017) demonstrated that the proteolytic processing of coronavirus spike proteins allows shedding of the S1 subunit.

Brun et al. (posted on-line November 2020) reported the process by which spike protein is processed within the host cell and soluble S1 subunit was secreted into the extracellular space via lysosomes. Their work indicated that the production of spike vaccine antigen protein without a virus to incorporate the protein into the viral envelope created an overexpression system and secretion of the protein by the cell (shedding). They suggest that the secreted spike proteins do not mimic the spike glycoproteins as they are presented on the actual virus and may effectively act as a decoy, eliciting more of the unwanted sub-optimal, non-neutralizing antibodies that are incapable of neutralizing the virus.

The authors state that the Pfizer BNT162b vaccines (and other similar type vaccines) rely on the supplied RNA sequence to use the host cell machinery to faithfully produce the spike protein in its fully folded, glycosylated and assembled state, resembling a natural infection, and they trigger a robust innate and humoral response; however, this does not happen. They go on to suggest a better vaccine design, one that abolishes the furin cleavage site (which is intact in the Pfizer construct) and introduces mutations that lock the spike protein in the prefusion conformation to prevent shedding and elicit a more potent antibody response.

Rhea et al. (2021, posted on-line December 2020) noted that coronavirus spike proteins are often cleaved; therefore, S1 could be shed and shed S1 may cross the BBB. Shedding of the S1 subunit of the spike protein was also noted by Liu et al. (2020), Letarov et al. (2021), Rhea et al. (2020), Zhang et al. (2020) and Henderson et al. (2020).

Given that the Pfizer mRNA construct design is sub-optimal; given that it has been well established (since 2005 to 2008) that spike proteins cause disease; and given that the spike protein S1 subunit is shed during binding of the virus or pseudovirus with the host cell, as well as secreted by host cells producing spike protein following injection with an mRNA-derived spike protein vaccine, why would Pfizer develop and release an mRNA vaccine that demonstrates all three of these deleterious qualities? Why would Pfizer develop and release an mRNA vaccine that demonstrates poor design with limited immunogenicity, requires storage at very low temperatures, and results in the production of a spike protein that readily sheds into the circulatory system to cause pathogenesis in multiple organ systems? And why would the FDA approve it?

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Report 5: “Safe and Effective? We beg to differ. Red Flags in the Pfizer Internal Documents” – Team 3.

Pfizer released the documents on their early efficacy and safety trials of their vaccine. (Pfizer 2.7.3 SUMMARY OF CLINICAL EFFICACY).

https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.3-Summary-of-Clinical-Efficacy.pdf.

The results of these documents are used to justify the claim the vaccines are safe and effective. Examine the document! It is evident beyond any doubt. Pfizer lied and misled; and upon this foundational lie, Moderna, and public health authorities, built the lie so big that it is believed alongside continual repetition that the mRNA vaccines are ‘safe and effective.’

Herein we will examine these claims, deconstruct them, and prove them false, using well-established foundational science.

Why did Pfizer want the original documents sealed for 75 years, buried in the labyrinth of the governmental archives, hidden in plain sight? After 75 years, the documents may be forgotten; or if not forgotten lost, and if found by some future scholar, stripped of their legal implication. Released after everyone who received the vaccine is dead. Released after those responsible for bringing this plague upon the world are dead. So, we ask: If there is nothing to hide, why hide it? And this so curious as they are already immune from legal action under the mantle of the EUA (with the profound power of the Federal Government protecting them). But the EUA immunity has an Achilles heel: If the EUA was granted on fraud, the Government is immune from legal action, but Pfizer is not.

This brings us to the essential question: Is the vaccine safe and efficacious? An in-depth look at Pfizer’s own documents challenges these assertions. The evidence is in plain sight. The vaccines are not proven safe nor effective. We need to know that they knew, and when they knew it. But as medical professionals, there is a higher burden. If they did not know, but they should have known because the knowledge was published in peer review literature, have they committed medical malfeasance?

First, we must look at the difference between vaccine efficacy and vaccine effectiveness. There is similarity. Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons. Vaccine efficacy is used when a study is carried out under ideal conditions, for example, during a clinical trial. Vaccine effectiveness is used when a study is carried out under typical field (that is, less than perfectly controlled) conditions ([Principles of Epidemiology | Lesson 3 - Section 6 \(cdc.gov\)](#)).¹ A vaccine may show efficacy in a clinical trial but be utterly ineffective when introduced at a societal level. This non-effectiveness may be due to unanticipated safety concerns (aka, excessive adverse reactions reported) or more subtle immunological reasons due to immune imprinting (aka, doctrine of original antigenic sin)(Monto et al., 2017)². In all cases, a vaccine can only be declared effective after widespread deployment at a societal level, and a risk/reward benefit has been determined. For a vaccine against a disease such as COVID-19, where the risk from the disease is only to a segment of the population, and the overall risk to society is extremely low, there needs to be essentially no risk or adverse reactions from the vaccine. Pfizer’s need to hire [2400 personnel](#) to deal with the unexpected adverse reactions of the vaccines, essentially precludes the designation of the vaccine as “effective”.

¹ [Principles of Epidemiology | Lesson 3 - Section 6 \(cdc.gov\)](#)

² Monto, A. S., Malosh, R. E., Petrie, J. G., & Martin, E. T. (2017). The Doctrine of Original Antigenic Sin: Separating Good From Evil. *J Infect Dis* <https://doi.org/10.1093/infdis/jix173>

We have historical precedent to help us understand this. The CDC uses two primary systems to monitor the safety of vaccines. Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink (VSD). VAERS is an early warning system that helps CDC and FDA monitor problems following vaccination. VSD is a collaboration between CDC and eight integrated health care organizations. (Vaccine Safety Datalink VSD | Monitoring | Ensuring Safety | Vaccine Safety | CDC). In 1967, the usual seasonal flu was replaced by a more virulent strain known as H1N1 swine flu. A vaccine was brought to market to combat this variant. The result was an unacceptably high level of Guillain-Barre (a neurological dysfunction of ascending motor paralysis). The vaccine was withdrawn as non-effective. ([Guillain-Barré syndrome and Flu Vaccine | CDC](#))³. (Breman & Hayner, 1984)⁴

The interesting thing about COVID-19 is that we are told that the VAERS system is unreliable (Gorski, 2022)⁵. And yet, it is sponsored by the CDC and despite a multi-billion-dollar budget, never upgraded to fix its deficiencies. How does the CDC see the VAERS database? Healthcare providers are required by law to submit any adverse events following vaccination. (CDC) COVID -19 vaccination requires its own reporting. (CDC). VAERS system is seen as underreporting not overreporting adverse events. (CDC). So, which is it? Government incompetence, government malfeasance the of highest official public health figure in the land, or the current VAERS system is highly valuable? The only valid conclusion is that the CDC sees the current VAERS system as incredibly valuable.

Is the Pfizer vaccine (as well as Moderna and other vaccines) safe? There is a basic problem. Each vaccine has its own proprietary formula. The conflation of all the vaccines into the single heading “the vaccines are safe” is not warranted and care must be taken to designate which vaccine is under discussion.

There is a very high standard to declare a vaccine safe. This standard is higher for a vaccine than for a medication. (A Burrell, 2022)⁶ This is derived from the first principle of medicine “First, do no harm.” The physician assesses the patient, renders a diagnosis, and then prescribes a medication. In the decision to prescribe a medication, the physician must balance the good of the medication against the harm of the medication against the disease of the individual. Several situations demonstrate the issue. A patient is suffering from cancer. The use of a chemotherapeutic agent may save the patient’s life but also may have serious and life-threatening side effects. A common dilemma for a physician is the patient suffering from a cold who demands an antibiotic. The physician knows the cold is due to a virus and will not respond to the antibiotic and so will not prescribe it for the cold. But he/she may reason that a cold often leads to a bacterial infection and an antibiotic will prevent that and so prescribes the antibiotic. If a healthy patient comes to a physician requesting a medication, but in which the physician cannot find reasonable grounds to prescribe the medication, the physician is obligated not to give that patient medication as it violates the first principle. The reason is obvious. Every medication has a potential negative side effect. If the patient is healthy, and any medication is given, there is the potential to do harm. In the case of a vaccine the situation is fundamentally different. The patient is healthy and there is a desire to prevent disease. But the vaccine itself may have undesirable side effects. Any harm to the patient is now weighed

³ [Guillain-Barré syndrome and Flu Vaccine | CDC](#)

⁴ Breman, J. G., & Hayner, N. S. (1984). Guillain-Barré syndrome and its relationship to swine influenza vaccination in Michigan, 1976-1977. *Am J Epidemiol*, 119(6), 880-889. <https://doi.org/10.1093/oxfordjournals.aje.a113810>

⁵ Gorski, D. (2022, January 7). *As 2021 shambles to a close, the misuse of VAERS by antivaxxers continues apace*. Science-Based Medicine. <https://sciencebasedmedicine.org/as-2021-shambles-to-a-close-the-misuse-of-vaers-by-antivaxxers-continues-apace/>

⁶ Santa Clara University, & Burrell, A. (2021, March 11). *First, do harm: The ethics of human challenge trials for COVID-19 vaccine development*. Markkula Center for Applied Ethics. Retrieved April 29, 2022, from <https://www.scu.edu/ethics/healthcare-ethics-blog/first-do-harm-the-ethics-of-human-challenge-trials-for-covid-19-vaccine-development/>

against the good to society. If the vaccination is for a terrible plague such as smallpox or polio the answer is clear: Everyone is at risk. The diseases are devastating to everyone and the side effects minimal. Not giving the vaccine is harmful and so the first principle is violated. As such, the vaccination is offered to healthy people.

In the case of COVID-19, this standard is not reached. The disease is only harmful to a small segment of the population and that harm must be weighed against the potential of harm of a vaccine to a much larger segment of the population not at risk. The question now presents itself: is there sufficient evidence that the COVID-19 vaccine is essentially harmless to the general population? The answer presents itself as it is summed up in the idiom, “the facts speak for themselves”. The demand of vaccine manufacturers against legal liability of their vaccines indicate that the manufacturers do not consider the vaccines safe. The need for Pfizer to hire 2400 full-time employees to evaluate adverse effects from the vaccine speaks for itself. The action by public medical officials to impeach the VAERS reporting system speaks for itself. The only valid conclusion: The Pfizer vaccine is not safe.

There are two paths that both lead to the conclusion that the Pfizer vaccine is not safe and effective. The first is the construction of the vaccine and the second is the construction of the study to evaluate the vaccine.

To start, let’s look at the vaccine. It is a marvel of biotechnology. It consists of four separate components. (Pardi et al., 2018)⁷. A mRNA core, surrounded by a lipid nanoparticle (ALC 0315 for Pfizer or SM-102 for Moderna; see diagram). This lipid nanoparticle is positively charged and will attach itself to the mRNA. It is surrounded by negatively charged PEG coating, and an emulsifier. The mRNA directs the cell to make the spike protein of the virus. The lipid nanoparticle, PEG and emulsifier helps get the mRNA into the cell. (Schlich et al., 2021)⁸, ([Lipid Nanoparticle - Creative Biolabs \(creative-biolabs.com\)](https://www.creative-biolabs.com))⁹, (Kowalski et al., 2019)¹⁰ Each component has its own use and its own potential hazard. Each component must be assessed for safety. And then the entire combination must be assessed for safety.

Figure 1 : Covid -19 nanotechnology in vaccines ¹¹

⁷Pardi, N., Hogan, M. J., Porter, F. W., & Weissman, D. (2018). mRNA vaccines - a new era in vaccinology. *Nat Rev Drug Discov*, 17(4), 261-279. <https://doi.org/10.1038/nrd.2017.243>

⁸ Schlich, M., Palomba, R., Costabile, G., Mizrahy, S., Pannuzzo, M., Peer, D., & Decuzzi, P. (2021). Cytosolic delivery of nucleic acids: The case of ionizable lipid nanoparticles. *Bioeng Transl Med*, 6(2), e10213. <https://doi.org/10.1002/btm2.10213>

⁹ [Lipid Nanoparticle - Creative Biolabs \(creative-biolabs.com\)](https://www.creative-biolabs.com)

¹⁰ Kowalski, P. S., Rudra, A., Miao, L., & Anderson, D. G. (2019). Delivering the Messenger: Advances in Technologies for Therapeutic mRNA Delivery. *Mol Ther*, 27(4), 710-728. <https://doi.org/10.1016/j.ymthe.2019.02.012>

¹¹ <https://www.cas.org/ja/resource/blog/understanding-nanotechnology-covid-19-vaccines>

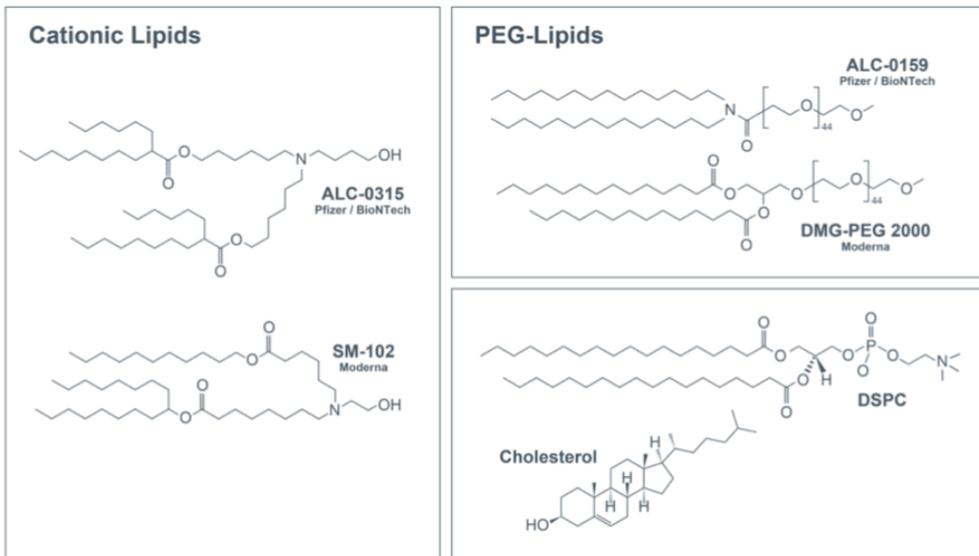
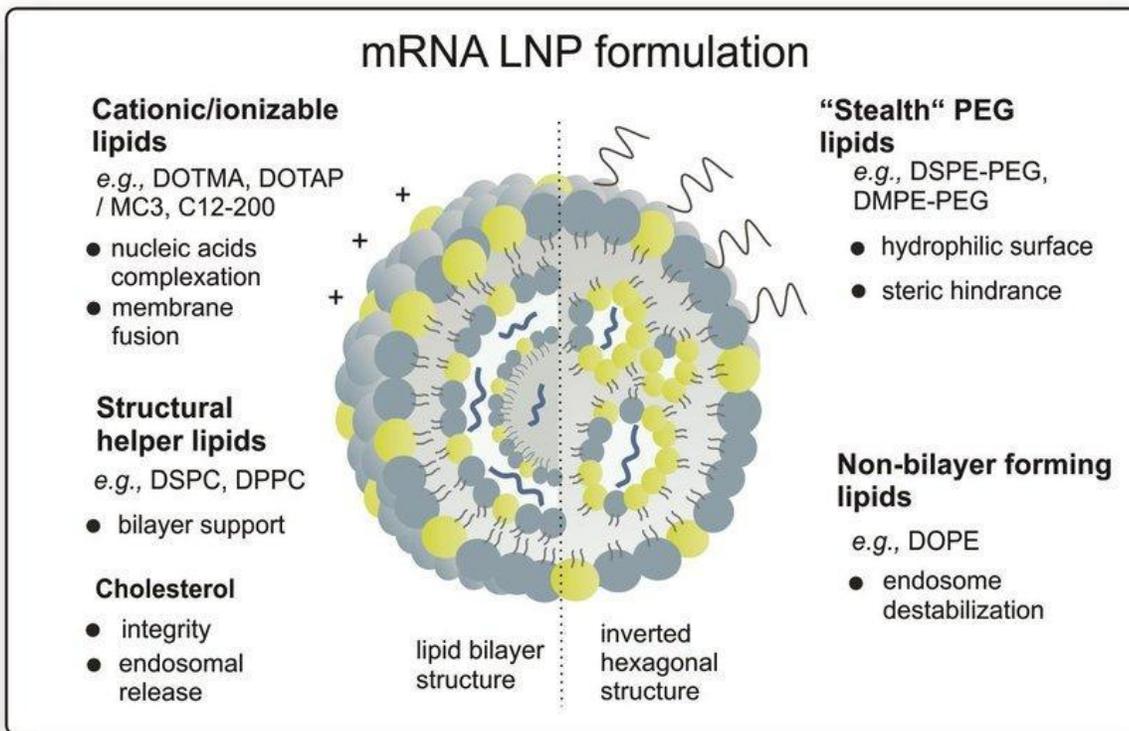


Figure 2: mRNA LNP formulation Verbeke et al., 2019¹²



¹² Verbeke, R., Lentacker, I., de Smedt, S. C., & Dewitte, H. (2019). Three decades of messenger RNA vaccine development. *Nano Today*, 28, 100766. <https://doi.org/10.1016/j.nantod.2019.10076>

The basic dictum of toxicology, the study of body toxins, is that all things are potentially toxins, and it is the dose that makes the difference.(Grandjean, 2016)¹³, (Frank & Ottoboni, 2011)¹⁴ .From this, two things follow: The mRNA directs the cell to make the spike protein of the virus (without making the entire viral particle). It is essential to demonstrate that the spike protein is innocuous. It is essential to demonstrate that the lipid nanoparticle delivery system is harmless.

Evaluation of the lipid nanoparticle delivery system:

The lipid nanoparticle delivery system used for vaccines was initially designed to deliver medicines and for gene therapy. It is the mechanism used to deliver chemotherapy for brain tumors and is designed to penetrate the blood brain barrier. The blood brain barrier (BBB) protects the brain from environmental hazards, including medicines and pathogens, such as bacterial and viruses. This barrier is overcome by lipid nanoparticles.(Shankar et al., 2018)¹⁵

This is our first area of concern. Lipid based nano therapy is acceptable for chemotherapy to target highly malignant brain tumors because the inherent disease is so deadly to the patient that any negative side effect of the delivery system, except the immediate death of the patient, can be ignored. In this setting, they are considered less toxic than alternatives, but this does not mean they are not toxic to the brain. (Shankar, 2018, et al).¹⁶ The situation for a vaccine is fundamentally different. The recipient is healthy. Any evaluation of the safety of this delivery system for a vaccine needs to evaluate whether penetration of the blood brain barrier by the lipid nanoparticle delivery system conveys its own harm. Studies have proven that ENMs (engineered nanomaterials) that can cross or bypass the blood–brain barrier and then access the central nervous system, carry the potential of neurotoxicity (Ge De, 2019).¹⁷ This evaluation was never done in the Pfizer safety and efficacy trials.

Therefore, it is impossible to know whether the vaccine is safe in this arena. Pfizer did not prove the safety of the nano-lipid delivery system for the brain.

A second question is whether the COVID-19 virus can hitch a ride on the delivery vehicle to penetrate the brain during the period when someone may be infected, full of replicating virus, but asymptomatic. It is known that a carrier is likely to be infectious during the asymptomatic replication phase of the virus. It is also known that the virus is capable of directly infecting cells. This question remains unanswered as such an evaluation is never done by Pfizer.

We were told ad nauseum that the injection would stay at the injection site. However, it was known since the inception of lipid nanoparticle delivery systems that they enter the systemic circulation and can find their way to many end points.(Christensen et al., 2014)¹⁸

¹³Grandjean, P. (2016). Paracelsus Revisited: The Dose Concept in a Complex World. *Basic Clin Pharmacol Toxicol*, 119(2), 126-132. <https://doi.org/10.1111/bcpt.12622>

¹⁴ Frank, P., & Ottoboni, M. A. (2011). *The dose makes the poison* (3rd ed.). Wiley.

¹⁵ Shankar, R., Joshi, M., & Pathak, K. (2018). Lipid Nanoparticles: A Novel Approach for Brain Targeting. *Pharm Nanotechnol*, 6(2), 81-93. <https://doi.org/10.2174/2211738506666180611100416>

¹⁶ *ibid*

¹⁷ Ge D, Du Q, Ran B, et al. The neurotoxicity induced by engineered nanomaterials. *Int J Nanomedicine*. 2019;14:4167-4186. Published 2019 Jun 6. doi:10.2147/IJN.S203352

¹⁸ Christensen, J., Litherland, K., Faller, T., van de Kerkhof, E., Natt, F., Hunziker, J., . . . Swart, P. (2014). Biodistribution and metabolism studies of lipid nanoparticle-formulated internally [3H]-labeled siRNA in mice. *Drug Metab Dispos*, 42(3), 431-440.

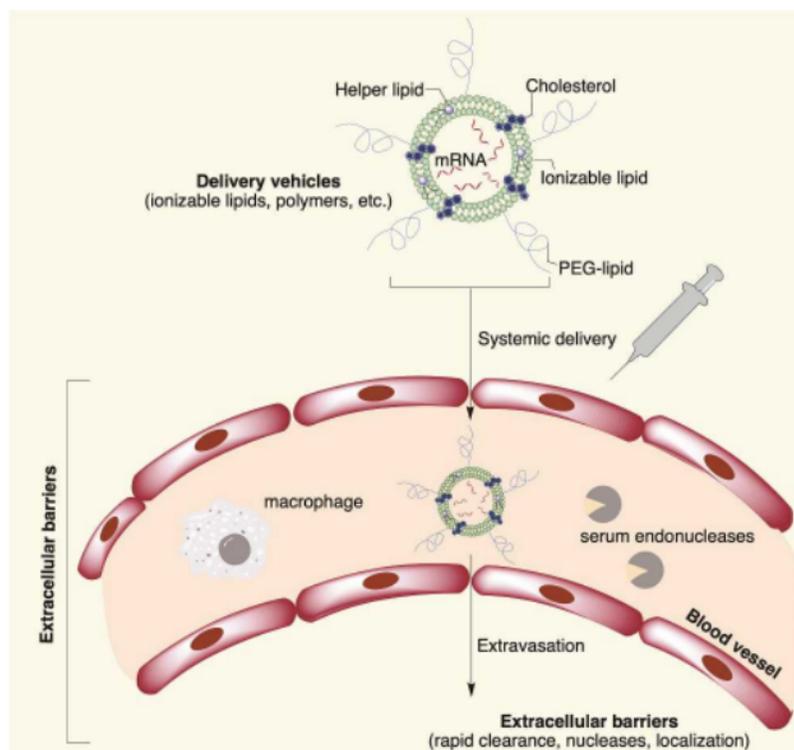


Fig.3 Schematic representation of extra- and intracellular barriers for mRNA delivery. (Kowalski, 2019)

This property of the mRNA/lipid nanoparticle delivery is utilized in many medications, and in fact, forms the basis of utilizing such delivery systems for chemotherapy for brain tumors, melanomas, and potentially other cancers(Lainé et al., 2014)¹⁹(Kowalski et al., 2019)²⁰ It is known almost from inception that the size of the lipo-nanoparticle and the exact chemical composition determine the distribution throughout the body and various tissues.(Lainé et al., 2014)²¹,(Hirsjärvi et al., 2013)²². **Therefore, it was known that the vaccine injection would not stay at the injection site. Stating that the vaccine would stay at the injection site is a lie of commission. As this information was not evaluated, it could not be concluded that the vaccine was safe.** The mRNA lipid nanoparticle is wrapped with PEG (also known as ALC 0159). PEG is utilized in many medications, as well as food stuffs and cosmetics. The incidence of severe allergic reaction to PEG (known as anaphylaxis, a life-threatening event) is rising as PEG is becoming more common in the environment. (Troelnikov

¹⁹ Lainé, A. L., Gravier, J., Henry, M., Sancey, L., Béjaud, J., Pancani, E., . . . Passirani, C. (2014). Conventional versus stealth lipid nanoparticles: formulation and in vivo fate prediction through FRET monitoring. *J Control Release*, 188, 1-8. <https://doi.org/10.1016/j.jconrel.2014.05.042>

²⁰ Kowalski, P. S., Rudra, A., Miao, L., & Anderson, D. G. (2019). Delivering the Messenger: Advances in Technologies for Therapeutic mRNA Delivery. *Mol Ther*, 27(4), 710-728. <https://doi.org/10.1016/j.ymthe.2019.02.012>

²¹ Lainé, A. L., Gravier, J., Henry, M., Sancey, L., Béjaud, J., Pancani, E., . . . Passirani, C. (2014). Conventional versus stealth lipid nanoparticles: formulation and in vivo fate prediction through FRET monitoring. *J Control Release*, 188, 1-8. <https://doi.org/10.1016/j.jconrel.2014.05.042>

²² Hirsjärvi, S., Dufort, S., Gravier, J., Texier, I., Yan, Q., Bibette, J., . . . Coll, J. L. (2013). Influence of size, surface coating and fine chemical composition on the in vitro reactivity and in vivo biodistribution of lipid nanocapsules versus lipid nanoemulsions in cancer models. *Nanomedicine*, 9(3), 375-387. <https://doi.org/10.1016/j.nano.2012.08.005>

et al., 2021)²³, (Erdeljic Turk, 2021)²⁴, (Sellaturay et al., 2021)²⁵, (Kim et al., 2021)²⁶. Although the consent form for the vaccine mentions the possibility of severe allergic reaction and anaphylaxis, it does not overtly tell the recipient that this is in the vaccine. If a person knows they have a PEG allergy, such a warning would warn them against receiving the vaccine. Likewise, the emulsifiers used in the vaccine delivery system may also induce an anaphylactic like reaction. **The vaccine is clearly not safe for someone who has an allergy to PEG and or related emulsifier. The warning should be more overt.**

The heart of the vaccine is modified mRNA. (Kim et al., 2022)²⁷. mRNA tells the cell to produce the spike protein. The foundational technology for the vaccine was developed by Malone, et al. (Park et al., 2021)²⁸ mRNA produced by the body is rapidly degraded in the body. The vaccine mRNA is modified to resist the degradation mechanisms of the body. (Schoenmaker et al., 2021)²⁹ Nevertheless, the mRNA vaccines are unstable. A special feature of mRNA is that even one change (strand break, or oxidation of the bases) in the long mRNA strand (typically between 1000 and 5000 nucleotides long) can stop translation. (Klauer & van Hoof, 2012)³⁰. This makes mRNA vaccines quite different from other vaccines in which small changes of the antigens do not necessarily have a measurable effect on their efficacy. Consequently, for mRNA vaccines, it is critical to monitor the integrity of the full molecule and that the strict guidelines are followed when administering the vaccine. This is an impossible standard, given the large number of facilities and different level personnel administering the vaccine. The failure to set up routine quality assurance standards in the huge number of facilities administering the vaccine precludes an assessment of the appropriate handling of the vaccine to ensure stability. **Therefore, it is not correct to state that the vaccines are safe, as this aspect is not monitored.**

The mRNA component was to be degraded within 48 hrs., but subsequent studies showed that it may persist for up to 8 weeks in draining lymph nodes (Turner et al., 2021)³¹, (Röltgen et al., 2022)³² and continue to direct cells

²³ Troelnikov, A., Perkins, G., Yuson, C., Ahamdie, A., Balouch, S., Hurtado, P. R., & Hissaria, P. (2021). Basophil reactivity to BNT162b2 is mediated by PEGylated lipid nanoparticles in patients with PEG allergy. *J Allergy Clin Immunol*, 148(1), 91-95. <https://doi.org/10.1016/j.jaci.2021.04.032>

²⁴ Erdeljic Turk, V. (2021). Anaphylaxis associated with the mRNA COVID-19 vaccines: Approach to allergy investigation. *Clin Immunol*, 227, 108748. <https://doi.org/10.1016/j.clim.2021.108748>

²⁵ Sellaturay, P., Nasser, S., Islam, S., Gurugama, P., & Ewan, P. W. (2021). Polyethylene glycol (PEG) is a cause of anaphylaxis to the Pfizer/BioNTech mRNA COVID-19 vaccine. In *Clin Exp Allergy* (Vol. 51, pp. 861-863). <https://doi.org/10.1111/cea.13874>

²⁶ Kim, M. A., Lee, Y. W., Kim, S. R., Kim, J. H., Min, T. K., Park, H. S., . . . Chang, Y. S. (2021). COVID-19 Vaccine-associated Anaphylaxis and Allergic Reactions: Consensus Statements of the KAAACI Urticaria/Angioedema/Anaphylaxis Working Group. *Allergy Asthma Immunol Res*, 13(4), 526-544. <https://doi.org/10.4168/aair.2021.13.4.526>

²⁷ Kim, S. C., Sekhon, S. S., Shin, W. R., Ahn, G., Cho, B. K., Ahn, J. Y., & Kim, Y. H. (2022). Modifications of mRNA vaccine structural elements for improving mRNA stability and translation efficiency. *Mol Cell Toxicol*, 18(1), 1-8. <https://doi.org/10.1007/s13273-021-00171-4>

²⁸ Park, J. W., Lagniton, P. N. P., Liu, Y., & Xu, R. H. (2021). mRNA vaccines for COVID-19: what, why and how. *Int J Biol Sci*, 17(6), 1446-1460. <https://doi.org/10.7150/ijbs.59233>

²⁹ Schoenmaker, L., Witzigmann, D., Kulkarni, J. A., Verbeke, R., Kersten, G., Jiskoot, W., & Crommelin, D. J. A. (2021). mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability. *Int J Pharm*, 601, 120586. <https://doi.org/10.1016/j.ijpharm.2021.120586>

³⁰ Klauer, A. A., & van Hoof, A. (2012). Degradation of mRNAs that lack a stop codon: a decade of nonstop progress. *Wiley Interdiscip Rev RNA*, 3(5), 649-660. <https://doi.org/10.1002/wrna.1124>

³¹ Turner, J. S., O'Halloran, J. A., Kalaidina, E., Kim, W., Schmitz, A. J., Zhou, J. Q., . . . Ellebedy, A. H. (2021). SARS-CoV-2 mRNA vaccines induce persistent human germinal centre responses. *Nature*, 596(7870), 109-113. <https://doi.org/10.1038/s41586-021-03738-2>

³² Röltgen, K., Nielsen, S. C. A., Silva, O., Younes, S. F., Zaslavsky, M., Costales, C., . . . Boyd, S. D. (2022). Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination. *Cell*, 185(6), 1025-1040.e1014. <https://doi.org/10.1016/j.cell.2022.01.018>

to make spike protein. The spike protein spills into the blood (coming from both spike protein production and the natural killing of cells making the spike protein by the immune system). The amount of spike protein in the blood is found in almost all vaccinated people after 1 to 2 days and in some maybe thousands of times higher than the spike protein reached by natural infection. (Röltgen K), 2022)³³ In about 63% of the vaccinated the spike protein is still present after 7 days and may persist up to 28 days. After the second dose, the spike protein in the blood may bind to the antibody to form a complex and then attach to a cell surface and at normal blood barriers (blood vessels, kidney, blood brain barrier). The result is a type III hypersensitivity reaction. This results in inflammation and injury to the cells. If the reaction is at a joint, the result is arthritis. If the injury is directed against the kidney, it is glomerulonephritis. If the blood vessel is damaged the result is endotheliosis (inflammation of the cells lining the blood vessel or the blood vessel walls (vasculitis). Note due to antigen/antibody interaction, the spike protein may not be readily detectable in the blood. Evaluation of such injuries may take weeks to months and individuals receiving the vaccine should be alerted to these types of injuries, especially they have an underlying immune condition. **Failure to evaluate these adverse reactions and correct for the inability to detect the spike protein in the blood prior to marketing makes it impossible to declare the vaccination safe for such individuals.**

At the heart of the vaccine is the spike protein. COVID-19 uses the spike protein to attach to and invade cells through the ACE2 receptor. The mRNA vaccines direct the body to make the spike protein, without making the entire virus, and thus initiate an immune response. The immune response is fundamentally different than natural infection. In natural infection the virus replicates in the upper respiratory tract (nose, nasopharynx, and throat). During this process the virus is attacked by the mucosal based immune system to make secretory IgA and simultaneously virus is swallowed and initiates an IgM and then IgG response against the spike protein and other viral proteins. The mRNA vaccines only direct a response against the spike protein. The amount of spike protein initiated by the viral vaccines is significantly higher in some patients (thousands of times higher than natural infection), without the IgM and IgA components. This high level of spike protein in the protein can initiate antigen/antibody interactions and type III immune reactions, especially after the second dose. **The failure to evaluate the inherent toxicity of the spike protein, and thus violate the prime principle of toxicology, precludes the statement that the vaccines are safe.**

This begs the essential question: is the spike protein inherently toxic and is this toxicity dependent on the dose (level or titer) achieved? The fundamental rule in toxicology is “the dose makes the toxin.” (*The Dose Makes the Poison Concept | Toxicity*, 2022).³⁴ The exact quote is from Paracelsus who said, “All things are poison, and nothing is without poison; only the dose makes a thing not a poison.” Why is this important? **The failure to account for variation in dose and the difference in biological effect of the level of spike protein attained precludes a statement as to the safety of the vaccine for general use.** The failure to assess the effect of the spike dependent on the level obtained strikes at the very heart of the principle of toxicology. If the vaccine induces a spike protein level several thousand times that of a natural infection, then the biological effect, “the toxin”, is likely to be profoundly different.

There are two issues at hand: the safety of the vaccine if it induced such a high level of spike protein and the efficacy of that antibody response. The spike protein is toxic to endothelial cells and to the blood brain barrier,

³³Ibid

³⁴ *The dose makes the poison concept | toxicity*. (2022, March 25). ChemicalSafetyFacts.Org. Retrieved April 30, 2022, from <https://www.chemicalsafetyfacts.org/dose-makes-poison-gallery/>

without being part of the coronavirus. (Theoharides & Conti, 2021)³⁵, (Dinetz, 2022)³⁶, (S et al., 2022)³⁷ This is the exact condition found with mRNA vaccination. **Pfizer did not investigate the level of spike protein but only the neutralizing antibody response to the spike protein. The antibody response was equated to the effectiveness of the vaccine. This was never proven but taken as established fact.** Many researchers pointed out that natural infection induced a T cell immunity not achieved by vaccination and measurement of the antibody response was insufficient to demonstrate immunity.

The spike protein consists of 2 subunits, called S1 and S2. S1 contains the RBD or Receptor Binding Domain that binds the ACE2 receptor. It is the target of the mRNA vaccine. (Dinetz, 2022)³⁸ (S et al., 2022)³⁹ S1 is removed from the spike protein to allow activation of the S2 subunit which will allow the virus to fuse with the cell. The S1 subunit is then released into the circulation and ends up in an immune cell called a macrophage. In normal time, the job of the macrophage is to clean up the mess left after an immune response. But if the macrophage eats the S1 subunit, like Dr. Jekyll and Mr. Hyde, it transforms from short-lived cell that controls inflammation (the Dr. Jekyll) to a monstrous Mr. Hyde, that lives for a long time and initiates a vascular inflammatory response (Shirato & Kizaki, 2021).⁴⁰ In turn, this initiates an inflammatory response against the endothelial cells, the cells that line the blood vessels, and results in an endothelialitis (Rotoli et al., 2021)⁴¹ and vasculitis (Kar et al., 2021).⁴²

Since the 1950's and the disastrous experience with thalidomide that was used during pregnancy, along with knowledge of the rapid tissue development that occurs with pregnancy, the adage has been to avoid every known noxious substance (such as alcohol and smoking) during pregnancy. As defects may be subtle and take years to manifest, normal vaccination evaluation requires years of follow up. **During the Pfizer safety evaluation, no pregnancy evaluation is done. It was impossible to declare the vaccine safe for pregnant women.** Later studies purported to show the safety of vaccination, but a close evaluation of the data showed a high abortion rate, if the vaccine was delivered before the 20th week (Shimabukuro et al., 2021)⁴³. Yet, many women were not

³⁵Theoharides, T. C., & Conti, P. (2021). Be aware of SARS-CoV-2 spike protein: There is more than meets the eye. In *J Biol Regul Homeost Agents* (Vol. 35, pp. 833-838). Copyright 2021 Biolife Sas. www.biolifesas.org. https://doi.org/10.23812/theo_edit_3_21

³⁶Dinetz, E. (2022). Case Series of Three Neurological Side Effects in Younger-Aged Individuals After Pfizer's mRNA Vaccine. *Cureus*, 14(4), e23779. <https://doi.org/10.7759/cureus.23779>

³⁷S, N. N., B, N. R., C, P., K, S. S., Ramakrishnappa, T., B, T. K., . . . Chandaragi, S. S. (2022). SARS-CoV 2 spike protein S1 subunit as an ideal target for stable vaccines: A bioinformatic study. *Mater Today Proc*, 49, 904-912. <https://doi.org/10.1016/j.matpr.2021.07.163>

³⁸ Dinetz, E. (2022). Case Series of Three Neurological Side Effects in Younger-Aged Individuals After Pfizer's mRNA Vaccine. *Cureus*, 14(4), e23779. <https://doi.org/10.7759/cureus.23779>

³⁹ S, N. N., B, N. R., C, P., K, S. S., Ramakrishnappa, T., B, T. K., . . . Chandaragi, S. S. (2022). SARS-CoV 2 spike protein S1 subunit as an ideal target for stable vaccines: A bioinformatic study. *Mater Today Proc*, 49, 904-912. <https://doi.org/10.1016/j.matpr.2021.07.163>

⁴⁰Shirato, K., & Kizaki, T. (2021). SARS-CoV-2 spike protein S1 subunit induces pro-inflammatory responses via toll-like receptor 4 signaling in murine and human macrophages. *Heliyon*, 7(2), e06187. <https://doi.org/10.1016/j.heliyon.2021.e06187>

⁴¹Rotoli, B. M., Barilli, A., Visigalli, R., Ferrari, F., & Dall'Asta, V. (2021). Endothelial Cell Activation by SARS-CoV-2 Spike S1 Protein: A Crosstalk between Endothelium and Innate Immune Cells. *Biomedicines*, 9(9). <https://doi.org/10.3390/biomedicines9091220>

⁴²Kar, B. R., Singh, B. S., Mohapatra, L., & Agrawal, I. (2021). Cutaneous small-vessel vasculitis following COVID-19 vaccine. In *J Cosmet Dermatol* (Vol. 20, pp. 3382-3383). <https://doi.org/10.1111/jocd.14452>

⁴³ Shimabukuro, T. T., Kim, S. Y., Myers, T. R., Moro, P. L., Oduyebo, T., Panagiotakopoulos, L., . . . Meaney-Delman, D. M. (2021). Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*, 384(24), 2273-2282. <https://doi.org/10.1056/NEJMoa2104983>

informed of the lack of safety evaluation. Reports in VAERS show infant death following maternal vaccination if the infant was breast fed.

So, is the vaccine safe? How would one know? There is no testing of penetration of the blood-brain barrier. There is no testing of pregnant women. There is no testing as to whether the spike protein itself may have noxious effect. The failure to indicate PEG and emulsifiers as components of the vaccine, certainly make it unsafe for those who have such allergies.

COVID-19 was declared to be an emergency. This was used to justify the lifting or sidestepping of normal safeguards that dictate vaccine development. As our understanding of the disease evolved, it rapidly became evident that it was only a risk to the elderly and the obese. We were promised a vaccine to prevent disease and thereby protect our vulnerable population. This was an admirable goal if the vaccine prevented infection. During the Pfizer Efficacy Trials, it unequivocally demonstrated that the vaccine did not prevent infection. Of the 40,000 plus participants in the trial, only 170 were evaluated for efficacy of the vaccine. Of these 170 in primary efficacy results ([Table 5 Page 36](#)), 8 were fully vaccinated and developed the disease, while 162 of the placebo group developed the disease.

During the trials, many patients were unblinded. Given the small number of patients evaluated for efficacy of the vaccine, any unblinding is likely to have altered the results. During the trial, approximately 400 participants did not receive the second dose, and another 400 participants were not fully vaccinated. ([Table 48 Page 145](#)) The explanation for this is incomplete. It suggests that many participants had sufficient adverse reactions to drop out of the trial or avoid the second dose.

The small number of evaluated patients, the lack of clarity over unblinding and its effect on evaluation of efficacy strongly suggests that at best, the results are compromised and an example of self-deception, and at worst, an overt act of fraud. This raises the additional question: of the 20,000 placebo participants, only 162 developed disease! How much of an emergency could this virus be?

During the trials it was also evident that between 5% and 20% of the population was already infected with COVID-19. This large number of infections indicated that lockdowns would be ineffective at controlling the disease. In a recent interview with Dr. Anthony Fauci, he acknowledged this fundamental truth of immunology and epidemiology. Dr. John Ioannidis, an eminent epidemiologist from Stanford University, early in the pandemic, told us that at least 5% of the population was already infected (and by implication, any lockdown would be ineffective). The three main authors of the Great Barrington Declaration, eminent and world-renowned epidemiologists told us so, and how best to address the issue.

The conclusions are evident. There are two types of sins: the overt sin of commission and the occult sin of omission. The overt sin of commission is blatant lying. The occult sin of omission is more subtle but aptly summed up as “lying with the truth”. Both were committed by Pfizer, Moderna and public health authorities.

There was no evaluation of vaccine penetration on the brain or distant organs, such as the ovary, or whether it passed through the placenta to the baby in the mother’s womb, or in her breast milk to her infant. The evaluation of spike protein in the blood with the formation and effect of high levels of IgG antibody as a cause of Type III immunological injury was never done.

The failure to point out the deficiencies of the study that were likely to alter the results was never done. In the absence of such evaluation, it is impossible to conclude that the vaccine was safe. The vaccine was never demonstrated to be effective or efficacious. The vaccine did not prevent disease. And the disease itself was nowhere near as big a threat to population as promoted by public health authorities and echoed in the chambers of the media.

Report 6: [“COVID-19 Vaccines and Pregnancy: Risky Business”](#) Team 1.

To date there have not been any human clinical trials conducted by a COVID-19 vaccine pharmaceutical company to determine if vaccines are safe during pregnancy or while breastfeeding. All Emergency Use Authorizations (EUA’s) exclude pregnant women and no COVID-19 vaccine has been approved for use during pregnancy. Astonishingly, however, many professional medical organizations have strongly advocated for their use during pregnancy despite the lack of any safety data. Unfortunately, as more pregnant women have been vaccinated, serious adverse events are being exposed in both Pfizer documents and in the Department of Defense (DOD) medical database.

Thanks to a court ordered release of confidential Pfizer documents (the FDA wanted these documents sealed for 75 years) we have learned that pregnant women and breastfeeding mothers were excluded from phase 1, 2 and 3 of the human trials. One recently released Pfizer document lists 21 groups of people who were excluded from all phases of the Pfizer trials and specifically singles out “women who are pregnant or breastfeeding” as not able to participate in any of the trials https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf (Annotated Study Book for Study Design: C4591001 Study Design Version: 11.0, 2020, Page 33 item 2.h 11, exclusion 11A00 under exclusion criteria).

Despite this, organizations such as the American College of Obstetrics and Gynecology (ACOG) and The Society for Maternal-Fetal Medicine (SMFM) are strong advocates for vaccinating pregnant and lactating women. In an unprecedented manner, ACOG persistently advocated for pregnant women to get vaccinated while acknowledging in their clinical guidelines that “none of the COVID-19 vaccines approved under EUA have been tested in pregnant individuals.” <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care> So how could they possibly be promoting an experimental and untested vaccine for pregnant women? As it turns out their clinical recommendations are based on a faulty study conducted on a few dozen rats in France.

Before any research trials can be performed on human pregnant women, a new drug must first be tested on pregnant animals. These are called Developmental and Reproductive Toxicity or (DART) studies. In ACOG’s clinical guidelines, they stated that the “DART studies for the Pfizer-BioNTech COVID-19 vaccine have been reported in Europe... According to the report animal studies using the Pfizer/BioNTech COVID-19 vaccine do not indicate direct or indirect harmful effects with respect to

pregnancy, embryo/fetal development, parturition, or postnatal development.”

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care>

So we see that their confidence in the safety of the Pfizer vaccine is based solely on animal studies. Given the extreme importance of studying the effects of a new vaccine technology on pregnant women and their offspring; one would expect this study to be conducted by independent researchers using a robust design that answers fundamental questions. Questions like were there any congenital abnormalities or developmental issues in the offspring and were there any long-term effects on fertility?

After a review of this study, it is astounding to discover that it was performed on a mere 44 rats and for a length of only 42 days! <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8163337/> To their credit it turns out that rats are the perfect mammal to do pregnancy studies on because they only need 21 days from conception to delivery. Half of the rodent pregnancies were terminated at day 21 via cesarean section and the fetuses were removed from the mother. All were euthanized and then anatomically studied. The other half were allowed to deliver naturally and then were monitored until they were weaned at 21 days of age when the rest were euthanized. This is long before any developmental issues could have been observed in the offspring and precludes any long-term safety or fertility studies of the mothers or their offspring. The effects on fertility in this study were determined by dissection and examination of the ovaries of the mother rats who were fully mature at the time of vaccination.

After this 42-day study on 44 pregnant rats they concluded that there were “no effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, mRNA-based COVID-19 vaccine.” Thus, supposedly, the prerequisite for a DART study was complete. However, there are at least two glaring problems with this study.

First, it does not fulfill the requirements of a DART study, which is “to detect any effects of a drug within a complete reproductive cycle as relevant to humans: from initial conception to reproductive capacity in the next generation.” There is no way to know if any adverse effects on the development of those newborn rats occurred, let alone to know if their reproductive capacity (fertility) was altered.

Second, there was a significant conflict of interest with the studies’ investigators. The “Declaration of Competing Interest” disclaimer at the bottom of the publication reveals that nine out of ten of the authors of the study were employed by and held stock in either Pfizer or BioNTech. There is no way these investigators could be unbiased; they all had a vested interest in a positive outcome for vaccine trials to move forward. Any negative result would have put a complete halt to any human

clinical trial. It would seem they hid this fact as best they could. These are the authors listed at the top of the article: Christopher J. Bowman, Marie Bouressam, Sarah N. Campion, Gregg D. Cappon, Natasha R. Catlin, Mark W. Cutler, Jan Diekmann, Cynthia M. Rohde, Rani S. Sellers, and Claudia Lindemann.

There is a disclaimer listed at the very bottom on the last page of the article. It only uses initials, so it is easy to miss. Compare the initials from the disclaimer at the very end to the authors listed at the beginning.



Despite this, pregnant women in the United States were encouraged to get vaccinated based on an extremely limited DART animal study that had obvious conflicts of interest. These women, likely out of fear of COVID-19 and with the reassurance of the CDC, FDA, and medical professional organizations, received the vaccine. By the end of 2020 and into 2021, thousands of pregnant women received vaccinations during pregnancy with no EUA approval.

It is notable that even with all the organizations promoting vaccination during pregnancy, the World Health Organization recommended against it until at least January of 2021. Now they don't recommend against it but instead recommend that pregnant women should weigh the potential risks against the benefits, while simultaneously admitting that there is no long-term safety data available. Either way, since the vaccines have been broadly deployed a great deal of data has been compiled.

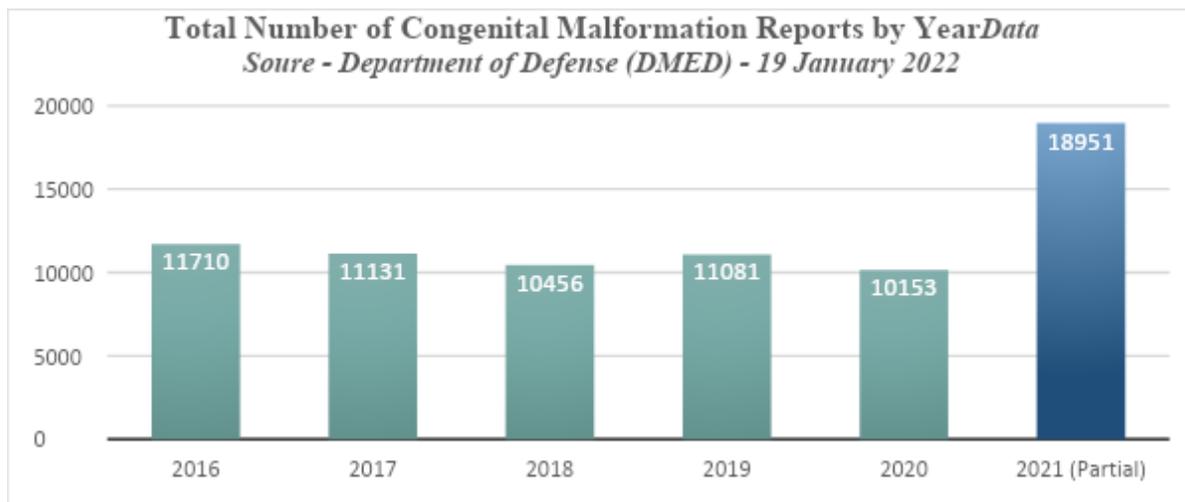
So, what does the "safety data" that has been collected on mRNA COVID-19 vaccinated pregnant women show? The FDA requires Pfizer to collect any publicly available data on adverse events related to vaccination once it goes to market. Confidential document (5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports) contains case reports for the first 68 days of vaccine rollout (from 12/20/2020 to 2/28/2021). The section covering pregnancy and lactation on pages 12-13, reveals that 20% of the 413 reported cases of adverse events were "serious." These included 25 miscarriages, 5 fetal deaths as well as uterine contractions during pregnancy, preterm deliveries, premature rupture of membranes and fetal growth restriction. Also included were serious and less serious adverse side effects of breast-fed babies that included infantile vomiting, fever, rash, agitation, and allergy to the vaccine.

There were also 6 cases of women having adverse events who received COVID-19 vaccine while breast feeding; some of these include paresis (partial paralysis), suppressed lactation, breast pain, migraines and breast milk discoloration. Pfizer’s response to the above alarming data was, “There were no safety signals that emerge from the review of these cases of use in pregnancy and while breast feeding.”

Probably the largest and most reliable health database on overwhelmingly healthy and fit military personnel is collected by the Department of Defense (DoD). This has recently been exposed by three whistleblowers represented by Attorney Thomas Renz.

<https://health.mil/Military-Health-Topics/Combat-Support/Armed-Forces-Health-Surveillance-Division/Data-Management-and-Technical-Support/Defense-Medical-Epidemiology-Database> They observed disturbing evidence of dramatic increases in serious medical conditions among military personnel in 2021, correlating directly with the roll out of COVID-19 vaccines. Among the numerous conditions listed are congenital malformations.

The rise in congenital malformations increased dramatically from a baseline rate of 10,906 cases per year, to 18,951 for only part of the year in 2021.



Having shown that there is significant risk involved in taking the vaccine when pregnant, let’s now consider the supposed benefits touted by the NIH, CDC and others.

The NIH says “The COVID-19 Treatment Guidelines Panel recommends against withholding treatment for COVID-19 and SARS-CoV-2 vaccination from pregnant or lactating individuals because of *theoretical safety concerns (AIII)*” (emphasis added). The (AIII) at the end is important. “A” indicates they strongly recommend this and “III” indicates the lowest available rating for evidence used, which is “Expert opinion.” <https://www.covid19treatmentguidelines.nih.gov/special-populations/pregnancy>

The CDC says, “Limited information suggests that pregnant women with COVID-19 might be at

increased risk for severe illness compared with nonpregnant women”.

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6944e3.htm> The word “suggests” has a specific meaning in this statement: “The word “suggested” is used when the strength and direction of the results are unified, but results do not achieve statistical significance.”

<https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/systematic-review-process.html>

In layman’s terms the NIH is saying that they strongly suggest that pregnant women be vaccinated for COVID-19 based upon the recommendation of “expert opinion” from groups such as ACOG and SMFM alone, not based on any reliable evidence from one or more randomized trials without major limitations. And we know that ACOG’s “expert opinion” relied heavily upon the limited Pfizer-BioNTech DART study. The CDC is acknowledging that there is limited information supporting the claim that pregnant women with COVID-19 might be at increased risk for severe disease compared with non-pregnant women because the study results claiming this risk cannot prove statistical significance to back up that claim.

The evidence is clear that the potential risks of pregnant women getting vaccinated with the new mRNA COVID-19 vaccines far outweigh the touted yet unproven benefits. The alarming safety signals revealed in the Pfizer documents and DOD database along with the lack of any long term safety data overwhelmingly leads to the conclusion that getting vaccinated during pregnancy is a Risky Business... *Risky* for the people getting vaccinated and big *Business* for the pharmaceutical industry.

Report 7: “What Did Pfizer Know, and When Did They Know It? Vast Neurological Harms Concealed.” Team 4.

By a DailyClout/War Room Pfizer Documents Analysis Project volunteer who wishes to remain anonymous

This report assists in answering, “What did Pfizer know, and when did they know it?” concerning its COVID-19 vaccine. The report focuses on neurological complaints post-injection with the Pfizer COVID-19 vaccine, as well as on several other, non-neurological reported symptoms.

The information presented comes from the Centers for Disease Control and Prevention (CDC) Wonder website ([CDC.Wonder.gov](https://wonder.cdc.gov)) through which anyone can access CDC’s VAERS system. VAERS is a reporting system for vaccine manufacturers, health care providers, and the general public to notify the CDC of issues, injuries, symptoms, any problem with a vaccine.

The Vaccine Adverse Event Reporting System (VAERS) provides answers to what Pfizer knew about vaccine injuries resulting from its COVID-19 vaccine and when they knew it. The purpose of VAERS is to alert Pfizer, the CDC, and the Food and Drug Administration (FDA) to safety signals requiring investigation.

Below are seven screenshots of six VAERS reports obtained directly from the VAERS system.

1) The first screenshot shows reports of deaths and headaches reported by those vaccinated in January, February, and March of 2021. The mass vaccination of Americans had just started in that time frame. VAERS reports from the first three months gave Pfizer, the CDC and the FDA critical safety signal information to act upon, though they chose not to address the clear safety signals.

This screenshot shows 3,385 deaths reported in three months, as well as 27,084 headaches which will be elaborated upon in another screenshot.

[<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=6227282DDE2B9107FA07D6EF49E0>]

The Vaccine Adverse Event Reporting System (VAERS) Results

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Messages:

- ▶ **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- ▶ **These results are for 28,465 total events.**

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↑↓	Percent (of 28,465) ←
DEATH	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	893	3.1
				Feb., 2021	1,357	4.8
				Mar., 2021	1,135	3.9
				Total	3,385	11.8
			Total	3,385	11.8	
HEADACHE	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	10,374	36.5
				Feb., 2021	6,690	23.5
				Mar., 2021	10,020	35.2
				Total	27,084	95.1
			Total	27,084	95.1	
Total	30,469	107.0				

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Figure 1: Deaths & headaches from COVID vaccine January through March of 2021 reported in VAERS screenshot

2) The second screenshot presents five categories of serious neurological complaints reported in January, February, and March of 2021: 900 cases of Bell's Palsy; 880 Cerebrovascular Accidents (CVA), also known as stroke; 138 reports of Guillain-Barre Syndrome; 118 reports of paralysis; and 175 of Transient Ischemic Attack (TIA), which is a temporary period of symptoms similar to – but not as severe as – those of a stroke.

[<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6>]

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↑↓
BELL'S PALSY	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	227
				Feb., 2021	263
				Mar., 2021	410
				Total	900
			Total	900	
CEREBROVASCULAR ACCIDENT	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	193
				Feb., 2021	314
				Mar., 2021	373
				Total	880
			Total	880	
GUILLAIN-BARRE SYNDROME	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	28
				Feb., 2021	50
				Mar., 2021	60
				Total	138
			Total	138	
PARALYSIS	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	26
				Feb., 2021	39
				Mar., 2021	53
				Total	118
			Total	118	
TRANSIENT ISCHAEMIC ATTACK	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	36
				Feb., 2021	60
				Mar., 2021	79
				Total	175
			Total	175	
Total					2,211

Figure 2: Bell's palsy, CVA, Guillain Barre, TIA from COVID vaccine January through March of 2021 reported in VAERS screenshot

3) Below are the results for three more categories of major neurological symptoms reported in January, February, and March of 2021 — 19 reports of Amyotrophic Lateral Sclerosis (ALS), a progressive nervous system disease that affects nerve cells in the brain and spinal cord, causing loss of muscle control; 50 reports of Multiple Sclerosis; and 656 seizures.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6)

The Vaccine Adverse Event Reporting System (VAERS) Results

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Messages:

▶ **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**

▶ **These results are for 667 total events.**

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↕	Percent (of 667) ←
AMYOTROPHIC LATERAL SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	11	1.6
				Feb., 2021	3	0.4
				Mar., 2021	5	0.7
				Total	19	2.8
			Total	19	2.8	
MULTIPLE SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	10	1.5
				Feb., 2021	12	1.8
				Mar., 2021	28	4.2
				Total	50	7.5
			Total	50	7.5	
SEIZURE	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	145	21.7
				Feb., 2021	165	24.7
				Mar., 2021	346	51.8
				Total	656	98.3
			Total	656	98.3	
Total					725	108.7



Figure 3: ALS, MS, Seizure from COVID vaccine January through March of 2021 reported in VAERS screenshot

4) While CVA and TIA, shown in the second screenshot above, are neurological complaints, they are caused by blood clots in the brain. Therefore, reviewing several other symptoms also caused by blood clotting issues is pertinent. The screenshot below shows reports of 294 Acute Myocardial Infarction (i.e., acute heart attack), 584 Deep Vein Thrombosis (DVT), and 790 Pulmonary Embolism in January, February, and March of 2021.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=51F5E583E6AEF7AE1A6A1BDCFD1B\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=51F5E583E6AEF7AE1A6A1BDCFD1B)

Messages:

- ▶ **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- ▶ **These results are for 1,549 total events.**

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↕	Percent (of 1,549) ←
ACUTE MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	52	3.3
				Feb., 2021	94	6.0
				Mar., 2021	148	9.5
				Total	294	18.9
			Total	294	18.9	
DEEP VEIN THROMBOSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	123	7.9
				Feb., 2021	188	12.1
				Mar., 2021	273	17.6
				Total	584	37.7
			Total	584	37.7	
MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	85	5.4
				Feb., 2021	108	6.9
				Mar., 2021	189	12.2
				Total	382	24.6
			Total	382	24.6	
PULMONARY EMBOLISM	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	163	10.5
				Feb., 2021	267	17.2
				Mar., 2021	360	23.2
				Total	790	51.0
			Total	790	51.0	
Total					2,050	132.3



Figure 4: Acute myocardial infarction, pulmonary embolism, DVT from COVID vaccine January through March of 2021 reported in VAERS screenshot

5) The following screenshot shows that there were no reports of Acute Myocardial Infarction, death, and Pulmonary Embolism from 2015 through 2019 after receiving *any* Pfizer vaccine, prior to the COVID-19 vaccine debuted. Hundreds of Pfizer vaccines are listed in the VAERS system for 2015-2019. Yet, no one reported incidences of Acute Myocardial Infarction, death, or Pulmonary Embolism after receiving a Pfizer vaccine during those five years.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=033107A2EA6A73EEDFA7EDAA68BE\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=033107A2EA6A73EEDFA7EDAA68BE)

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Messages:

- ▶ No non-zero results were found for your query. Use Quick Options above to show zero rows.
- ▶ You can also check for Caveats in the Notes section; they might contain information about why only non-zero results were returned.
- ▶ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▶ These results are for 0 total events.

Symptoms ↓	Vaccine Manufacturer	Year Vaccinated	Events Reported ↑↓	Percent (of 0) ↑↓
ACUTE MYOCARDIAL INFARCTION	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
DEATH	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
PULMONARY EMBOLISM	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
Total		0	0.00%	



Figure 5: Death, Acute myocardial infarction, pulmonary embolism from all Pfizer vaccines reported in VAERS 2015-2019 screenshot

6) These final two screenshots show the first and last pages of a VAERS request for all symptom complaints in VAERS for *all* Pfizer vaccines administered from 2015 through 2019, before the COVID-19 vaccine was available. The total of reported symptoms complaints was only 559 for those five years. In contrast, there were 584 reports of Deep Vein Thrombosis in just the first three months of 2021, all related to Pfizer's COVID-19 vaccine. The most frequent complaints in this report before 2020 were for headaches, weakness, and muscle pain, all with less than 20 examples. In contrast, as shown in Figure 1 above, there were 27,000 headaches reported in association with Pfizer's COVID-19 vaccine. [<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=8EE87DA751B1EC168FBD8432A2E6>]

THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) RESULTS

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Messages:

- ▶ The full results are too long to be displayed, only non-zero rows are available.
- ▶ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▶ These results are for 86 total events.

Symptoms ↓	Vaccine Manufacturer	Year Vaccinated	Events Reported ↑↓	Percent (of 86) ↑↓
ABDOMINAL DISCOMFORT	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ABDOMINAL PAIN	PFIZER\BIONTECH	2019	3	3.49%
		Total	3	3.49%
	Total	3	3.49%	
ABDOMINAL PAIN LOWER	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ABDOMINAL PAIN UPPER	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ACOUSTIC STIMULATION TESTS	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ACOUSTIC STIMULATION TESTS ABNORMAL	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
AGEUSIA	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ALOPECIA	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	

f | | | in | |

Figure 6: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, first page of report

VISION BLURRED		Total	1	1.16%
	Total		1	1.16%
VISUAL IMPAIRMENT	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
VITAMIN D	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
VOMITING	PFIZER\BIONTECH	2017	1	1.16%
		2018	1	1.16%
		2019	2	2.33%
		Total	4	4.65%
	Total		4	4.65%
WEIGHT	PFIZER\BIONTECH	2018	1	1.16%
		2019	1	1.16%
		Total	2	2.33%
	Total		2	2.33%
WEIGHT DECREASED	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
WEIGHT INCREASED	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
WOUND	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
X-RAY	PFIZER\BIONTECH	2016	1	1.16%
		2019	2	2.33%
		Total	3	3.49%
	Total		3	3.49%
X-RAY LIMB	PFIZER\BIONTECH	2016	1	1.16%
		2019	1	1.16%
		Total	2	2.33%
	Total		2	2.33%
Total			559	650.00%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the



Figure 7: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, last page of report

Steve Kirsch noted, “The CDC knew in January 2021 that the vaccines were unsafe, but they said nothing.” [<https://stevekirsch.substack.com/p/the-cdc-knew-in-january-2021-that?s=r>] The evidence identified from VAERS that has been identified in the reports shows conclusively that Pfizer, the CDC, and the FDA knew that severe neurological and blood clotting harms were resulting from the mRNA vaccines on grand scale. To date, they remain silent and are not taking action to stop the life-altering and sometimes fatal outcomes from Pfizer’s COVID-19 vaccine.

Report 8: “Why Was the Pfizer COVID-19 Vaccine Recommended for Use in and Administered to Children When It Was Not Tested in That Age Group?” Team 1.

Thanks to a court ordered release of confidential Pfizer documents we have learned that 21 groups of individuals were excluded from phase 1, 2 and 3 of their human trials. Children under the age of 18 were one of these excluded groups. https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf (Annotated Study Book for Study Design: C4591001 Study Design Version: 11.0, 2020, Page 33).

Despite this exclusion criteria, many children were given the vaccine anyway. Why was the vaccine recommended for use in and administered to children when it was never tested in that age group? In Pfizer document 2.5.4 Summary of Clinical Safety, dated May 5, 2020, it states on page 294, “Further study of pediatric use of the vaccine and/or immunobridging study will be undertaken to characterize the vaccine response in children.” Immunobridging is the extrapolation of the safety and efficacy results of one study group to another. One must ask then, can the results of studies done only on individuals over the age of 18 be extrapolated to children under 18 with any degree of certainty?

The Pfizer COVID-19 vaccine was first authorized for Emergency use only in healthy adults aged 19-80 on December 11, 2020. In the three months following the EUA, Pfizer reported 175 cases of adverse events in adolescents and children under age 17. Thirty-four of these cases were in children under the age of 12.

The Vaccine Adverse Events Reporting System (VAERS) database is maintained by the FDA. The VAERS database relies on self-reported information and because there is no systematic way to gather data for every possible case of an adverse event that occurred, it is well known that adverse events are largely underestimated by the methods in current use. Keeping in mind that the VAERS data represents only a fraction of the actual adverse events, what did the data show in the children who first received the vaccine without any authorization? In the United States alone, in 2021 there were 313 serious events reported in children aged 6-17 resulting in 37 deaths. There was also 1 report of a serious adverse event in a child aged 3-5 which resulted in the death of that child.

Why would any Pediatrician recommend that their patients be vaccinated prior to any vaccine trials in children? It seems that they are viewing this new mRNA vaccine as similar to all other childhood vaccines and even recommend combining it with the other well established and thoroughly tested childhood immunizations. Observe what the

American Academy of Pediatrics (AAP) recommends. This information appears on the American Academy of Pediatrics website: (*Pediatrics* (2021) 148 (2): e2021052336. <https://doi.org/10.1542/peds.2021-052336>)

“The American Academy of Pediatrics (AAP) recommends the following related to coronavirus disease 2019 (COVID-19) vaccine in children and adolescents:

- *Given the importance of routine vaccination and the need for rapid uptake of COVID-19 vaccines, the AAP supports coadministration of routine childhood and adolescent immunizations with COVID-19 vaccines (or vaccination in the days before or after) for children and adolescents who are behind on or due for immunizations (based on the CDC and AAP Recommended Child and Adolescent Immunization Schedule) and/or at increased risk from vaccine-preventable diseases.”*

In these recommendations which were published in August of 2021, the AAP supports co-administration of routine childhood and adolescent immunizations with COVID-19 vaccines. At that point, the Pfizer vaccine had never been formally tested in circumstances where it was administered simultaneously with other routine child and adolescent vaccines.

Could the COVID-19 vaccine alter the ability of the other vaccines to produce adequate immunity to the diseases that they are targeted to prevent such as measles, mumps, rubella, etc. when co-administered with COVID-19 vaccines?

On January 16, 2022 the peer reviewed journal of Influenza and Other Respiratory Viruses ([\(Influenza Other Respiratory Viruses\)](#) 2022 Jan; 16(1): 3–6. Published online 2021 Oct 3. doi: ([10.1111/irv.12917](#)) reported:

“The US CDC has recently recommended that routine vaccines could be co-administered with authorized COVID-19 vaccines, in order to facilitate the catch-up of missed immunizations. *This public health decision was not based on new clinical trial evidence but on the accumulated safety experience of the currently authorized COVID-19 vaccines in millions of recipients, albeit over a relatively short time frame, and the previous experience of safe and effective administration of multiple antigens simultaneously.*

Safety data on the coadministration of influenza and COVID-19 vaccines are currently being acquired.

As COVID-19 vaccines are further studied and potentially authorized for young children and infants, careful consideration and evidence for safe and effective coadministration with influenza and other routine vaccines is in children also warranted. As the available data to date indicate that coadministration of vaccines is a viable approach, there is benefit in continuing to generate more data to support this as it would facilitate the catch-up of missed vaccinations and would also expedite an efficient outcome for dual protection against influenza and COVID-19.”

Note that the endorsement of co-administration of COVID-19 vaccine and other routine childhood and adolescent vaccines was published by the American Academy of Pediatrics in August 2021 while in the article published in January 2022 in the *Influenza and Other Respiratory Viruses* journal states that sufficient data *does not yet exist* to establish the safe and effective coadministration with influenza and other routine vaccines in children and that more data is needed.

The same article also states that the CDC recommendation is based upon “previous experience of safe and effective administration of multiple antigens simultaneously”.

While it may be true that other antigens can be administered safely and effectively such as the combination vaccine of measles, mumps, and rubella, the mRNA vaccines employ a completely different mechanism in the development of antigenicity than any other vaccine that has been developed to date. Can we really assume that the same safety and effectiveness profile exists for this brand-new mRNA vaccine when compared to those in the past? It seems to me that one is comparing apples to an orange.

The families of 38 dead children cry out for a stop to this unscientific comparison.

Report 9: "Even Big Pharma CEOs recognized that not everyone could be vaccinated - so why Vaccine Mandates?" by Chris Flowers, M.D. – Team 1.

Recently, Project Veritas revealed that the CEO of AstraZeneca, Pascal Soriot, told his company in a Zoom call in Dec 2020 that not everyone could be vaccinated; Soriot identified the immune-compromised and people with multiple sclerosis as examples of those who should not be vaccinated with mRNA vaccines. He raised this issue in the context of explaining that the company AstraZeneca had a great opportunity in the marketplace — to make antibody treatments for those vulnerable populations, treatments, that is, which could give protection to those who should not be vaccinated.

(<https://www.projectveritas.com/news/astrazeneca-source-recording-from-2020-shows-ceo-pascal-soriot-saying>).

Project Veritas broke the story on April 19, 2022, where Soriot admits that immunocompromised populations should not consider the AstraZeneca vaccine safe.

YouTube also has this incriminating video - <https://www.youtube.com/watch?v=Lk00JwZwE5g>).

Soriot's comments were contradictory to remarks about the safety of the vaccine for immunocompromised people made by the World Health Organization (WHO) at the time. More recently, on March 16, 2022, a Health Advisory from the WHO restated the assertion that the vaccine was SAFE for immunocompromised individuals.

(<https://www.who.int/multi-media/details/who-press-conference-on-covid-19-ukraine-and-other-emergencies---16-march-2022> - Time marker: 39 mins). Those statements appear to give false assurance.

There have been serious problems with the AstraZeneca vaccine even for the general population. AstraZeneca is the maker of one of the main COVID vaccines used in Europe, which along with Johnson and Johnson's (Janssen vaccine) has been plagued with reports of the vaccines' causing small vessel blood clots:

(<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html#ingredients>)

In admitting the fact that vaccine-induced immunity is not viable for immunocompromised patients, AZ saw the commercial opportunity to develop and manufacture monoclonal antibodies against the S (SPIKE) protein. This is the important argument that they make, in stark contrast to the CDC and FDA pronouncements in the USA where vaccine mandates were National Policy, that you cannot produce antibodies to a vaccine if you are immunocompromised and need to have a different source of antibodies.

Why should this matter in the US?

AstraZeneca (AZ), like Johnson and Johnson, used a conventional approach of a modified viral vector (rather than using mRNA) for producing immunity. AZ recognized the issues this would create with patients whose natural immunity was depressed due to illness or to chemotherapy drugs (a state known as being 'immunocompromised').

So why weren't Monoclonal antibodies the first line of attack against COVID?

Steps were taken by several States, who targeted their vulnerable populations with protective efforts (such as closing visits to care homes in the early days), and purchased monoclonal antibodies to use in the fight against COVID. Vaccines were not available until late November 2021.

Patients with a compromised immune system could have their immunity provided by externally administered antibodies.

Antibodies from patients who had recovered from COVID, known as Convalescent Plasma was first approved by the FDA in August 2020.

<https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

In November, 2021, the FDA approved the first two monoclonal antibody treatments manufactured by Regeneron Pharmaceutical Inc. (Casirivimab and Imdevimab)

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>

Subsequently monoclonal antibodies became one of the important mainstays of treatment in a number of US States, where the priority was to protect the vulnerable population, rather than to make use of a 'one size fits all' vaccine treatment.

So why mandate a vaccination for 100% of the population if vaccination is NOT effective for immunocompromised patients?

If the CEOs of Vaccine Manufacturers can recognize the lack of effectiveness in part of the population, why do the CDC/FDA as well as W.H.O. continue to advocate for additional boosters for these patients? In view of the serious side effects of the mRNA vaccines already known, why are they still being mandated?

The only conclusion that I can come to is that vaccine mandates are both unwise and downright wrong

Recording of AstraZeneca CEO Pascal Soriot 'Millions of [Immunocompromised] People Can't Be Vaxxed': <https://www.youtube.com/watch?v=Lk00JwZwE5g>

Report 11: [“PFIZER VACCINE: FDA Fails to Mention Risk of Heart Damage in Teens”](#) by Chris Flowers, M.D. – Team 1.

BOMBSHELL: FDA MUST HAVE KNOWN THAT MYOCARDITIS IN TEENS WAS A RISK WHEN THEY ISSUED THE EMERGENCY USE AUTHORIZATION THAT DID NOT MENTION IT.

In a paper published in pre-print last week (25th March, 2022) in the Journal of Pediatrics [https://www.jpeds.com/article/S0022-3476\(22\)00282-7/fulltext#%20](https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext#%20) Shauer et al. from the Seattle Children’s Hospital at the University of Washington:

Report on their findings of 35 cases of myocarditis in children within one week after receiving the second dose of the Pfizer mRNA vaccine.

They present the evolution of changes on Cardiac MRI (Magnetic Resonance Imaging)

1) Myopericarditis has emerged as an important adverse event following COVID-19 mRNA vaccination, particularly in adolescents. This affects both the lining of the heart (pericardium) and the cardiac muscle (myocardium) itself. [Ref: Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, et al. Morbidity and Mortality Weekly Report Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices-United States, June 2021 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8312754/>]

The report acknowledged the risks of myocarditis post vaccine, but still recommended vaccination to everyone.

This initial report established the serious problem of myopericarditis in adolescents following MRNA vaccination was published in June 2021.

June 2021 was one month AFTER the FDA received the priority review for an EUA for 16 years and older to receive the mRNA vaccine.

[125742 S1 M1 priority-review-request-1](#) (released March 24, 2022)



REQUEST FOR PRIORITY REVIEW

COVID-19 Vaccine (BNT162, PF-07302048)

BLA 125742

MAY 2021

2) This timeline raises grave questions about what the FDA knew and when they knew it, since the results of this paper would have been 'peer reviewed' some months BEFORE the May 2021 publication took place.

That is, the risk of heart damage to teenagers would have been part of the medical knowledge base BEFORE the emergency use authorization for teenagers was issued by the FDA in June 2021.

The finding of heart damage in teenagers, thus, would have been available to the FDA at the time of the May 2021 EUA application.

The FDA did not disclose the risk of these harms to the general public at that time.

3) The Emergency Use Authorization itself in May 2021 does NOT mention any risk of myocarditis in adolescents, even though the 16+ age group was being filed for in this EUA.

An FDA committee reviews and then grants the EUA. The FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss newly available data for the currently available COVID-19 vaccines

We [the volunteers in the Pfizer War Room documents review group Team 3] have not seen any discussions of the issues [of myopericarditis] by the FDA approvals committee as they are not available to the public.

There is no press release from the FDA about the approval of the May 2021 EUA application, but in an August 2021 press release <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> the FDA report that myocarditis is a known side effect and a warning is in the data sheet of the newly authorized commercial vaccine (COMIRNATY).

See below from press release.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Thus, it appears that the Food and Drug Administration should or must have known about elevated risk of heart damage to teenagers in a peer-reviewed publication and failed to disclose it to the public when announcing the Emergency Use Authorization. (We don't actually have any data on this. This is an educated assumption only.)

Due to the lack of disclosure by the FDA, of the known harms, the parents who chose to have their teenagers vaccinated with mRNA vaccines, therefore, could not have made use of fully informed consent. That was remedied a few months later in the data sheet of the commercial (COMIRNATY) vaccine, as described in the press release above.

Dr. Chris Flowers MBBS, FRCR, FSBI is a retired Associate Professor of Radiology at University of South Florida. He was previously an Associate Professor of Radiology and Biomedical Imaging at University of California, San Francisco. He is also a retired academic cancer radiologist, author, and scientific paper reviewer for multiple radiology journals.

Report 10: [“Secret Documents: How Pfizer Covered Up a Flood of Adverse Events”](#) by Stevan Douglas Looney, J.D.

I am a civil trial and appellate attorney in New Mexico, with experience litigating complex matters. My prior essay for DailyClout.io regarding the Pfizer War Room Document Review — for which I volunteer as one of 250 attorneys — argued that the documents clearly show evidence of fraud on the part of Pfizer. The latest tranche of documents, released on April 1, 2022, show an equally dramatic revelation: Pfizer *knew* by February of 2021, that there were had been ‘a large number of adverse events’ in the three months prior.

Pfizer also realized that these adverse events were so abundant — and they expected so many more in the months to come — that they advised the FDA that they would hire 2400 additional staffers to deal with the paperwork and data processing they expected due to the anticipated volume of adverse events!

I reviewed the April 1, 2022, tranche of Pfizer documents the FDA produced pursuant to a federal court order. A document produced on November 17, 2021, was also produced as “reissued” on April 1, 2022. At first glance they appear identical, but they are not. Importantly, information redacted (deleted) from the document produced in the March 2022 production, was included in the April 1, 2022, production. This information is quite telling and some conclusions can be drawn.

The document produced on November 17, 2021, is titled “[5.3.6 postmarketing experience.pdf](#)” (November 17, 2021 (984 KB)). That same document in the April 1, 2022, production is titled “[reissue 5.3.6 postmarketing experience.pdf](#)”. (April 1, 2022 (958 KB)). The word “reissue” is absent in the November 2021 version. That made me curious, so I did a comparison of the two documents. Here is what one will find on page 6. (The “Bates” number in both documents in the bottom, right-hand corner is “FDA-CBER-2021-5683-0000059.”)

The lengthy paragraph on page 6 of the November 2021 document concerns adverse events reports received by Pfizer as of February 28, 2021. The third sentence of that paragraph in both documents reads: “Due to the large number of spontaneous adverse events reports received for the product [i.e., BNT162b2], the MAH [Marketing Authorization Holder] has prioritized the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity.”

This paragraph ends: “Pfizer has also taken a [sic] multiple actions to help alleviate the large increase of adverse event reports.” Think about that sentence.

“This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately 600 additional full-time employees (FTEs). More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021 [emphasis added].”

Also on page 6, under the heading “3. RESULTS”, at “3.1.1 General Overview”, Pfizer discloses in the document produced on April 1, 2022, what it redacted from the same document produced in November of 2021. What Pfizer had produced in April 2022 to take the place of the redacted document in November 2021 document was the fact that for the three-month period beginning December 1, 2020, to February 28, 2021, Pfizer shipped “approximately 126,212,580 [emphasis added] doses of [the FDA emergency use authorized] BNT162b2” worldwide.

The 126,212,580 figure is redacted in the document produced in November 2021 but is included in the “reissue” document of April 1, 2022.

Likewise, the new, full-time 600 and 1,800 employees, amounting to a total of 2,400 full-time employees, hired to deal with all the anticipated adverse events, are included in the document produced on April 1, 2022, but had been redacted from the same document the FDA had produced in November of 2021. Why the foregoing data were redacted, but then disclosed, we do not know, yet. We do know that the redacted information is damning. What did we learn by comparing the two documents?

First, between December 1, 2020 and February 28, 2021, a period of three months, “a large number of spontaneous adverse events reports” were made to Pfizer regarding the administration to humans of the BNT162b2 “vaccine” for which the FDA had provided emergency use authorization (EUA).

Second, by February 28, 2021, (the date of the document) Pfizer knew that by June of 2021 it would hire at least an additional 2,400 full-time employees to process the adverse events reports Pfizer was receiving. (Appendix 1 to these documents is a list of 1,290 adverse events of special interest (AESI) received in connection with the BNT162b2 “product.” Based upon my research to date, I have found no evidence that these AESI were disclosed publicly prior to November of 2021.)

Lastly, and incredibly, despite having this information, on August 23, 2021, the FDA granted continued EUA status for the BNT162b2 “vaccine” and also approved Bio-N-Tech/Pfizer’s product known as COMIRNATY. Notably, according to the FDA, both the EUA BNT162b2 and the “approved” COMIRNATY are identical and interchangeable products. Thus, it is reasonable to conclude that COMIRNATY also causes “a large number of spontaneous adverse events,” including the adverse events and AESI listed in Appendix 1 to these documents.

In sum, Pfizer did not only apparently commit fraud, but they also compounded the fraud by hiring 2,400 full-time employees to deal with the flood of adverse events that they expected – and yet they told no one about this publicly.

I will continue to issue analyses of these historic documents.

Mr. Looney is a civil trial and appellate attorney with 42 years of experience, concentrating on complex matters. Mr. Looney is licensed in New Mexico and practices in all its courts, as well as the United States District Court for the District of New Mexico, the Tenth Circuit Court of Appeals, the US Tax Court and the US Supreme Court. Mr. Looney served in the U.S. Army as an infantryman from 1970-1972, assigned to the 82nd Arbrn. Div.

Report 11: [“Missing: 50 Pregnant Women from Pfizer Clinical Trials”](#) by Cindy Weis.

In the first batch of Pfizer documents released, the volunteer group I am a part of was assigned to review Document 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports. Because there were a significant number of Adverse Events reported in pregnant women, I decided to pay close attention to future documents as regarding vaccine effects on pregnancy.

According to the Pfizer Clinical Protocol Document, women who are pregnant or breastfeeding were to be excluded from the vaccine trials. They were not allowed to begin them if pregnant:

Page 42

Exclusion Criteria

11. Women who are pregnant or breastfeeding.

And, if they became pregnant during the study, they were withdrawn from receiving further vaccinations:

“Stopping Rule Criteria for Each BNT162 Vaccine Candidate:”

Pg 65

8.2.6. Pregnancy Testing

Pregnancy tests may be urine or serum tests, but must have a sensitivity of at least 25 mIU/mL. *Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant’s receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs/ECs or if required by local regulations. In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study.*

https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

The Clinical Overview document below lists 50 women who were a part of the Clinical Trials that reported pregnancies.

As I read it, 16 of them withdrew from the study due to pregnancy. The wording is confusing, but it appears that at least the remaining 34 women “continue to be followed for pregnancy outcomes.” It could also be construed to mean all 50 are to be followed. See below:

2.5 Clinical Overview Document

Pg. 320, 321

2.5.5.7.2. Pregnancies

At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2. In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 54). These participants continue to be followed for pregnancy outcomes. No births have been reported from individuals who have become pregnant in Study C4591001 as of the time of this submission.

https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.5-Clinical-Overview.pdf

According to the Clinical Protocols Document these women should be followed for a minimum of 6 months from their last visit, ostensibly the date when they were withdrawn:

4.4. End of Study Definition

A participant is considered to have completed the study if he/she has completed all phases of the study, including the last visit. Note that participants enrolled in Phase 1 in groups that do not proceed to Phase 2/3 may be followed for fewer than 24 months (but no less than 6 months after the last vaccination).

The end of the study is defined as the date of last visit of the last participant in the study.

Using Abstractor [<https://vaccines.shinyapps.io/abstractor/>], a front-end search tool that searches all released Pfizer documents, I did a search using the terms “pregnant and pregnancy” and yet found no updated information on these women and their pregnancy outcomes.

As more information on the dangers to pregnant women from the mRNA vaccines surfaces, some of which the manufacturers had at their disposal very early on, I feel it is imperative that we hear the stories of these 50 women and their babies.

Report 12: [“Were We Lied to by the FDA?”](#) by Stevan Douglas Looney, J.D.

What’s the difference between Pfizer’s FDA approved COMIRNATY and the emergency use authorized “vaccine?”

Only the law, not science, says the FDA.

Were we lied to by the U.S. Food and Drug Administration (FDA) and the media when they told us that, if we received the Pfizer “vaccine” after August 23, 2021, we, along with our children, would receive the FDA-approved COMIRNATY? Unfortunately, the answer is a clear “yes,” and the FDA itself tells us so.

On August 23, 2021, the FDA issued two letters to Pfizer, Inc. [One letter](#) was addressed to Pfizer at its office in Collegeville, Pennsylvania, and concerned the FDA’s extension of the emergency use authorization (EUA) of “Pfizer-BioNTech COVID-19 Vaccine,” i.e. the experimental mRNA gene therapy referred to in clinical trials (which are ongoing) as BNT162b2.

[The other letter](#) was addressed to both BioNTech Manufacturing GmbH (BNT) and to Pfizer, Inc., at an address in New York, New York, and concerned the FDA’s approval of Pfizer/BNT’s “COVID-19 Vaccine, mRNA.” This product was licensed, or “approved,” by the FDA to be made publicly available for injection into humans 16 years of age and older under the proprietary name COMIRNATY. We learn from the FDA’s August 23, 2021 letter regarding the EUA-authorization of “Pfizer-BioNTech COVID-19 Vaccine” that this “vaccine” was first granted EUA by the FDA on December 11, 2020. The FDA reissued the EUA an additional five times prior to August 23, 2021. The last EUA prior to that date was on August 12, 2021. (EUA or approval letters from the FDA to Pfizer/BNT after August 23, 2021, typically pertain to “boosters.”)

On August 23, 2021, the FDA concluded that revisions to the August 12, 2021, EUA were “appropriate to protect the public health or safety.” Tellingly, the revisions and the reissuance of the EUA coincided with the FDA’s approval of COMIRNATY, also on August 23, 2021. In the EUA letter, the FDA reissued:

*“The August 12, 2021, letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved **BLA** [emphasis added].”*

“BLA” means “Biologics License Application.” The “approved BLA” is an express reference to the FDA’s approval of COMIRNATY in the August 23, 2021, letter to both BioNTech and Pfizer.

What the FDA is saying is that, pursuant to the EUA of the “Pfizer-BioNTech COVID-19 Vaccine,” which does not have FDA approval, Pfizer is authorized to administer COMIRNATY for uses and purposes for which the FDA did not approve the use of COMIRNATY. One could reasonably ask: Is there any difference between these two products to warrant FDA approval of COMIRNATY?

What’s The Difference? It’s The Law, Not Science and Medicine.

The FDA itself answers this question in the letter addressed only to Pfizer regarding the EUA-authorization of “Pfizer-BioNTech COVID-19 Vaccine.” In that letter, the FDA makes clear that there is no scientific difference between the EUA-authorized “vaccine” and the approved COMIRNATY “vaccine.” Rather, any difference is a matter of law, not science. This is what lawyers call a legal fiction.

From that letter we learn that:

“Pfizer-BioNTech COVID-19 Vaccine [the EUA product] contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and [COMIRNATY] can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.”

This quote ends with reference to footnote 8, which reads:

“The licensed vaccine [COMIRNATY] has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.”

(https://www.armstrongeconomics.com/wp-content/uploads/2021/08/FDA-Letter-Final_Pfizer-LOA-to-issue-with-BLA-approval-08.23.21_v2.pdf, p. 2.)

There you have it. The FDA EUA-authorized product and the FDA-approved COMIRNATY are scientifically identical and can be used, medically-speaking, interchangeably; but they are “legally distinct.” This legal distinction is based upon an alleged, and fraudulent, ongoing health emergency and the statutory law, rules and regulations applicable to the FDA when such an emergency – real, imagined or trumped-up – is declared to exist by the people and agencies in which the public is expected to dutifully repose trust and confidence.

Unconscionably, these so-called laws have been applied by the FDA to authorize use of COMIRNATY for children aged 12-15, when COMIRNATY has not been licensed/approved for that age group. Given that there is admittedly no scientific and medical difference between these two products, there is no rationale and defensible justification for the FDA to authorize the use of COMIRNATY when it has not approved the use of COMIRNATY for children aged 12-15.

Why Have Concerns About Safety and Effectiveness For Children? The FDA Isn’t Concerned. Or is it?

In the FDA’s August 23, 2021, letter to Pfizer/BNT granting a license/approval for COMIRNATY in the USA, the FDA approved the manufacture of COMIRNATY to be administered to humans 16 years of age and older. (The FDA set a number of conditions to this approval which have yet to be met and will take years to do so, if at all.) However, Pfizer/BNT’s BLA (Biologics License Application) also sought a license to administer COMIRNATY to 12–15-year-old children, as well as to humans 16 years of age and older. Notably, the FDA advised Pfizer/BNT that it had concerns about the pediatric use of COMIRNATY in children ages 12-15 because Pfizer had not fulfilled the pediatric study requirements for this age group. In part, for that reason, as well as others, the FDA did not license/approve COMIRNATY for the 12-15 age group. Instead, it required Pfizer/BNT to conduct a number of studies and set timetables to do so. Many of the dates in the timetables do not expire until 2025, 2026 or 2027. Meanwhile, employing an expedient legal fiction, the FDA has authorized the use of the EUA product on children age 12-15 when it does not (and should not) approve the use of COMIRNATY for this age-group (or for any age group).

Unsurprisingly, the FDA did find that Pfizer/BNT had fulfilled the pediatric study requirements for the 16-17 age group. How much weight, if any, should the public put on the FDA’s finding? Interestingly, regarding the 16 and older age group, the FDA stated:

“We did not refer your application to the Vaccines and Related Biological Products Advisory Commission because our review of the information submitted in your BLA, including the clinical study

design and trial results, did not raise concerns or controversial issues that would have benefitted from an advisory committee discussion.” (<https://www.fda.gov/media/151710/download>), p. 2.)

No concerns. Oh, really? The clinical study design and trial results, as well as the safety, efficacy and medical necessity of the Pfizer products (not to mention the other “vaccines” for “COVID-19 disease”), have been reasonably and effectively challenged by many qualified medical and other experts, many of whom also question the FDA’s decision to bypass the Vaccines and Related Biological Products Advisory Commission. It is reasonable to conclude that the FDA and Pfizer did not want such a review, as it would have shed light on and called into question, the FDA’s conclusion that these products are safe, effective and medically necessary.

On a related note, after the FDA issued the August 23, 2021, letters many media outlets falsely claimed that the FDA had licensed and approved both Pfizer mRNA products. To that end, these media sources intentionally and recklessly gave the impression to the public that everyone who received the Pfizer injection would be administered only the “approved” COMIRNATY. That was not, and is not, true. Consequently, in the opinion of this writer, any discussions about whether COMIRNATY is available and being administered in the United States are rendered moot and non-productive. What difference does it make when the only distinction between the two is artificial and expedient? The distinction is to be found only in the law and not the science. Indeed, to again quote the FDA, “the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns.”

While the FDA expressed no concerns about administering COMIRNATY to humans 16 years of age and older, it expressed concerns about administering COMIRNATY to children aged 12-15. Yet, incredibly, inconsistently and dangerously, despite the EUA-authorized product and COMIRNATY being scientifically identical and interchangeable, the concerns the FDA had about administering COMIRNATY to children aged 12-15 were intentionally and reprehensively tossed to the way-side when the FDA gave EUA-authorization to Pfizer to administer COMIRNATY to children age 12-15 under the pretext of an alleged health emergency. There’s that legal distinction, actually legal fiction, at work in real-life, with its severe and irreparable injurious and deadly consequences.

The so-called legal distinction, but without any scientific/medical difference, between the EUA-authorized product on the one hand, and the licensed/approved COMIRNATY on the other hand, must come as little or no consolation to parents whose children received COMIRNATY and to those who have been administered COMIRNATY and/or the EUA-authorized product and are suffering, or will suffer, adverse events as a direct result — regardless of their age.

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Report 13: [“Adverse Events Rise in Babies Breastfed by Vaccinated Mothers”](#) – Team 3.

Is COVID-19 vaccination safe for pregnancy and breastfeeding?

BREASTFEEDING AND COVID VACCINATION

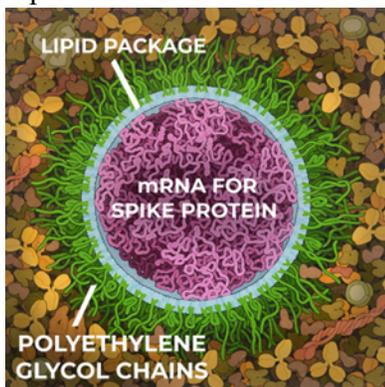
In pregnancy and breastfeeding, any substance is guilty until proven innocent. The COVID-19 vaccines are declared safe for pregnancy and breastfeeding by authorities in their field, such as the ABM (Academy of Breast Feeding Medicine., 2021). Is this recommendation based on science or fantasy? Is the COVID-19 vaccine safe for pregnancy and breastfeeding? I do not know the answers to these questions. We look to “The Science” to find out. And we find that the authorities in medicine and medical sciences don’t know the answers because no one has done the evaluation. But those who adhere to the known science have a strong foundation to question safety because “Before a product is declared safe for breastfeeding or pregnancy, the answer be known”. The great tragedy of thalidomide in the 1950s and disaster of widespread smallpox vaccination during an epidemic in the late 1870s taught us the bitter lesson.

Our journey to understand the safety or lack of safety will be based on the strict science. We will begin with what is known. In some cases, we will need to bring in some foundational information. If a recommendation by an authority is based on opinion and not science, this will be pointed out. If the recommendation goes contrary to the known science, that will be pointed out.

Before we start, we need to emphasize that there are 3 vaccines on the market in the US. Two of them are mRNA vaccines (made by Pfizer/BioNTech and Moderna, respectively) and one is adenovirus vaccine (made by JNJ but now pulled from the market).

When we talk about a COVID-19 vaccine being safe for breastfeeding or pregnancy, it is not clear that one size fits all and we should not lump all COVID-19 vaccines together. Nor can we look at pregnancy and breastfeeding as a single entity and assume if one is safe or harmful for one it is the same for the other. That said, we will lump the mRNA vaccines together to an extent as they are similarly constructed and look at the adverse effects from their individual components and if the adverse reaction is due to the spike protein.

The mRNA vaccine is a composite product consisting of an mRNA core wrapped in a lipid blanket. Lipid is the scientific term for fat.



The core of vaccine is the mRNA which will code for the spike protein. The core is surrounded by 3 layers of lipid to facilitate entry into cells. The first layer is the lipid

nanoparticle. The second layer is PEG. PEG is polyethylene glycol. PEG is similar to anti-freeze and there are many different types of PEGs. The vaccines use ALC 0159. A third lipid is added called an emulsifier along with cholesterol. The vaccine is unstable at room temperature requiring it to be kept at very cold temperatures. Wrapping the mRNA core in these lipid layers allows it to merge with cells. The lipid nanoparticle penetrates the blood brain barrier (Christensen, 2014), the placental barrier (Huang et al., 2015), (Wick, 2010), fatty breast tissue (Golan Y. e., 2021) and breast milk. The lipid nanoparticle, even without the mRNA component, is highly inflammatory. (Ndeupin, 2021). The mRNA vaccine induces a potent immunological response in the breast and in the breast milk. (Narayanaswamy et al., 2022)

Before we delve into the adverse reactions and the actual science as to why these occur, it behooves us to examine the misleading advice given by prominent medical societies.

The Academy of Breastfeeding Medicine. ABA M Statement tells us that the vaccine is made of lipid nanoparticles that contain mRNA (which will code) for the SARS-CoV-2 spike protein (once it is in the cells). *(Parenthesis added for clarification)*. These particles are injected into muscle. Here the nanoparticles are taken up by muscle cells. These muscle cells then transcribe the mRNA to produce spike protein. The spike protein made by the cell stimulates an immune response. (Academy of Breast Feeding Medicine., 2021). *Note: All of these statements are true but are not relevant as to the safety of the vaccine for breastfeeding.*

According to the ABM, during lactation it is unlikely that the vaccine lipid would enter the blood stream and reach breast tissue. *(Note: This is speculation unsupported by experimental evidence. It is irresponsible for an authority figure to make such a speculation in the absence of evidence. Additional evidence showed this statement to be false)*. If it does, it is even less likely that either the intact nanoparticle or mRNA transfer into milk. *(Note: This is speculation proved to be false)*. In the unlikely event that mRNA is present in milk, it would be expected to be digested by the child and would be unlikely to have any biological effects. *(Note: This is speculation and given the asymmetrical risk of being wrong, it is not worthy of any who has had training in medicine, who first oath is to do no harm. It is a question of the utmost importance. Preliminary evidence indicates that this is a false statement, and the immunological effects are profound (Narayanaswamy et al., 2022))*.

Compare the above statements to the actual experimental evidence. In every case the speculation is proved wrong by experimental evidence. Experimental evidence is the foundation of the science that we are to follow.

While there is little plausible risk for the breast-fed infant *(Note: the lack of plausible risk is speculation)*, there is a biologically plausible benefit. Antibodies and T-cells stimulated by the vaccine may passively transfer into milk. *(Note: This is a true statement)*. Following vaccination against other viruses, IgA antibodies are detectable in milk within 5 to 7 days. *(Note: This is a true statement but there is speculation that antibodies produced by vaccination are equivalent to IgA antibodies of natural infection. It is assumed that passive transfer of activated T cells is a good thing. This is spectacularly wrong)*. Antibodies transferred into milk may therefore protect the infant from infection with SARS-CoV-2. Although the biology is reassuring, for definitive information, we will have to wait for data on outcomes once the vaccine is used in lactating individuals and their children. *(Note: this is the only valid statement)*.

It is essential to note that the ABM assumes, without evidence, that the vaccine and transfer of antibodies and other inflammatory cytokines are beneficial to the breastfeeding infant and fails to consider the question as to

whether they are harmful. They are only concerned with ability to protect from SARSCOV-2. This tunnel vision is reprehensible as SARSCOV-2 offers little harms to the infant, but initiation of an inflammatory response may prove fatal as explained below.

The ABM does not stand alone. The American College of Obstetrics and Gynecology and The Society for Maternal Fetal Medicine have recommended that these mRNA vaccines be made available for lactating women, despite acknowledging that initial trials excluded breastfeeding women and no assessment could be made concerning their safety. (Bertand, 2021-04-25). The World Health Organization recommends that breastfeeding individuals be vaccinated and does not advise cessation of breastfeeding following vaccine administration. (Golan Y. e., 2021). The Academy of Breastfeeding Medicine states that there is little plausible risk that vaccine nanoparticles or mRNA would enter breast tissue or be transferred to milk. (Golan Y. e., 2021). The ABM notes that if the mRNA vaccine entered the breast milk there is a theoretical possibility of priming the infant immune system. (Golan Y. e., 2021).

Let's compare this to the actual science: the mRNA does enter the breast, does initiate an immune response (Narayanaswamy et al., 2022) and is highly inflammatory. (Ndeupin, 2021)

As the original trials did not look at breastfeeding, two studies at breastfeeding were done. One evaluated breast-fed children for a 4 to 48 hr. period following vaccination. (Golan Y. e., 2021). The second found approximately 10% of breast-fed children had adverse events, the events were worse after the second dose and with Moderna but concluded that the adverse events were not serious (Bertand, 2021-04-25). Little comfort can be drawn from these studies as the studies are small, underpowered, non-randomized and not blinded. One of the studies used self-reporting. We have been lectured ad nauseum by Dr. Anthony Fauci that only randomized, controlled, double blind studies count.

Underpowered studies mean that is not enough data to draw valid conclusions. Not only is the conclusion not valid, but it is also often opposite of the true effect.

Any study that examines the safety of breastfeeding following vaccination needs to evaluate the recipient infant. The breastfeeding infant is taking the breast milk by mouth and so the GI tract is the target organ. This means that studies looking at adverse vaccination events from intra-muscular injections cannot be used. A better model is from natural infection. In natural infection, the virus infects the upper respiratory tract and then is swallowed into the GI tract where it initiates a systemic, IgG based immunological response. A newborn infant and up to about 6 months has an immature immune system. The key question is how the immature immune system of the breastfeeding infant reacts the inflammatory cytokines and chemokines found in breast milk. **We don't know the answer as it was not evaluated. But we do know this.** The breast immune response produces potent chemicals called chemokines and cytokines that have profound immunological effect. One that is of particular concern is interferon gamma and the very high levels of interferon gamma that are produced. (Narayanaswamy et al., 2022) These are transferred to the infant in the breast milk. High dose interferon gamma is a liver toxin. The other cytokines may change the infant's immune response from Th2 mediated, that leads to antibody protection, to Th1 response that increases interferon gamma even more.

The mRNA vaccine induces the mother's cells to produce spike protein. This protein is cleaved with the S1 subunit discarded into the circulation. This S1 component of the vaccine lasts for weeks and produces far higher S1 protein subunits than natural infection. (Röltgen et al., 2022) This means that which each breastfeeding, the amount of spike protein and S1 sub-unit protein is building in the infant's gastrointestinal tract. Even if the first exposure is miniscule, continued feeding increases the dose. The

level of spike and S1 protein is likely builds over time in the infants GI tract and may be find entrance into circulation.

The lipid nanoparticle, without the mRNA payload, is highly inflammatory by itself. (Ndeupin, 2021). The lipid nanoparticle can cross the placenta and induce trophoblast to undergo apoptosis (programmed cellular death of a damaged cell). (Huang et al., 2015)

The other component of the mRNA vaccine is PEG. Assessment of likelihood of adverse reaction needs to evaluate whether PEG or PEG antibodies are transferred from mother to the infant and results in sensitization and potential of initiating a severe allergic adverse reaction.

PEG ALLERGY and the COVID VACCINE

One of major components of the mRNA vaccine is PEG. PEG is polyethylene glycol. It comes in many variants and each variant has its own chemical properties. The PEG used for mRNA vaccine is known by the chemical identifier ALC 0159. It is used in many medications, cosmetics, and food products. The widespread use of PEG has sensitized many in the population to PEG and this sensitization is often unknown or unsuspected. (Hypersensitivity to Polyethylene Glycols & Polysorbates - Physician's Weekly, n.d.)

The seriousness of the allergic response is not only dependent on the dose of the PEG but also whether the immune system is primed to react towards PEG. The amount of PEG in a vaccine is qualitatively minute, bordering on undetectable (Golan Y. e., 2021) but the amount of PEG present can induce anaphylaxis or a serious allergic response. ((Golan Y. e., 2021). (Sellaturay, 2021) , (Hypersensitivity to Polyethylene Glycols & Polysorbates - Physician's Weekly, n.d.) Many normal individuals also have pre-existing antibodies against PEG in their circulation and are primed to react against PEG. (Chen, 2021). When a mother is immunized her breast milk carries many cytokines and chemokines. (Narayanaswamy et al., 2022) These chemokines and cytokines are the same chemicals that are released in an anaphylactic reaction to PEG. (Janeway, 2001)

The gut reaction to PEG is different than the intradermal or skin reaction. The amount of PEG in breast milk is negligible (Golan Y. e., 2021) and below detection ((Golan et al., 2021)) but still present. If the mother has been sensitized and passes on this sensitization in her breast milk to the infant, even if she is not showing signs of sensitization, then the immature immune system of the infant may be triggered and undergo a reaction even to a minute amount of PEG.

In a separate issue, the breastfeeding infant may initiate an immune response independent of PEG. This is dependent on the amount of interferon gamma that the mother is passing to the breastfeeding infant. The mother is also passing the S1 subunit of the spike protein. The S1 subunit is produced in abundance by the vaccinated mother, and it is likely that this excess is distributes into the breast milk. In the presence of excessive interferon and S1 subfraction, a non-specific hyperactivation of the cell immune response result. (University of Pittsburgh, 2022). (Brodin, 2022)

We are back at our beginning question: Is it safe to vaccinate a breastfeeding mother? The science raises many questions that preclude a blanket statement of safety. Wisdom paid for by the unmeasurable disasters of the past answers decisively: No, as the risk to the infant from

COVID-19 is virtually zero, but the potential risk of adverse reactions from the vaccine are real and measurable.

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Report 14: [“MicroRNA, the Hidden RNA in the Pfizer mRNA Vaccine”](#) by Daniel B. Demers, PhD – Team 5.

Introduction

MicroRNAs (miRNAs) are a class of non-coding RNAs that play a role in a multitude of cellular processes. The first miRNA was discovered in 1993 in a nematode (O’Brien et al., 2018; Lee et al., 1993). The first viral miRNA was only identified in 2004 (Pfeffer et al., 2004). Thus, the history of miRNAs is short, and therefore, limited scientific data has been gathered on this special class of RNA.

On average mature miRNAs are just 19-22 nucleotides in length (O’Brien et al., 2018; Mallick et al., 2009). By comparison with messenger RNA (mRNA), a coding RNA, the average mature mammalian mRNA is typically 2,200 nucleotides long. The full-length mature SARS-CoV-2 mRNA is about 29,900 nucleotides long while the Pfizer vaccine spike protein mRNA is 4,284 nucleotides long (Nance et al., 2021; Kim et al., 2020).

MicroRNAs are highly stable molecules, contrary to mRNA molecules (O’Brien et al., 2018). The SARS-CoV-2 spike protein mRNA is unstable (Pallesen et al., 2017), which is why Pfizer made modifications to stabilize it and prevent its degradation in the body.

Although miRNAs are small, they are abundant and critical for normal animal development. They function in gene expression, mRNA stability and degradation, regulation of translation (protein production), and wound healing. They can act as chemical messengers to mediate cell-cell communication and can be released into the extracellular fluids and delivered to other cells and organs, thus exhibiting hormone-like activities. It is estimated that 60% of mammalian genes are influenced by miRNAs which affect regulatory pathways including cancer, apoptosis (cell death), metabolism and development. MicroRNAs have been detected in plasma and serum, cerebrospinal fluid, saliva, breast milk, urine, tears and seminal fluid (Marchi et al., 2021; Abedi et al., 2021; Khan et al., 2020; O’Brien et al., 2018).

There is a delicate balance within the miRNA regulatory system. There is an interaction of miRNAs with their target genes, mRNA molecules, other endogenous miRNAs as well as exogenous miRNA and other nucleic acids (viral and bacterial). It is a highly dynamic system that is dependent on many factors including miRNAs’ relative abundance. O’Brien et al. (2018) point out that alterations in host miRNA levels would interfere with specific cellular processes crucial for host biology. In fact, evidence indicates that miRNA expression and dysregulation are associated with the development of pathological processes and chronic diseases, including viral infections and the diseases caused by viral infections (Marchi et al., 2021; Zhang et al., 2021; Giardi et al., 2008).

It has been shown that miRNAs play a crucial role in host antiviral responses and viral pathogenesis of various viruses. MicroRNAs can modulate innate and adaptive immunity by

affecting protein levels. Viral genomes can express their own miRNAs and can “hijack human miRNAs to the repertoire of the infected cells” (Abedi et al., 2021). MicroRNAs are known to play a role in the pathogenesis of other coronaviruses, such as SARS-CoV and the Middle East Respiratory Syndrome coronavirus (MERS-CoV) that caused epidemic outbreaks in 2003 and 2012, respectively (Mallick et al., 2009; Hasan et al., 2014). The SARS-CoV-2 genome, including the spike protein mRNA, have been shown to encode their own miRNAs, some of which interact with human miRNAs (Liu et al., 2020).

SARS-CoV-2 encoded miRNAs can target different organ-specific cellular functions including insulin signaling and heart development related pathways which might lead to diabetes and consequences similar to viral myocarditis, respectively. These viral encoded miRNAs might also target genes associated with brain development which might provide a clue about neurological signs like headaches, vomiting and nausea (Khan et al., 2020).

Viral miRNAs encoded by the SARS-CoV-2 genome can target several host genes. One study predicted that 3,377 human genes were potential targets of 170 miRNAs produced from the SARS-CoV-2 genome. Also, 10 human miRNAs were identified that possess binding sites across the SARS-CoV-2 genome. Said another way, there are human miRNAs binding to the SARS-CoV-2 mRNA and there are SARS-CoV-2 encoded miRNAs binding within the human genome (Abedi et al., 2021). Using prediction analysis (theoretical), Sacar Demirci et al. (2020) identified 67 human miRNAs with potential targets in the SARS-CoV-2 spike protein region. If human miRNAs are binding to regions within the spike protein mRNA, then what does a spike protein mRNA vaccine do to the delicate balance within the miRNA regulatory system that O’Brien et al. (2018) described?

“Manipulating the level of host miRNAs could have unintended consequences because the physiological functions of the miRNAs might be altered or viral pathology might be enhanced” (Mallick et al., 2009).

It is clear that viruses encode their own miRNAs that can interact with host DNA, mRNA and miRNAs thereby altering the delicate balance of the miRNA regulatory system. Mishra et al. (2021) proposed that the SARS-CoV-2 spike protein itself is able to modify the host exosomal cargo (with two human miRNAs, miR-148a and miR-590) that get transported to distant uninfected tissues and organs to “initiate a catastrophic immune cascade within the central nervous system” (Mishra et al., 2021). In other words, miRNAs encoded within the SARS-CoV-2 spike protein mRNA cause the infected host cells to package human miRNAs, miR-148a and miR-590, into exosomes (vesicles that release cellular molecules into the extracellular fluid) for export out of the cell to the central nervous system where they initiate pathogenesis.

When a vaccinee receives a Pfizer BNT162b2 mRNA vaccine, they not only receive the vaccine’s mRNA, they also receive an unknown number of miRNAs, hidden within the sequence of the vaccine mRNA. How do the miRNAs introduced by the Pfizer vaccine disrupt

the balance of the host miRNA system? What pathogenesis do they cause? What are the long-term toxicity, carcinogenicity and pharmacological concerns? None of this was studied by Pfizer. In fact, there is no mention of miRNAs in the Pfizer document 2.4 NONCLINICAL OVERVIEW

(https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

Good science demands answers to these important questions, and the answers should have been obtained before injecting hundreds of millions of people globally (billions of doses) with such an experimental substance.

In summary, miRNAs are being recognized as an enormously important component of gene expression and regulation and are associated with many diseases as well as host immunity (Zhang et al., 2021; O'Brien et al., 2018). It has been demonstrated that SARS-CoV-2 encoded miRNAs, including miRNAs from the spike protein region, bind to the host genome and that host miRNAs bind within the SARS-CoV-2 genome. But there is a delicate balance within the host miRNA regulatory system and it has been shown that these exogenous miRNAs, as well as exogenous mRNA encoding them, alter this delicate balance with potential deleterious consequences (O'Brien et al., 2018). This undeniably important biomolecule was not mentioned by Pfizer.

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Zhang, S., et al., *Brief Bioinform*, 2021; 22(2): 1137-1149. The miRNA: a small but powerful RNA for COVID-19.

Report 15: [“Why COVID-19 Vaccine Consent Must Be Informed”](#) by Vicki F. Goldstein, R.N., J.D. – Team 1.

The doctrine of informed consent has been a bedrock of our health care system for over 60 years. And yet, in pursuit of mass vaccination, the federal government, pharmaceutical companies, and medical associations, including the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), have blocked truthful information regarding Covid-19 vaccines from the public and significantly interfered with the duty of physicians to inform their patients of the serious risks and limited benefits of the vaccine prior to consent. We are in a battle for information.

The American Medical Association recognizes that “medical ethics, common law and statutory law mandate the informed consent process.”

<https://www.ama-assn.org/delivering-care/ethics/informed-consent> We have the right to exercise autonomy to make our own medical care decisions, including the important right to decline medical treatment. And the physician has a duty to inform, without which there is no consent. Traditionally, we have trusted the medical profession to honestly discuss with us the risks, benefits and alternative options prior to our consent for treatment. Inexplicably, this vital process has been cast aside with Covid-19 vaccines.

Before examining the failures of informed consent in the context of the Covid-19 vaccine, we look briefly at the doctrine as it evolved through the courts, beginning with the opinion written by Justice Benjamin Cardozo. In this seminal case, the court identified the basis for patient consent, holding that “every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages...” *Schloendorff v. Society of N.Y. Hospital*, 105 N.E. 92, 93 (N.Y. 1914)

One of the first courts to recognize a physician’s duty to inform the patient of potential risks and alternatives of a procedure prior to consent, reasoned that “the patient, being unlearned in medical sciences, has an abject dependence upon and trust in the physician...” *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (Cal. 1972)

And in a case relevant to the issue at hand, the court examined a physician’s duty to disclose information of an experimental treatment to the patient. In that case, the patient signed a consent for radiation treatment, which traditionally utilized X-rays. However, the physician chose a new type of radiation treatment using powerful radioactive cobalt that was compared to a three-million-volt X-ray machine. The patient, unaware of the dangers of this new experimental treatment, sustained severe burns. The court held that the physician was obligated and failed to inform his patient of the nature of the treatment and possible dangers within his knowledge. And furthermore, such failure to inform his patient was considered malpractice. *Natanson v. Klein*, 186 Kan.393, 350 P.2d 1093, rehearing denied 187 Kan. 186, 354 P.2d 670 (1960)

Similarly, Pfizer’s mRNA Covid-19 vaccine is experimental. It is not a traditional vaccine, such as measles and polio, that the public understands and has experienced through a lifetime of vaccinations.

Rather, it is a new biological agent consisting of (1) mRNA, which is genetic material containing instructions to train cells to make a spike protein, which is the protein found on the outer wall of coronavirus; (2) lipid nanoparticles, which surround the mRNA as it is transported to the cell; and (3) polyethylene glycol (PEG), which protects lipid nanoparticles that deliver the mRNA. It is “a triad never used in clinical vaccines and is going to be tested on hundreds of millions of people.” <https://biomedres.us/pdfs/BJSTR.MS.ID.005501.pdf>

Additionally, Pfizer’s Covid-19 vaccine does not provide immunity, a fact that prompted the CDC in 2021 to remove the word “immunity” from the long-standing definition of vaccines.

While Covid-19 vaccines are clearly a departure from traditional vaccines, the devastating facts that further compel informed consent are the unknown risks and the volume of known serious adverse events reported in VAERS, medical journals, and the monthly release of court ordered Pfizer documents. The mRNA vaccine is leaving a trail of injury and death as it sweeps across this country.

Against this backdrop, it is a tragedy that medical associations, the federal government, pharmaceutical companies, and the media are holding hostage the truthful information that is required for informed consent. For the safety of the public, informed consent is imperative.

Turning to the unethical conduct of medical associations, Daily Clout and a Team 1 physician recently exposed ACOG for persistently advocating for pregnant women to get the experimental Pfizer Covid-19 vaccine. They did this with full knowledge that pregnant women were not explicitly approved or authorized during pregnancy and lactation. According to the report, ACOG relied on a faulty rat study (DART), which was incomplete and biased, in order to determine that the vaccine was safe for pregnant women. In fact, the Pfizer Covid-19 vaccine is not safe, as evidenced by the volume of data included in the report that indicates multiple serious adverse events to mother and baby.

Not only did ACOG promote the experimental vaccine for pregnant women but it also provided guidance to its 58,000 physician members that informed consent was not required prior to vaccination. The ACOG clinical practice advisory, published December 13, 2020, stated that “a conversation between the (pregnant) patient and their clinical team may assist with decisions regarding the use of the vaccines approved under EUA for the prevention of Covid-19...including...the potential efficacy of the vaccine.... (and) the safety of the vaccine for the pregnant patient and the fetus. *While a conversation with a clinician may be helpful, it should not be required prior to vaccination as this may cause unnecessary barriers to access.*”

https://web.archive.org/web/20210218030246/http://e-lactancia.org/media/papers/Vaccinating_Pregnant_and_Lactating_Patients_Against_COVID-19_ACOG20201213.pdf

ACOG’s disturbing message to the medical community is that vaccination is paramount, even if it requires the erosion of patient rights to make informed medical care decisions. ACOG’s message is contrary to the prevailing law and medical code of ethics.

A clinician has a duty to discuss with a pregnant patient the information vital to make an informed decision prior to vaccination. The list of vital information is long and growing. It includes the following: (1) the mRNA Covid-19 vaccine is experimental; (2) it is not licensed by the FDA but rather

is authorized for emergency use; (3) there is no authorization for emergency use for pregnant women; (4) pregnant women were excluded from clinical trials; (5) the vaccine does not provide immunity or stop transmission of the virus; (6) the vaccine lacks durability; (7) the vaccine does not stay at the injection site but instead travels through the blood stream; and (8) the vaccine has serious unknown and known safety risks to the mother and baby, including fetal death and congenital abnormalities.

This is not an exhaustive list of vital information important to a pregnant patient prior to vaccination. Dr. Russell Blaylock, a retired neurosurgeon, warned that “immune stimulation during the third trimester dramatically increases the risk of the child becoming autistic or developing schizophrenia later in life... We will not know if women vaccinated during their third trimester will have children with a higher risk of becoming autistic for at least 6 years, the usual time span for symptom appearance.” He also noted that it will take until a child reaches adolescence before schizophrenic symptoms can be observed. Dr. Blaylock opines that women need to be warned of this real danger prior to vaccination. Blaylock RL. COVID UPDATE: What is the truth? Surg Neurol Int 2022;13:167

Given all the concerning safety data, it is reasonable to conclude that pregnant women referenced in the Daily Clout report, had they been informed and had a choice, would have exercised their right and declined the vaccine, a decision that would have protected their fetuses.

Unfortunately, the trampling of informed consent is not just limited to ACOG. The Assistant Secretary for Planning and Evaluation (ASPE), an office of HHS, is tasked with improving population acceptance of Covid-19 vaccination. In pursuit of that goal, ASPE identified attitudes, such as vaccine hesitancy, individual beliefs, lack of trust in vaccines, and low perceived severity of the disease as “*barriers that can interfere with vaccine uptake.*” “The solution for these barriers is to have health care providers use the right words...”

Gonzales, A.B. et al, Overview of Barriers and Facilitators in Covid-19 Vaccine Outreach (Research Report No. HP- 2021-19) Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, August 2021.

Mayo Clinic, cited by ASPE, found that clinicians have consistently obtained higher vaccination rates. “Strong recommendations from trusted clinicians may improve vaccine confidence, reduce concerns about safety and *improve uptake of the COVID-19 vaccine.*”

So, this trusted clinician is directed to say to the patient: “Covid-19 vaccination is safe and effective, and I strongly recommend that you get your Covid-19 vaccine today.” And to address patient concerns, the clinician is advised to explain that “your concern about vaccine safety...is a common misperception that has been sensationalized in popular media.”

<https://reader.elsevier.com/reader/sd/pii/S0025619620314877?token=A515C8C125EEB578BE5665F3B49A5F56BDE90E1681461E524E710BAD26899E84A9810BE7DF7895CCD711B79589D3B0E2&originRegion=us-east-1&originCreation=20220502123532>

Is there a clinician we can trust to provide honest information about the mRNA Covid-19 vaccine? Pediatricians have long been trusted guardians of the health and safety of children. However, based on a

letter and subsequent actions exposing the Covid-19 vaccine position of the American Academy of Pediatrics, parents need to seriously question the information they receive from their pediatricians.

On February 25, 2021, Dr. Lee Beers, President of the AAP, wrote a letter to Dr. Fauci, the FDA, DHHS and the White House, urgently requesting that adolescents and younger children be enrolled in the clinical trial as soon as possible. Even though Dr. Beers acknowledged that *“studies have shown that children under the age of 10 may be less likely to become infected and less likely to spread the virus to others,” she reasoned that “children of all ages need to be vaccinated in order for the United States to achieve herd immunity against Covid-19.”*

https://web.archive.org/web/20210329214059/https://downloads.aap.org/DOFA/AAP%20Letter%20Urging%20Inclusion%20of%20Children%20in%20COVID-19%20Trials_02_25_21.pdf

It is shocking to learn that the AAP has been aggressively pursuing the experimental vaccine, not for the benefit of the child, but for herd immunity that cannot actually be achieved through vaccinations.

Echoing the AAP position, a Pfizer supported publication, the Vaccine Education and Equity Project, stated that *“most children who become infected with Covid-19 virus have only a mild illness but vaccinating kids against covid 19 also plays a role in protecting the health of the broader community.”*

https://web.archive.org/web/20210713183805/https://covidvaccineproject.org/wp-content/uploads/2021/06/WhatToKnowAfterReceivingCovid_Adolescents_R2.pdf

On herd immunity for Covid-19, a group of Israeli physicians wrote that “the increasingly prevalent opinion within the scientific community is that the vaccine cannot lead to herd immunity, therefore there is currently no 'altruistic' justification for vaccinating children to protect at-risk populations.”

<https://www.israelnationalnews.com/news/304124>

With virtually no benefit, children face known and unknown risks of serious injury or death from Pfizer’s Covid-19 vaccine. Sadly, it is the child who must bear the risk of a significant vaccine injury or death and it is the parents who must bear the cost of those injuries.

And those vaccine injuries are real. In April 2021, Israel reported 62 cases of *myocarditis*, mostly in male adolescents and young men days after receiving the Pfizer vaccine, resulting in two deaths. Israel shared these findings with Pfizer.

https://web.archive.org/web/20210808081436/https://americasfrontlinedoctors.org/wp-content/uploads/2021/06/60a600a8de9ddedc233dbb06_4120Toi20Staff20202120Israel20said20probing20link20between20Pfizer20shot20and20heart20problem.pdf

Since the early report from Israel, VAERS has received hundreds of reports of pericarditis, chest pain, myocarditis and elevated Troponin, all indicating cardiac issues, in adolescents and young adults post Pfizer vaccination.

Between December 2020 and August 2021, there were 1,691 reports submitted to VAERS that met the case definition of myocarditis. 826 cases of myocarditis were among those younger than 30 years of age, and 96% were hospitalized. The actual rate of myocarditis during that interval is likely higher due to underreporting.

Oster ME, Shay DK, Su JR, et al. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021. *JAMA*. 2022;327(4):331–340. doi:10.1001/jama.2021.24110

In the news media, we have learned of sudden, unexpected deaths of young people, including a 17-year-old Canadian hockey player who complied with a mandate in order to play hockey and died of a heart attack shortly after being vaccinated.

Responding to the Canadian teen's death, Dr. Steven Pelech pointed out that the "chances of dying from COVID is about .003% for people under the age of 24 in Canada" and that for those under 19, the chances of injury from the "vaccine is about four to five times higher than getting infected with SARS-CoV-2 itself."

<https://www.lifesitenews.com/news/doctor-blasts-covid-19-vaccination-for-kids-no-such-thing-as-mild-myocarditis/>

And in the United States, physicians with Boston Children's Hospital reported a three month follow-up of 15 adolescents under the age of nineteen, previously admitted to the hospital for acute vaccine-induced myocarditis post Pfizer's Covid-19 vaccination. Cardiac Magnetic Resonance (CMR) imaging showed improvement but unfortunately the majority of the teens also showed persistent late gadolinium enhancement (LGE), which may predict adverse cardiac outcomes, such as sudden cardiac death and overall mortality. The physicians concluded that "follow-up CMR 6-12 months after acute episode should be considered to better understand the *long-term cardiac risks*."

<https://pubmed.ncbi.nlm.nih.gov/35482094/>

The AAP acknowledged that "since April 2021, rare cases of myocarditis and pericarditis have been reported in adolescents and young adults following receipt of mRNA vaccines...."

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/about-the-covid-19-vaccine-frequently-asked-questions/>

However, the serious safety data for previously healthy children did not deter the AAP. In July, 2021, after an abbreviated clinical trial of several thousand children, the AAP recommended that children aged 12 and older get the Pfizer Covid-19 vaccine as soon as possible.

And on October 29, 2021, in a senseless rush to vaccinate everyone, even though the pandemic is apparently over, the FDA issued an EUA for Pfizer's Covid-19 vaccine in children aged five to eleven years old. The Advisory Committee on Immunization Practice (ACIP), a federal committee that includes the AAP and the CDC, recommended approval of the vaccine for young children. The AAP applauded the CDC's Advisory Committee approval of "*safe, effective Covid-19 vaccine for children Ages 5-11.*"

Dr. Beers stated that “sharing this life-saving vaccine with our children is a huge step forward...*Pediatricians are eager to participate in the immunization process and talk with families about this vaccine...*”

<https://www.aap.org/en/news-room/news-releases/aap/2021/american-academy-of-pediatrics-applauds-cdc-approval-of-safe-effective-covid-19-vaccine-for-children-ages-5-11/>

It is astonishing that a medical association would declare the vaccine “safe and effective,” given all the evidence to the contrary. In light of the AAP’s Covid-19 vaccine policy, which guides its 67,000 members, it is unlikely that parents will be afforded an honest discussion with their pediatricians regarding the vaccine’s serious safety data, unknown risks, lack of efficacy and minimal benefit for children.

Informed consent is on life support. Truthful information regarding the serious lack of safety, efficacy, and benefit of Pfizer’s Covid-19 vaccine for children and pregnant women is an essential protection for individual patients and a *barrier* to mass vaccination, which is the goal of the pharmaceutical industry, federal government and medical associations.

Ethics and law require that clinicians discuss with their patients information that is vital for them to carefully weigh the risks of the vaccine against the benefits. Armed with information to place on that scale, the risks of serious known and unknown injuries to mother, fetus and child tip heavily against the vaccine, as it is clear there is virtually no vaccine benefit. Failure of clinicians to inform their patients before consent is malpractice. We must demand accountability.

Report 18: [“Vaccine ‘Shedding:’ Can This Be Real After All?”](#) by Cindy Weis.

That question, as we have been told, was put to rest over a year ago by the experts who follow the science.

But recently, I have been reading with alarm the reports of hepatitis in young children. Currently, the suspected cause seems to be pointing to an adenovirus infection. Upon reading these reports, my thoughts immediately returned to the vaccines as a possible contributor, the Johnson & Johnson in particular, since it’s based on an adenovirus.

I recalled the concerns of forward-thinking medical professionals who during the vaccine development and testing phases warned of a possibility of the vaccines “shedding” in such a way as to be able to transfer from the vaccinated to the unvaccinated.

<https://americasfrontlinedoctors.org/about-us/issue-briefs/identifying-post-vaccination-complications-and-their-causes-an-analysis-of-covid-19-patient-data/>

(Points 3 & 4)

And a more recent observation by Dr Robert Malone, inventor of the mRNA Vaccine technology:

<https://www.onenewspage.com/video/20220317/14528668/Dr-Robert-Malone-Can-Vaccinate-d-People-Infect-Unvaccinated.htm>

When these concerns were initially circulated, the fact checker sites were full of articles debunking the idea and calling anyone who entertained it a conspiracy theorist. The arguments presented pretty much convinced me that it was impossible for the Johnson & Johnson or mRNA vaccines to spread from one person to another.

<https://www.healthline.com/health/vaccine-shedding>

<https://www.usatoday.com/story/news/factcheck/2021/05/07/fact-check-covid-19-vaccinate-d-people-dont-shed-virus/4971413001/>

At the same time, there were also cautions being voiced that the vaccines had the potential to travel to and collect in various organs of the body, such as the liver. Of particular concern was the damage that could cause to women’s reproductive organs.

One article that so eloquently refuted the possibility of shedding the vaccines also argued that it was improbable for components of the mRNA vaccines to migrate from the injection site to other areas of the body since they would degrade within 24-48 hours. Thus, they wouldn’t be

able to have any negative effects on women's reproductive systems. Their concerns were adamantly debunked by the experts in this Reuters article dated April 23, 2021:

<https://www.reuters.com/article/factcheck-covid19vaccine-reproductivepro-idUSL1N2MG256>

Well, we are now finding out how heartbreakingly untrue the naysayers claims about women's reproductive health were. The evidence is mounting that not only are components of the vaccines traveling to and collecting in various organs, they also appear to be having devastating effects on pregnant women and their babies.

'What I've Seen in the Last 2 Years Is Unprecedented': Physician on COVID Vaccine Side Effects on Pregnant Women

https://link.theepochtimes.com/mkt_app/what-ive-seen-in-the-last-two-years-is-unprecedented-physician-on-covid-vaccine-side-effects-on-pregnant-women_4428291.html

The agencies involved in regulating the vaccines were aware of these potential negative impacts. They were negligent in having approved them at all, but particularly recommending them for pregnant women.

Flawed CDC Study Wrongly Concludes COVID Vaccines Safe in Pregnancy

https://link.theepochtimes.com/mkt_app/flawed-cdc-study-wrongly-concludes-covid-vaccine-safe-in-pregnancy_4437106.html

With these inconsistencies in the narrative now coming to light concerning the danger to women from the vaccines, is it unreasonable for one to question some of the other claims made by these same experts?

I have recently been taking a deep dive into the Pfizer documents, researching any references to pregnancy.

According to the Pfizer Clinical Protocol Document, I found that women who are pregnant or breastfeeding were to be excluded from the vaccine trials. They were not allowed to begin them if pregnant:

Page 42

Exclusion Criteria

11. Women who are pregnant or breastfeeding.

And if they became pregnant during the study, they were withdrawn from receiving further vaccinations:

“Stopping Rule Criteria for Each BNT162 Vaccine Candidate:”

Pg 65

8.2.6. Pregnancy Testing

Pregnancy tests may be urine or serum tests, but must have a sensitivity of at least 25 mIU/mL. *Pregnancy tests will be performed in WOCBP at the times listed in the SoA, immediately before the administration of each vaccine dose. A negative pregnancy test result will be required prior to the participant's receiving the study intervention. Pregnancy tests may also be repeated if requested by IRBs/ECs or if required by local regulations.* In the case of a positive confirmed pregnancy, the participant will be withdrawn from administration of study intervention but may remain in the study.

As I continued my journey through the Protocol document, I found something related to pregnant women that basically scrambled my brain.

It is a description of what constitutes an EDP- an Exposure During Pregnancy.

Pfizer Clinical Protocol Doc:

https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

Amended Document:

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

Pg 67-69 (Pg 111-113 in Amended document.)

8.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure

Exposure to the study intervention under study during pregnancy or breastfeeding and occupational exposure are reportable to Pfizer Safety within 24 hours of investigator awareness.

8.3.5.1. Exposure During Pregnancy

An EDP occurs if:

- **A female participant is found to be pregnant while receiving or after discontinuing study intervention.**
- **A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.**
- **A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:**
 - **A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.**
 -
 - **A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.**

While these descriptions of EDP may not specifically involve “shedding” as the means of transfer, there was apparently concern on Pfizer’s part that the vaccine could spread between people. So, riddle me this:

1. If there is no way for the vaccine to spread from the vaccinated to the unvaccinated, why would several of these scenarios be considered an exposure to the pregnant women?
2. If it is possible for the some part of the vaccine to travel between Pfizer’s test subjects and their partners, why is it not possible between say, a vaccinated parent and their unvaccinated child?

In researching this topic, the many fact check articles “debunking” the idea of vaccine shedding focused their arguments completely on viral shedding, something technically impossible with the current Covid vaccines as none are based on a live virus. However, as noted above, there are alarming signals that the spike proteins introduced by the vaccines are traveling to many areas of the body and causing damage.

Although the following study was done with Covid patients rather than vaccine recipients, I include it to show that spike protein is present in urine with Covid infection. It seems plausible that it could also be present in bodily fluids due to dissemination via the vaccination:
<https://www.news-medical.net/amp/news/20220406/Study-evaluates-the-presence-of-the-SARS-CoV-2-spike-protein-in-urine-samples-collected-during-the-COVID-19-pandemic.aspx>

Finally, a recent study at the University of Colorado Anschutz Medical Campus School of Medicine has found evidence that vaccinated individuals can pass (shed) vaccine induced antibodies to unvaccinated individuals:
<https://www.medrxiv.org/content/10.1101/2022.04.28.22274443v1>

In closing, I reiterate the question I began with: Could any of these mechanisms of vaccine related “shedding”, or one we have yet to discover be responsible for the mysterious outbreak of hepatitis in our children?

I don’t have the answer to these questions and so many others that have been swirling in my mind throughout this pandemic. These most recent questions are not just swirling, they are screaming to be answered.

The experts have been so wrong on so many levels during the two plus years of Covid insanity. This is yet one more instance where we must keep digging, keep asking questions, keep demanding answers until all that has been hidden away in dark corners becomes illuminated by the piercing light of truth.

Report 19: [“Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine”](#) – Team 5.

Team Five: Review of Polack with comments and questions.

Fernando P. Polack, M.D., Stephen J. Thomas, M.D., Nicholas Kitchin, M.D., Judith Absalon, M.D., Alejandra Gurtman, M.D., Stephen Lockhart, D.M., John L. Perez, M.D., Gonzalo Perez Marc, M.D., Edson D. Moreira, M.D., Cristiano Zerbini, M.D., Ruth Bailey, B.Sc., Kena A. Swanson, Ph.D., Satrajit Roychoudhury, Ph.D., Kenneth Koury, Ph.D., Ping Li, Ph.D., Warren V. Kalina, Ph.D., David Cooper, Ph.D., Robert W. Frenck, Jr., M.D., Laura L. Hammitt, M.D., Ozlem Türeci, M.D., Haylene Nell, M.D., Axel Schaefer, M.D., Serhat Unal, M.D., Dina B. Tresnan, D.V.M., Ph.D., Susan Mather, M.D., Philip R. Dormitzer, M.D., Ph.D., Uğur Şahin, M.D., Kathrin U. Jansen, Ph.D., and William C. Gruber, M.D., for the C4591001 Clinical Trial Group*

NEJM 383:27 12/31/2020.

Abstract:

BNT162b2: full length spike protein, nucleoside modified

21,720 BNT162b2 21728 Placebo

Severe covid after first dose:

- 9 in Placebo group
- 1 in BNT162b2

Cases of covid onset after at least 7 days after second dose:

- 8 cases in BNT162b2
- 162 cases in Placebo:

“The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of adverse events was low and was similar in the vaccine and placebo groups.” P2603 p3.

Main Body of Paper:

“A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728)”, P2603 p4.

“Safe and effective prophylactic vaccines are urgently needed to contain the pandemic, which has had devastating medical, economic, and social consequences.” P2604 p 1.

“Findings from studies conducted in the United States and Germany among healthy men and women showed that two 30 mg doses of BNT162b2 elicited high SARS-CoV-2 neutralizing antibody titers and robust antigen-specific CD8+ and Th1-type CD4+ cell responses.”

“Here we report safety and efficacy findings from the phase 2/3 part of a global phase 1/2/3 trial evaluating the safety, immunogenicity, and efficacy of 30 mg of BNT162b2 in preventing Covid-19 in persons 16 years of age or older.” P2604 p3.

“Collection of phase data on vaccine immunogenicity of phase 2/3 data on vaccine immunogenicity and the durability of the immune response to immunization is ongoing, and those data are not reported here.” P 2604 p 3.

Study group included HIV, hep B or C patients.

Exclusion: Prior history of covid-19, immunosuppression. P. 2604 p 5.

Pfizer conducted trial, collected the data, performed the data analysis, data interpretation, and the writing of the manuscript. “This data set and these trial results are the basis for an application for emergency use authorization.[9](#)” P2604 p 3.

Study Design:

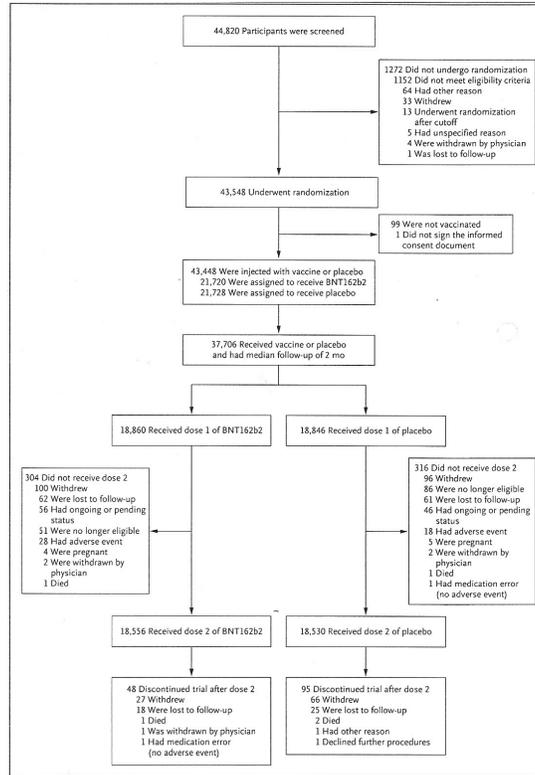


Table S1, Online Supplementary Appendix: Explanation of the various denominator values for use in assessing the results (available NEJM.org)

Figure/Table Number	Figure/Table Title	Population(s)/Sample Size	Explanation
Figure 1	Disposition of participants (CONSORT)	All enrolled population N=37,706 "main safety subset"	All randomized ≥16 years of age, N=43,548 <ul style="list-style-type: none"> [minus 99 non-vaccinated, 1 no ICD] Vaccinated N=43,448 Main safety subset (N=37,706) needed to have been enrolled by October 9, 2020 for EUA application
Figure 2	Local and Systemic Reactions Reported within 7 Days after Receipt of 30 µg BNT162b2 or Placebo by Age Group	Reactogenicity subset of ≥16 years old N=8,183	Per protocol
Figure 3	Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1	N=43,355 (modified intention-to-treat)	All randomized ≥12 years of age N= 43,651 <ul style="list-style-type: none"> [minus 99 non-vaccinated, 1 no ICD] Vaccinated (dose 1 efficacy) N=43,551 <ul style="list-style-type: none"> [minus 196 HIV+] All efficacy N=43,355
Table 1	Demographics	N=37,706 main safety subset	As above
Table 2	Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 [Primary Endpoints]	1st primary efficacy endpoint: Includes those without evidence of prior infection (N=36,523) 2nd primary efficacy endpoint: Includes those with and without evidence of prior infection (N=40,137)	Evaluable population: <ul style="list-style-type: none"> received 2 vaccinations as randomized no major protocol deviations Excludes HIV+
Table 3	Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection Prior to 7 Days After Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S2	Baseline Comorbidities	N=37,706 main safety subset	
Table S3	Participants Reporting at Least 1 Adverse Event From Dose 1 (All Enrolled Participants)	N=43,252	Vaccinated N=43,448 minus 196 HIV+
Table S4	Vaccine Efficacy from 7 Days After Dose 2 by Underlying Comorbidities among Participants without Evidence of Infection Prior to 7 Days after Dose 2	N=36,523 (same as 1st primary endpoint)	
Table S5	Vaccine Efficacy of Severe COVID-19 Occurrence after Dose 1 (Modified Intention-to-Treat)	N=43,355 (modified intention-to-treat)	See comments to Figure 3

Table S1 | Explanation of the Changes in Denominator Numbers in Various Analyses.

7

- 44,820 subjects screened & 43,448 participants injected:
 - BNT162b2
 - 18,860 dose 1: 28 withdrew after adverse reaction.
 - 18,556 dose 1 & 2: 48 discontinued after second

- 18,508 dose 1 & 2: completed 2-month follow-up
- Placebo
 - 18,846 dose 1: 18 withdrew after adverse reaction.
 - 18,530 dose 1 & dose 2: 95 discontinued after 2nd
 - 18,435 dose 1 & dose 2 completed 2-month follow-up.
- 43,355 subjects Modified intention-to-treat (mITT) efficacy population.
 - All age groups 12 years of age or older.
 - 100 participants who were 12 to 15 years of age “...contributed to person time years but included no cases.” P2605 p5.
- 40,137 subjects evaluated 7 days after the second dose “with or without evidence of prior infection”.
- 37,706 subjects “**Safety population**” (defined by the FDA):
 - Persons 16 years of age or older.
 - Median of 2 months of follow-up as of October 9, 2020.
- 36,523 subjects evaluated for efficacy 7 days after the second dose and “who had no evidence of prior infection”.
- 8183 subjects = Reactogenicity Subset

Methods:

“Participants received two injections, 21 days apart, of either BNT162b2 or placebo, delivered in the deltoid muscle.” P2604 p6. **Aspiration not mentioned.**

Adults 16 years of age or older who were:

- Healthy or had
- Stable chronic medical conditions, including but not limited to
 - Human immunodeficiency virus (HIV),
 - Hepatitis B virus, or
 - Hepatitis C virus infection

Division of work:

- Pfizer:
 1. Design and conduct of the trial,
 2. Data collection,
 3. Data analysis and interpretation
 4. Writing of the manuscript.

- BioNTech:
 - Trial sponsor
 - Manufactured BNT162b2
 - Contributed: interpretation of the data and the writing of the manuscript.

- **All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol, which is available with the full text of this article at NEJM.org. This data was not on the web site 4/13/2022.**

- An independent data and safety monitoring board reviewed efficacy and unblinded safety data.

Safety:

- Observation for 30 minutes after injection.

- Solicited data:
 1. End points.
 2. Specific local or systemic adverse events.
 3. Use of antipyretic or pain medication within 7 days after the receipt of each dose of vaccine or placebo, as prompted by and recorded in an electronic diary in a subset of participants (the reactogenicity subset)

- Unsolicited: Unsolicited serious adverse events through 6 months after the second dose.

- Adverse event data through approximately 14 weeks after the second dose are included.

- Safety data are reported for all participants who provided informed consent and received at least one dose of vaccine or placebo.
- Per protocol, safety results for participants infected with HIV (196 patients) will be analyzed separately and are not included here.
- A stopping rule for the theoretical concern of vaccine-enhanced disease was to be triggered if the one-sided probability of observing the same or a more unfavorable adverse severe case split (a split with a greater proportion of severe cases in vaccine recipients) was 5% or less, given the same true incidence for vaccine and placebo recipients. Alert criteria were to be triggered if this probability was less than 11%.

Efficacy:

Efficacy of BNT162b2 against **confirmed Covid-19**:

- o **First Primary End Point**: Onset of confirmed Covid-19 at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose. P. 2604

Restated: Confirmed Covid-19 after 28 days following the initial dose. Covid-19 positives prior to 28 days were considered unvaccinated. P2605 p 3.

- Confirmed COVID Diagnosis: FDA criteria. (No reference provided).
 - **One** of the following Symptoms:
 - Fever
 - Chills
 - Diarrhea
 - Vomiting
 - Loss of Taste
 - Loss of smell
 - New or increased:
 - Cough
 - SOB
 - Muscle pain

- **Plus:** a respiratory specimen in suspected SC2 + by NAAT obtained during symptomatic period +/- four days before.
- Second Primary End Point: was “efficacy in participants with and without evidence of prior infection.” P2605 p 3.
- Major secondary end points: Efficacy against severe covid. “Details are provided in the protocol.” P2605 p4.
 - Confirmed covid.
 - One of the following:
 - Respiratory failure.
 - Acute neurologic event.
 - Renal dysfunction.
 - Hepatic dysfunction.
 - ICU Admission.
 - Death.

Results:

Reactogenicity: n = 8183.

Local:

- Younger recipients reported symptoms more often than older >55

Local Pain	< 55	>= 55
First Dose	83%	71%
Second Dose	78%	66%

- **Systemic:** More reports after second dose than first:
 - Fatigue: 59% <55, 51% => 55, placebo 23%

- Headache: 51% < 55, 39% = >55, placebo 24%
- Temperature > 38 Deg C after second dose:
 - 16% < 55, 11% => 55
 - 38.9-40 deg C: 0.2% after 1st dose, 0.8% after 2nd dose; 0.1% placebo 1st and 2nd.
 - > 40 deg C: 2 subjects one in injected and placebo.
- Antipyretic/analgesic:
 - < 55: dose 1 = 28% & dose 2 = 45%.
 - => 55: dose 1 = 20% & dose 2 = 38%.
 - Placebo: dose 1 = 10 % & dose 2 = 14%.

Adverse Events: Table S3 (available online):

	BNT162b2 (30 µg) (N ^a =21621)	Placebo (N ^a =21631)
Adverse Event	n ^b (%)	n ^b (%)
Any event	5770 (26.7)	2638 (12.2)
Related ^c	4484 (20.7)	1095 (5.1)
Severe	240 (1.1)	139 (0.6)
Life-threatening	21 (0.1)	24 (0.1)
Any serious adverse event	126 (0.6)	111 (0.5)
Related ^c	4 (0.0)	0
Severe	71 (0.3)	68 (0.3)
Life-threatening	21 (0.1)	23 (0.1)
Any adverse event leading to withdrawal	37 (0.2)	30 (0.1)
Related ^c	16 (0.1)	9 (0.0)
Severe	13 (0.1)	9 (0.0)
Life-threatening	3 (0.0)	6 (0.0)
Death ^c	2 (0.0)	4 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 (All Enrolled Participants). The 'all enrolled' population included all participants who received at least 1 dose of vaccine irrespective of follow-up time. a. N = number of participants in the specified group. This value is the denominator for the percentage calculations. b. n = Number of participants reporting at least 1 occurrence of the specified event category. For 'any event', n = the number of participants reporting at least 1 occurrence of any event. c. Assessed by the investigator as related to investigational product.

n = 43,252 according to published article. P2608 p 3.

n = 43,252 according to online Table S1 P 7. "Vaccinated N=43,448 minus 196 HIV+."

n = 43,252 according to online Table S3 P 9. "All enrolled." At least 1 dose.

Any Event, Any Event Related and Any Event Severe are statistically significant, Appendix 1.

	BNT162b 2	Placebo
n =	21621	21631
All events	5770	2638

Related	4484	1095
% AE React	69%	31%
% All AE Total	27%	12%
% Rel. AE Total	21%	5%

Rel = Related AE; P = Placebo

	BNT162b2	Placebo
Lymphadenopathy	64	6

Efficacy:

	BNT162b 2	Placebo	VE*
n =	18198	18325	
Surveillance Time	2.214	2.222	
Covid-19: >= 28 days after dose 2	8	80	
Covid-19: <28 days after dose 2+ Placebo	39	82	52%
All	47	162	
Study comparison	8	162	95%

*VE = Vaccine Efficacy

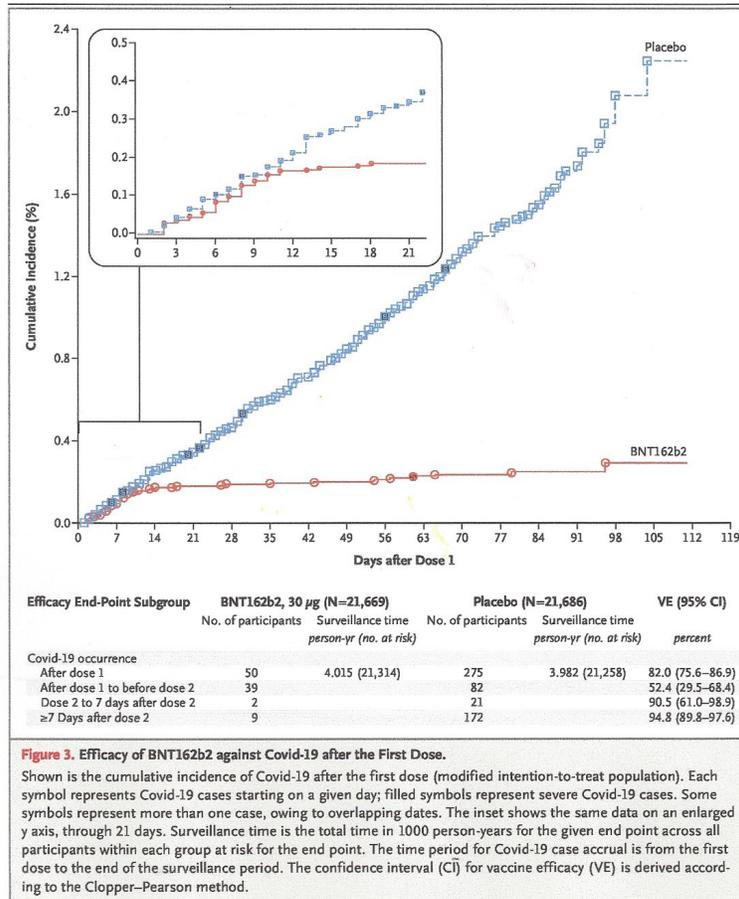


Figure 3. Efficacy of BNT162b2 against Covid-19 after the First Dose.
 Shown is the cumulative incidence of Covid-19 after the first dose (modified intention-to-treat population). Each symbol represents Covid-19 cases starting on a given day; filled symbols represent severe Covid-19 cases. Some symbols represent more than one case, owing to overlapping dates. The inset shows the same data on an enlarged y axis, through 21 days. Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from the first dose to the end of the surveillance period. The confidence interval (CI) for vaccine efficacy (VE) is derived according to the Clopper–Pearson method.

Discussion:

“A two-dose regimen of BNT162b2 (30 µg per dose, given 21 days apart) was found to be safe and 95% effective against Covid-19.”

“The vaccine met both primary efficacy end points, with more than a 99.99% probability of a true vaccine efficacy greater than 30%.”

“These results met our prespecified success criteria, which were to establish a probability above 98.6% of true vaccine efficacy being greater than 30%, and greatly exceeded the minimum FDA criteria for authorization.⁹”

“...in the interval between the first and second doses, the observed vaccine efficacy against Covid-19 was 52%, and in the first 7 days after dose 2, it was 91%, reaching full efficacy against disease with onset at least 7 days after dose 2.”

“Of the 10 cases of severe Covid-19 that were observed after the first dose, only 1 occurred in the vaccine group. This finding is consistent with overall high efficacy against all Covid-19 cases.”

“The severe case split provides preliminary evidence of vaccine mediated protection against severe disease, alleviating many of the theoretical concerns over vaccine-mediated disease enhancement.¹¹”

“Although the study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities.”

Comments/Questions:

1. Diagnosis of covid-19 required only one symptom and a positive NAAT test. Why was only one symptom + a positive NAAT rather than an actual clinical diagnosis based upon symptoms, signs, and supportive laboratory data?
2. NAAT have proven unreliable leaving only one symptom as the basis to diagnose covid-19. Are there any other studies of experimental gene therapy that are dependent upon a single symptom to diagnose a disease? How can this be adequate?
3. What NAAT was used and what are the statistics for false negatives and positives? Was the same test used throughout the study?
4. Aspiration was not reported as the technique for injection of the BNT162b2.
5. “All the trial data”, reported to have been available to all the authors, is no longer available with the full text of the article at NEJM.org as reported in the text. Why not?
6. Participants received “informed consent”. Where can the consent documenting risks, benefits and alternative be found?
7. Were participants with prior infection with SC2 included or not?
8. Where is the raw data for reactogenicity?
9. Complete reporting of symptoms, signs, laboratory and diagnostic studies is not provided.
10. Table S2 lists 14 disease categories after consolidating All Malignancies, Diabetes, and Liver Disease. The CDC identifies 21 disease categories.¹

- a. There were 18 subjects with dementia. What legal process was required for each of these individuals? How were they able to communicate their symptoms?
 - b. What was the distribution of co-morbidities the control versus experimental groups given that a major risk factor is clustering of co-morbidities in subjects? Data presented in Table S2 provides no information about clustering of co-morbidities in the study subjects. Some studies have indicated that covid-19 fatalities were associated with multiple co-morbidities average 3.8 per fatality.
 - c. Hypertension is a major risk factor that was not reported.
 - d. Coronary artery disease and arrhythmia are risk factors for covid-19 and Prevalence Data was not reported.
 - e. The number of smokers and drug users was not given.
 - f. Age is a continuous variable. It is also a risk factor. Table 1 gives age data for 16-55 and >55 years. These categories are overly broad. More granular data is required.
11. "The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively)." This data needs to be carefully examined. P2610 p2.
 12. "Lymphadenopathy, which generally resolved within 10 days, is likely to have resulted from a robust vaccine-elicited immune response." Given that lymphocytopenia is associated with BNT162b2, are there other explanations for lymphadenopathy? Was splenomegaly found in these cases? What were the lymphocyte counts for study subjects?
 13. "...the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain (sic) to be determined." Shouldn't a longer follow-up period be required given the experimental nature of this gene therapy?
 14. Physicians look to the NEJM as a trusted source for guiding their recommendations to patients. This publication is quite superficial given the gravity of the pandemic and the implications of administering this drug to a significant portion of the human race.
 15. The medical files of all covid-19 patients should be carefully reviewed as well as random sampling of the study population.

Appendix 1:

Test and CI for Two Proportions Any Event Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	5770	21621	0.266870
2	2638	21631	0.121955

Difference = $p(1) - p(2)$
Estimate for difference: 0.144916
95% CI for difference: (0.137582, 0.152249)
Test for difference = 0 (vs not = 0): Z = 38.73 P-Value = 0.000

Test and CI for Two Proportions Related Events Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	4484	21621	0.207391
2	1095	21631	0.050622

Difference = $p(1) - p(2)$
Estimate for difference: 0.156769
95% CI for difference: (0.150626, 0.162913)
Test for difference = 0 (vs not = 0): Z = 50.02 P-Value = 0.000

Test and CI for Two Proportions Severe Events Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	240	21621	0.011100
2	139	21631	0.006426

Difference = $p(1) - p(2)$
Estimate for difference: 0.00467436
95% CI for difference: (0.00291817, 0.00643054)
Test for difference = 0 (vs not = 0): Z = 5.22 P-Value = 0.000

Test and CI for Two Proportions Any Serious AE Sample 1 Vax Sample 2 Placebo

Sample	X	N	Sample p
1	126	21621	0.005828
2	111	21631	0.005132

Difference = p (1) - p (2)
 Estimate for difference: 0.000696143
 95% CI for difference: (-0.000695265, 0.00208755)

Appendix 2:

Pfizer Co-Morbidities	CDC Co-Morbidities
1 AIDS/HIV	1 Cancer
2 Any Malignancy	2 Chronic Kidney Disease
3 Cerebrovascular Disease	3 Chronic Liver Disease
4 Chronic Pulmonary Disease	4 Chronic Lung Disease
5 Congestive Heart Failure	5 Cystic Fibrosis
6 Dementia Report	6 Dementia
Diabetes With Chronic	
7 Complication	7 Diabetes
Diabetes Without Chronic	
8 Hemiplegia or Paraplegia	8 Disabilities
Leukemia	9 Heart Conditions
Lymphoma	10 HIV/AIDS
Metastatic Solid Tumor	11 Immunocompromised
9 Mild Liver Disease	12 Mental Health
Moderate or Severe Liver Disease	13 Obesity
10 Myocardial Infarction	14 Inactivity
11 Peptic Ulcer Disease	14 Pregnancy
12 Peripheral Vascular Disease	16 Sickle Cell Disease
	17 Smoking
	Solid organ/Stem Cell
13 Renal Disease	18 Transplant

14 Rheumatic Disease

19 Stroke or CVA

20 Substance Use

21 Tuberculosis

Report 18: “Concerns About Vaccine Candidate Used as Basis for Emergency Use Authorization” – Team 5.

At least one Pfizer study left many safety concerns unanswered, concerns that one would expect to be investigated and resolved before any mRNA vaccine was authorized for emergency use.

Beginning in April 2020, Pfizer, along with study sponsor BioNTech, conducted a Phase 1/2 study to identify preferred vaccine candidates and dose levels (<https://clinicaltrials.gov/ct2/show/NCT04368728>). One vaccine candidate that Pfizer studied was BNT162b1, which was *not* chosen as the final version of the Pfizer mRNA vaccine but which was discussed in documents submitted to the Food and Drug Administration (FDA) in support of the Pfizer vaccine emergency use authorization.

One of those documents was a paper based on the Phase 1/2 trial of vaccine candidate BNT162b1 published by Mulligan et al. (2020) in the journal *Nature* (https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). The paper describes the results of administering BNT162b1 to adults over 18 at three different dosages and at one or two different times (10 or 30 micrograms on days 1 and 21; or 100 micrograms on day 1).

Mulligan et al. argue that in RNA-based vaccines, the RNA is not incorporated into the host genome (p. 3, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). But this is contrary to findings by other researchers who demonstrate that RNA from the SARS-CoV-2 virus integrates into the host genome (Zhang et al., 2021, <https://www.pnas.org/doi/10.1073/pnas.2105968118>). It is also contrary to findings that the final version of the Pfizer mRNA vaccine, BNT162b2, is reverse-transcribed into host DNA beginning 6 hours after contact with the vaccine (Alden et al., 2022, https://mdpi-res.com/d_attachment/cimb/cimb-44-00073/article_deploy/cimb-44-00073.pdf). Alden et al. noted that whether the DNA that is reverse-transcribed from BNT162b2 is integrated into the cell genome is not known.⁴⁴

The research paper by Mulligan et al. raises additional safety questions. They note that the vaccine candidate they studied (BNT162b1) incorporates N1-methyl-pseudouridine “which dampens innate immune sensing and increases mRNA translation *in vivo*” (p. 3, https://phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf). They report that for the patients who showed changes in their blood after

⁴⁴ mRNA is reverse transcribed into DNA in both studies cited in this paragraph. It is not known whether the DNA resulting incorporates into the host genome.

receiving the mRNA vaccine, the largest changes were decreased numbers of lymphocytes (a type of white blood cell that plays a vital role in immune response). In fact, about 50% of the patients receiving their first 30 or 100 microgram dose showed decreased lymphocyte counts. Could the incorporation of N1-methyl-pseudouridine in the vaccine formulation be related to decreased lymphocyte counts? Could N1-methyl-pseudouridine be related to the unexpectedly long bioavailability of mRNA products?

Changes in blood cell counts were not the only side effects for patients in this study. In a Phase 1/2 study, “patients usually receive the highest dose of treatment that did not cause harmful side effects in the phase 1 part of the clinical trial”

(<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/phase-1-phase-2-clinical-trial>). Mulligan et al. found that as the dosage increased from 10 to 100 micrograms, adverse events such as fever, fatigue, headache, chills, diarrhea, and muscle and joint pain also increased. Reactogenicity was dose-related, as shown by Daily Clout volunteer researchers in Team 5, at a statistically significant level (<https://www.dropbox.com/home/Pfizer%20Research/Team%20Reports?preview=Team+5+Report++++Phase+1+2+f.pdf>).

These concerns and more arise from the research by Mulligan et al. on a variant of the mRNA vaccine that was ultimately approved by FDA for emergency use. And in spite of these concerns, the researchers state that “the clinical findings for the BNT162b1 RNA-based vaccine candidate are encouraging and strongly support accelerated clinical development . . . for the rapid production of a SARS-CoV-2 vaccine to prevent COVID-19” (p. 5, https://phmp.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-publications.pdf).

Instead of giving a green light to further development, perhaps Pfizer should have thoroughly investigated all safety questions and resolved these concerns before FDA approved any version of the vaccine?

Report 19: “What Did Pfizer Know, and When Did They Know It? Neurological Harms Concealed.” – Team 4.

This report assists in answering, “What did Pfizer know, and when did they know it?” concerning its COVID-19 vaccine. The report focuses on neurological complaints post-injection with the Pfizer COVID-19 vaccine, as well as on several other, non-neurological reported symptoms.

The information presented comes from the Centers for Disease Control and Prevention (CDC) Wonder website ([CDC.Wonder.gov](https://wonder.cdc.gov)) through which anyone can access CDC’s VAERS system. VAERS is a reporting system for vaccine manufacturers, health care providers, and the general public to notify the CDC of issues, injuries, symptoms, any problem with a vaccine.

The Vaccine Adverse Event Reporting System (VAERS) provides answers to what Pfizer knew about vaccine injuries resulting from its COVID-19 vaccine and when they knew it. The purpose of VAERS is to alert Pfizer, the CDC, and the Food and Drug Administration (FDA) to safety signals requiring investigation.

Below are seven screenshots of six VAERS reports obtained directly from the VAERS system.

1) The first screenshot shows reports of deaths and headaches reported by those vaccinated in January, February, and March of 2021. The mass vaccination of Americans had just started in that time frame. VAERS reports from the first three months gave Pfizer, the CDC and the FDA critical safety signal information to act upon, though they chose not to address the clear safety signals.

This screenshot shows 3,385 deaths reported in three months, as well as 27,084 headaches which will be elaborated upon in another screenshot.

[<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=6227282DDE2B9107FA07D6EF49E0>]

The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/15/2022

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Messages:

▶ **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**

▶ **These results are for 28,465 total events.**

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↑↓	Percent (of 28,465) ←
DEATH	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	893	3.1%
				Feb., 2021	1,357	4.8%
				Mar., 2021	1,135	3.9%
				Total	3,385	11.8%
				Total	3,385	11.8%
HEADACHE	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	10,374	36.5%
				Feb., 2021	6,690	23.5%
				Mar., 2021	10,020	35.2%
				Total	27,084	95.1%
				Total	27,084	95.1%
Total					30,469	107.0%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Figure 1: Deaths & headaches from COVID vaccine January through March of 2021 reported in VAERS screenshot

2) The second screenshot presents five categories of serious neurological complaints reported in January, February, and March of 2021: 900 cases of Bell's Palsy; 880 Cerebrovascular Accidents (CVA), also known as stroke; 138 reports of Guillain-Barre Syndrome; 118 reports of paralysis; and 175 of Transient Ischemic Attack (TIA), which is a temporary period of symptoms similar to – but not as severe as – those of a stroke.

[<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6>]

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↑↓
BELL'S PALSY	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	227
				Feb., 2021	263
				Mar., 2021	410
				Total	900
			Total	900	
CEREBROVASCULAR ACCIDENT	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	193
				Feb., 2021	314
				Mar., 2021	373
				Total	880
			Total	880	
GUILLAIN-BARRE SYNDROME	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	28
				Feb., 2021	50
				Mar., 2021	60
				Total	138
			Total	138	
PARALYSIS	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	26
				Feb., 2021	39
				Mar., 2021	53
				Total	118
			Total	118	
TRANSIENT ISCHAEMIC ATTACK	COVID19 VACCINE (COVID19)	PFIZER BIONTECH	2021	Jan., 2021	36
				Feb., 2021	60
				Mar., 2021	79
				Total	175
			Total	175	
Total					2,211

Figure 2: Bell's palsy, CVA, Guillain Barre, TIA from COVID vaccine January through March of 2021 reported in VAERS screenshot

3) Below are the results for three more categories of major neurological symptoms reported in January, February, and March of 2021 — 19 reports of Amyotrophic Lateral Sclerosis (ALS), a progressive nervous system disease that affects nerve cells in the brain and spinal cord, causing loss of muscle control; 50 reports of Multiple Sclerosis; and 656 seizures.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=676830642B26323B16BB6DEF1AF6)

The Vaccine Adverse Event Reporting System (VAERS) Results

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Messages:

- ▶ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▶ These results are for 667 total events.

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↕	Percent (of 667) ←
AMYOTROPHIC LATERAL SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	11	1.6
				Feb., 2021	3	0.4
				Mar., 2021	5	0.7
				Total	19	2.8
			Total	19	2.8	
MULTIPLE SCLEROSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	10	1.5
				Feb., 2021	12	1.8
				Mar., 2021	28	4.2
				Total	50	7.5
			Total	50	7.5	
SEIZURE	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	145	21.7
				Feb., 2021	165	24.7
				Mar., 2021	346	51.8
				Total	656	98.3
			Total	656	98.3	
Total					725	108.7

Figure 3: ALS, MS, Seizure from COVID vaccine January through March of 2021 reported in VAERS screenshot

4) While CVA and TIA, shown in the second screenshot above, are neurological complaints, they are caused by blood clots in the brain. Therefore, reviewing several other symptoms also caused by blood clotting issues is pertinent. The screenshot below shows reports of 294 Acute Myocardial Infarction (i.e., acute heart attack), 584 Deep Vein Thrombosis (DVT), and 790 Pulmonary Embolism in January, February, and March of 2021.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=51F5E583E6AEF7AE1A6A1BDCFD1B\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=51F5E583E6AEF7AE1A6A1BDCFD1B)

Messages:

- ▶ **VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.**
- ▶ **These results are for 1,549 total events.**

Symptoms ↓	Vaccine Type	Vaccine Manufacturer	Year Vaccinated	Month Vaccinated	Events Reported ↕	Percent (of 1,549) ←
ACUTE MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	52	3.3
				Feb., 2021	94	6.0
				Mar., 2021	148	9.5
				Total	294	18.9
			Total	294	18.9	
DEEP VEIN THROMBOSIS	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	123	7.9
				Feb., 2021	188	12.1
				Mar., 2021	273	17.6
				Total	584	37.7
			Total	584	37.7	
MYOCARDIAL INFARCTION	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	85	5.4
				Feb., 2021	108	6.9
				Mar., 2021	189	12.2
				Total	382	24.6
			Total	382	24.6	
PULMONARY EMBOLISM	COVID19 VACCINE (COVID19)	PFIZER\BIONTECH	2021	Jan., 2021	163	10.5
				Feb., 2021	267	17.2
				Mar., 2021	360	23.2
				Total	790	51.0
			Total	790	51.0	
Total					2,050	132.3



Figure 4: Acute myocardial infarction, pulmonary embolism, DVT from COVID vaccine January through March of 2021 reported in VAERS screenshot

5) The following screenshot shows that there were no reports of Acute Myocardial Infarction, death, and Pulmonary Embolism from 2015 through 2019 after receiving *any* Pfizer vaccine, prior to the COVID-19 vaccine debuted. Hundreds of Pfizer vaccines are listed in the VAERS system for 2015-2019. Yet, no one reported incidences of Acute Myocardial Infarction, death, or Pulmonary Embolism after receiving a Pfizer vaccine during those five years.

[\[https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=033107A2EA6A73EEDFA7EDAA68BE\]](https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=033107A2EA6A73EEDFA7EDAA68BE)

Data current as of 04/15/2022

Request Form Results Map Chart Report About

Dataset Other Data Help for Printing Help with
 Documentation Access Results Tips Exports Save Export Reset

Quick Options More Options Top Notes Citation Query Criteria

Messages:

- ▶ No non-zero results were found for your query. Use Quick Options above to show zero rows.
- ▶ You can also check for Caveats in the Notes section; they might contain information about why only non-zero results were returned.
- ▶ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▶ These results are for 0 total events.

Symptoms ↓	Vaccine Manufacturer	Year Vaccinated	Events Reported ↑↓	Percent (of 0) ↑↓
ACUTE MYOCARDIAL INFARCTION	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
DEATH	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
PULMONARY EMBOLISM	PFIZER\BIONTECH	2015	0	0.00%
		2016	0	0.00%
		2017	0	0.00%
		2018	0	0.00%
		2019	0	0.00%
		Total	0	0.00%
Total		0	0.00%	
Total		0	0.00%	



Figure 5: Death, Acute myocardial infarction, pulmonary embolism from all Pfizer vaccines reported in VAERS 2015-2019 screenshot

6) These final two screenshots show the first and last pages of a VAERS request for all symptom complaints in VAERS for *all* Pfizer vaccines administered from 2015 through 2019, before the COVID-19 vaccine was available. The total of reported symptoms complaints was only 559 for those five years. In contrast, there were 584 reports of Deep Vein Thrombosis in just the first three months of 2021, all related to Pfizer's COVID-19 vaccine. The most frequent complaints in this report before 2020 were for headaches, weakness, and muscle pain, all with less than 20 examples. In contrast, as shown in Figure 1 above, there were 27,000 headaches reported in association with Pfizer's COVID-19 vaccine. [<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=8EE87DA751B1EC168FBD8432A2E6>]

THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) RESULTS

Data current as of 04/15/2022

Request Form Results Map Chart Report About

Dataset Other Data Help for Printing Help with
 Documentation Access Results Tips Exports Save Export Reset

Quick Options More Options Top Notes Citation Query Criteria

Messages:

- ▶ The full results are too long to be displayed, only non-zero rows are available.
- ▶ VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- ▶ These results are for 86 total events.

Symptoms ↓	Vaccine Manufacturer	Year Vaccinated	Events Reported ↑↓	Percent (of 86) ↑↓
ABDOMINAL DISCOMFORT	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ABDOMINAL PAIN	PFIZER\BIONTECH	2019	3	3.49%
		Total	3	3.49%
	Total	3	3.49%	
ABDOMINAL PAIN LOWER	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ABDOMINAL PAIN UPPER	PFIZER\BIONTECH	2016	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ACOUSTIC STIMULATION TESTS	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ACOUSTIC STIMULATION TESTS ABNORMAL	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
AGEUSIA	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	
ALOPECIA	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total	1	1.16%	

f | | | in | |

Figure 6: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, first page of report

VISION BLURRED		Total	1	1.16%
	Total		1	1.16%
VISUAL IMPAIRMENT	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
VITAMIN D	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
VOMITING	PFIZER\BIONTECH	2017	1	1.16%
		2018	1	1.16%
		2019	2	2.33%
		Total	4	4.65%
	Total		4	4.65%
WEIGHT	PFIZER\BIONTECH	2018	1	1.16%
		2019	1	1.16%
		Total	2	2.33%
	Total		2	2.33%
WEIGHT DECREASED	PFIZER\BIONTECH	2018	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
WEIGHT INCREASED	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
WOUND	PFIZER\BIONTECH	2019	1	1.16%
		Total	1	1.16%
	Total		1	1.16%
X-RAY	PFIZER\BIONTECH	2016	1	1.16%
		2019	2	2.33%
		Total	3	3.49%
	Total		3	3.49%
X-RAY LIMB	PFIZER\BIONTECH	2016	1	1.16%
		2019	1	1.16%
		Total	2	2.33%
	Total		2	2.33%
Total			559	650.00%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the



Figure 7: All symptoms, all Pfizer vaccines reported in VAERS 2015-2019 screenshots, last page of report

Steve Kirsch noted, “The CDC knew in January 2021 that the vaccines were unsafe, but they said nothing.” [<https://stevekirsch.substack.com/p/the-cdc-knew-in-January-2021-that?s=r>] The evidence identified from VAERS that has been identified in the reports shows conclusively that Pfizer, the CDC, and the FDA knew that severe neurological and blood clotting harms were resulting from the mRNA vaccines on grand scale. To date, they remain silent and are not taking action to stop the life-altering and sometimes fatal outcomes from Pfizer’s COVID-19 vaccine.

Report 20: [“Effects of N1-methyl-pseudouridine in the Pfizer mRNA Vaccine”](#) – Team 5.

Introduction

The use of messenger RNA (mRNA) vaccines has been developing since 1990. Historically, there have been three significant problems associated with mRNA vaccines. First, it has always been a challenge for vaccine developers to get the desired mRNA into the cells of choice (the delivery problem). Second, introducing a foreign RNA (the vaccine mRNA) into a patient causes their body to initiate an innate immune response thereby causing pathogenesis when there actually was no infection (the immunogenicity problem). And third, RNAs are rapidly degraded by ribonucleases (RNases) which are enzymes that degrade RNA. These RNases are found virtually everywhere which not only hinders development, but also makes it difficult to get a desired mRNA in a vaccine to stay around long enough to elicit the desired response (the degradation problem). There are many summaries of these historical facts (Morais et al., 2021; Jain et al., 2021; Kariko et al., 2008).

The claim among mRNA vaccine manufacturers and some scientists is that the three problems cited above have been solved; but have they?

Both Pfizer and Moderna claim that they solved these problems by encasing the mRNA inside of a lipid nanoparticle (LNP) and by modifying the mRNA through the substitution of N1-methylpseudouridine for the nucleotide uridine (Morais et al., 2021; Jain et al., 2021; Nance and Meir, 2021; Pardi et al., 2018; Andries et al., 2015). The use of LNPs allegedly solves the delivery problem by getting the vaccine’s modified mRNA into the cells and helping to protect the mRNA molecules from degradation during their trip from injection site to target cells. Their use of LNPs is another matter to be addressed in a subsequent report.

The use of a modified uridine (N1-methylpseudouridine) to replace uridine was suppose to solve the last two problems: the inherent immunogenicity of foreign mRNAs and degradation of the mRNA. These matters are the topic of this report.

Does the use of a modified uridine (N1-methylpseudouridine) solve the problem of the immune response to a foreign RNA such as the vaccine delivered modified mRNA and premature degradation of the vaccine delivered mRNA?

It is difficult to dissect these two issues (mRNA immunogenicity and degradation) because they are so interconnected. But first, what is N1-methylpseudouridine and what does it do?

Modified Uridine

In nature, modified uridines (such as pseudouridine and N1-methylpseudouridine) incorporated into RNA allow the body’s immune system to distinguish “self” from “non-self”; that is, the body’s own RNA molecules (self) from foreign (non-self) RNA molecules (Kariko et al 2005). mRNA-based vaccine development was hindered for years because the body

recognized the vaccine mRNA as foreign and initiated an immune response to eliminate the foreign material. Vaccine manufacturers needed a way to suppress that immune response if mRNA vaccines were to be used. But what are the consequences of suppressing the body's first line of defense, innate immunity?

Pseudouridine was first described in yeast in 1957 (Davis and Allen, 1957) and named the fifth nucleotide, a name it still carries (Borchardt et al., 2020). Pseudouridine is an isomer of uridine; that is, pseudouridine has the same identical atomic composition as uridine but with a slightly different structure. For pseudouridine, although this change is structurally minor, when incorporated into an RNA molecule by the cell in a *strategic and specific* manner, the changes in properties it imparts to RNA molecules are major.

Besides being involved in gene expression and protein production, natural conversion of uridine to pseudouridine stabilizes the molecule and protects it from degradation by RNases and helps it to evade immune detection (Borchardt et al., 2020).

There is considerable evidence that the use of pseudouridine in vaccine mRNA does in fact protect the mRNA molecule from RNases and thus, slows its degradation and can suppress the unwanted immune response mechanism (Morais et al., 2021; Borchardt et al., 2020; Eyer et al., 2019; Zhao et al., 2018; Kariko et al., 2008). In addition, but not always mentioned, is that pseudouridine increases protein (including spike protein) production (Svitkin et al., 2017). Use of pseudouridine was justified by researchers on the basis that it is a naturally occurring modified nucleotide within our cells and gets *strategically and specifically* incorporated into many RNA molecules including mRNA. It is known to be involved in multiple aspects of gene expression and protein production (Morais et al., 2021).

However, pseudouridine contributes a universal base character to the nucleotide. Whereas uridine (U) normally base pairs only with adenine (A), pseudouridine exhibits a “wobble” character to it and will allow uridine to base pair with adenine (A), guanine (G), cytosine (C) and uridine (U). These natural modifications in a RNA molecule evidently contribute to its function (Morais et al., 2021; Parr et al., 2020; Svitkin et al., 2017). However, in a vaccine mRNA this would be problematic as it would change the amino acid sequence of the resulting protein; in this case, the spike protein. For a more thorough description of base pairing see the YouTube video <https://www.youtube.com/watch?v=7AtO8DuWsck> .

The vaccine manufacturers addressed the “wobble” characteristic of pseudouridine by substituting N1-methylpseudouridine into their mRNA construct rather than pseudouridine. N1-methylpseudouridine is different from uridine or pseudouridine, but has been shown to demonstrate the beneficial attributes of pseudouridine that the manufacturers sought (protection from degradation, evasion of immune detection, increased protein production, molecule stability) while eliminating the “wobble” character that pseudouridine exhibited (Svitkin et al., 2017; Parr et al., 2020; Morais et al., 2021; Nance et al., 2021).

N1-methylpseudouridine is also naturally occurring but with much lower frequency, and structurally and chemically, it differs considerably from pseudouridine.

N1-methylpseudouridine has an added methyl group (CH₃) and this modification probably contributes to its higher affinity for pairing with adenine, a much desired attribute for a vaccine mRNA because it is the normal pairing (Morais et al., 2021).

But in nature, modified nucleotides are *strategically and specifically* inserted and required for proper folding, stability and accurate decoding of RNA molecules (Wurm et al., 2012). Wu et al. (2015) found that abolishing specific pseudouridines in another type of RNA (ribosomal RNA or rRNA) severely affects ribosome function.

Borchardt et al. (2020) used mass spectrometry to analyze mRNA pseudouridine content. They found that pseudouridine was present at 0.2 to 0.6% of total uridine in mRNA from human HEK293T cells (a human immortalized cell line). They hypothesized that mRNA pseudouridylation controls metabolism in response to cellular conditions, and stress conditions induce changes in expression of these modified nucleotides. The placement of pseudouridines affects the RNA backbone conformation and stability of base pairs. Furthermore, pseudouridine alters RNA-protein interactions for several RNA binding proteins (RBPs) that regulate RNA processing. Borchardt et al. (2020) states that “artificial pseudouridylation of a single position can inhibit function.” Furthermore, they state that “pseudouridine is not always treated as a uridine by the ribosome and could affect translation of the protein.”

Therefore, given that the amount of pseudouridine is relatively small in nature (0.2 to 0.6% of total uridine in mRNA), and that the points of pseudouridine insertion are *strategic and specific*, and that even this amount of pseudouridylation is not well understood, what would be the anticipated outcome of total replacement of a foreign mRNA uridine population with an even more rare modified nucleotide, N1-methylpseudouridine? That is precisely what Pfizer did in its mRNA vaccine. They did not strategically and specifically replace some uridines in their already modified mRNA (already producing two amino acid substitutions in the spike protein), they replaced **all** uridines in the mRNA (Nance et al., 2021). But this issue is not mentioned in the Pfizer document 2.4 NONCLINICAL OVERVIEW (https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf) or in two papers published as a result of Pfizer’s Phase 1/2 trials (https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-int-erim-publications.pdf).

The knowledge base of pseudouridine is limited. Borchardt et al. (2020) summarizes it well; “Despite intensive investigation of the structural and biochemical effects of pseudouridine in various systems, the biological role of most endogenous pseudouridine remain unknown.” They continue, “Pseudouridine likely affects multiple facets of mRNA function including

reduced immune stimulation by several mechanisms, prolonged half life, as well as potentially deleterious effects on translation fidelity and efficiency.” Furthermore, the authors stated “The functions of endogenous pseudouridine in mRNA remain to be discovered.” They go on to state that RNA pseudouridylation could have widespread effects on RNA metabolism and gene expression and that “much remains to be known.”

Given that there is still so much to learn about how endogenous pseudouridine affects biological systems, we must ask ourselves what effects N1-methylpseudouridine might have on these same biological systems, especially considering that so little is known about N1-methylpseudouridine. After all, the enzyme, N1-methyltransferase, the enzyme that catalyzes the synthesis of N1-methylpseudouridine, was only identified in 2012 (Wurm et al., 2012). Studies on N1-methylpseudouridine began in earnest in 2015 (Andries et al., 2015). The history of pseudouridine dates back to the 1950s whereas the history of N1-methylpseudouridine only dates back to 2012. Obviously, science has barely scratched the surface of N1-methylpseudouridine and its effects on biological systems.

The incorporation of N1-methylpseudouridine in a mRNA vaccine is obviously not *strategic and specific* as in natural incorporation. Rather, Pfizer used a shotgun approach and they had no idea what the ramifications and unintended consequences of such a modification would be. How are the folding, function, localization and clearance of the subsequent protein affected? What does such a massively modified foreign mRNA do to the delicate balance of cells and bodies (homeostasis) that receive it?

To date, there has been nothing identified in nature that resembles the Pfizer modified mRNA, nothing even close. How does this Pfizer modified mRNA interact with the cell’ protein machinery? Where does it localize within the human body? How long does it last? Are there long-term toxicity, carcinogenicity or pharmacological concerns? None of this has been studied. In fact, there is no mention of pseudouridines or N1-methylpseudouridines in the Pfizer document 2.4 NONCLINICAL OVERVIEW (https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf).

Good science demands answers to these important questions, and the answers should have been obtained before injecting hundreds of millions of people globally (billions of doses) with such an experimental substance.

Immunogenicity: Solution or Problem?

Vertebrates, including humans, have evolved an immune system to eliminate pathogens. That system has two major branches, innate and adaptive immunity. The innate immune system is the body’s first line of defense. Frizinsky et al. (2019) states that it is “more than the first line of defense, it is crucial to the survival of the host.” The body reacts quickly to foreign RNA molecules by producing interferon, cytokines and chemokines (Kang and Compans, 2009;

Pardi et al., 2018). These molecules, and others, are released by the cells to protect the body through cell signals and pro-inflammatory responses. They may also impact the adaptive immune response which is the second line of defense. This report will only consider the innate immune response to a modified mRNA invader.

The effects of innate immunity on vaccine mRNA are incompletely understood but there does seem to be agreement that it prevented traditional mRNA vaccines from being used because the foreign RNA gets cleared by the immune system (Kariko et al., 2005; Svitkin et al., 2017; Borchardt et al., 2020; Parr et al., 2020; Morais et al., 2021; Jain et al., 2021). Pardi et al. (2018) noted that some mRNA-based vaccine platforms induce interferon which is associated with inflammation and potentially autoimmunity, edema, blood coagulation and thrombosis. It also increases cytotoxicity leading to apoptosis (cell death) which of course reduces the effectiveness of the vaccine.

Pepini et al. (2017) stated that “activation of the innate immune response by RNA vaccines is potentially a double-edged sword.” On the one hand, with activation of an innate immune response comes release of interferon and cytokines which facilitate the adaptive immune response (which might be needed later). On the other hand, it may, as discussed by Pardi et al. (2017), cause an inflammatory response to the vaccine leading to flu-like symptoms and potentially autoimmunity, edema, blood coagulation and thrombosis, as well as degradation of the vaccine mRNA. As early as February 2020, at that critical time of conception of the Pfizer mRNA construct, it was reported that “the influence of modified bases on the function of a synthetic RNA is poorly understood” (Parr et al., 2020). But it was known that modified RNA, containing pseudouridine or N1-methylpseudouridine, did suppress innate immunity. Aside from helping the vaccine’s modified mRNA to survive in the body, the consequences of suppressing innate immunity simply were not known.

Despite this lack of knowledge involving suppression of the innate immune system, Pfizer still chose to use mRNA modified with N1-methylpseudouridine (Morais et al., 2021; Nance et al., 2021). It was a trade off between maintaining the body’s innate immunity (its first line of defense) and ability to degrade and deactivate the vaccine’s mRNA, and a good adaptive immune response (the second line of defense) needed if a SARS-CoV-2 infection were subsequently encountered (Parr et al., 2020; Ivanova et al., 2021; Seneff et al., 2022). Although there is still much to learn about compromised innate immunity, it has for many years been recognized as a vital part of the adaptive immune system, which is critical in responding to an infection. Dysregulated innate immune responses are considered lethal early in life and many diseases are linked to malfunction in this system (Frizinsky et al., 2019).

It was by design, that N1-methylpseudouridine, as well as lipid nanoparticles, were used by Pfizer to modify the SARS-CoV-2 mRNA. As discussed above, they were specifically used to prevent degradation of the mRNA and suppress the innate immune response (Morais et al 2021, Nance et al 2021, Wadhwa et al 2020; Borchardt et al., 2020).

Already, the approach of suppressing the innate immune response in COVID-19 vaccinees is proving problematic. Suppressing the body's innate immune response downregulate critical systems related to cancer surveillance, infection control and cellular homeostasis (ability to maintain a steady state of chemical and physical conditions). Vaccinees are unable to upregulate their interferons (as described above) which affect numerous downstream sequences to protect the body (Pepini et al., 2017; Pardi et al., 2017; Parr et al., 2020; Liu et al., 2021).

Ivanova et al. (2021) evaluated the immune response of patients with acute COVID-19 (unvaccinated) and healthy adults after receiving the Pfizer BNT162b2 vaccine. Although infection with SARS-CoV-2 and vaccination have both been shown to stimulate an immune response, that response in the two groups was qualitatively different. In the COVID-19 patients the immune response was characterized by augmented interferon signaling and upregulation of genes associated with cytotoxicity. These responses were missing in the vaccinated group. The antibody and cellular profiles between the two groups also differed. The vaccine group elicited reduced levels of IgA and IgM antibodies compared to the COVID-19 group (Ivanova et al., 2021). This was also observed by Röltgen et al. (2022).

Another indication of impaired immune response is increased cell damage. Jain et al. (2021) reported on a study of 63 patients with "coronavirus disease 2019 vaccination-associated myocarditis (C-VAM)". All patients were less than 21 years of age, 92% were male, all had an mRNA vaccine and except for one patient, all presented after the second dose. This is not surprising considering that Avolio et al. (2021) demonstrated that SARS-CoV-2 spike protein may prompt damage to cardiac pericytes (part of microcirculation) *in vitro*. The Vaccine Adverse Event Reporting System (VAERS) reported 8,090 heart disorders associated with COVID-19 vaccines in 2021 which accounts for 97.7% of all vaccine adverse events in that year (<https://vaers.hhs.gov/about.html>).

Degradation: Solution or Problem?

Röltgen et al. (2022) reported that they found vaccine mRNA in germinal centers (secondary lymphoid organs including lymph nodes and spleen which are important for B-cell activation) up to 2 months after a second dose. Mauger et al. (2019) also demonstrated that increased guanine-cytosine (GC) content (a feature of the Pfizer modified mRNA) as well as modified nucleotides such as N1-methylpseudouridine could extend the mRNA half life and as a result, increase protein production.

Pfizer employed all of the known methods ((5'-cap, 5'-UTR, sequence modification, 3'-UTR and a 3' poly A tail) to prevent degradation and thereby increase the half life of their mRNA (Mauger et al., 2019; Wadhwa et al., 2020; Nance et al., 2021). Thus, it is not surprising that clearance of the vaccine mRNA is delayed and can be found 2 months post-injection (Röltgen et al., 2022). Yet, in the Pfizer document 2.4 NONCLINICAL OVERVIEW (p. 20,

https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf)

Pfizer states that “RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. *Therefore, no RNA or protein metabolism or excretion studies will be conducted*” (emphasis added). The modifications to the SARS-CoV-2 mRNA made by Pfizer were clearly made to prevent degradation and extend the half life of the vaccine’s mRNA (McKernan et al., 2021; Seneff et al., 2022; Nance et al., 2021; Morais et al., 2021; Mauger et al., 2019; Svitkin et al., 2017; Kierzek et al., 2013), yet Pfizer ignored this well-established fact and contradicted its own development logic and decided that “no RNA or protein metabolism or excretion studies will be conducted” (p. 20,

https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf)

. And the FDA accepted that contradiction in Pfizer’s science.

Spike Protein Production

One final issue related to the Pfizer mRNA vaccine to be briefly mentioned here is the enhanced spike protein production, generated from the vaccine mRNA. It is included here because it is, in part, related to the use of N1-methylpseudouridine in the vaccine’s modified mRNA. There are numerous other issues but they exceed the scope of this report. See Seneff et al. (2022) for a thorough discussion.

A side effect of N1-methylpseudouridine substitution is enhanced translation of mRNAs (enhanced protein production) (McKernan et al., 2022; Morais et al., 2021; Nance et al., 2021; Parr et al., 2020; Mauger et al 2019; Svitkin et al., 2017; Kariko et al., 2008). What problems are associated with over production of spike protein?

Brun et al. (2020) reported the process by which spike protein (S) is processed within the host cell and soluble S1 subunit is secreted into the extracellular space via lysosomes. Mishra et al. (2021) reported that excess spike protein causes microRNA (miRNA, a special type of RNA important in cellular regulatory function) to be exported out of the cells via exosomes. These released microRNAs get transported to distant tissues and organs, including the brain and central nervous system (CNS) where they are internalized and initiate a cascade of deleterious effects (Mishra et al., 2021).

MicroRNAs are being recognized as an enormously important component of gene expression and regulation and are associated with many diseases as well as immune response (O’Brien et al., 2018; Zhang et al., 2021). By the way, SARS-CoV-2 genome, including the spike protein mRNA, have been shown to encode their own miRNAs, some of which interact with human miRNAs (Liu et al., 2020). This undeniably important biomolecule was not mentioned by Pfizer either.

Conclusion

To summarize, Pfizer utilized lipid nanoparticles and a modified mRNA in which all natural uridine nucleotides were replaced with a rarely encountered nucleotide, N1-methylpseudouridine. While it solved their problems of RNA delivery, immunogenicity and degradation, it created some new problems. While uridine substitution was found to reduce the body's immune response to the foreign RNA and protect the mRNA from degradation, there are adverse effects from this strategy.

There is practically no scientific data available on how total uridine substitution in an mRNA will affect the delicate balance of the cellular and bodily physiology of the host and what downstream effects may be initiated. Yet Pfizer conducted no studies on this issue.

Suppressing the body's innate immune system also has downstream consequences, particularly if a SARS-CoV-2 infection is subsequently encountered. Increasing the stability and half life of the vaccine mRNA, along with increasing its translation, means increased production of the spike protein which, as it turns out, is itself a cause of pathogenesis.

Problems with the Pfizer vaccine design and failure to adequately investigate their effects on the delicate cellular systems of the human body are already manifesting themselves. These problems are summarized in VAERS (<https://vaers.hhs.gov/about.html>). The long list of adverse events is a reflection of these issues.

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Report 21: [“Cytokines: A Cause for Concern in Pregnant and Nursing Women?”](#) by Elon Espey, PMHNP, FNP, BC – Team 5.

Cytokines and their effects have been in the headlines as long as Covid-19 has been with us. But what do we know about cytokines, and what do we know about the effects of cytokines on pregnant and nursing women? How are cytokines related to mRNA vaccines and breast milk? This essay explores these questions and more.

What are cytokines? Cytokines are a large, diverse family of small proteins or glycoproteins that play an important role in regulating inflammatory and immune responses. According to Manoylov, M. K. (2020) these proteins are produced by many different immune cells, such as neutrophils, mast cells, macrophages, B-cells, and T-cells. Cytokines radiate out from immune cells and bind to specific receptors on other immune and non-immune cells. There the cytokines signal to the cell how it needs to behave, which is why cytokines are often referred to as “messenger cells” because they carry a “message” with them as they travel through the body. For instance, they may give the message to increase inflammation or pain. Nearly every organ of the body contains cells with cytokine receptors. Some of the various types of cytokines include: interleukins (IL 1-13), interferons (α , β , and γ), tumor necrosis factor (TNF), and transforming growth factor (TGF- β).

How do cytokines work? When a pathogen or harmful substance enters the body, immune cells, cytokines, and organs work together to respond. The first cell to notice the pathogen directs all the other cells by creating and sending out messages (cytokines) to the rest of the cells or organs, which respond as directed. Because cytokines derived from the immune system (immunokines) are toxic to cells, they have been used against certain types of cancer. However, their clinical usefulness is limited due to their short half-life and their wide ranging and unpredictable side effects (Farlex Partner Medical Dictionary, 2012).

Cytokines play a broad role in helping the immune system respond to diseases and drugs which modulate their effect and have led to some beneficial therapies. Cytokines may be “good” when stimulating the immune system to fight a foreign pathogen, attack tumors, or reduce an immune response, such as inflammation in patients with multiple sclerosis. On the other hand, cytokines may be “bad” when their expression causes inflammatory diseases. Therapeutic modulation of cytokine expression can tell the “good” cytokines to generate or control the immune system and block the “bad” cytokines to prevent damaging inflammatory events. However, care must be exercised, as some antibody therapeutics can cause “ugly” cytokine release which can be deadly (Ramani, T., et al., 2015).

A severe immune reaction in which the body releases too many cytokines into the blood too quickly is known as a cytokine storm. A cytokine storm can occur as a result of infection, autoimmune condition, or other disease, or even after treatment with some types of immunotherapy (National Cancer Institute, 2022). This phenomenon was first described in 1993 as an uncontrolled inflammatory response caused by an excess number of cytokines being released, leading to over-activation of other immune cells like T-cells, macrophages, and natural killer cells. The uncontrolled activity of these cells can lead to tissue damage, organ dysfunction, and sometimes death. They were even thought to have been responsible for the high number of deaths in young people during the 1918 flu pandemic (de Wit, E., et al., 2018).

How do cytokines affect pregnant and nursing women? A literature review of “Inflammatory Breast Diseases during Lactation: Health Effects on the Newborn” was conducted in 2008 by Wöckel, A., et al. The review revealed that an imbalance in cytokines in breast milk may have severe consequences for the child, which in turn affects the child’s development. On one hand, a rise in cytokines in breast milk is useful to activate a mechanism of maternal self-defense against infectious processes and could also be useful in breastfed infants in order to activate or stimulate their immunity. However, it is possible that a permanent oversupply of cytokines leads to an excessive stimulation/threat of the child’s immune system and subsequent onset of diseases. The review further

showed evidence of increased cytokines in breast milk during inflammatory processes and possible pathological effects of these higher cytokine levels on the newborn. Further study was recommended.

A study conducted by Dammann, O. and O'Shea, M. (2008) pointed out that evidence from epidemiological studies and experiments over more than 30 years in animals indicated that infection remote from the brain is a potential cause of cerebral white matter damage in human neonates. Since then, a large body of evidence suggests a link between infection and brain damage involving various mediators of inflammation, including cytokines, chemokines, and immune cells. These inflammatory mediators are also involved in brain-damaging processes that follow energy deprivation, as may occur with intrapartum asphyxia (deprivation of oxygen in a newborn). Equally as important is the role of cytokines in modulation of inflammation and repair after inflammation-related brain damage. The researchers suggest that strategies to reduce the frequency and extent of pre- and perinatal brain damage may derive from therapeutic interventions which either enhance the production or activity of certain "damage protectors" (e.g., anti-inflammatory cytokines) or inhibit the production or activity of specific "damage mediators" (e.g., inflammatory cytokines).

According to Pickler, R., et al. (2010), there is a growing body of literature supporting the relationship between maternal inflammation with preterm birth and adverse neonatal outcomes. Mediators of inflammation, most notably proinflammatory cytokines, have been implicated as having an association with adverse neonatal outcomes. Lyon, D., et al. (2010) conducted a systematic review of evidence from human studies for the association of levels of cytokines in the blood and preterm labor and adverse early fetal outcome. The most consistent finding was increased levels of proinflammatory cytokines; particularly interleukin (IL) 6, IL-1 β , and tumor necrosis factor α (TNF α) were associated with preterm birth. A follow up review by Pickler, R., et al. (2010) of evidence from human studies on the association of cytokine levels in blood with two early adverse outcomes in preterm infants found early infection and increased risk of neurological damage. The review revealed that the proinflammatory cytokines most frequently linked with sepsis are in the IL-1 family as well as TNF α and IL-6. The proinflammatory cytokines most frequently associated with neurologic insult in the reviewed studies were IL-1 β , IL-6, and IL-8. In all cases where IL-1 β was studied, the levels were increased when there was a neurologic insult.

Other studies reveal a correlation with miscarriages and cytokine levels. Calleja-Agius, J., et al. (2011) conducted an observational study over a 1-year period of 94 Maltese women presenting with threatened abortion (TM) compared to 564 age-matched controls from the National Obstetric Information System (NOIS) of Malta. A pilot study was carried out with subgroups of 10 women with TM (n=10), non-pregnant women (n=12), normal pregnant controls (n=9), and women presenting with missed miscarriage (n=11), whose plasma levels of β -human chorionic gonadotropin (β -hCG), tumor necrosis factor α (TNF α), interferon γ (IFN γ), interleukin-6 (IL-6), interleukin-10 (IL-10), and TNF receptors 1 (R1) and 2 (R2) were measured. Of the 94 women with TM, 25 (26.6%) proceeded to complete miscarriage and had a significantly higher incidence of antepartum hemorrhage (p<0.005), preeclampsia (p<0.05), fetal growth restriction (p<0.05), premature labor (p<0.001), and retained placenta (p<0.005). Significantly (p<0.05) higher level of TNF α and lower levels of TNF R2 were found in the TM subgroup compared to non-pregnant controls. The ratio of TNF α /IL-10 was significantly (p<0.05) higher and the β -hCG levels were significantly lower (p<0.01) in missed miscarriages and non-pregnant subgroups than in TM and normal pregnant controls. The IFN γ /IL-10 and IFN γ /IL-6 were significantly (p<0.001) different between the four subgroups with the lowest level found in the TM group. No similar gradient was found for the TNF α /IL-6 ratio. Therefore, it was concluded that changes in levels of cytokines could help predict and prevent the development of some of these complications.

Recently, a study conducted at the University of Massachusetts by Narayanaswamy, V., et al. (2022) found that immune responses to mRNA Covid-19 vaccination were present in most women's breast milk. The milk reportedly neutralized the spike protein in four (4) variants of concern, with the potential to confer passive immunity to the breastfed infant against SARS-COV2. The study measured levels of 10 key cytokines in milk of the 26 vaccinated lactating women who completed a questionnaire on side effects. The levels of IFN γ were

significantly higher in milk provided after the first dose and after the second dose as compared to milk provided before receiving the vaccine. For women who reported side effects (n=13), compared with samples provided before vaccinations, the levels of IFN γ increased by approximately 2.5-fold in samples provided after the first dose and by more than 20-fold in samples provided after the second dose. Overall, among women who reported any side effects, the levels of IFN γ were significantly higher in milk after vaccination than in milk provided before receiving the vaccine. Among the women who reported no side effects after either the first or second dose (n=13), compared with samples provided before vaccination, the median levels of IFN γ increased by approximately 2-fold in samples provided after the first dose and by 3-fold in samples provided after the second dose. Levels of five of the seven other tested cytokines were comparable across the three time points; levels of the remaining two cytokines were not consistently detectable. While the study showed antibodies to SARS-COV2 being transferred via breast milk, they also found that levels of antibodies/cytokines correlated with vaccine side effects that mothers experienced.

The above University of Massachusetts study has since been heavily cited and reported on frequently in support of vaccinating women while pregnant and lactating. One of the researchers, K. F. Arcaro was quoted as saying “women who did feel sick from the vaccine was [sic] associated with greater antibodies in the infant stool...so you might have felt badly, but that was a benefit for your infant” (Science Daily, 2022).

A cause for concern? Clearly cytokines are a diverse group of protein molecules that can be both beneficial and harmful. Increased levels of certain cytokines are shown to have deleterious effects in infants when passed from the mother’s milk during other (non-Covid-19) inflammatory events. So why would increased cytokine levels following maternal vaccination with mRNA Covid-19 “vaccines”, that are also noted to be associated with increases in maternal side effects, be any less harmful or cause for concern?

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Science Daily, January 10, 2022, University of Massachusetts Amherst, Vaccinated women pass COVID-19 antibodies to breastfeeding babies, study finds: Research detects SARS-CoV2 antibodies in infant stool.

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Report 22: [“Dr. Fernando Polack: Real Person or Ghost?”](#) – Team 5.

Who is Dr. Fernando Polack, and where does he work? Vanderbilt in Nashville? No. Johns Hopkins in Baltimore? No. Buenos Aires? Not that I can find.

In this brief foray into Dr. Polack’s background, he appears to be more of a well-funded ghost than a real person.

Program notes from CIPP XVI in Lisbon Portugal dated June 22-25, 2017 reads:

*“[Dr. Fernando Polack](#) is a Specialist in Pediatric Infectious Diseases, graduated with Honors from the University of Buenos Aires in 1990. Dr. Polack completed residency training at the French Hospital in Buenos Aires and at William Beaumont Hospital in Michigan followed by a post-doctoral fellowship at Johns Hopkins University. Dr. Polack is the **Cesar Milstein Professor in the Department of Pediatrics at Vanderbilt University** and the **Scientific Director of the INFANT Foundation in Buenos Aires which coordinates a network of 26 hospitals in Argentina**. Dr. Polack has led numerous scientific manuscripts in reputed journals, including New England Journal of Medicine (NEJM), Nature Medicine, Journal of Experimental Medicine and Proceedings of the National Academies of Sciences (PNAS), among others. His work is funded by the Bill & Melinda Gates Foundation, the National Institutes of Health (NIH), the Thrasher Research Fund, the Optimus Foundation and other international organizations.”*

[\(Source\)](#)

Dr. Polack is listed as Cesar Milstein Professor in the Department of Pediatrics at Vanderbilt University.

“PLENARY SESSION

08:30 – 10:00 – Room A

Chairmen:

Paulo Camargos – Belo Horizonte, Brazil

Renato Stein – Porto Alegre, Brazil

- 1. Maintaining Respiratory Health in Resource-poor Populations.
Catherine Byrnes – Auckland, New Zealand*
- 2. Mortality Associated with Severe Viral Infections in Early Life.
Fernando Polack – Buenos Aires, Argentina*
- 3. Food Allergy for Respiratory Pediatricians.
Adnan Custovic – London, UK*

Respiratory Viruses and Their Relation to Disease

10:30 – 12:00 – Room B

Chairpersons:

Milagros Salvani Bautista – Manila, Philippines

Antonio Martinez Gimeno – Toledo, Spain

1. *Viral Bronchiolitis in Children.*

Giovanni Rossi – Genoa, Italy

2. *The Drakenstein Child Health Study: New Insights into Childhood LRTI.*

Heather Zar – Cape Town, South Africa

3. *Advances in Prevention of RSV Disease.*

Fernando Polack – Buenos Aires, Argentina”

However, [Vanderbilt Department of Pediatrics](#) has no such faculty member or chaired position.

There is also no listing for Dr. Polack at [Vanderbilt Children’s Hospital](#).

[Vanderbilt Institute for Global Health](#) has no listing in Buenos Aires and no record of Dr. Polack.

[International Training Programs](#) through Vanderbilt has no listing for Dr. Polack or for Buenos Aires, past or present.

“INFANT Foundation

This program will provide participants with the opportunity to conduct biomedical translational research or pediatric rotations at hospitals and medical centers in Buenos Aires.”

“Fernando received the Award for Excellence in Research and Young Pediatric Investigator by the Pediatric Research Society and the Pediatric Society of the United States; The Thomas and Carol McCann Award in Respiratory Research, from the Johns Hopkins School of Public Health and the Pasteur Mèrieux Connaught Laboratories Fellowship in Pediatrics from the Infectious Diseases Society of America In Argentina, the B’nai B’rith at the Human Rights Award; Louis Pasteur Prize, O.S. Health, National Academy of Medicine and Distinguished Citizen in the Field of Sciences, of the Government of the City of Buenos Aires. He is also a Member of the Argentina 2030 Presidential Council and Honorary Professor, Maimonides University and Doctor Honoris Causa, Antenor Orrego Private University, Trujillo, Peru. In addition, Fernando is a Member of the Society for Pediatric Research (SPR), the American Pediatric Society (APS), the Society of Clinical Investigators (ASCI) of the Committee of the International Respiratory Syncytial Virus Society and the American Association for the Advancement of Science (AAAS). He is advisor to the Food and Drugs Administration (FDA) Vaccine Safety Committee and Consultant to the World Health Organization (WHO) Pediatric Vaccine Development Committee in Geneva.”

[Doximity](#) gives an office for Dr. Polack in Baltimore:

“Office

600 N Wolfe St
Baltimore, MD 21287

Phone (410) 614-3917

Summary: *Dr. Fernando Polack, MD is a pediatric infectious disease specialist in Baltimore, Maryland.”*

But there are No office hours or listing for Dr. Polack as a staff member at [Johns Hopkins](#).

So where does Dr. Polack work? Nowhere that I can find. The following are a few other sources I have searched.

- <https://diariodeflores.com.ar/quien-es-fernando-polack-el-director-de-la-fundacion-infant-que-t-rajo-la-vacuna-que-probara-el-pais-contra-el-coronavirus/>
- <https://doctor.webmd.com/doctor/fernando-polack-9dc76de1-e317-49cf-a305-2aab73df9851-overview>
- <https://www.resvinet.org/fernando-polack.html>

Yet, Dr. Polack was a major contributor to the Pfizer Phase 3 trial and was lead author of NEJM article presenting results before widespread distribution of BNT162b2. There have been others who have questioned the veracity of the Polack contribution.

- <https://threadreaderapp.com/thread/1523617233255436289>
- <https://stevekirsch.substack.com/p/if-this-isnt-covid-vaccine-clinical?s=r>
- https://boriquagato.substack.com/p/are-we-pfinding-pfizer-pfraud-part?r=chkp3&s=r&utm_campaign=post&utm_medium=web
- https://boriquagato.substack.com/p/are-we-pfinding-pfizer-pfraud-part-fa2?r=chkp3&s=r&utm_campaign=post&utm_medium=web
- <https://davidhealy.org/fishy-business-in-the-rio-de-la-plata/>

The topic of Dr. Polack warrants further investigation given his alleged role in the Pfizer COVID-19 vaccine trials.

Dr. Polack appears to be a ghost who produces prodigious research funded by NIH, the Gates Foundation and Pfizer.

Report 23: [“Risks to Babies of Vaccinated Mothers as Reported in VAERS”](#) by Maria Ziminsky and Linnea Wahl – Team 5.

If you are pregnant, your baby is more likely to die at or before birth if you receive a COVID-19 vaccine than if you receive measles, mumps, flu, tetanus, or any other vaccine. This and other alarming facts about risks to babies of vaccinated mothers comes from the U.S. government’s own Vaccine Adverse Event Reporting System ([VAERS](#)).

According to VAERS, between 1998 (the earliest VAERS reporting date) and May 2022, the total number of pregnant women who were vaccinated for all diseases and then lost their babies was 6,695. These babies died in spontaneous abortions and fetal disorders such as cardiac arrest and cystic hygroma (a tumor that forms on a newborn’s neck). But just in the past couple years, 3,816 babies died after their mothers received a COVID-19 vaccine manufactured by Moderna, Pfizer/BioNTech, or Janssen (Table 1). These women were vaccinated between December 2020 and March 2022. That means 57% of all the vaccinations that resulted in a baby or fetus dying in the past 25 years or so occurred when pregnant women started receiving COVID-19 vaccines.

Also according to VAERS, we know that very soon—within the first 10 days—after these mothers were vaccinated against COVID-19, 1,559 of their babies or fetuses died. The remaining 2,257 babies died from day 10 on. Of the pregnant women who had spontaneous abortions or their babies died of other fetal disorders, 20% lost their babies on the same day the mothers were vaccinated, and 21% lost their babies in the following 9 days (Table 2). Could it be a coincidence that a COVID-19-vaccinated woman loses her baby, and 41% of the time the baby dies within 10 days of the mother’s vaccination?

In spite of this unusual “coincidence,” many pregnant women go ahead with COVID-19 vaccination as [recommended](#) by the Centers for Disease Control. Does VAERS suggest which vaccine is safest for an unborn baby? Indeed, for women vaccinated between December 2020 and March 2022, VAERS reports that of the 3,816 pregnant women whose babies died after COVID-19 vaccination, 2,819 women—nearly 74%—received the Pfizer/BioNTech vaccine (Table 1). About 21% received Moderna’s vaccine and less than 5% received Janssen’s vaccine. Babies’ deaths were roughly equal after the mothers’ first and second shots. These figures are rough; they would be more accurate if we knew how many pregnant women were vaccinated with each of the three vaccines. Still as we have [reported](#) before, the Pfizer/BioNTech vaccine appears to be putting unborn babies at increased risk of death.

These are alarming figures, and they are even more so when we understand what VAERS data represent. The U.S. government’s [guide to VAERS](#) states that “‘Underreporting’ is one of the main limitations of passive surveillance systems, including VAERS. The term, underreporting refers to the fact that VAERS receives reports for only a small fraction of actual adverse events.” So we must keep in mind the 3,816 babies who died after their mothers were vaccinated between December 2020 and March 2022 are probably only a fraction of the actual number of adverse events such as spontaneous abortions and fetal deaths.

There are other limitations to data gathered in VAERS. The total count of unborn babies who died after their mothers were vaccinated (6,695) varies depending on the data selection criteria, such as symptoms, vaccine manufacturer, and vaccine products (Fig. 1). In addition, VAERS has data integrity

issues; for example, sometimes intervals have no data associated with them, the system doesn't collect information on how old a fetus was at death (how far along the woman's pregnancy was), and follow-up health records are not available (from the [VAERS website](#): "amended [followup] data are not available to the public"), making it difficult to verify cause and effect. Usefulness of the VAERS data also suffers because VAERS does not tell us the total number of doses given to pregnant women for each vaccine.

Nonetheless, the VAERS data suggest, as do [Pfizer sources](#), grave danger to pregnant women and their babies from COVID-19 vaccines. When will the U.S. Centers for Disease Control and the Food and Drug Administration acknowledge and act on these alarming safety signals?

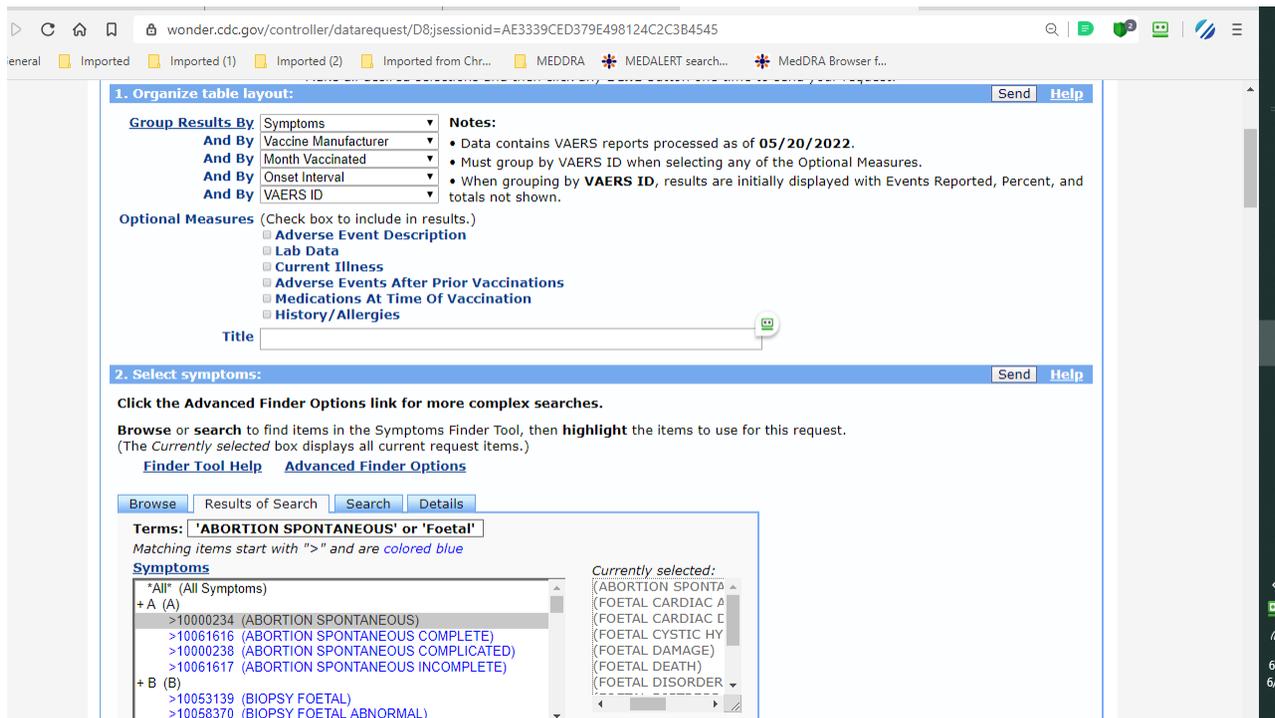


Fig. 1. Sample VAERS Query

Table 1. VAERS Fetal Deaths After COVID-19 Vaccination

COVID-19 vaccine manufacturer	VAERS symptom resulting in fetal death	Number of cases	% of total cases	
Moderna	Fetal exposure during pregnancy	32		
	Spontaneous abortion	693		
	Fetal death	73		
	Fetal disorder	18		
	Fetal cardiac disorder	4		
	Fetal distress syndrome	1		
	Subtotal	821	21.5%	
	Pfizer/BioNTech	Fetal exposure during pregnancy	89	
Spontaneous abortion		2418		
Fetal death		236		
Fetal cystic hygroma		9		
Fetal cardiac arrest		20		
Fetal disorder		16		
Fetal cardiac disorder		15		
Fetal distress syndrome		15		
Fetal damage		1		
Subtotal		2819	73.9%	
Janssen		Fetal exposure during pregnancy	43	
		Spontaneous abortion	115	
		Fetal death	11	
	Fetal cystic hygroma	1		
	Fetal cardiac arrest	2		
	Fetal disorder	1		
	Fetal cardiac disorder	2		
	Fetal distress syndrome	1		
Subtotal	176	4.6%		

Total cases		3816
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Table 2. VAERS Days After Mother's COVID-19 Vaccination of Reported Fetal Death

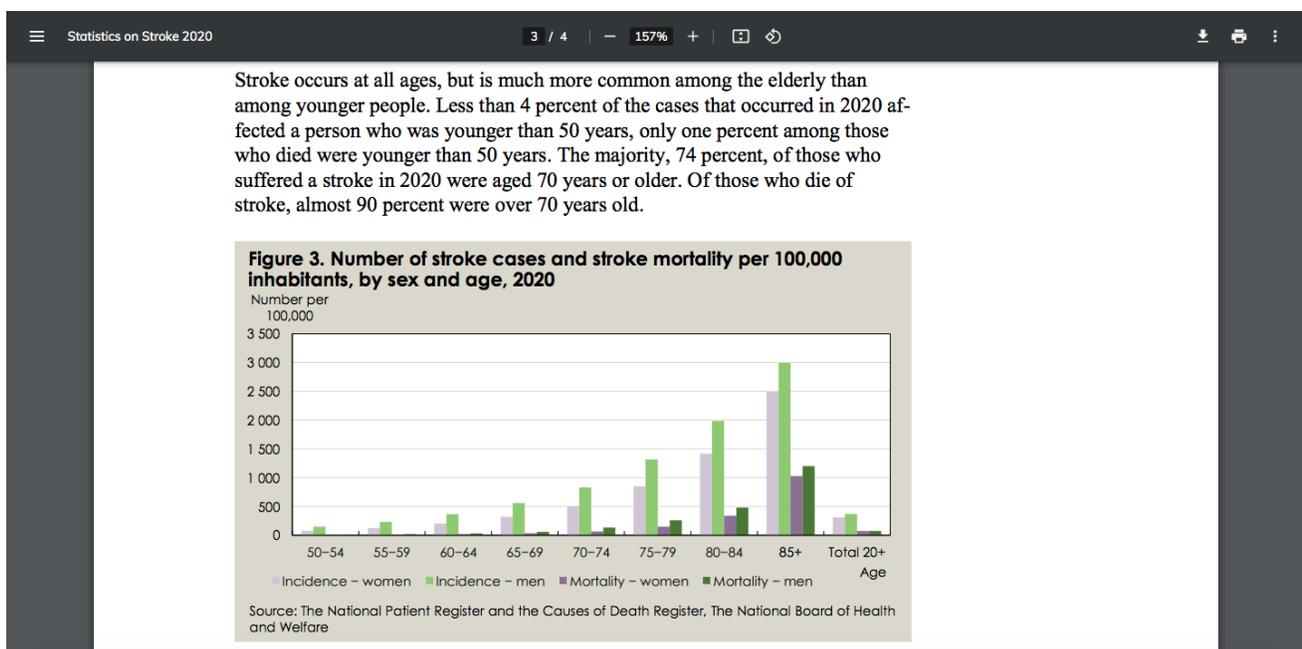
VAERS symptom resulting in fetal death	Day 0	Day 1–9	Day 10–14	Day 15–30	Day 31–60	Day 61–120	> 121 Days	Not known	Total cases
Fetal exposure during pregnancy	64	7	4	8	7	2	6	66	164
Spontaneous abortion	601	707	233	455	396	218	112	504	3226
Fetal death	71	70	25	44	30	20	14	46	320
Fetal cystic hygroma	2	1	1	1	1	2	0	2	10
Fetal cardiac arrest	10	4	0	1	1	0	0	6	22
Fetal disorder	3	5	4	1	5	8	5	4	35
Fetal cardiac disorder	3	4	1	2	1	2	3	5	21
Fetal distress syndrome	3	4	0	0	1	3	2	4	17
Fetal damage	0	0	0	0	1	0	0	0	1
Total cases	757	802	268	512	443	255	142	637	3816
% of total cases	20%	21%	7%	13%	12%	7%	4%	17%	

Report 24: Strokes: “What Did Pfizer Know, and When Did They Know It?” by Melanie Brown – Team 4.

Strokes are a serious, often life-threatening event that can result in death or permanent life altering disability. The incidence of stroke is much more common in the elderly than in younger people. A series of reports are being done to determine what Pfizer knew about any dangers with their vaccine and when did they know it. In this report, a few searches of the Centers for Disease Control and Prevention (CDC) Wonder website Vaccine Adverse Event Reporting System (VAERS) [<https://wonder.cdc.gov/controller/datarequest/D8>] shows that strokes are a fairly common adverse effect occurring in people of all ages that received the Pfizer vaccine. This report delves into some of these cases to determine if the vaccine may be the cause.

The first report [<https://dailyclout.io/what-did-pfizer-know-and-when-did-they-know-it-neurological-harms-concealed/>] in this series answering, “What did Pfizer know, and when did they know it?” in regard to the Pfizer BioNTech COVID-19 vaccine, looked at the number of neurological adverse events reported in the VAERS [<https://wonder.cdc.gov/controller/datarequest/D8>]. It showed the incidence of neurological adverse events reported. Conclusions were startling: the Pfizer vaccine is causing great neurological harm, and this harm was evident early 2021. Pfizer failed to pause the rollout to look at these adverse events.

This new report takes a closer look at just one neurological adverse event type: stroke. Strokes are due to a sudden disruption of the blood supply in the brain, usually a clot, blocking the blood supply (ischemic stroke) or by the leaking or rupturing of an artery (hemorrhagic stroke). Ischemic strokes are the most common. Brain cells will die within minutes due to a lack of oxygen during an ischemic stroke or due to damage from the pressure created by bleeding in the case of the hemorrhagic stroke. According to Statistics on Stroke 2020, Socialstyrelsen, 2/12/21, Art No. 2021-12-7644, 1(4), ISSN 1400-3511, less than four percent of the cases that occurred in 2020 affected a person under age 50, and only one percent of them died. [<https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf>, p. 3] The majority (74%) of those who had a stroke in 2020 were over the age of 70. [<https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf>, p. 3] Figure 3 from this journal article is depicted in the screenshot below clearly showing the incidence of stroke in different age groups.



This next screenshot is the first page of a VAERS database search offering an overall look at those who received the Pfizer COVID vaccine and reported having a stroke during 2021 (all ages). It shows 561 strokes. Of these, 44 were reported in January and February of 2021 alone. [<https://wonder.cdc.gov/controller/datarequest/D8>]

The Vaccine Adverse Event Reporting System (VAERS) Results
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Messages:

- The full results are too long to be displayed, only non-zero rows are available.
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 516 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Vaccine Manufacturer	Age	Month Reported	Adverse Event Description
0928572-1	PFIZER/BIONTECH	65-79 years	Jan., 2021	Facial drooping on 1/4/2021 6 days after the vaccine suffered a mild TIA or bells palsy event. appointments for a CT scan. Has mild facial drooping on the side that is already affected by TIA / cerebral hemorrhage. The long-term or permanent outcome is unknown.
0932145-1	PFIZER/BIONTECH	80+ years	Jan., 2021	Patient came into the emergency department on 1/8/21 with an acute ischemic stroke with complete occlusion of her left MCA. She had acute and complete flaccid paresis of her right face, arm, and leg, complete aphasia, and neglect of the right side of her body. NIHSS of 27. Onset of deficit was between 6:30pm-7:10pm. She received her 1st COVID-19 vaccine dose that morning at 10:31am.
0938118-1	PFIZER/BIONTECH	50-59 years	Jan., 2021	on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm
0942237-1	PFIZER/BIONTECH	60-64 years	Jan., 2021	She got the vaccine on Dec 23, and then on Jan 4 she had a mild stroke with left sided arm and face weakness. She did recover fully. She already has known CAD and risk factors for CVD. It is possible, but by no means certain, that the vaccine was an indirect cause of the event. Since the vaccine provoked an immune response, as it was supposed to, it is possible that this inflammation may have set up a metabolic predisposition that may have contributed to the event, which was 12 days later.
0943266-1	PFIZER/BIONTECH	80+ years	Jan., 2021	Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - aneurism lead to death approximately 14 hours after initial symptoms.
0949555-1	PFIZER/BIONTECH	65-79 years	Jan., 2021	Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficulty walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.
0951101-1	PFIZER/BIONTECH	80+ years	Jan., 2021	PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASNT ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMENT IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITAL DETERMED THAT SHE HAD A STROKE. ACUTE KIDNEY INJURY, ABNORMAL LFTS.
0960018-1	PFIZER/BIONTECH	65-79 years	Jan., 2021	Pt reported difficulty in swallowing and wife noticed left-sided facial droop morning of 1/10. Patient admitted for concerns of TIA. Symptoms resolved prior to hospitalization. Patient had MRI brain without contrast of the find evidence of acute infarct. Neurology recommended treatment patient has TIA and having dual anti-platelet therapy for 21 days followed by monotherapy of Plavix for stroke prevention. Patient was stable discharge to home 1/12/21
				Internal brain bleeding 10 days after 1st dose covid vaccine; Brain damage; confused; suffering memory loss; This is a spontaneous report from a non-attending physician (patient). This 30-year-old female patient received the 1st dose of BNT162B2 / BNT162B3

A similar search for all Pfizer influenza vaccines (over 10 of them) for the years 2015 through 2019, showed not a single stroke was reported, as seen in the following screenshot. [<https://wonder.cdc.gov/controller/datarequest/D8>]

wonder.cdc.gov/controller/datarequest/D8;sessionid=848853EFD8B81D285E6069B0B7AC

The Vaccine Adverse Event Reporting System (VAERS) Results

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MESSAGES:

- No non-zero results were found for your query. Use Quick Options above to show zero rows.
- You can also check for **Caveats** in the **Notes** section; they might contain information about why only non-zero results were returned.
- The full results are too long to be displayed, only non-zero rows are available.
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 0 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Vaccine Manufacturer	Age	Month Reported	Adverse Event Description
<p>Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).</p>				

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Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.

The next two screenshots are the results of a search on the VAERS database for the Pfizer vaccine only in conjunction with strokes within three days of receiving the vaccine during the time frame of December 2020 through 2021. The search resulted in 41 stroke incidences in people under the age of 50 [<https://wonder.cdc.gov/controller/datarequest/D8>]. According to the article from Socialstyrelsen, this is the age group with less than 4% of the strokes. [<https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2021-12-7644.pdf>, p. 3] Most importantly, these 41 strokes occurred within three days of taking the vaccine, and about 44% occurred the very same day. This is highly suggestive of the vaccine being a strong contributing factor to, if not the cause of, the strokes. The search did not include the number of shots the person received, though many of the individual's reports did include this information. The number of shots varied from person to person. Some experienced a stroke after their second shot, but others experienced a stroke after just 1 shot. Most of the strokes were equally distributed between the 30-39 and the 40-49 age categories, but several were also seen in the 6-17 and the 18-29 age groups. In general, strokes in these age groups are rare.

The Vaccine Adverse Event Reporting System (VAERS) Results
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MESSAGES:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 41 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Age	Onset Interval	Events Reported	Percent (of 41)
CEREBELLAR INFARCTION	6-17 years	3 days	1	2.44%
CEREBELLAR INFARCTION	6-17 years	Total	1	2.44%
CEREBELLAR INFARCTION	18-29 years	0 days	1	2.44%
CEREBELLAR INFARCTION	18-29 years	Total	1	2.44%
CEREBELLAR INFARCTION	40-49 years	0 days	1	2.44%
CEREBELLAR INFARCTION	40-49 years	1 day	1	2.44%
CEREBELLAR INFARCTION	40-49 years	Total	2	4.88%
CEREBELLAR INFARCTION	Total	Total	4	9.76%
CEREBELLAR STROKE	30-39 years	1 day	1	2.44%
CEREBELLAR STROKE	30-39 years	3 days	1	2.44%
CEREBELLAR STROKE	30-39 years	Total	2	4.88%
CEREBELLAR STROKE	Total	Total	2	4.88%
CEREBRAL ARTERY EMBOLISM	30-39 years	0 days	1	2.44%
CEREBRAL ARTERY EMBOLISM	30-39 years	Total	1	2.44%
CEREBRAL ARTERY EMBOLISM	Total	Total	1	2.44%
CEREBRAL ARTERY OCCLUSION	30-39 years	0 days	1	2.44%
CEREBRAL ARTERY OCCLUSION	30-39 years	Total	1	2.44%
CEREBRAL ARTERY OCCLUSION	40-49 years	0 days	1	2.44%

CEREBRAL THROMBOSIS	40-49 years	3 days	2	4.88%
CEREBRAL THROMBOSIS	40-49 years	Total	5	12.20%
CEREBRAL THROMBOSIS	Total	Total	8	19.51%
CEREBRAL VENOUS SINUS THROMBOSIS	6-17 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	6-17 years	Total	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	2 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	3 days	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	18-29 years	Total	4	9.76%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	2 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	30-39 years	Total	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	0 days	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	1 day	1	2.44%
CEREBRAL VENOUS SINUS THROMBOSIS	40-49 years	Total	2	4.88%
CEREBRAL VENOUS SINUS THROMBOSIS	Total	Total	9	21.95%
CEREBRAL VENOUS THROMBOSIS	40-49 years	0 days	1	2.44%
CEREBRAL VENOUS THROMBOSIS	40-49 years	Total	1	2.44%
CEREBRAL VENOUS THROMBOSIS	Total	Total	1	2.44%
Total		Total	46	112.20%

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

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The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or other attributes associated with vaccine.

Taking a closer look at the individuals who suffered these strokes shows that many of these people were young and healthy without much medical history. The following screenshots are a few examples.

<https://wonder.cdc.gov/controller/datarequest/D8>

This screenshot details two cerebral venous sinus thrombi detected in a 27-year-old female that received the second dose of a Pfizer COVID-19 vaccine. The onset of her symptoms started the same day she received the injection. [\[https://wonder.cdc.gov/controller/datarequest/D8\]](https://wonder.cdc.gov/controller/datarequest/D8)

Details for VAERS ID: 1194661-1

Event Information			
Patient Age	27.00	Sex	Female
State / Territory	Washington	Date Report Completed	2021-04-11
Date Vaccinated	2021-03-21	Date Report Received	2021-04-11
Date of Onset	2021-03-21	Date Died	
Days to onset	0		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	Yes

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 "Not Applicable" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EN7534	2		LA

Symptom
BLOOD TEST
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAPH
HEAD DISCOMFORT
HEADACHE
PAIN

Adverse Event Description

had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *	Days in Hospital	1
Mfr/Imm Project Number	NONE	Report Form Version	2	Existing Hospitalization Prolonged	No
Recovered	No	Serious	Yes	Emergency Room / Office Visit **	N/A
* VAERS 2.0 Report Form Only ** VAERS-1 Report Form Only "Not Applicable" will appear when information is not available on this report form version.				Emergency Room *	Yes
				Office Visit *	Yes
				* VAERS 2.0 Report Form Only ** VAERS-1 Report Form Only "N/A" will appear when information is not available on this report form version.	

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EN7534	2		LA

Symptom
BLOOD TEST
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAPH
HEAD DISCOMFORT
HEADACHE
PAIN

Adverse Event Description

had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Blood Test, CT scan with and without contrast,	none	

Medications At Time Of Vaccination	History/Allergies
Birth Control: BLSOVI FE 1/20), multivitamin	none, None

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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The next two screenshots show a 32-year-old healthy woman, with no prior medical history other than some allergies, having an immediate reaction to the first dose of vaccine. She had a stroke and was put into a medical coma, during which she coded and had seizures. She had to be intubated and ventilated but, fortunately, recovered enough to be released from the hospital eight days later. [\[https://wonder.cdc.gov/controller/datarequest/D8\]](https://wonder.cdc.gov/controller/datarequest/D8)

Details for VAERS ID: 1697184-1

Event Information			
Patient Age	32.00	Sex	Female
State / Territory	New York	Date Report Completed	2021-09-14
Date Vaccinated	2021-01-25	Date Report Received	2021-09-14
Date of Onset	2021-01-25	Date Died	
Days to onset	0		
Vaccine Administered By	Work *	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 Not Applicable will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	9
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 N/A will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EL83247	1	SYR	LA

Symptom
BLOOD PRESSURE INCREASED
CARDIAC ARREST
CEREBRAL ARTERY EMBOLISM
CEREBROVASCULAR ACCIDENT
ENDOTRACHEAL INTUBATION
HYPERHIDROSIS
HYPOAESTHESIA
IMMEDIATE POST-INJECTION REACTION
MEDICAL INDUCTION OF COMA
NEUROLOGICAL SYMPTOM
SEIZURE

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 N/A will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EL83247	1	SYR	LA

Symptom
BLOOD PRESSURE INCREASED
CARDIAC ARREST
CEREBRAL ARTERY EMBOLISM
CEREBROVASCULAR ACCIDENT
ENDOTRACHEAL INTUBATION
HYPERHIDROSIS
HYPOAESTHESIA
IMMEDIATE POST-INJECTION REACTION
MEDICAL INDUCTION OF COMA
NEUROLOGICAL SYMPTOM
SEIZURE

Adverse Event Description
 1/25 2021 immediately started sweating and blood pressure was elevated. At 2am couldnt feel legs and was rushed to ER with strok like symptoms. Brain Embolism was found which caused the stroke on left side . W as put in medical induced coma . Coded and had seizures. had to be intubated. released from hospital on 2/2 .

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	12/15/2020 Covid	

Medications At Time Of Vaccination	History/Allergies
no	no,Benadryl Augmentin penicillin amoxicillin shrimp egg whites cod fish walnuts milk soy wheat scallops

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

The next two screenshots are from a 29-year-old female that suffered a severe headache and vomiting due to a cerebral venous sinus thrombosis after her second dose. Her medical history included asthma and GERD (Gastroesophageal Reflux Disease) and a few allergies, none of which would make her at risk for a stroke.
[\[https://wonder.cdc.gov/controller/datarequest/D8\]](https://wonder.cdc.gov/controller/datarequest/D8)

Details for VAERS ID: 1227231-1

Event Information			
Patient Age	29.00	Sex	Female
State / Territory	Pennsylvania	Date Report Completed	2021-04-16
Date Vaccinated	2021-03-25	Date Report Received	2021-04-18
Date of Onset	2021-03-28	Date Died	
Days to onset	3		
Vaccine Administered By	Other	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	USPFIZER INC2021376236	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 Not Applicable will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	1
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 N/A will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	EP7534	2		LA

Symptom
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEADACHE
THROMBOSIS
VOMITING

Adverse Event Description
 cerebral venous sinus thrombosis; CT scan that revealed the clot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastroesophageal reflux disease, peanut and tree nut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), bedometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had her first dose of bnt162b2 on 04Mar2021 at 9:45 am in left arm for COVID-19 immunisation. On 28Mar2021 at 09:45 the patient was diagnosed with cerebral venous sinus thrombosis a few days after receiving the second dose of the vaccine. She had a horrible headache after intercourse, went to the ER after vomiting, and had a CT scan that revealed the clot. The patient was hospitalized for cerebral venous sinus thrombosis. The patient underwent lab tests and procedures which included computerised tomogram: revealed the clot. Patient received Heparin and Eliquis as treatment for the events. Outcome of the events was recovering. No follow-up attempts needed. No further information expected.

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Update

Symptom
CEREBRAL VENOUS SINUS THROMBOSIS
COMPUTERISED TOMOGRAM
HEADACHE
THROMBOSIS
VOMITING

Adverse Event Description
 cerebral venous sinus thrombosis; CT scan that revealed the clot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastroesophageal reflux disease, peanut and tree nut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), bedometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had her first dose of bnt162b2 on 04Mar2021 at 9:45 am in left arm for COVID-19 immunisation. On 28Mar2021 at 09:45 the patient was diagnosed with cerebral venous sinus thrombosis a few days after receiving the second dose of the vaccine. She had a horrible headache after intercourse, went to the ER after vomiting, and had a CT scan that revealed the clot. The patient was hospitalized for cerebral venous sinus thrombosis. The patient underwent lab tests and procedures which included computerised tomogram: revealed the clot. Patient received Heparin and Eliquis as treatment for the events. Outcome of the events was recovering. No follow-up attempts needed. No further information expected.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
Test Name: CT Scan; Result Unstructured Data: Test Result:Clot; Comments: Revealed the clot		

Medications At Time Of Vaccination	History/Allergies
ZYRTEC ALLERGY, DEPO PROGESTIN, QVAR, OMEPRAZOLE, SERTRALINE HYDROCHLORIDE	Medical History/Concurrent Conditions: Allergy to nuts; Asthma; GERD; Peanut allergy,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

[Top](#) [New Report](#) [Notes](#) [Citation](#)

Notes:
Caveats:
 Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. [More information.](#)

This next example is a 14-year-old healthy male with no medical history. One day after one dose of vaccination, he suffered a cerebral thrombosis and a third-degree heart block. He was left permanently disabled. [<https://wonder.cdc.gov/controller/datarequest/D8>]

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Event Information			
Patient Age	14.00	Sex	Male
State / Territory	North Carolina	Date Report Completed	2021-09-21
Date Vaccinated	2021-09-20	Date Report Received	2021-09-21
Date of Onset	2021-09-21	Date Died	
Days to onset	1		
Vaccine Administered By	Unknown	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 "Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	Yes
Permanent Disability	Yes
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknown
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 "N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	NONE	1	IM	LA

Symptom
ATRIOVENTRICULAR BLOCK COMPLETE
BLOOD TEST
CEREBRAL THROMBOSIS
CEREBROVASCULAR ACCIDENT
COMPUTERISED TOMOGRAM
DROOLING
MAGNETIC RESONANCE IMAGING
MENTAL STATUS CHANGES
SPEECH DISORDER
THROMBECTOMY

Adverse Event Description

Student was drooling, and had an altered state. Speech was mumbled, student was able to smile and it was equal. Student's heart rate was in the 50s. SpO2 98-99%. EMS/911 was

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Symptom
ATRIOVENTRICULAR BLOCK COMPLETE
BLOOD TEST
CEREBRAL THROMBOSIS
CEREBROVASCULAR ACCIDENT
COMPUTERISED TOMOGRAM
DROOLING
MAGNETIC RESONANCE IMAGING
MENTAL STATUS CHANGES
SPEECH DISORDER
THROMBECTOMY

Adverse Event Description

Student was drooling, and had an altered state. Speech was mumbled, student was able to smile and it was equal. Student's heart rate was in the 50s, SpO2 98-99%, EMS/911 was called, student transported to hospital after monitor showed 3rd degree heartblock. EMS took student to hospital where a code stroke was called. student had a CT and an MRI, student then was taken to surgery to remove clot from brain.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
CT, MRI, blood work	none	

Medications At Time Of Vaccination	History/Allergies
NONE	none,none

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

Caveats: Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. [More information.](#)

Help: See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

A previously healthy 26-year-old male with no medical history is now permanently disabled. He noticed memory, balance and speech problems just 12 hours after receiving his first dose of the Pfizer vaccine. He was diagnosed with an acute infarct involving the left caudate head, anterior limb of the internal capsule, anterior putamen and left insular cortex. He also suffered a second ischemic stroke three to four weeks later. [<https://wonder.cdc.gov/controller/datarequest/D8>]

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Details for VAERS ID: 2102116-1

Event Information			
Patient Age	26.00	Sex	Male
State / Territory	Texas	Date Report Completed	2022-02-10
Date Vaccinated	2021-03-27	Date Report Received	2022-02-10
Date of Onset	2021-03-28	Date Died	
Days to onset	1		
Vaccine Administered By	Private	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	Yes	Serious	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories			
Death	No		
Life Threatening	No		
Permanent Disability	Yes		
Congenital Anomaly / Birth Defect *	No		
Hospitalized	Yes		
Days in Hospital	Unknown		
Existing Hospitalization Prolonged	No		
Emergency Room / Office Visit **	N/A		
Emergency Room *	No		
Office Visit *	No		

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	ER8727	1	SC	AR

Symptom
BALANCE DISORDER
CEREBRAL INFARCTION
ISCHAEMIC STROKE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
MEMORY IMPAIRMENT
SPEECH DISORDER

Adverse Event Description

Patient noticed problems with memory, balance and speech twelve hours after receiving the Pfizer Covid vaccination. He was taken to hospital for diagnosis and treatment.

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Symptom
BALANCE DISORDER
CEREBRAL INFARCTION
ISCHAEMIC STROKE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
MEMORY IMPAIRMENT
SPEECH DISORDER

Adverse Event Description

Patient noticed problems with memory, balance and speech twelve hours after receiving the Pfizer Covid vaccination. He was taken to hospital for diagnosis and treatment.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
An MRI of his brain showed an acute infarct involving the left caudate head, anterior limb of the internal capsule, anterior putamen and left insular cortex consistent with a left MCA territory infarct. It should be included that he experienced a second ischemic stroke 3 to 4 weeks later with less extensive damage.	none	

Medications At Time Of Vaccination	History/Allergies
none	none,no known allergies

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

Caveats: Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. [More information.](#)

Help: See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

Query Date: May 4, 2022 11:45:27 PM

A 46-year-old female experienced headache and nausea starting just 3 days post vaccination. Four days later she was found unresponsive. CT and MRI scans showed massive blood clot in the brain with hemorrhage. She died 11 days after vaccination. Her report indicates no medical history or co-morbidities. [<https://wonder.cdc.gov/controller/datarequest/D8>]

wonder.cdc.gov/controller/daterequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Details for VAERS ID: 2042133-1

Event Information			
Patient Age	46.00	Sex	Female
State / Territory	Texas	Date Report Completed	2022-01-18
Date Vaccinated	2021-12-30	Date Report Received	2022-01-18
Date of Onset	2022-01-02	Date Died	2022-01-10
Days to onset	3		
Vaccine Administered By	Pharmacy *	Vaccine Purchased By	Not Applicable *
Mfr/Imm Project Number	NONE	Report Form Version	2
Recovered	No	Serious	Yes

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	4
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
 ** VAERS-1 Report Form Only
 N/A will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER/BIONTECH	FJ1611	UNK	SYR	LA

Symptom
CEREBRAL HAEMORRHAGE
CEREBRAL THROMBOSIS
COMPUTERISED TOMOGRAPH HEAD ABNORMAL
DEATH
HEADACHE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
NAUSEA
UNRESPONSIVE TO STIMULI

Adverse Event Description

Headache and Nausea started 01/02/2022; Patient found unresponsive 01/06/2022; CT scan and MRI showed massive blood clot in brain leading to brain hemorrhage Patient died 01/10/2022

wonder.cdc.gov/controller/daterequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

Symptom
CEREBRAL HAEMORRHAGE
CEREBRAL THROMBOSIS
COMPUTERISED TOMOGRAPH HEAD ABNORMAL
DEATH
HEADACHE
MAGNETIC RESONANCE IMAGING HEAD ABNORMAL
NAUSEA
UNRESPONSIVE TO STIMULI

Adverse Event Description

Headache and Nausea started 01/02/2022; Patient found unresponsive 01/06/2022; CT scan and MRI showed massive blood clot in brain leading to brain hemorrhage Patient died 01/10/2022

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None	

Medications At Time Of Vaccination	History/Allergies
Sprintec Allegra	None,Ancel, Amoxicillin

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

Caveats: Data contains VAERS reports processed as of 04/22/2022. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. [More information.](#)

Help: See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

Query Date: May 5, 2022 12:06:58 AM

It is known that adverse reactions to vaccinations are under-reported in the VAERS database. It normally only reflects a small fraction of the adverse event occurrences. [<https://vaers.hhs.gov/data/dataguide.html>] So, if this is true, it is more likely that 410 to 4100 strokes have occurred in the United States alone within three days of Pfizer vaccination in people under 50 years of age. Bear in mind that this age group normally reflects only four percent of the incidences of stroke overall. VAERS also states that just because an event is recorded it may not be caused by the vaccine [[https://www.fda.gov/files/vaccines.%20blood%20&%20biologics/published/Understanding-the-Vaccine-Adverse-Event-Reporting-System-\(VAERS\).pdf](https://www.fda.gov/files/vaccines.%20blood%20&%20biologics/published/Understanding-the-Vaccine-Adverse-Event-Reporting-System-(VAERS).pdf)], which could very well be true for some. But the sheer number of these adverse events compared to adverse events for other vaccinations, the ages and health status of the victims, and the timing of the adverse events relative to COVID vaccination are all indicative of the COVID vaccine being the cause.

The next several screenshots are of the VAERS database searches for death or permanent disability due to strokes within three days of Pfizer vaccination for a 13-month period.

[<https://wonder.cdc.gov/controller/datarequest/D8>] One death was reported in the under-50 age category, and 35 deaths reported in the 50-and-over age range. Seventeen people under 50 have been permanently disabled, and 51 people in the 50-or-above age range are permanently disabled all within three days post-Pfizer COVID-19 vaccination. [<https://wonder.cdc.gov/controller/datarequest/D8>]

The Vaccine Adverse Event Reporting System (VAERS) Results
Data current as of 04/22/2022

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Quick Options | More Options | Top | Notes | Citation | Query Criteria

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 1 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
2042133-1	40-49 years	3 days	Death

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

Caavets: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

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The Vaccine Adverse Event Reporting System (VAERS) Results
Data current as of 04/22/2022

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Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 35 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
0938116-1	50-59 years	3 days	Death
0943266-1	80+ years	0 days	Death
0951103-1	80+ years	3 days	Death
0968846-1	80+ years	0 days	Death
0997571-1	80+ years	1 day	Death
1010223-1	80+ years	0 days	Death
1014559-1	80+ years	0 days	Death
1026196-1	80+ years	1 day	Death
1048698-1	80+ years	1 day	Death
1081416-1	65-79 years	3 days	Death
1113713-1	80+ years	0 days	Death
1122643-1	80+ years	1 day	Death
1134398-1	65-79 years	1 day	Death
1138291-1	60-64 years	1 day	Death
1140696-1	65-79 years	2 days	Death
1162930-1	50-59 years	1 day	Death
1172711-1	80+ years	2 days	Death
1177384-1	65-79 years	0 days	Death
1208484-1	80+ years	0 days	Death
1225903-1	65-79 years	3 days	Death

The Vaccine Adverse Event Reporting System (VAERS) Results
Data current as of 04/22/2022

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Quick Options More Options Top Notes Citation Query Criteria

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 17 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
1016772-1	30-39 years	1 day	Permanent Disability
1238951-1	30-39 years	0 days	Permanent Disability
1277549-1	18-29 years	0 days	Permanent Disability
1360967-1	30-39 years	0 days	Permanent Disability
1387371-1	40-49 years	1 day	Permanent Disability
1623811-1	30-39 years	1 day	Permanent Disability
1655110-1	40-49 years	0 days	Permanent Disability
1719069-1	6-17 years	1 day	Permanent Disability
1741268-1	18-29 years	0 days	Permanent Disability
1761707-1	40-49 years	1 day	Permanent Disability
1773652-1	40-49 years	0 days	Permanent Disability
1909899-1	40-49 years	0 days	Permanent Disability
1919242-1	40-49 years	0 days	Permanent Disability
1923395-1	6-17 years	3 days	Permanent Disability
1981096-1	30-39 years	3 days	Permanent Disability
2102118-1	18-29 years	1 day	Permanent Disability
2128661-1	40-49 years	1 day	Permanent Disability

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

wonder.cdc.gov/controller/datarequest/D8;jsessionid=5516D275DF5DB3454DB5C97C457A

The Vaccine Adverse Event Reporting System (VAERS) Results
Data current as of 04/22/2022

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Quick Options More Options Top Notes Citation Query Criteria

Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 51 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Some measures are hidden, use Quick or More Options above to restore them.

VAERS ID	Age	Onset Interval	Event Category
0932145-1	80+ years	0 days	Permanent Disability
0949555-1	65-79 years	1 day	Permanent Disability
1010235-1	80+ years	0 days	Permanent Disability
1046413-1	80+ years	0 days	Permanent Disability
1047410-1	65-79 years	2 days	Permanent Disability
1049717-1	80+ years	1 day	Permanent Disability
1051563-1	60-64 years	1 day	Permanent Disability
1094566-1	65-79 years	2 days	Permanent Disability
1097729-1	65-79 years	1 day	Permanent Disability
1113713-1	80+ years	0 days	Permanent Disability
1126961-1	60-64 years	2 days	Permanent Disability
1140696-1	65-79 years	2 days	Permanent Disability
1178308-1	50-59 years	1 day	Permanent Disability
1203511-1	60-64 years	1 day	Permanent Disability
1221443-1	50-59 years	3 days	Permanent Disability
1225501-1	80+ years	0 days	Permanent Disability
1226764-1	65-79 years	1 day	Permanent Disability
1230006-1	60-64 years	2 days	Permanent Disability
1240173-1	65-79 years	1 day	Permanent Disability
1261818-1	60-64 years	0 days	Permanent Disability
1284857-1	80+ years	1 day	Permanent Disability
1293024-1	65-79 years	1 day	Permanent Disability
1293462-1	60-64 years	0 days	Permanent Disability
1317805-1	65-79 years	0 days	Permanent Disability

In conclusion, the number of stroke reports for the Pfizer vaccine in its first year was 561 for all ages compared to zero strokes reported for over 10 different Pfizer influenza vaccines over a four-year period. This alone is a reason for concern. Taking a closer look at the timing of the strokes in relation to vaccination in previously healthy people adds even more credence that the Pfizer COVID vaccine is unsafe. Keep in mind that many of these people were also in an age group in which strokes are generally not prevalent. Stroke is just one of the many adverse events reported in the VAERS database for the Pfizer vaccine. These reports were occurring as early as January 2021; and the CDC, FDA, and Pfizer did not pause in pushing for mass vaccination of the unsuspecting and trusting public, resulting in deaths and permanent disabilities.

Report 25: “Proof the TrialMax App Unequivocally Contributed to Pfizer’s Deception of Safety” by Camille Villa – Team 1.

In the latest batch of the court-ordered release of Pfizer documents, there is unbelievable evidence supporting THE BIG LIE - that Pfizer’s vaccine was safe. In a document titled, "Annotated Study Book for Study Design," we discover Pfizer contracted with a company called Signant Health to create an app in which trial participants could enter all their side effects. https://www.phmpt.org/wp-content/uploads/2022/04/125742_S1_M5_5351_c4591001-fa-interim-sample-crf.pdf The app, called TrialMax, was used to collect patient data in phase one and phase two of Pfizer’s COVID vaccine clinical trials (the C4591001-Post-12-July-2020 study). Pfizer required all participants to log their side effects daily, however, this app was intentionally created to exclude nearly all adverse events!

According to Signant Health, the user-friendly healthcare app developer, the goal of this app was to collect and manage a high volume of data from Pfizer’s “reactogenicity and COVID-19 illness diaries” in an effort to gain approval of the emergency use authorization. <https://www.signanthealth.com/wp-content/uploads/2021/09/Case-Study-Coronavirus-Vaccines.pdf> A considerable failure of the app, however, was that it purposefully limited a trial participant’s input to only specific pre-determined side effects.

Pfizer’s deception of safety was further supported by the basic philosophy of the TrialMax app developer. In a 2019 Clinical Research News article, discussing the company’s focus on simplified solutions, Signant Health’s CEO states, “. . . the more difficult it is to participate—the more impactful it is on somebody’s life, the more complex the technology or the process is—the less likely somebody is going to stay in a trial.” <https://www.clinicalresearchnewsonline.com/news/2019/06/10/crf-bracket-relaunches-as-signant-health> The article goes on to state that Signant Health’s objective is “to make it easier to participate in—and run—clinical trials.” In a supposed effort to keep the participants engagement uncomplicated, we can deduce that Pfizer purposefully substituted simplicity for safety by directing Signant Health to create a platform that prevented trial participants from reporting ALL unique side effects.

In order to purposefully limit a participant’s input, the TrialMax “Vaccination Diary” module asked specific questions regarding ONLY the following symptoms: fever, redness at the injection site, swelling at the injection site, pain at the injection site, fatigue, headache, vomiting, diarrhea, chills, muscle pain, and joint pain. These are commonly known side effects of most vaccines.

The additional symptoms of cough, shortness of breath, loss of taste/smell, and sore throat could supplementally be recorded in the TrialMax “COVID-19 Illness Diary” module. The app, however, did not allow for any independent reporting of symptoms. Therefore, these two modules were the only places available to record any side effect. For example, if a trial participant opened the app to report experiencing possible symptoms of Guillain-Barre Syndrome; pins and needles sensation in the toes, weakness in the legs, or difficulty with eye muscles or vision, there would be absolutely no place to record this information. And what if one experienced chest pain, facial droop, or any other unusual side effect? Pfizer did not allow the collection of ANY OTHER side effect data. They purposefully limited these participants to enter ONLY the specific side effects they asked about!

Although tracking inflammation side effects, also referred to as reactogenic side effects, is beneficial, Pfizer's primary objective here was to collect only inflammation-related side effects, and nothing else. The CDC advertises "common side effects" but limits their list to inflammation related effects only. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html> In any clinical trial, however, the safety profile should refer to ALL adverse events and not just those related to inflammation. <https://www.nature.com/articles/s41541-019-0132-6#Sec1> Pfizer limiting the reporting of side effects to those of inflammation appears deceptive and intentional.

In conclusion, Pfizer contracted Signant Health to intentionally collect only specific vaccine side effects through the TrialMax app. This app was the primary collection tool that allowed for quick organization of data and a significant factor in Pfizer attaining their EUA, period. They only collected the side effects that they wanted to collect, and this was willfully unethical and misleading!

Report 26: [“Even Big Pharma CEOs recognized that not everyone could be vaccinated - so why Vaccine Mandates?”](#) by Dr. Chris Flowers – Teams 1 and 3.

Recently, Project Veritas revealed that the CEO of AstraZeneca, Pascal Soriot, told his company in a Zoom call in Dec 2020 that not everyone could be vaccinated; Soriot identified the immune-compromised and people with multiple sclerosis as examples of those who should not be vaccinated with mRNA vaccines. He raised this issue in the context of explaining that the company AstraZeneca had a great opportunity in the marketplace — to make antibody treatments for those vulnerable populations, treatments, that is, which could give protection to those who should not be vaccinated.

(<https://www.projectveritas.com/news/astrazeneca-source-recording-from-2020-shows-ceo-pascal-soriot-saying>).

Project Veritas broke the story on April 19, 2022, where Soriot admits that immunocompromised populations should not consider the AstraZeneca vaccine safe.

YouTube also has this incriminating video. - <https://www.youtube.com/watch?v=Lk00JwZwE5g>).

Soriot’s comments were contradictory to remarks about the safety of the vaccine for immunocompromised people made by the World Health Organization (WHO) at the time. More recently, on March 16, 2022, a Health Advisory from the WHO restated the assertion that the vaccine was SAFE for immunocompromised individuals.

(<https://www.who.int/multi-media/details/who-press-conference-on-covid-19-ukraine-and-other-emergencies---16-march-2022> - Time marker: 39 mins). Those statements appear to give false assurance.

There have been serious problems with the AstraZeneca vaccine even for the general population. AstraZeneca is the maker of one of the main COVID vaccines used in Europe, which along with Johnson and Johnson's (Janssen vaccine) has been plagued with reports of the vaccines’ causing small vessel blood clots:

(<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html#ingredients>)

In admitting the fact that vaccine-induced immunity is not viable for immunocompromised patients, AZ saw the commercial opportunity to develop and manufacture monoclonal antibodies against the S (SPIKE) protein.

This is the important argument that they make, in stark contrast to the CDC and FDA pronouncements in the USA where vaccine mandates were National Policy, that you cannot produce antibodies to a vaccine if you are immunocompromised and need to have a different source of antibodies.

Why should this matter in the US?

AstraZeneca (AZ), like Johnson and Johnson, used a conventional approach of a modified viral vector (rather than using mRNA) for producing immunity. AZ recognized the issues this would create with

patients whose natural immunity was depressed due to illness or to chemotherapy drugs (a state known as being 'immunocompromised').

So why weren't Monoclonal antibodies the first line of attack against COVID?

Steps were taken by several States, who targeted their vulnerable populations with protective efforts (such as closing visits to care homes in the early days), and purchased monoclonal antibodies to use in the fight against COVID. Vaccines were not available until late November 2021.

Patients with a compromised immune system could have their immunity provided by externally administered antibodies.

Antibodies from patients who had recovered from COVID, known as Convalescent Plasma was first approved by the FDA in August 2020.

(<https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>)

In November, 2021, the FDA approved the first two monoclonal antibody treatments manufactured by Regeneron Pharmaceutical Inc (Casirivimab and Imdevimab)

(<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>)

Subsequently monoclonal antibodies became one of the important mainstays of treatment in a number of US States, where the priority was to protect the vulnerable population, rather than to make use of a 'one size fits all' vaccine treatment.

So why mandate a vaccination for 100% of the population if vaccination is NOT effective for immunocompromised patients?

If the CEOs of Vaccine Manufacturers can recognize the lack of effectiveness in part of the population, why do the CDC/FDA as well as W.H.O. continue to advocate for additional boosters for these patients? In view of the serious side effects of the mRNA vaccines already known, why are they still being mandated?

The only conclusion that I can come to is that vaccine mandates are both unwise and downright wrong

Recording of AstraZeneca CEO Pascal Soriot 'Millions of [Immunocompromised] People Can't Be Vaxxed': <https://www.youtube.com/watch?v=Lk00JwZwE5g>

Report 27: [“Vaccine Trials for Infants and Children Show Little to No Benefit”](#) by Chris Flowers, M.D. – Teams 1 and 3.

On June 15, 2022, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPA) met to authorize the expansion of the EUA Pfizer BNT162b2 vaccine to children as young as 6 months. Evidence and public comments were given, but despite the FDA accepting that the evidence for this action was poor (given a grade of C), they decided to extend the EUA to this group.

Why are we concerned about young children receiving a vaccine that we have been told is ‘safe and effective’?

As confirmed in a letter to the FDA committee by the Children’s Health Defense (R.F. Kennedy, Jr., 2022. <https://childrenshealthdefense.org/wp-content/uploads/CHD-Letter-to-FDA-VRBPAC-2022-06-10.pdf>), there are virtually no deaths in children under 5 from COVID and a 99.995% recovery rate for children without an underlying condition.

The vaccine does not prevent infection or reduce transmission. Furthermore, CDC published data show a poor efficacy of 31%, reducing to 12% after 7 weeks in the 5-11 year age range (Vajeera Dorabawila, PhD, Dina Hoefler, PhD, Ursula E. Bower, PhD et al., “Effectiveness of the BNT162b2 Vaccine among Children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant,” medRxiv, Feb. 28, 2022. <https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1>). The mRNA vaccines do not stop infection, replication, or spread of the Omicron variants. They are not fulfilling their intended purpose.

How do we determine whether the benefits outweigh the risks in young children?

As infants and young children are so unlikely to be seriously ill or die from COVID, what are the potential risks? Sure, there are similar general effects following vaccination of pain and fever, but there are other rarer risks of serious adverse events, including respiratory problems and seizures. This is in addition to the effects on the Thymus (which is maturing and plays a major part in immunity in young children).

What did the Pfizer trial show?

Run at 65 trial sites, they recruited a total of 4526 children of which, 3000 children dropped out before the end of the trial.

Pfizer presented evidence that the only antibodies produced in the children were to the Wuhan (alpha strain) spike with no detectable antibodies to the Omicron variant (Craig, HART Group, 2022. <https://www.hartgroup.org/fda-approve-covid-vaccine-for-0-4-years/>).

However, the trial also shows other alarming results.

There were 30% more covid cases in the vaccine arm after first dose than the placebo, so they ignored that data. The same occurred with the second and third rounds.

In total, after 2 months, COVID developed twice as much in the vaccinated vs placebo group, suggesting that there was a higher likelihood that the vaccine was causing severe COVID than the likelihood that it was not. In fact, 12 of the children got COVID twice, 11 of which were in the vaccination arm!

What should parents take away from the results of this trial?

There is a lack of evidence to support giving the BNT162b2 COVID vaccine to children six months to four years.

The risks vastly outweigh the benefits.

Parents should be demanding decisionmakers at the FDA and CDC to explain themselves as to why they ignored the data and put their child at risk from adverse events, when they are so unlikely to get severe illness or die from COVID.

Further Reading:

Dr. Craig published a video de-constructing the trial (Craig, 2022).

<https://rumble.com/v18s66i-bombshell-dr.-clare-craig-exposes-how-pfizer-twisted-their-clinical-trial>

<https://rumble.com/v197mj7-eua-amendment-request-for-pfizer-biontech-covid-19-vaccine-for-children.html>

Statement from Governor Ron DeSantis: <https://youtu.be/fyad-OVxqho>.

Report 28: [“Did Pfizer and the FDA Conceal an Existing Remedy for COVID?”](#) by Don – Team 4.

Did Pfizer Know Prevnar Prevented COVID?

Summary:

Research has shown that Pfizer may have known its pneumococcal drug Prevnar (PCV13) may have helped prevent COVID or SARS-COV-2 and that thus there was not a need for ‘Operation Warp Speed’ by the Trump Administration. Prevnar is an already-approved drug currently used to treat pneumonia. However, it has been shown to have general anti-viral effects and can thus be effective in protecting against bacterial respiratory infections. Despite Prevnar being a Pfizer drug, Pfizer did not present Prevnar to the public as an option for fighting against SARS-COV-2. Additionally, the new vaccines would fall under Emergency Use Authorization, which would ensure protection from liability for Pfizer. Not only did Pfizer fail to present Prevnar to Americans as a preventative option against COVID to the public, but the FDA also failed to reveal effective uses to the public. Instead, both Pfizer and the FDA moved forward with the release of the mRNA vaccines.

Article:

Did Pfizer and the FDA know that Prevnar (PCV13) prevented SARS-COV-2? Research reveals that they did.

Pfizer’s internal documents, released under court order, show that in Pfizer’s phased trials for their BioNTech mRNA vaccine, the company excluded any participant from the trials who was taking *medications intended to prevent COVID-19*. The interesting thing about this exclusion is that Pfizer knew that their pneumococcal drug Prevnar may prevent COVID (SARS-COV-2) in older patients aged 65 or older. In other words, Pfizer excluded participants who were already being helped by therapeutics. Once again, in Pfizer’s science, we see scientists excluding what they do not wish to find. This screenshot from our first tranche of Pfizer documents. I have included page 29:

- Phases 1 and 2 only: Known infection with HIV, HCV, or HBV.
- History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).
- **Receipt of medications intended to prevent COVID 19.**
- Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19.
- **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

How do we know that Prevnar may prevent COVID? Prior research points to the protective effects of Prevnar (PCV13) in viral and ‘*bacterial respiratory diseases*.’ In a retrospective study published in *The Journal of Infectious Diseases*, PCV13 also showed protective effects against SARS-COV-2 infections.

Among 531, 033 adults, there were 3677 COVID-19 diagnoses, leading to 1075 hospitalizations and 334 fatalities between March 1st and July 22nd 2020.

[<https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiab128/6164926>]

[<https://www.infectiousdiseaseadvisor.com/home/topics/covid19/pneumococcal-conjugate-vaccine-pev13-protective-against-sars-cov-2-infections/>]

Why didn't the FDA make this revelation available to the public? Notice that this discovery was from March – July of 2020 — in other words, “*the height of the pandemic*” — and yet the public was never formally informed about this protective drug.

If the FDA had informed America about Prevnar in 2020, there would have been no need for the fast-track status that the FDA gave to drug companies to develop the mRNA vaccines for COVID. That silence could have cost lives.

[STN-125742_0_0-section-2.7.4-summary-clin-safety (listed on dailyclout.io under Campaigns/Pfizer documents)]

[https://phmpt.org/wp-content/uploads/2021/12/STN-125742_0_0-Section-2.7.4-summary-clin-safety.pdf]

H.R. 5546 – The National Childhood Vaccine Injury Act of 1986 – established a vaccine injury schedule for pain and suffering with a maximum payment of \$250,000 per incident, otherwise absolving drug companies of liability.

The Act provides that no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death: (1) resulting from unavoidable side effects; or (2) solely due to the manufacturer's failure to provide direct warnings. It also ensures that a manufacturer may be held liable where: (1) such manufacturer engaged in the fraudulent or intentional withholding of information; or (2) such manufacturer failed to exercise due care. Lastly, it permits punitive damages under certain circumstances.

Did Pfizer engage in fraudulent or intentional withholding of information and fail to exercise “due care”? A court may well rule “yes.”

We now know from the Pfizer's Internal Phase 1 trials of the COVID vaccine, the company identified “receipt of medications intended to prevent COVID-19.”

The above evidence may well prove that Pfizer knew that medications such as Prevnar could indeed prevent COVID-19 and this knowledge should have been revealed to the world before thousands died. What did Pfizer and the FDA know and when did they know it?

Report 29: [“Inconsistencies in Pfizer Clinical Trials Are Surfacing”](#) by Sean Ludford.

Summary:

This report is based on the currently released Pfizer documents. There is evidence to support that, at the start of the clinical trials, there were two groups. One group was given the vaccine, the other was given a placebo. However, contrary to the usual practice of spacing out the timing to account for side effects, only four months after the second group was given a placebo, the vaccine was administered to them. Because of this, there would have been no way to tell if the vaccinated group was experiencing side effects if the placebo group was given the vaccine as well, thus eliminating the control group. Analysis on this will continue as new documents are released.

I would like to share my findings based on three FDA-released Pfizer documents: [125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf](#) (Demographic File), [125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#) (Two Shots File), and [125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf](#) (Four Shots File). Please refer to the end of this document for a full description of these three files.

I have also discovered numerous files (greater than a dozen) that have repetitive information to the three files that I have converted to a database. It's unclear if these files were documents used internally or simply documents exported from their database and presented in a slightly different form.

The *Demographic File* [[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf](#)] was the first discovery. Presented from Pfizer as a nearly 3,000-page document, it seemed far too daunting a task to make any discoveries in that document form. The flat file was converted to a fully searchable database. I created the database using the Filemaker Pro application. This is a well-known and respected database application with a 37-year history.

I initially believed that there was a unique identifier (an ID number) to be found within each record presented in the Demographic File. This proved to be true. I further believed that there would be additional documents revealed in the future that would be related to the Demographic File allowing us to track the subjects introduced in the Demographic File. This also proved to be true.

Next, I found a similar file called, *Two Shots File* for short. [[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)] This PDF followed a similar format to the Demographic File [[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf](#)] and, most importantly, it included the unique ID number. After converting the Two Shots File to database form, I was able to create a relationship between the Demographic File [[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf](#)] and the Two Shots File [[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)] based on the ID number. This provided a subject's demographic information, as well as information regarding their first two test shots. Subjects were placed in “Randomization Vaccine Groups” that included a “Placebo” group. The dose of each shot given to the test subjects was also recorded.

Next, I discovered a similar file called, *Four Shots File* for short.[[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf](#)] This PDF followed a similar format to the Demographic File [[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf](#)] and Two Shots File [[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)] and again it importantly included the unique ID number. After converting the Four Shots File [[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf](#)] to database form I was able to create a relationship between the three files based on the ID number. Further, the second two files also include a “Randomization Number” that is also unique to each subject. This provided a subject’s demographic information, as well as information regarding their first four test shots.

However, not all subjects were given a third and fourth shot. Shockingly, *only* the Placebo group were given third and fourth shots — with actual vaccine, not a placebo. These third and fourth shots were identified with a vaccine group value (consistent with the previously vaccinated subjects) and a designated dose. In this case, all the doses were 30 micrograms.

Just four months after entering the trial and being given a placebo, the Placebo Group was given the vaccine, thus eliminating a control group. I am not a doctor, but this seems to make the entire trial null and void.

I consider this an ongoing investigation, and I will be examining current and future document releases to find more related data.

Other Related Findings

I found 625 subjects included in the Four Shots File [[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf](#)] that were not in the Two Shots File [[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)]. 428 (77%) of these 625 subjects are under the age of 18. I’m not sure if this is significant or if it has any significance that these subjects were not included in the Two Shots File.[[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)] Based on the data, they should have been included as they received either a vaccine or a placebo.

The Two Shots File [[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf](#)] reveals that 2,449 subjects were given the first shot but not a second shot. No explanation is given.

Among the 19,645 subjects in the Placebo Group who received a third shot of 30 micrograms of vaccine, 3,626 did not receive a fourth. No explanation is given.

In all three files the “Subject” field offers one of 154 unique values for a respective test subject. The second of three numbers expressed here appears to be a physical/geographic test location. I have a breakdown of the number of subjects that hail from each site.

About the three Pfizer files I have used:

125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf (Demographic File)

[\[125742_S1_M5_5351_c4591001-interim-mth6-demographics.pdf\]](#)

Downloaded from the DailyClout site on April 11, 2022

This file is 2,951 pages in length and contains 44,257 unique records. Within the document the data is described in the header as: “16.2.4 Listing of Demographic Characteristics – All Subjects \geq 16 Years of Age.”

The information provided is organized in 11 fields as follows:

1. “Age Group (Years)” — This field is blank with the exception of:

Page 1 – record 1 of 15, value = “16-55”

Page 1745 – record 12 of 15, value = “18-55”

Page 1752 – record 12 of 15, value = “65-85”

Page 1758 – record 12 of 15, value = “>55”

2. “Subject” — This field contains three set of values. The first is an eight-character, alphanumeric value = “C4591001” that is constant in all records. Next is a four-digit number that is not unique to each record. There are 154 unique four-digit numbers in this second value. It is now understood that this number represents a test location. Third is an eight-digit number that is unique to each record. Among the 44,257 records this number does not repeat. Once this was discovered, I considered this number to be the subject’s unique ID number hoping that it would appear in future files giving a basis to track individual subjects.
3. “Age (Years)” — the subject’s age expressed in two digits ranging from 15 to 91.
4. “Sex” — expressed as Male or Female
5. “Height (cm)” — height expressed in centimeters
6. “Weight (kg)” — weight expressed in kilograms
7. “Body Mass Index (BMI)” — expressed numerically rounded to one decimal
8. “Race”
9. “Racial Designation” — most often left blank
10. “Ethnicity”
11. “Informed Consent Date (Screening)” — date expressed, example, 26AUG2020

125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf (Two Shots File)

[\[125742_S1_M5_5351_c4591001-fa-interim-randomization-sensitive.pdf\]](#)

Downloaded from the DailyClout site on April 18, 2022

This file is 4,412 pages in length and contains 43,746 unique records. This document is two documents in one file. The first 37 pages are described in the header as: “16.1.7.2 Listing of Randomization Scheme and Actual Vaccine Received – Phase 2.”

Pages 38 through 4,412 are described in the header as: “16.1.7.4 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects.”

It’s unclear why this document is in two parts especially when considering that the first 37 pages contain data that is exactly duplicated in the following pages.

The information provided is organized in 10 fields as follows:

1. “Subject Study Identifier” — This field is the third eight-digit number that I had previously identified as a unique ID number.
2. “Subject” — same as “Subject” in previous file.
3. “Age Group (Years)” — expressed as an age range, example, 18-55.
4. “Randomization Date” — date expressed, example, 26AUG2020.

5. “Randomization Number” — a second unique ID number expressed as four-to-six-digit number.
6. “Randomization Vaccine Group” — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
7. “Date” — date of first dose expressed as previous dates.
8. “Dose 1” — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
9. “Date” — date of second dose expressed as previous dates.
10. “Dose 2” — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”

125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf (Four Shots File)

[\[125742_S1_M5_5351_c4591001-interim-mth6-randomization-sensitive.pdf\]](#)

Downloaded from the DailyClout site on May 4, 2022

This file is 4,376 pages in length and contains 44,360 unique records. Within the document the data is described in the header as: “16.1.7.1 Listing of Randomization Scheme and Actual Vaccine Received – All Subjects ≥16 Years of Age.”

The information provided is organized in 10 fields as follows:

1. “Subject Study Identifier” — This field is the third eight-digit number that I had previously identified as a unique ID number.
2. “Subject” — same as “Subject” in previous files.
3. “Age Group (Years)” — expressed as an age range, example, 18-5.
4. “Randomization Date” — date expressed, example, 26AUG2020.
5. “Randomization Number” — a second unique ID number expressed as four-to-six-digit number.
6. “Randomization Vaccine Group” — expressed as eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
7. “Date/Dose 1” — date of first dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
8. “Date/Dose 2” — date of second dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms EXCEPT if the group value = “Placebo.”
9. “Date/Dose 3” — date of third dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms.
10. “Date/Dose 4” — date of fourth dose expressed as previous dates with an eight-character, alphanumeric value, as well as a dose expressed in micrograms.

All data presented to the best of my understanding.

Report 30: [“Pfizer-BioNTech ‘Equivalent’ Half Truths or a ‘Lot’ of Lies?”](#) by Kathleen Willis, MD.

Summary

1. The public was not told only 4% of Pfizer lots were “equivalent/interchangeable.”
2. Pfizer published a letter (still online) to healthcare professionals stating only certain lots met the “equivalent/interchangeable” criteria.
3. Due to the lack of disclosure, the public falsely believed that the Pfizer-BioNTech vaccine available in the United States was all equal to the approved Comirnaty. Due to this belief, and their assumption that mandates were legal if not under an EUA, they complied and took the genetic therapy to keep their jobs. Legal precedent was set based on information provided by Pfizer and the FDA in regards to the “equivalent/interchangeable” narrative. As far as I know, the courts were not aware that only 4% of the lots met the criteria. If they had, it would’ve been impossible to rule in favor of a vaccine mandate as there wouldn’t have been enough of the “FDA approved equivalent/interchangeable” genetic therapy to distribute to all parties who were being required to take it. Our military has been decimated with ADE’s as well as disciplinary actions and dismissals due to refusal to take the genetic therapy. The actions taken by military leadership was based on the “equivalent/interchangeable” narrative as evidenced by their order requiring all military to comply with the genetic therapy on Aug 24, 2021, the day after the FDA approval of Comirnaty. This is a serious national security threat.
4. Pfizer, FDA and CDC need to answer why this information was not released to the public instead of implying that all vaccine in the US was the same as Comirnaty.
5. This is fraud of the highest order. The scale of this deception is massive, and the collateral damage is far and wide. Improperly imposed mandates based on deception, court cases decided with incomplete information, decimation of our military due to ADEs.

In the Fall of 2021, the Food and Drug Administration (FDA) approved Pfizer’s COVID-19 vaccine which led to extensive policy changes, imposed mandates, societal conflict, job loss, discrimination and much more. The country was turned upside down. Government health agencies whom we have depended on for medical expertise and truth failed us. This failure resulted in unnecessary policy changes and mandates that caused job losses and worse. Whether intentional or otherwise, our trusted agencies left out a small but significant detail that would have stopped the mandates.

On August 23, 2021, the FDA announced the approval of Pfizer-BioNTech’s Biologics License Application (BLA) for Comirnaty, a branded mRNA COVID-19 vaccine. The FDA reported that the Pfizer-BioNTech FDA-approved product, Comirnaty, and the Pfizer-BioNTech Emergency Use Authorization (EUA) product were equivalent and could be used interchangeably. The public heard this ad nauseam from health officials in public briefings, news articles and even government committee hearings.

FDA grants full approval to Pfizer/BioNTech Covid-19 vaccine, opening door to more vaccine mandates



By [Jacqueline Howard](#), CNN

Updated 12:25 PM EDT, Mon August 23, 2021

“Health care providers can continue to use the vaccine on their shelves,” Woodcock added. “The FDA-approved vaccine and the EUA-authorized vaccine have the same formulation and can be used interchangeably to provide the Covid-19 vaccine series.”

However, that was not the whole story. A pertinent disclaimer was left out of the announcement as evidenced by a document Pfizer quietly posted on their website dated Aug 23, 2021, the same day as of the FDA approval announcement. The subject line says it all. *“Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA).”* Screenshot below.

August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
**Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use
comply with the Biologics License Application (BLA)**

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,



Donna Boyce
Senior Vice President, Global Regulatory Affairs



COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229



2021TA035 v1.0

If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...

WHAT?	If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least <u>one copy of the letter with QR code</u> in each of the smaller, portable packaging containers being used for transport.
WHY?	Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved.
HOW?	To create additional copies of the letter to include in smaller transport containers, you may: <ul style="list-style-type: none">• Make copies of this letter using a copy machine• Make printouts by visiting cvdvaccine-us.com/resources

For questions related to this notification please contact
Pfizer Customer Service at 1-800-666-7248.



COMIRNATY
(COVID-19 Vaccine, mRNA)

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The letter states, “Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered “BLA-approved” lots for administration to individuals 16 years of age and older.**” The corresponding lot numbers were not

included in letter. Rather, a website was provided to access the information, which was not easy to find. The letter also stated that the QR code was intended to provide direct access to prescribing information, indication and usage, dosing and administration and other important safety information. However, accessing the QR code produced the lot numbers instead. It seems Pfizer may have made an error and reversed the link and QR code in their instructions. Here are the lot numbers posted on Pfizer's webpage:

Additional Lot Details – Lot Numbers

<i>FD7220</i>
<i>FE3592</i>
<i>FF2587</i>
<i>FF2588</i>
<i>FF2590</i>
<i>FF2593</i>
<i>FF8841</i>
<i>FH8027</i>
<i>FH8028</i>

***This author was told by the Pfizer rep on the phone that all of these lots were purple cap vials.**

Only nine lot numbers are “equivalent” to the FDA approved Comirnaty.

There are only nine. These are the lot numbers that are “equivalent” and “interchangeable,” per the letter, but what makes them different than the other Pfizer-BioNTech EUA lots? This author had multiple communications with Pfizer via email and/or phone on the following dates: October 11, 2021; February 7, 2022; February 8, 2022; Apr 14, 2022; and May 13, 2022. In a follow-up email after one of the calls, Pfizer sent an explanation of the difference. See screenshot below of paragraph from their email.

- While the products are manufactured using the same processes, they may have been manufactured at different sites or using raw materials from different approved suppliers. FDA closely reviews all manufacturing steps and has found explicitly that the EUA and BLA products are equivalent.⁷

Pay close attention to the verbiage here. It states that the processes are the same. *“While the products are manufactured using the same process, they may have been manufactured at different sites or using raw materials from different approved suppliers.”* Therefore, according to Pfizer’s explanation, the variables that differentiate the “equivalent” version from others is where they are manufactured and the raw materials used. In another email, they sent information seen in screenshot below. This time it states the ingredients and process are the same; therefore, the facility would be the only variable that is different.

- In terms of its ingredients and how it is made, the vaccine FDA-approved for those 16 years and older is no different from the vaccine that has been administered under the Emergency Use Authorization (EUA). ¹

On page nine of the Pfizer document titled *CBER CMC BLA Review Memo, STN 125742, COVID-19 mRNA Vaccine (nucleoside modified)* that was submitted with their Comirnaty approval application, it states, *“Note, the facilities proposed for use to manufacture COMIRNATY™ under the BLA are facilities that are used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA), which was originally issued on December 11, 2020. However, not all facilities used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under EUA are proposed for use under the BLA.”* Screen shot of cover page below. This supports what Pfizer said over the phone and in follow-up emails as stated above.

CBER CMC BLA Review Memo, STN 125742, COVID-19 mRNA Vaccine
(nucleoside modified)

CBER CMC BLA Review Memorandum

BLA STN 125742

COVID-19 mRNA Vaccine (nucleoside modified) [COMIRNATY™]

CDR Donald Ertel, Regulatory Officer, OCBQ/DMPQ/MRB1
Laura Fontan, Consumer Safety Officer, OCBQ/DMPQ/MRB1
Alifliya Ghadiali, Consumer Safety Officer, OCBQ/DMPQ/MRB1
Kathleen R. Jones, Biologist, OCBQ/DMPQ/MRB1
Nicole Li, Microbiologist, OCBQ/DMPQ/MRB1
Gregory Price, Biologist, OCBQ/DMPQ/MRB1

9. REVIEWER SUMMARY AND RECOMMENDATION A. EXECUTIVE SUMMARY

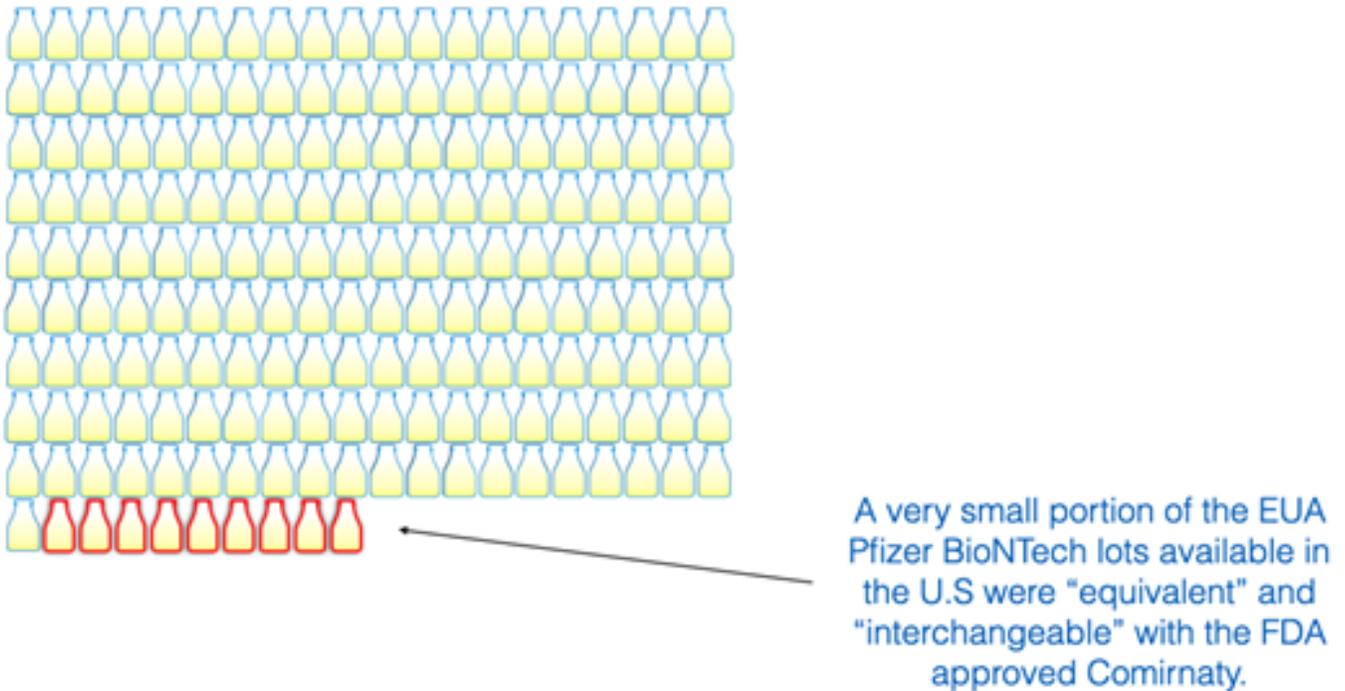
Pfizer-BioNTech submitted documentation to Biologics License Application (BLA) 125742/0 to support licensure of COMIRNATY™, a COVID-19 vaccine intended for the prevention of COVID-19 in adults ≥ 16 years of age. DMPQ reviewed and evaluated the (b) (4) DS and DP manufacturing process and facilities proposed for use to manufacture COMIRNATY™. Coverage of information in this review memo includes data to validate and support the consistency of the manufacturing process and product quality; facility information which includes utilities, cross-contamination prevention measures, and maintenance of controlled environments; and equipment for use in manufacturing including qualification, cleaning and sterilization, and types of equipment used (i.e., dedicated or shared, multi-use or single-use). Note, the facilities proposed for use to manufacture COMIRNATY™ under the BLA are facilities that are used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA), which was originally issued on December 11, 2020. However, not all facilities used to manufacture the Pfizer-BioNTech COVID-19 Vaccine under EUA are proposed for use under the BLA.

viii

Also of note in the same document, is the description of evaluating quality control measures at the manufacturing facilities, such as cross contamination prevention measures, maintenance of controlled environments, cleaning and sterilization, etc. Based on this information, it seems logical that Pfizer would only submit for FDA approval with facilities that met the quality standards described in the Biologics License Application. This begs the question, were there quality issues with other facilities that were making the majority of the product circulating in the United States?

If there are quality differences, and only the “equivalent” lots were produced in facilities that met quality standards, what was the chance of getting the FDA-approved “equivalent” product?

We can calculate that chance using a June 14, 2022, document leaked by a Centers for Disease Control and Prevention (CDC) staff member to the *How Bad Is My Batch?* website [<https://howbadismybatch.com/>]. The document showed a total of 190 Pfizer lots. Although it would be more accurate to use the number of doses for the calculation, that information is not publicly available. The graphic below helps to put this in perspective visually.



This indicates that potentially very few people got the “interchangeable” formula that is supposed to be “equivalent” to the FDA-approved version of the Pfizer vaccine. If there were 190 lots available in the United States and only nine met the “equivalent” criteria, that would be a 4.7% chance of receiving the equivalent formulation.

There is another important thing to note on the second page of the letter where distribution is addressed. Here is the screenshot again:

If you plan to redistribute the Pfizer-BioNTech COVID-19 Vaccine, please read on...

COMIRNATY[®]
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 11017

US License No. 2229

WHAT? If you plan on redistributing the Pfizer-BioNTech COVID-19 Vaccine, you must include at least one copy of the letter with QR code in each of the smaller, portable packaging containers being used for transport.

WHY? Once the Pfizer-BioNTech COVID-19 Vaccine arrives at its final destination, the QR code may be used to look up the lot number on the carton to determine if the product is BLA-approved.

HOW? To create additional copies of the letter to include in smaller transport containers, you may:

- Make copies of this letter using a copy machine
- Make printouts by visiting covidvaccine-us.com/resources

For questions related to this notification please contact
Pfizer Customer Service at 1-800-666-7248.

BIONTECH

 Pfizer

2021TA035 v1.0

It states that if unused product is going to be shipped to another location, the shipment must include a copy of the letter with the QR code, referenced on the second page of this report, so that it can be *used to determine if the lot number on the carton is the BLA-approved product*. To know and follow this requirement, one must know the letter exists. This author has spoken to several physicians and pharmacists, and none have been aware of the letter.

SPECIAL INFORMATION FOR CHILDREN: Please note, according to the Pfizer representative via phone, the nine lots equivalent to the FDA-approved Comirnaty are all purple cap vials for ages 16 years and older. Therefore, these nine lots would not be suitable for the newly authorized age range of 6 months to 5 years old. There is no formula that is “equivalent” to FDA-approved version for children under the age of 16.

The bottom line?

Americans are being deceived. Public disclosure has not given. Only some of the available lots are “equivalent.” The chances of getting the “equivalent” formulation are very slim. Americans were led to believe that *all* the Pfizer-BioNTech vaccines were “equivalent” and “interchangeable” with the FDA-approved product, which is not at all the case.

This lack of transparency led to a tidal wave of policy changes, including vaccine mandates, thus destroying many Americans’ lives. People lost their jobs. Students were not allowed to attend colleges.

Soldiers were kicked out of the military. Americans were prevented from entering businesses, sporting events, and much more. If this information had been publicly available and widely disseminated, COVID-19 vaccine-related court cases may have played out much differently. Additionally, military leaders may have made much different choices. Unfortunately, we do not get a do-over.

The most important take away is that the American public was lied to. That is truly all we need to know. In 23 years of medicine, this is may be the most unethical thing this author has seen. It will take decades for healthcare to recover from the damage that has been done.

Report 31: [“If Pfizer Controlled the ‘Data’ They Controlled the Outcome”](#) by Ed Clark – Team 3.

I am a participant in the independent study to review the Pfizer vaccine documents currently being released under FOIA request by the Public Health and Medical Professionals for Transparency (PHMPT) and now enforced by a Federal Judge Mark Pittman (Greene, 2022). One of the released documents sheds some light on events previously hidden from the public and demonstrate Pfizer BioNTech’s effort to achieve the level of efficacy needed for a vaccine preventing SARS-CoV-2 unleashed unfavorable side effects that make the experimental gene therapy shots not safe for humans. [reissue_5.3.6 post marketing experience.pdf
– https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-

The post-marketing experience document marked as ‘Confidential’ offers insight into the biological associated risk or adverse reaction(s) [ADRs] with the Pfizer BioNTech vaccine. These are also categorized as adverse events [AEs], serious adverse events [SAEs] adverse events of special interest [AESIs] or just events. The telling information is presented in Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval [thru 28 February 2021]. [https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf]

This table shows there were 42,086 relevant [patient] cases containing a whopping 158,893 adverse events. The cases shown are broken down into three categories: Gender, Age range and Case outcome. 7.1% or 2,290 cases have No Data for Gender; 16% or 6,876 cases list Age unknown; and 23% or 9,400 cases list an Unknown outcome. It gets worse: 46.5% or 19,582 cases Recovered/Recovering were mixed together. The most revealing number of cases was 1,223 [2.91%], patients with ‘Fatal’ outcomes.

Report 32: [“Pfizer’s New Two-in-One COVID-19 Booster: Are We the Clinical Trial?”](#) by Linnea Wahl – Team 5

The Pfizer booster vaccine that people get this fall may have some surprises. The fall 2022 booster will be formulated to respond to two different strains of SARS-CoV-2, one of which is already extinct and the other, an Omicron variant, will surely be in decline by fall. And this fall’s Pfizer “bivalent” – i.e., “conferring immunity to two diseases”⁴⁵ – booster may be formulated to deliver twice the amount of mRNA than previous Pfizer shots. All with no clinical trials completed. Will the next Pfizer booster have as many (or more) serious side effects as the current vaccine?

On June 30, 2022, the US Food and Drug Agency issued [recommendations](#) to vaccine manufacturers for their fall 2022 vaccination campaign. Their recommendation: develop a two-component, or bivalent, COVID-19 booster vaccine that contains mRNA to produce spike protein from both the original virus and from the Omicron strains currently circulating in the United States.

Pfizer seems to have anticipated the FDA’s recommendation, as Pfizer has already begun [developing](#) bivalent booster vaccines. One bivalent booster vaccine that Pfizer is developing will deliver a total dose of 30 micrograms (the same total dose as the original vaccines and boosters): 15 micrograms of the original vaccine and 15 micrograms of Omicron variant vaccine. Will they be safe? Not if the safety [findings](#) for Pfizer’s original 30-microgram vaccines, as reported by DailyClout analysts, hold true.

Another bivalent booster vaccine that Pfizer is developing will deliver a total dose of 60 micrograms (twice the total dose as the original vaccines and boosters). This high-dose bivalent booster vaccine will provide 30 micrograms of the original vaccine and 30 micrograms of Omicron variant vaccine—twice the amount that has already resulted in [increased risk](#) of serious side effects.

If Pfizer continues with a 60-microgram bivalent booster vaccine, will it be safe? We know that [Walsh et. al](#) (2020) reported on Pfizer’s clinical studies of doses of 10, 20, 30, and 100 micrograms of the original mRNA vaccine. We know that Pfizer chose the 30-microgram dose because the “immune response and toxicity profile at the selected, relatively low, 30-microgram dose level indicate . . . a favorable balance of reactogenicity [side effects] and immunogenicity [viral protection]” ([Walsh et al.](#), p.11). And we know that Pfizer suddenly stopped the clinical study of the 100-microgram dose in 12 participants early, noting that “the second dose was not administered because of reactogenicity [side effects] in the participants . . .” ([Walsh et al.](#), p. 7). What we don’t know is how many serious side effects will result from a 60-microgram dose of mRNA bivalent booster vaccine.

⁴⁵ Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/bivalent>.

Nor do we know *why* the FDA has recommended booster vaccines that target both the original virus and the Omicron strains currently circulating in the United States. By the FDA's own admission, "there is no evidence to suggest that earlier strains of virus such as the original prototype strain represented in current vaccines . . . are in existence" ([FDA](#), p. 5). Why would the FDA recommend that bivalent booster vaccines continue to target the original virus strain, which is already extinct?

Additionally, Pfizer has [demonstrated](#) to the FDA that Omicron strains circulating in the United States have a history of changing quickly, within a matter of a few months. As shown in Pfizer's chart (Fig. 1), the currently circulating Omicron strains will probably already be in decline or extinct, like the original strain, when Pfizer introduces its bivalent booster vaccines this fall.

In making their recommendations for COVID-19 mRNA bivalent booster vaccines, the FDA is proposing to adopt the same approach it uses for updating seasonal influenza vaccines. This approach involves choosing which strains of influenza will dominate the next flu season and then modifying existing influenza vaccines to target those strains. And this approach works (with an effectiveness of [10 to 60%](#)) for influenza in part because influenza is predictable—it strikes in the fall everywhere around the world. But by the FDA's own admission, "SARS-CoV-2 variants have not appeared in a predictable seasonal pattern and have not always spread globally" ([FDA](#), p. 9).

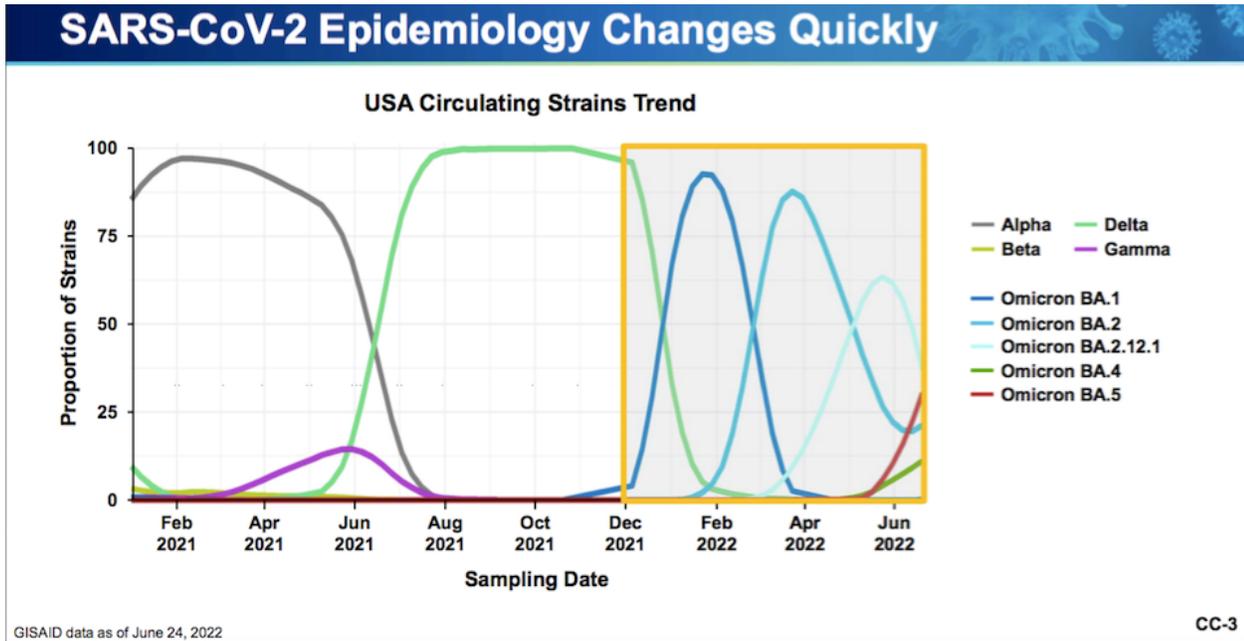
So will the approach to seasonal influenza vaccines be safe and effective if it is applied to developing bivalent booster vaccines for COVID-19? Not if Pfizer's own clinical trials with two versions of its vaccine, with different mRNA sequences, is any indication. Researchers determined that one mRNA version caused too many side effects, noting that "the nucleotide composition of RNA has been reported to affect its immune stimulatory activity and reactogenicity profile . . ." ([Walsh et al.](#), p. 11). What unknown or variable physiological side effects can we expect from Pfizer's modified mRNA bivalent booster vaccines?

Sadly, we won't know the answers to important questions about this fall's bivalent booster vaccines until well after they are available to the public. The [FDA has asked](#) manufacturers to *begin* clinical trials with bivalent booster vaccines, but clinical trials take time, and results of these trials will not be available before the FDA's expected rollout in fall 2022. Instead, the FDA is content "to rely on comparative immunogenicity data due to the time constraints involved in vaccine manufacturing and clinical efficacy evaluation" ([FDA](#), p. 7).

Pfizer's new bivalent booster vaccines: are they safe and effective? We will know eventually, but certainly not before the bivalent booster vaccines are in wide use. Are we, the public, going to be Pfizer's experimental population, yet again?

Fig. 1 SARS-CoV-2 Epidemiology Changes Quickly

Source: Pfizer/BioNTech COVID-19 Vaccine and Candidate Variant-modified Vaccine, FDA Vaccines and Related Biological Products Advisory Committee, June 28, 2022, <https://www.fda.gov/media/159496/download>



Summary

Most important finding: Pfizer's planned bivalent booster vaccines will not be tested for safety or efficiency before they are rolled out to the public this fall.

Key detail leading to finding: Pfizer's fall 2022 booster will be formulated to respond to two extinct or nearly extinct strains of SARS-CoV-2, may be formulated to deliver twice the amount of mRNA than previous Pfizer vaccines, and may be formulated by modifying the mRNA of the previous Pfizer vaccines without safety testing.

Events of concern: On June 30, 2022, the US Food and Drug Agency issued recommendations to vaccine manufacturers for their fall 2022 vaccination campaign. Their recommendation was to develop a two-component, or bivalent, COVID-19 booster vaccine that contains mRNA to produce spike protein from both the original virus and from the Omicron strains currently circulating in the United States.

Pfizer has already begun developing bivalent booster vaccines. One bivalent booster vaccine that Pfizer is developing will deliver a total dose of 30 micrograms (the same total dose as the original vaccines and boosters): 15 micrograms of the original vaccine and 15 micrograms of Omicron variant vaccine. Another bivalent booster vaccine that Pfizer is developing will deliver a total dose of 60 micrograms (twice the total dose as the original vaccines and boosters).

The FDA has asked manufacturers to *begin* clinical trials with bivalent booster vaccines, but clinical trials take time, and results of these trials will not be available before the FDA's expected rollout in fall 2022.

Further investigation: Will the next Pfizer booster have as many (or more) serious side effects as the current vaccine? If Pfizer continues with a 60-microgram bivalent booster vaccine, will it be safe? Why would the FDA recommend that bivalent booster vaccines continue to target the original virus strain, which is already extinct? Will the approach to seasonal influenza vaccines be safe and effective if it is applied to developing bivalent booster vaccines for COVID-19? What unknown or variable physiological side effects can we expect from Pfizer's modified mRNA bivalent booster vaccines?

Scale of situation: The FDA has directed all COVID-19 vaccine manufacturers to develop bivalent booster vaccines to be ready for fall 2022 without first testing them for safety or efficiency.

Plain language explanation of key scientific term: Reactogenicity means the side effects that occur soon after vaccination as the body reacts to the vaccine by mounting an inflammatory response.

Report 33: [“Understanding C-19 Vaccine Efficacy Clinical Trial in Lay Terms”](#) by Melanie Brown – Team 4

The Moderna vaccine decreases the production of antibodies to the nucleocapsid in a dose dependent fashion in those who acquire COVID after vaccination.

Four months after injection, **40% of vaccinated participants who acquired COVID after the second injection produced antibodies to the nucleocapsid**, compared to 93% of those who received placebo injections.

In participants that were COVID positive on the day of Dose 1 injections (before the vaccinations had time to work) a robust production of anti-nucleocapsid antibodies occurred in both placebo and vaccinated groups, with no difference between the groups. In the participants that acquired COVID between doses, a reduction in anti-nucleocapsid antibodies was observed in those who received the vaccine compared to those who received placebo. The reduction was not as severe as the group who acquired COVID after the second dose. Thus, **it appears the more doses received, the more severe the reduction in anti-nucleocapsid antibody production.**

Moderna vaccination in people that have never had COVID previously reduces the production of anti-nucleocapsid antibodies compared to placebo. This may reduce the strength and duration of immunity to COVID compared to unvaccinated immune responses. The more doses, the less the production of anti-nucleocapsid antibodies.

Further investigation is warranted with all COVID vaccine types in larger populations, to determine if this phenomenon is observed in all COVID vaccine products, because they all use the spike protein mRNA. This would include Pfizer/BioNTech, Janssen, Astra-Zeneca and Novavax. Also, it is important to determine the relative effectiveness of the anti-nucleocapsid antibodies versus the anti-spike antibodies against COVID and its variants.

If the mRNA vaccines decrease the production of anti-nucleocapsid antibodies in a dose dependent fashion, immunity would be short-lived and possibly lessened with additional boosters, the opposite of the desired outcome. This decreased immunity would affect all vaccinated people who had no COVID previous to their vaccination.

A nested sub-study was performed on participants that got COVID during the blinded phase in Moderna’s Phase 3 clinical trial for the mRNA-1273 COVID vaccine. The purpose of this nested study was to determine if vaccinated people produce or maintain the anti-N ab at the same level as those who are not vaccinated after getting COVID. The sub-study was [discussed in](#) medRxiv, “Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the blinded phase of the mRNA-1273 Covid-19 vaccine efficacy clinical trial” by Follmann, D., Janes, H.E., et al.

This study compared the production of antibodies (from the viral nucleocapsid) in participants that received placebo to those who received the vaccine.

*A **nucleocapsid** is a protein that envelops the viral genetic material for its protection.*

In contrast, the **spike proteins** protrude out from the nucleocapsid and are responsible for the virus being able to enter human cells to cause COVID.

The antibodies against this nucleocapsid are abbreviated as “**anti-N Ab.**”

The antibodies to the spike protein are abbreviated as “**anti-S Ab.**”

For simplicity, this summary will just use the term “**vaccine**” when discussing the Moderna mRNA-1273 COVID vaccine. SARS-CoV-2 is the name of the virus that causes COVID.

The **blinded phase** of a clinical trial is the portion in which the participants did not know if they received placebo or vaccine.

Briefly, the blinded portion of the Phase 3 clinical trial design consisted of two groups: those receiving two doses of placebo, and those receiving two doses of the vaccine, 28 days apart. Treatments were given on Day 1 and Day 29, and participants were followed for approximately four months, at which time they were told which treatment they received and the trial was, thus, unblinded. This time point was called the “Participant Decision Visit” or “PDV.” The nested portion included COVID tests taken from all participants on Day 1, Day 29, and during any symptom-prompted illness visits to diagnose COVID infection. Serum samples from Days 1, 29, 57, and the PDV were tested for anti-N Ab levels by immunoassay.

The Results

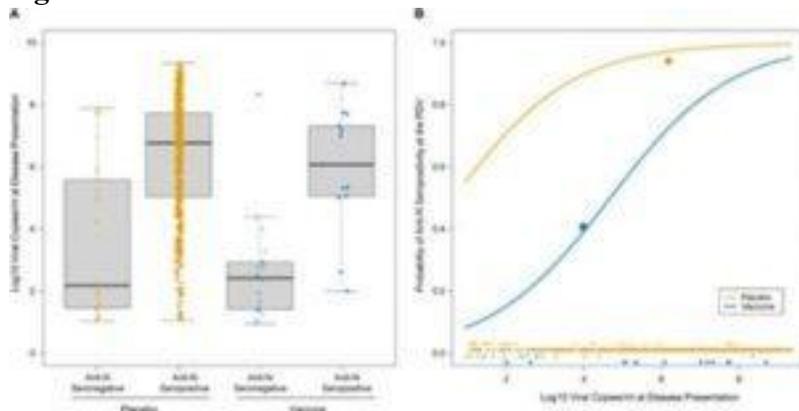
Table 1 shows positive anti-N ab tests at the PDV for participants with COVID detected at an illness visit during the study. These participants had no previous COVID illness prior to the study so therefore acquired it during the study. A substantial difference in anti-N ab production was shown between groups: 40.4 percent (21/52) in vaccine recipient COVID cases versus 93.3 percent (605/648) in placebo-recipient COVID cases. Thirty-six of the 52 vaccine recipients also had anti-S ab levels measured. Twenty of them were anti-N ab negative, and 16 of them were anti-N ab positive. Among these 36 individuals, the anti-S ab titers were not significantly different between those who were anti-N ab negative or those who were anti-N ab positive. **This indicates that the vaccine did not negatively impact the level of the anti-S ab as it did with the anti-N Ab.** Not surprising, considering that the vaccine causes the body to produce the spike protein only, without a nucleocapsid. It makes sense that vaccinated individuals would have robust anti-S ab production due to large amounts of the spike protein present.

Table 1

Days from Disease to PDV	Placebo		mRNA-1273	
	N	% Anti-N Seropositivity (95% CI)	N	% Anti-N Seropositivity (95% CI)
5-150 days	648	93.4% (91.5%, 95.3%)	52	40.4% (27.1%, 53.7%)
5-53 days	324	93.8% (91.2%, 96.4%)	28	32.1% (14.8%, 49.4%)
54-150 days	324	92.9% (90.1%, 95.7%)	24	50.0% (30.0%, 70.0%)

COVID viral loads were also measured and compared (Figure 1). The viral load at the illness visit was significantly higher in placebo recipients who were positive for anti-N Ab on the PDV (6.8 log₁₀ copies/ml) than in placebo recipients who were negative for anti-N Ab on the PDV (2.2 log₁₀ copies/ml). It makes sense that the higher the viral load an individual has, a greater number of antibodies would be generated. Similar results were seen in the vaccine group (6.1 log₁₀ copies/ml for anti-N ab positive individuals and 2.4 log₁₀ copies/ml for anti-N ab negative individuals). Thus, **the viral load does not offer much insight into the difference in anti-N ab positivity at the PDV between the placebo and vaccinated groups that got COVID during the clinical trial.**

Figure 1



These data show that, among the participants with PCR-confirmed COVID, anti-N Ab positivity about 53 days post diagnosis occurred in 40% of the vaccine recipients vs. 93% of the placebo recipients. Though it is possible the vaccine caused a loss of anti-N ab, given the short time frame it is more likely that the vaccine reduced the production of the anti-N ab.

A comparison was made of ‘anti-N ab levels per viral load’ in study participants that were ill on Day 1 to the ‘average anti-N ab level per viral load’ over all illness visits. This comparison showed the virus reproducing at Day 1 illness more than at other time points in the study, meaning that at Day 1 (before the vaccinations had time to work) more anti-N ab was produced in response to the magnitude of the viral load.

Comparison of placebo versus vaccinated recipients with COVID detected at baseline showed similar anti-N ab production rates at both Day 29 and PDV for both groups (Table 2). These robust ab titers were also maintained through the PDV for both groups, which **indicates that actual infection before vaccination created robust anti-N ab titers that were long-lasting.**

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

Table 2

Infection Detection	Anti-N Serostatus at Day 29				Anti-N serostatus at PDV				Median Days (IQR)
	Placebo		mRNA		Placebo		mRNA		
	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	
Baseline Seropositive	284	95.1% (92.6%, 97.6%)	281	96.1% (93.8%, 98.4%)	244	94.3% (91.4%, 97.2%)	260	93.8% (90.9%, 96.7%)	149.0 (76.0-236.0)
Baseline PCR+*	27	74.1% (57.6%, 90.6%)	30	73.3% (57.5%, 89.1%)	23	82.6% (67.1%, 98.1%)	31	71.0% (55.0%, 87.0%)	153.5 (86.0-220.0)

*Also baseline seronegative.

Comparison of participants from both groups that became ill at Day 29 and were anti-N ab positive, showed no difference between placebo and vaccinated groups at day 57 and at PDV. For those participants that were anti-N ab negative but had a positive PCR test for COVID on Day 29, the positivity rates are 60.0 percent (18/30) for the placebo group and 38.5 percent (5/13) for the vaccinated group at Day 57 and 70.4 percent (19/27) and 50.0 percent (6/12), respectively at the PDV. Consistent with the effects seen among baseline infections, the Day 57 and PDV anti-N ab positivity rates are significantly lower for Day 29 PCR-positive. Anti-N ab-negative participants were also compared to Day 29 anti-N ab-positive participants in both groups, but the vaccinated group was significantly lower than the placebo group. This indicates that **even one vaccine on board seems to depress the anti-N antibody production**, though not as severely, suggesting that **the more vaccinations taken the greater the reduction in anti-N ab production**.

Table 3

	Anti-N Serostatus at Day 57				Anti-N serostatus at PDV				Median Days (IQR)
	Placebo		mRNA		Placebo		mRNA		
	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	N	% Positive (95% CI)	
New Seropositive Day 29*	41	86.9% (78.4%, 95.4%)	39	84.6% (73.3%, 95.9%)	31	84.3% (74.3%, 94.3%)	36	86.1% (74.8%, 97.4%)	118.0 (61.0-189.0)
New PCR+ Day 29**	30	60.0% (42.5%, 77.5%)	13	38.5% (12.0%, 65.0%)	27	70.4% (53.2%, 87.6%)	12	50.0% (21.7%, 78.3%)	112.0 (49.0-168.0)

*Also baseline seronegative and baseline PCR negative.

**Also baseline and Day 29 seronegative, and baseline PCR negative.

This data shows that, **among the participants with COVID, anti-N Ab production occurred in 40 percent of the vaccine recipients versus 93 percent of the placebo recipients**. While an increase in the loss of these

Tables 1-6 AES

antibodies cannot be ruled out, given the short time frame, the more likely explanation is a vaccine-induced reduction in production of them. Anti-N ab production correlated with viral load, with each log increase in viral load nearly doubling the odds of anti-N ab production at the PDV. These lower anti-N ab titers in the vaccine recipients could be partly explained by their reduced exposure to the nucleocapsid antigen and/or overwhelming spike protein exposure. Alternatively, it could be explained by a combination of these. There may be other features of the initial course of infection that influence anti-N Ab production and are affected by vaccination. **The average viral load across post-COVID illness visits did not correlate or influence anti-N ab titers at PDV.**

The authors of the original article were more concerned with determining a population's prevalence and incidence of past COVID infections while using the anti-N ab titer. However, this author thinks the main takeaway is that **vaccination with the Moderna vaccine actually reduces the production of anti-N ab compared to placebo and, thus, may reduce the strength and duration of immunity toward COVID compared to unvaccinated immune responses.** This phenomenon increases with the number of vaccinations received. The sub study authors believe that the anti-S abs alone provide enough immune protection, which in the short-term may be true since 648 placebo recipients fell ill during the study compared to 52 vaccine recipients. This was a very short time period that was studied, only four months. Natural immunity after getting a disease often protects for a lifetime.

Statistics do not support long-lasting immunity for the COVID vaccines since many **more vaccinated people are getting COVID than unvaccinated** (Mercola, J., May 25, 2022, [“Is this the worst excuse for vaccine failure yet?”](#) Z3News). This remains true even with people receiving up to three or four vaccinations. Another paper published online discusses this as well ([Eur J Epidemiol](#). 2021; 36(12): 1237–1240. “Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States.” [Subramanian](#), SV and [Kumar](#), A. [Published online](#) 2021 Sep 30). Finally, this [article](#) from National Library of Medicine shows **the higher the vaccination rate in a country, the higher the number of COVID cases**; and countries with lower vaccination rates have lower numbers of COVID cases.

In conclusion, **the immunity provided by the vaccines is short-lived, and it could partially be explained by the lack of anti-N ab production after vaccination.**

Report 34: “[Pfizer Evidence So Far: Coverups, Heart Damage, and More](#)” by Robert W. Chandler, MD, MBA, and Linnea Wahl – Team 5

*Less than three months after Pfizer’s COVID-19 vaccine rollout, there were many known **significant adverse events (AEs)**. So many, in fact, that **Pfizer had to hire 2,400 employees to handle the volume reports they were receiving**. Despite the flood of adverse events being reported, **there was no move** by Pfizer, the U.S. government, or government entities such as the CDC or FDA to stop or slow down the rollout of the mRNA vaccines.*

At least four or more appendixes may have been omitted from [this report](#). There has also been some modification of the primary source document:

- *Pericarditis and myocarditis are included in the cardiac (heart-related) organ system rather than under autoimmune disorders. Adverse events of special interest (AESIs) are organized as organ systems.*
- *1,972 cases of Lymphadenopathy (swelling of lymph nodes) appear with no reporting of low white blood cell count (lymphocytopenia) or other measurements of infection or dysfunction including the formation of cancers.*
- *Absence in the reporting of Troponin and d-dimer (protein fragment present in the blood after a blood clot) levels. Without the raw data, we have no way of knowing just how high d-dimer levels were. **This is significant because of the correlation between high d-dimer levels and blood clots.***

Following the granting of Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) in late fall of 2020, Pfizer, with assistance from private and government agencies, began widespread “vaccination” of the public. The following report is a series of tables and charts meant to make access to data contained in primary source document 5.3.6 *Reissue* more transparent.

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

**"Relevant" Adverse Events:
Subjects**

Table 1	N =	42086	
Gender	F	29914	71%
	M	9182	22%
	ND	2990	7%
	Total	42086	

<12	34
<16	46
<= 17	95

Age

18-30	4953
31-50	13886
51-64	7884
65-74	3098
>=75	5214
Ukn	6876
Total	42086

Outcome	N =	42086
---------	-----	-------

Of (total)-(unknown)	Recovered/Recovering	19582	60%
Of (total)-(unknown)	Not recovered	11361	35%
Of 42,086	Unknown*	9400	22%

Fatal* 1223 4%

Of (total)-(unknown)	Recovered with sequelae*	520	2%
----------------------	--------------------------	-----	----

N - Unknown = 32686

Estimated range in all cases not recovered after removing unknowns

Died or not Recovered 40-87%

Percent recovered to percent not recovered	Recovered e	Not Recovered e
	17624	1958

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

9 to 1			
6 to 4	11749	7833	
5 to 5	9791	9791	
4 to 6	7833	11749	
1 to 9	4209	15373	
Recovered/Recovering Estimation Calculations	Estimated Not Recovered + Died	Estimate d percent not recovered	
Fatal + Not recovered + Sequelae	13104	40%	
Fatal + NR + S + estimated recovering*	15062	46%	
* Scaled estimated Recovering	20937	64%	
	22895	70%	
	24853	76%	
	28477	87%	
Table 1 Disorders >= 2%	WHERE IS THIS DATA?		
General and admin site	51335	122%	Compare with 42086
Nervous System	25957	62%	
MS & Connective Tissue	17283	41%	
GI	14096	33%	
Resp, Thoracic, and Mediastina	8848	21%	
	8476	20%	
Injury, poisoning, and procedur	5590	13%	WHERE IS THIS TOXICITY DATA?
Covid-19	1927	5%	
Investigations	3693	9%	????
Total 93473	137205		????
Table 2 Events >=2% Cases		N = 42086	
Blood and lymphatic	1972	4.69%	
Cardiac Table 2	1098	"Tachycardia"	

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

	Tables 1-6 AES		Table 2 + 7
	Cardiac Table 7	1403	
	Auto immune Myocarditis	25	
	Auto immune Pericarditis	32	
	Total Cardiac	1460	3.47%
	GI	8760	20.81%
	General and admin site	39451	93.74%
See total from Table 7	COVID19	1927	4.58%
Total procedural errors	Procedural complications	1708	4.06%
3416	Off label use	880	2.09%
	Product use issue	828	1.97%
	Musculoskeletal & CT	12399	29.46%
	Nervous system	16350	38.85%
	Respiratory, Thoracic, Mediastinal	4151	9.86%
	Skin and SubQ	5657	13.44%
	Total number of events	93473	2.2 per subject

Table 3-5 Safety Concerns	Cases	
Anaphylaxis BC1-4	1002	4 patients died on the same day the injection was given
Potential Anaphylaxis Cases	2958	9.4%
Vaccine Enhanced Disease	138	317 events
Use in Pregnancy and Lactation	413	84 S/329 NS
Pregnancy outcomes	N = 270	

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

No Outcome	238	88%
Outcome Pending	5	
Known outcome	27	
Spontaneous abortions	23	85%
Premature birth neonatal death	2	7%
Spontaneous abortion intrauterine death	2	7%
Spontaneous abortion neonatal death	1	4%
<u>Normal outcome</u>	<u>1</u>	<u>4%</u>
Mother cases	124	
Spontaneous abortion	25	20%
Myalgia	16	13%
Pyrexia	16	13%
Lymphadenopathy	7	6%
Chest pain	6	5%
Dizziness	6	5%
Asthenia	6	5%
Malaise	5	4%
Covid-19	5	4%
Uterine contraction	1	1%
Premature membrane rupture	1	1%
Abortion	1	1%
Abortion missed	1	1%
Fetal death	1	1%
Serious fetus/baby cases	4	
Fetal growth restriction/premature baby	2 each	
Neonatal death	1	
Breast feeding baby cases	133	
No adverse events	116	87%
Breast feeding infant child reactions Of those with AEs	17	13%
Fever	5	29%
Rash	4	24%

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

Irritability	3	18%
Vomiting	2	12%
Diarrhea	2	12%
Insomnia	2	12%
Illness	2	12%
Poor feeding	1	6%
Lethargy	1	6%
Abdominal discomfort	1	6%
Vomiting	1	6%
Allergy to vaccine	1	6%
Increased appetite	1	6%
Anxiety	1	6%
Crying	1	6%
Poor quality sleep	1	6%
Eructation	1	6%
Agitation	1	6%
Pain	1	6%
Urticaria	1	6%
Breast feeding mother cases	6	
Chills, malaise, and pyrexia	1	
Suppressed lactation	4	
Unknown AE	1	
Breast milk discoloration	1	
Pediatric age <12	34	132 AEs
Age range (Youngest 28 days not 2		3.7 years
2 mos. To 9 years		
months)		average
Serious	24	71%
Non-serious	10	29%

Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

1 seven year

Product administered to Pt of

27

old had a

inappropriate age

stroke

Off label use	11
Pyrexia	6
Product use issue	5
Fatigue	4
Headache	4
Nausea	4
Injection site pain	3
Abdominal pain	2
COVID-19	2
Facial paralysis	2
Lymphadenopathy	2
Malaise	2
Pruritis	2
Swelling	2

"Vaccine" effectiveness

Table 6

7 days after two

Confirmed

Failure 19

doses

C19

Unknown: 2

doses?,# days

Suspected

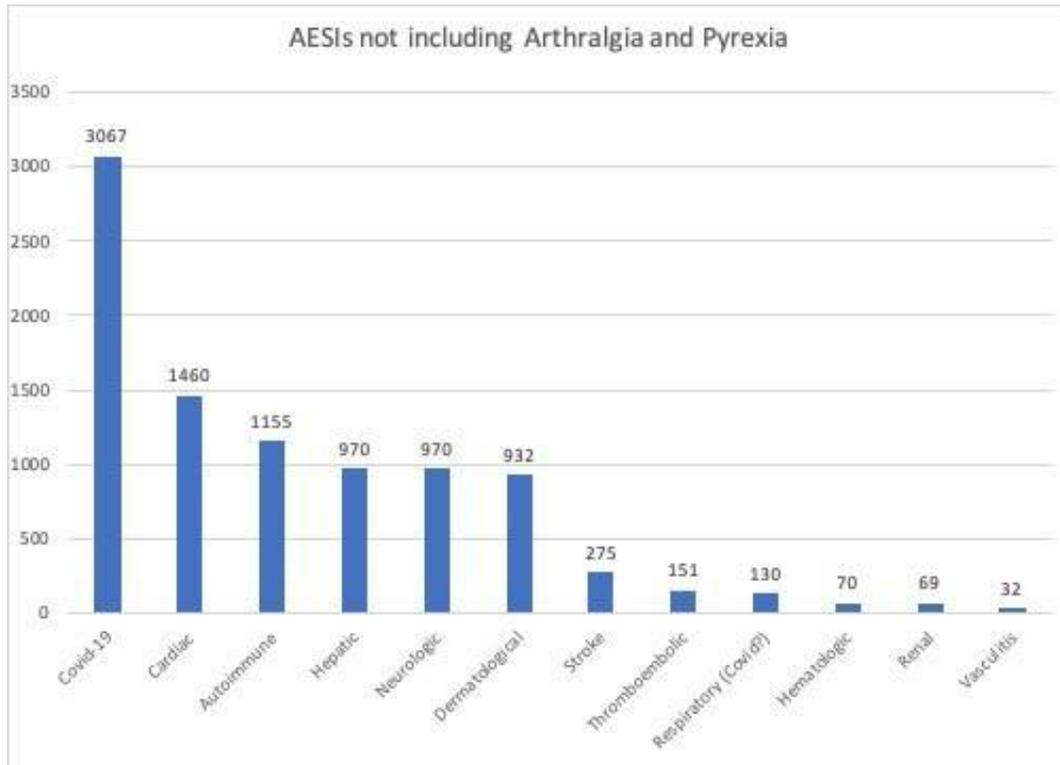
Cumulative Analysis of Post-authorization Adverse Events
Through 2/28/2021

Tables 1-6 AES

"Vaccine" ineffective 1649 since 1st dose,
C19
unk. Time since
2nd.

COVID-19	3067	
Outcome unknown	1230	74%
Fatality	65	15%

From Table 7 Analysis



Covid is the leading adverse event after arthralgia and fever

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

"Relevant" Adverse Events: Subjects	N = 42086	
Autoimmune (# and % of AEs)	1155	3%
Gender	838	
Female	682	
Male	156	
Age	944	
12-17	2	
18-64	746	
>=65	196	
Diagnoses	855	
Hypersensitivity	596	
Arthritis*	70	*From Musculoskeletal
Peripheral neuropathy	49	
Rheumatoid arthritis*	26	*From Musculoskeletal
Dermatitis	24	
Encephalitis	16	
Diabetes	16	
Psoriasis	14	
Bullous dermatitis	13	
Autoimmune disorder	11	
Reynaud's phenomena	11	
Polyarthritis*	5	*From Musculoskeletal
Polyneuropathy*	4	*From Musculoskeletal
Outcome	1078	
Other	517	
Unknown	312	28.9%
Not resolved	215	
Resolved with sequelae	22	2.0%
Fatal	12	1.1%
	AEs	N =
Cardiac (# and % of AEs)	1460	3.5%

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
Gender	1403	
Female	1076	
Male	291	
Unknown	36	
Age	1346	
2-11	1	
12-17	1	
18-64	1078	
>= 65	266	
Diagnoses	1498	
Arrythmia¹	1200	
Myocardial Infarction	130	
Cardiac Failure	91	
Pericarditis*	32	From Autoimmune
Myocarditis*	25	From Autoimmune
Cardiogenic shock	7	
Postural orthostatic tachycardia syndrome	7	
Coronary artery disease	6	
<p>¹ 7666 subjects had "pyrexia". Fever is accompanied by elevation in heart rate 10 beats/min for females per degree C and 7 b/m for males per degree C.</p>		
Outcome	1444	
Other	767	
Unknown	380	26.0%
Not resolved	140	
Fatal*	136	9.3%
Resolved with Sequelae	21	
<p>*May not include Myopericarditis fatalities</p>		

Assuming tachycardia listed in Table 7 refers to SVT etc.

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
N =		
COVID-19 (# and % of total AEs)	3067	7.3%
Gender	3067	
Female	1650	
Male	844	
Unknown	573	
Age	1880	
Infant*	2	*28 days to 27 mos.
2-11	1	
12-17	2	
18-64	1315	
>= 65	560	
Diagnoses	3356	
COVID-19	1927	
SC2 test +	415	
Suspected C19	270	
Ageusia	228	
Anosmia	194	
SC2 Antibody test negative	83	
Exposure to SC2	62	
SC 2 Antibody test positive	53	
C 19 pneumonia	51	
Asymptomatic C19	31	
Coronavirus infection	13	
Occupational exposure SC2	11	
SC2 false positive test	7	
SC2 test positive	6	
SC 2 test negative	3	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086	
SC 2 antibody test negative	2		
Outcome	3360		
Unknown	2110		62.8%
Other	558		
Fatal	136		4.0%
Resolved with sequelae	9		
Not resolved	547		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
N=		
Dermatological (# and % of total AEs)	20	0.05%
Gender	19	
Female	17	
Male	1	
Unknown	1	
Age	19	
Infant	0	
2-11	0	
12-17	0	
18-64	18	
>= 65	1	
Diagnoses	20	
Erythema multiforme	13	
Vasculitis	7	
Outcome	21	
Not resolved	8	
Other	7	
Unknown	6	29%
N =		
Hematological (# and % of Total AEs)	932	
Gender	898	
Bleeding		
Female	676	731
Male	222	87%

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
Unknown	N/A	
Age	837	
Infant	1	
2-11	0	
12-17	0	
18-64	543	
>= 65	293	
Diagnoses	888	
Epistaxis	127	
Contusion	112	
Site bruising	96	
Site hemorrhage	51	
Petechia	50	
Hemorrhage	42	
Hematochezia	34	
Thrombocytopenia	33	
Site hematoma	32	
Conjunctival hemorrhage	29	
Vaginal bleeding	29	
Hematoma	27	
Hemoptysis	27	
Menorrhagia	27	
Hematemesis	25	
Eye hemorrhage	23	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
Rectal hemorrhage	22	
Immune thrombocytopenia	20	
Hematuria	35	
Neutropenia	16	
Purpura	16	
Hemorrhagic diarrhea	15	
Outcome	1082	
Other	393	
Unknown	371 34%	
Not resolved	267	
Fatal	34 3.1%	
Resolved with sequelae	17	
		N
		=
Hepatic (# and % of Total AEs)	70	
Gender	70	
Female	43	
Male	26	
Unknown	1	
Age	64	
Infant	0	
2-11	0	
12-17	0	
18-64	37	
>= 65	27	
Diagnoses	82	
LFTs elevated	70	
Hepatic pain	9	
Ascites	3	
Outcome	94	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	42086
Unknown		47
Other		27
Not resolved		14
Fatal		5
Resolved with sequelae		1
	AEs	N = 42086
Musculoskeletal (# and % of total AEs)		3495
(-)Arthritis/polyneuropathy		
Gender		3471
Female		2760
Male		711
Age		3372
Infant		1
2-11		4
Arthralgia		2
18-64		2850
>= 65		515
Diagnoses		3534
Arthralgia		3525
Post viral fatigue syndrome		4
Chronic fatigue syndrome		4
Bacterial arthritis		1
Outcome		3662
Other		1801
Not resolved		959
Unknown		853
Resolved with sequelae		49

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021 Table 7: Adverse Events of Special Interest

	AEs	N= 42086
Neurological AESIs (# and % of total AEs)	950	
Gender	927	
Female	623	
Male	283	
Unknown	21	
Age	889	
Infant	1	VIIth nerve palsy
2-11	1	
12-17	0	
18-64	642	
>= 65	245	
Diagnoses		
Facial paralysis	401	Facial Nerve Injury
=		
Seizure	204	492
Epilepsy	83	Seizure =
Facial paresis	64	404
Generalized seizure	33	Demyelinating =
Guillain-Barre syndrome	24	28
Fibromyalgia	17	GB =
Trigeminal neuralgia	17	24
Febrile convulsion	15	
Status epilepticus	12	
Aura (petit mal?)	11	
Transverse myelitis	11	
Multiple sclerosis relapse	10	
Optic neuritis	10	
Petit mal epilepsy	9	
Tonic convulsion	9	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	N= 42086
Ataxia	8
Encephalopathy	7
Tonic-clonic movements	7
Foaming at mouth	5
Polyneuropathy	4
Multiple sclerosis	4
Narcolepsy	4
Partial seizures	4
Bad sensation	3
Demyelination	3
Meningitis	3
Post ictal state	3
Seizure like phenomena	3
Tongue biting	3
Outcome	1011
Other	449
Not resolved	272
Unknown	258
Fatal	16
Resolved with sequelae	16
Other AESIs (# and % of total ASEs)	8152
Gender	7829
Female	5969
Male	1860
Unknown	N/A
Age	7479
Infant	6
2-11	9

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

		N= 42086
12-17	9	
18-64	6330	
>= 65	1125	
Diagnoses	8207	Fever = 94% of category.
Pyrexia	7666	Herpes 391 cases
Herpes zoster (shingles)	259	
Inflammation	132	
Oral herpes	80	
Multiple organ dysfunction synd.	18	
Herpes virus infection	17	
Herpes simplex	13	
Ophthalmic herpes	10	
Herpes ophthalmic	6	
Herpes zoster reactivation	6	
Outcome	8218	
Other	5008	
Unknown	1685	21%
Not resolved	1429	
Fatal	96	1%
	AEs	
Renal AESIs (# and % of total ASEs)	69	
Gender	69	
Female	46	
Male	23	
Unknown	N/A	
Age		
Infant	1	
2-11	0	
12-17	0	
18-64	7	
>= 65	60	
Diagnoses		
Acute kidney injury	40	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

		N= 42086	
Renal failure	30		
Outcome	70		
Fatal	23		33%
Unknown	22		32%
Not resolved	15		
Other	10		

	AEs	N= 42086	Respiratory
AESIs 130			
Gender	130		
Female	72		
Male	58		
Unknown	N/A		
Age	126		
Infant	0		
2-11	0		
12-17	1		
18-64	47		
>= 65	78		
Diagnoses	137		
Respiratory failure	44		
Hypoxia	42		
Respiratory disorder	36		
ARDS	10		
Chronic respiratory syndrome	3		
Severe acute respiratory syndrome	2		
Outcome	137		
Other	47		
Fatal	41		32%
Unknown	31		24%
Not recovered	18		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

	AEs	N=
		42086
Stroke AESIs (# and % of total ASEs)	275	
Gender	273	
Female	182	
Male	91	
Unknown	N/A	
Age	265	
Infant	0	
2-11	1	
12-17	0	
18-64	59	
>= 65	205	
Diagnoses	292	
Ischemic	237	81%
Cerebrovascular accident	160	
Ischemic stroke	41	
Cerebral infarction	15	
Cerebral ischemia	3	
Cerebral thrombosis	3	
Cerebral venous sinus thrombosis	3	
Ischemic cerebral infarction	3	
Lacunal infarction	3	
Basal ganglia stroke	2	
Cerebellar infarction	2	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

		N=	
		42086	
Thrombotic stroke	2		
Hemorrhagic	55		19%
Cerebral hemorrhage	26		
Hemorrhagic stroke	11		
Hemorrhage intercranial	5		
Subarachnoid hemorrhage	5		
Cerebral hematoma	4		
Basal ganglia hemorrhage	2		
Cerebellar infarction	2		
Outcome	300		
Not resolved	85		
Unknown	83		28%
Fatal	61		20%
Other	61		
Resolved with sequelae	10		

AEs

Thromboembolic event (# and % of total ASEs)	
151	
Gender	144
Female	89
Male	55
Unknown	N/A
Age	136
Infant	0

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

Table 7: Adverse Events of Special Interest

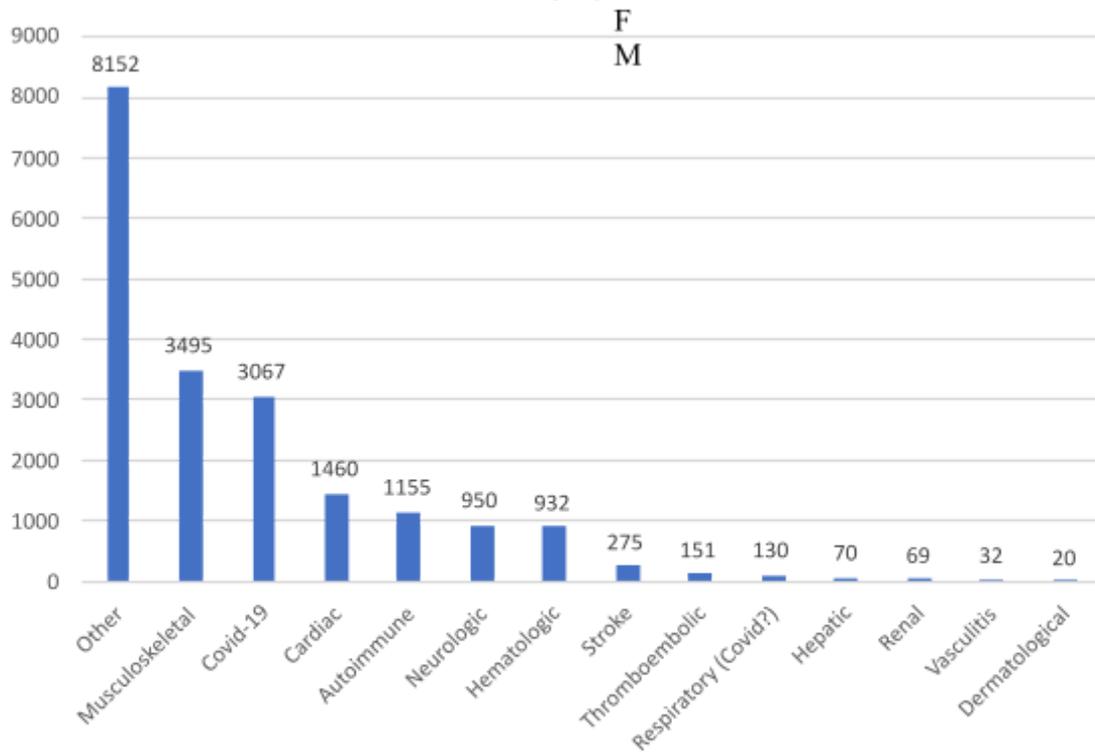
		N= 42086	
2-11		0	
12-17		0	
18-64		66	
>= 65		70	
Diagnoses		151	
Pulmonary embolism		60	
Thrombosis		39	
DVT		35	
Thrombophlebitis peripheral		6	
Venous thrombosis		4	
Embolism		3	
Microembolism		3	
Thrombophlebitis		3	
Venous thrombosis		3	
Blue toe syndrome		2	
Outcome		169	
Other		54	
Not resolved		49	
Unknown		42	25%
Fatal		18	11%
Resolved with sequelae		6	
	AEs		
Vasculitis (# and % of total ASEs)		32	
Gender		32	
Female		26	
Male		6	
Unknown		N/A	
Age		31	
Infant		0	
2-11		0	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021

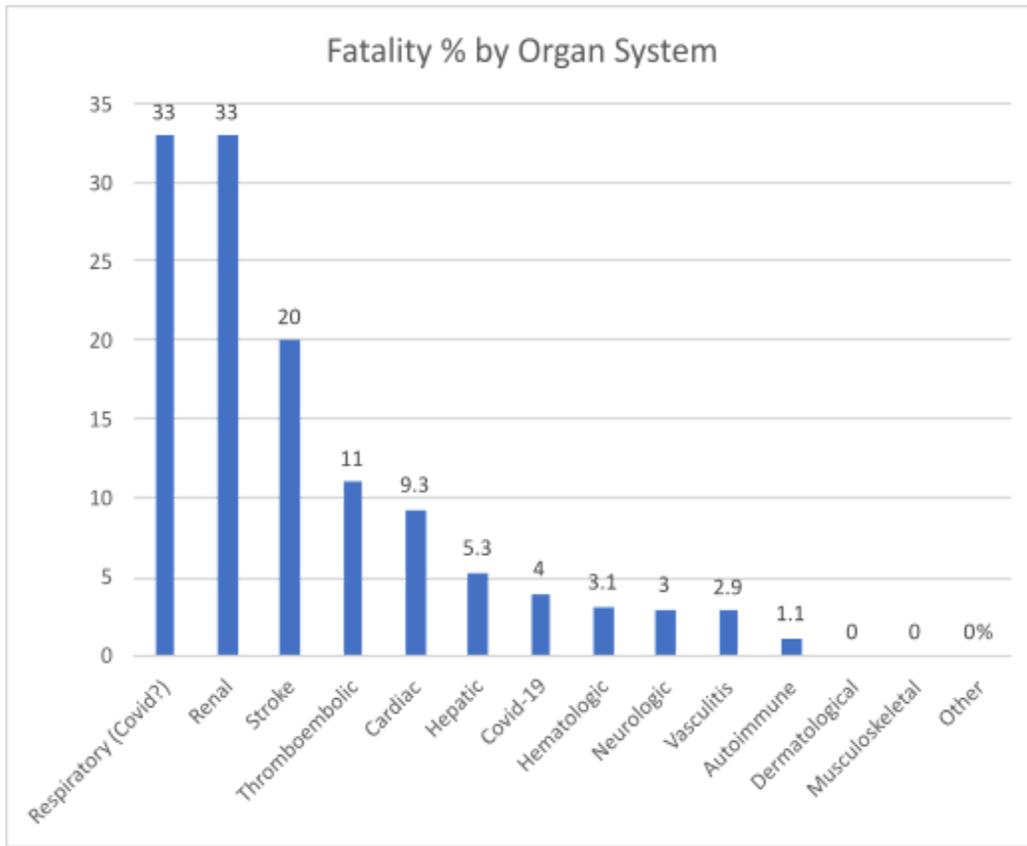
Table 7: Adverse Events of Special Interest

		N=	
		42086	
12-17	0		
18-64	15		
>= 65	16		
Diagnoses	32		
Vasculitis	14		
Cutaneous vasculitis	4		
Vasculitic rash	4		
Giant cell arteritis	3		
Peripheral ischemia	3		
Bechet's syndrome	2		
Hypersensitivity vasculitis	2		
Palpable purpura	1		
Takayasu's arteritis	1		
Outcome	34		
Other	13		
Not resolved	12		
Unknown	8		24%
Fatal	1		3%

**"Relevant" Adverse Events: Subjects
AESIs by System**



Category*	N =
Other	8152
Musculoskeletal	3495
Covid-19	3067
Cardiac	1460
Autoimmune	1155
Neurologic	950
Hematologic	932
Stroke	275
Thromboembolic	151
Respiratory (Covid?)	130
Hepatic	70
Renal	69
Vasculitis	32
Dermatological	20
Total	19958



Category	% Fatality	% Unknown	# Unknown	Outcome
Respiratory (Covid?)	33	31%	22	70
Renal	33	31%	22	70
Stroke	20	28%	83	300
Thromboembolic	11	25%		
42	169			
Cardiac	9.3	26%		
380	1444			
Hepatic	5.3	52%		
47	90			
Covid-19	4	63%		
21103360				
Hematologic	3.1	34%		
371	1082			

Neurologic 161 544	3	30%
Vasculitis 8 34	2.9	24%
Autoimmune 312	1.1 1078	29%
Dermatological 6	0 21	29%
Musculoskeletal 853	0 2809	30%
Other 16856533	0%	26%
	Totals 17604	6102

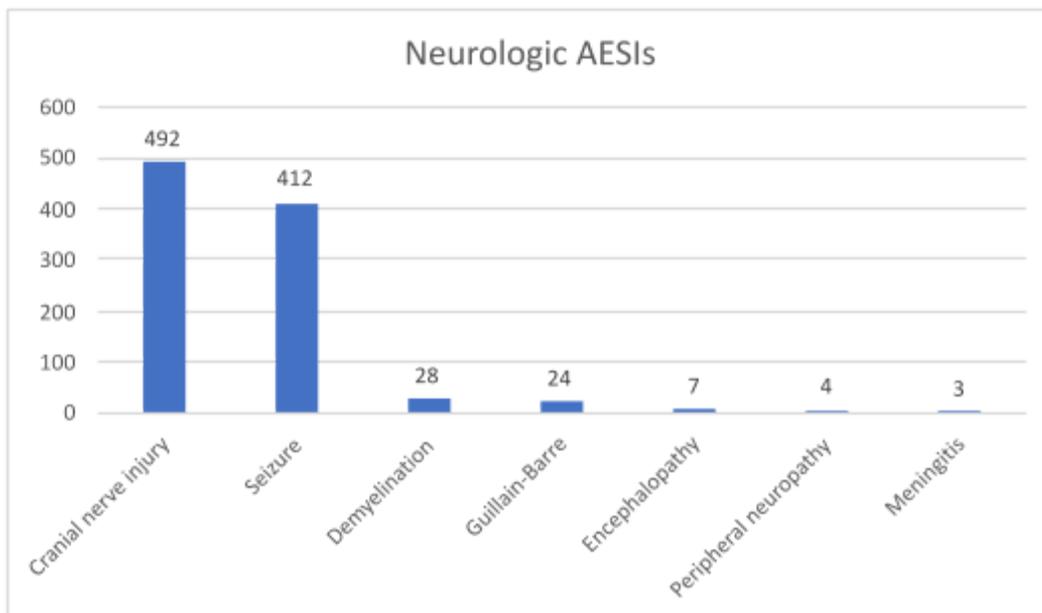
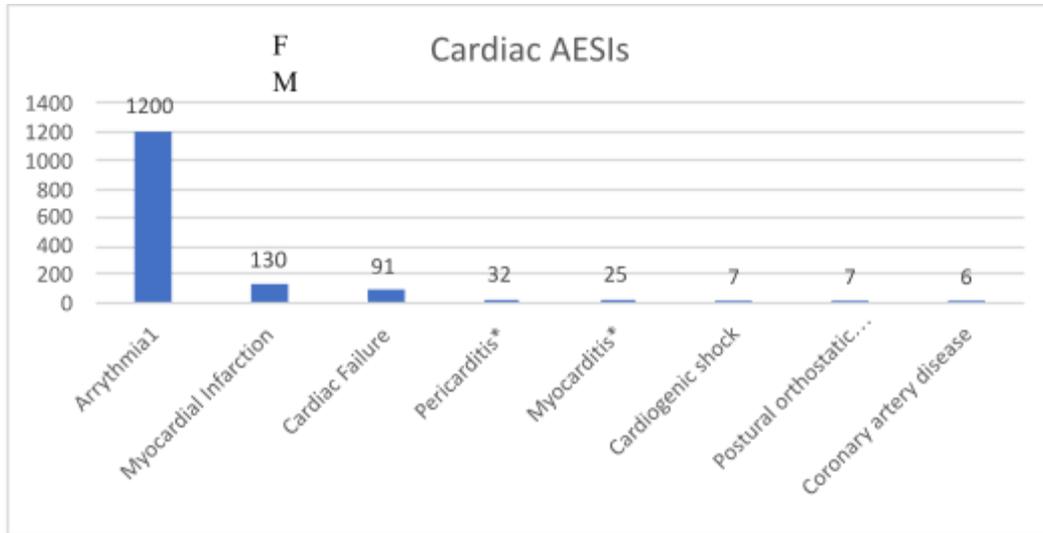
AESI Outcome % Unknown outcome 31%

AESI Fatalities Category*	N =	Fatalities
Percent Fatal		
Cardiac 9%	1460	136
Covid-19 4%	3067	136
Other 1%	8152	96
Stroke 22%	275	61
Respiratory (Covid?) 32%	130	41
Hematologic 4%	932	34
Renal 33%	69	23

Thromboembolic 12%	151	18
Neurologic 2%	950	16
Autoimmune 1%	1155	12
Hepatic 7%	70	5
Vasculitis 3%	32	1
Dermatological 0%	20	0
Musculoskeletal 0%	3495	0
Totals 3%	19958	579

Table 1 Fatalities	1223
Fatalities accounted for	579
Missing	644
Missing %	53%

AEs + AESIs	Cases not reported or lost	
Table 1	"Relevant cases" per Pfizer	42086
Table 7	Organ systems	19958
Table 1	Outcome Unknown	9400
	Known Outcome	29358
	"Missing"	12728
		30%



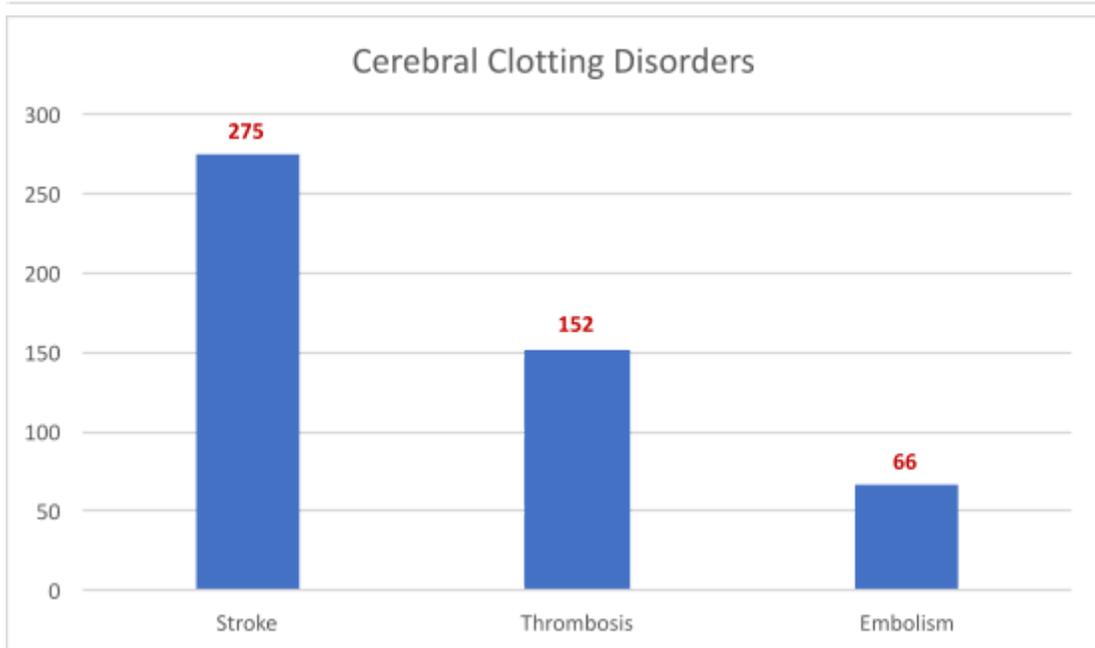
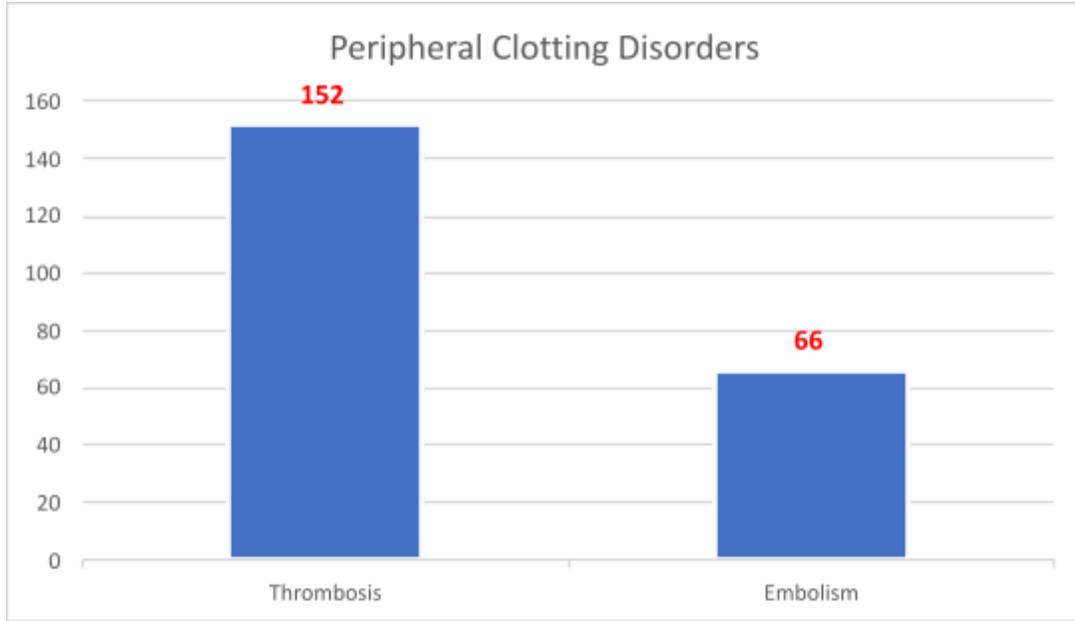
Neurologic

Cranial nerve injury 492
 Seizure 412

Demyelination 28
 Guillain-Barre 24

Encephalopathy 7
 Peripheral neuropathy 4
 Meningitis 3

970



Stroke	275
Thrombosis	152
Embolism	66

As the numbers of those receiving the vaccine rose, **Pfizer was confronted with such a flood of Adverse Event reporting that they had to hire 2,400 employees to handle the volume.** [5.3.6 postmarketing experience.pdf](#) reports on 42,086 subjects or patients considered relevant with 93,473 Adverse Events (AEs) or Adverse Events of Special Interest (AESIs), although there appears to have been 137,205 actual events. As noted, at least four or more appendixes may have been omitted, as the document references “Appendix 5,” which is not included in the document.

The Pfizer report, [Reissue 5.3.6](#), presents a selection of that reporting. Denominators are largely not provided, making statistical analyses of prevalence nearly impossible. This document is highly significant in identifying AEs/AESIs signal detection that would lead responsible scientific and medical professionals to:

- **Incorporate warnings of specific disorders resulting from Pfizer’s COVID-19 BNT162b2 vaccine** in Public Service Announcements (PSAs) and in written, signed, and witnessed Informed Consents.
- Acknowledge that **these disorders were identifiably associated with BNT162b2** as of December 2020 through data capture completion February 28, 2021:
 - **Covid-19 was one of the most common AEs/AESIs.** According to document [5.3.6](#), COVID-19 was the third most common adverse event. The top two most common adverse events were Arthralgia (achiness, etc. around or near joints) and Pyrexia (raised body temperature, fever). The COVID-19 cases were unbundled and scattered through the reporting.
 - **Clotting disorders:** stroke, thrombosis, embolism
 - **Bleeding disorders:** hematoma, hemorrhage
 - **Neurological disorders:** seizures and nerve damage to both central and peripheral nervous systems
 - **Autoimmune disorders:** arthritis, cerebritis, peri cardiomyopathies
 - **Organ system damage:** cardiac, hematopoiesis, reproductive
 - **Viral Antibody-Dependent Enhancement (VADE)**
- **Intensify targeted data collection and detailed investigation** of these disorders including a statically, sufficiently powered series of autopsies and outcome studies.
- Establish an agency up to **manage in a medically responsible way all reported AEs/AESIs patients.**

Additionally, the primary source document is modified to include pericarditis and myocarditis in the cardiac organ system rather than under autoimmune disorders. This is done because the AESIs are organized as organ systems. The conclusion that these inflammatory disorders of the heart are a result of an immune system disorder is in itself a remarkable admission. This topic is worthy of follow-up investigations.

Similar adjustments to some diagnostic categories are also present. For, example, arthritis and rheumatoid arthritis were moved from the Musculoskeletal to the Autoimmune category. This is significant because the sudden appearance of these disorders put them in the Autoimmune category – until otherwise proven.

Another interesting inclusion is the case of “Tachycardia” (1,098 cases). **Tachycardia** means elevated heart rate. Heart rates go up roughly 10 beats per minute for each degree of temperature gain. Strangely, there were 7,666 cases of Pyrexia (fever) using Celsius degrees that eliminated all temperature elevations between 99.6- and 100.3-degrees Fahrenheit. The **under-reporting of fevers makes this reporting questionable**. Were these “Tachycardias” cases actually cases of erratic heartbeat (arrhythmia) that affect the heart’s upper chambers? The matter can only be resolved with **raw data access that has not been provided**.

Finally, in Table 2, 1,972 **cases of Lymphadenopathy (swelling of the lymph nodes) appear without any reporting of low white blood cell count (lymphocytopenia)** or measuring of infection or dysfunction including the formation of cancers. Similar concerns can be directed toward the **absence in the reporting of Troponin and d-dimer levels**. Without the raw data, we have no way of knowing just how high d-dimer levels were. D-dimers are protein fragments present in the blood after a blood clot. This is significant because of the correlation between high d-dimer levels and frequency of blood clots.

These are just a few of the concerns raised by Pfizer’s [5.3.6 postmarketing experience](#) document. Once raw data has been released in usable form, many outstanding questions can be answered.

By April 30, 2021, Pfizer and the FDA knew diverse, dangerous, sometimes life-altering, and even fatal adverse events resulted from the administration of the mRNA vaccines. Yet, the FDA and Pfizer failed to inform the public of these side effects except for a June 25, 2021, warning about myocarditis and pericarditis. To date, that is the only mRNA vaccines' adverse event warning published.

[<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021>]

Informed consent is not possible without clear, public warnings about clotting, bleeding, neurological, and autoimmune disorders, as well as organ systems’ damages and Viral Antibody-Dependent Enhancement.

[<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>]

Report 35: “Pfizer Used Dangerous Assumptions, Rather than Research, to Guess at Outcome” by Robert Chandler, M.D., M.B.A. – Team 5

At the launch of widespread mass inoculation of the public with Pfizer’s mRNA vaccine, BNT162b2, media, physicians’ spokespeople, and government officials communicated widely that the injected drug would be retained at the injection site muscle tissue and in local lymph nodes. The components were supposed to be metabolized in a day or so, leaving only induced SARS CoV-2 Spike antigen to evoke a therapeutic immune response. A short pulse of drug effect would be followed, they claimed, by limited production of Spike antigen.

However, newly released internal Pfizer documents show that this is not true. In fact, the injection causes widespread distribution of the material in tissues and this distribution persists for at least two days, and probably much longer. These facts are the exact opposite of what was publicized.

A cluster of FDA-released Pfizer documents — “*Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats*” [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf], 2.4 NONCLINICAL OVERVIEW [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf], “MODULE 2.6.5. PHARMACOKINETICS TABULATED SUMMARY” [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_26_pharmkin-tabulated-summary.pdf] and the heavily redacted report “*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODERNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION*” [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf] — all examine tissue distribution of Pfizer’s mRNA vaccine BNT162b2. These documents will be addressed in this report.

Pfizer Study 185350,” *Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat*”, is one of 21 preclinical Pfizer studies involving mice, rats and rhesus macaque non-human primates. Study No. 185350 (Sponsor Reference ALC-NC-0552) was summarized in Pfizer’s “2.4 Nonclinical Overview” and was separately published as a Final Report dated September 24, 2020.

Contained in that document is the following identification of the source:

Test Facility Study No. 185350 **REDACTED**
SPONSOR: Acuitas,
6190 Agronomy Road,
Ste. 402,
Vancouver, V6T 1Z3 Canada
Sponsor Reference No. ALC-NC-0552

This study was made up of 42 male and 21 female Wistar Han rats. These rats were injected with 50 or 100 micrograms of BNT162b2 mRNA/LNP (lipid nanoparticle) product labelled with a radioactive tracer material, ³H. Then the rats were sacrificed at intervals of 0.25 hours (15 minutes); 1 hour; 2 hours; 4 hours; 8 hours; and then at 1 and 2 days.

The results of 21 male and 21 female sacrificed rats are presented.

The 100-microgram dose was associated with loss of weight and apparent toxicity in two animals. Unfortunately, the full results of the 100-microgram dose were not presented at all.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 11.]

Initially, 21 male rats were dosed at 100 µg mRNA/animal. Some adverse clinical signs were observed after approximately 24 hours post-dose and a subsequent review of the data showed concentrations were well detected in tissues. After discussions with the Sponsor, the target dose level was lowered to 50 µg mRNA/animal by amendment for the remainder of the study. Reference is made to the 100 µg mRNA /animal group in some sections of the report, however, the results are not discussed.

This is very important. The 100-microgram dose was considered too toxic to continue to use in the experiment, so the dosage was cut in half. 100 micrograms is the amount in the Moderna injections.

The 50-microgram dose was not safe. One female rat in the 50-microgram dose exhibited piloerection and hunched posture.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p.19.]

The injection did not stay at the injection site, as we were promised it would. Rather, following injection, the drug was persistent at the injection site, with a third of the dose remaining in muscle tissue for two days in males, and a sixth of the dose remained in females for the same duration.

Timepoint (h)	Injection site (µg equiv lipid/g)		Injection site (% dose)	
	Male	Female	Male	Female
0.25	219.940	36.566	32.887	6.815
1	587.670	199.950	68.829	36.411
2	529.210	93.144	39.053	24.094
4	619.850	56.227	47.710	9.056
8	299.590	125.930	18.731	24.993
24	267.170	122.540	31.957	26.295
48	268.770	61.088	32.823	16.426

But it did not all stay in the deltoid muscle. From the injection site in the deltoid muscle, mRNA/ Lipid Nanoparticles appeared in blood and plasma fifteen minutes after injection and persisted for the entire duration of the two-day study.

Timepoint (h)	Blood (µg equiv lipid/g)		Plasma (µg equiv lipid/mL)		Blood:plasma ratio	
	Male	Female	Male	Female	Male	Female
0.25	3.003	0.936	6.035	1.894	0.48	1.15
1	2.809	5.928	5.379	10.884	0.49	0.54
2	4.028	6.773	8.714	9.091	0.46	0.64
4	3.400	2.698	8.755	4.251	0.42	0.60
8	2.000	0.628	3.573	1.147	0.56	0.55
24	1.274	0.544	2.621	0.945	0.49	0.57
48	0.535	0.305	1.085	0.524	0.50	0.58

On page 20 of “*Final Report: A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rat,*” the authors note that widespread distribution to “most tissues” occurs by the time of first analysis at 15 minutes after injection.

There was greater accumulation in blood when compared to plasma, and males generally had higher concentrations than females with lower blood to plasma ratios. No explanation for these differences was offered.

The major tissues that contained the drug concentration, aside from muscle at the injection site, were identified as being the liver, spleen, adrenal glands, and ovaries. The drug persisted in tissues throughout the duration of the study. The meaning and potential implications of the persistence in tissues was not addressed. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 21.]

Timepoint (h)	Values expressed as µg equiv lipid/g)						
	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	1.151	0.323	0.354	*0.313	0.302	*0.240	*0.104
1	4.006	5.244	2.140	2.801	0.580	2.388	1.339
2	9.574	12.370	5.255	10.213	1.206	4.232	1.638
4	18.525	14.569	8.945	11.646	2.569	3.206	2.341
8	27.916	25.172	24.434	19.747	6.387	7.218	3.088
24	23.360	15.119	22.819	17.341	19.948	7.595	5.240
48	18.164	30.411	19.550	27.155	21.476	14.942	12.261

=Mean includes results calculated from data less than 30 cpm above background

Timepoint (h)	Liver		Spleen		Adrenal glands		Ovaries
	Male	Female	Male	Female	Male	Female	Female
0.25	0.995	0.209	0.014	*0.011	0.001	*0.001	*0.001
1	2.834	2.907	0.087	0.098	0.002	0.012	0.009
2	7.629	7.030	0.232	0.418	0.005	0.015	0.008
4	15.027	8.699	0.351	0.419	0.012	0.018	0.016
8	21.519	14.580	1.118	0.845	0.026	0.043	0.025
24	19.901	10.977	0.957	0.685	0.083	0.049	0.037
48	13.953	18.357	0.914	1.146	0.104	0.108	0.095

=Mean includes results calculated from data less than 30 cpm above background

Top: highest mean concentrations. Bottom: equivalent % dose.

The next two tables present the overall tissue distribution data from this study. It is reasonable to conclude, thus, that BNT162b2 is distributed throughout the body and persists for at least two days, the duration of the study.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, pp. 7-8.]

Tissue specimens were harvested but, unfortunately, no microscopic analysis of these specimens is presented at all, so potential damage to various organs was not evaluated.

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [³H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 18S350

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	6.02	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

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [³H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 18S350

Sample	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
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	--	--	--	--	--	--	--

A separate pharmacokinetic study, "PF-07302048," looked at the persistence of the LNP (lipid nanoparticle) transport vessel with a test mRNA inside consisting of LNP coating wrapped around

Luciferase mRNA, Figure 2.4.3-1 below. [*R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODRNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION*”, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf.]

The object of this study was to follow the LNP vessel in plasma and liver, and then measure transcription of mRNA inside target organs to validate the delivery model using the bioluminescent properties of Luciferase to identify transcription of the mRNA in target tissues. [https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_R-20-0072.pdf]

From this study, we learn that the two measured components of the lipid nanoparticle coating, ALC-0315 [(4-hydroxybutyl) azanediyl]di(hexane-6, 1-diyl) bis (2-hexyldecanoate)] and ALC-0159 (2-[2-(polyethylene glycol)-2000]-N, N-ditetradecylacetamide) are detectable in plasma after 300 hours – that is to say, 12.5 days – which fact raises the issue of how long the contents of the LNP vessel with the mRNA inside persists, and what the implications are of prolonged occupation of host cells by this material. In this study, the BNT162b2 was injected intravenously, accelerating the dissemination of drug. [2.4 NONCLINICAL OVERVIEW, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p.16.]

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg

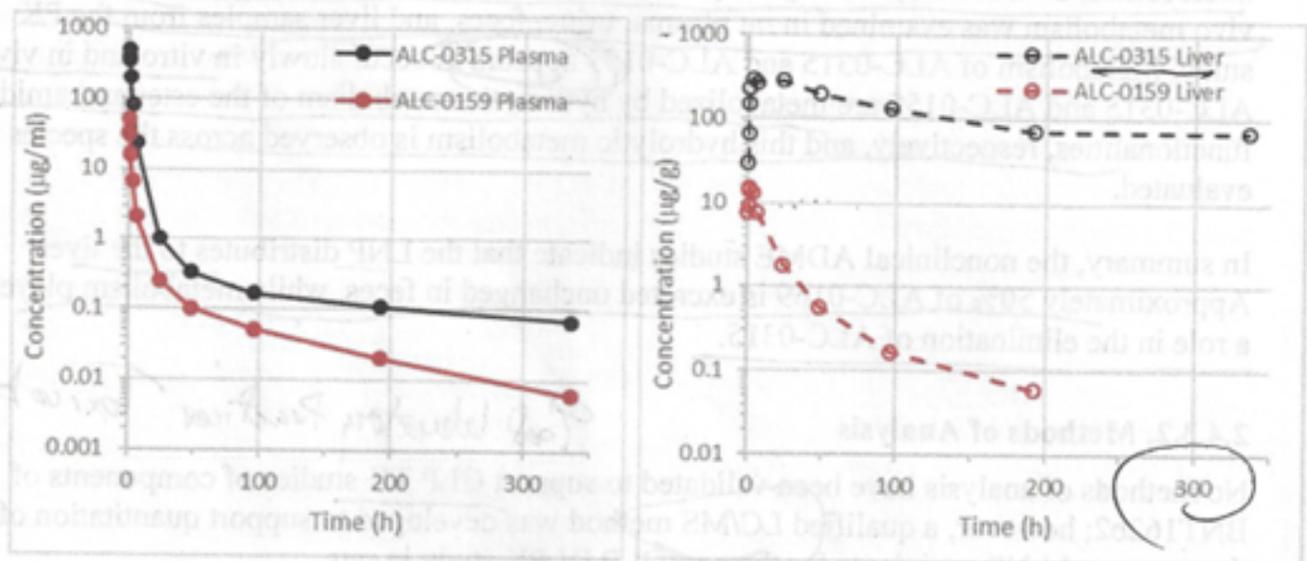


Figure 1: From R&D STUDY REPORT No. R-20-0072 – EXPRESSION OF LUCIFERASE-ENCODING MODRNA AFTER I.M. APPLICATION OF GMPREADY ACUITAS LIPID NANOPARTICLE FORMULATION.

This study of the biodistribution of the LNP coating containing Luciferase mRNA found that not only was the mRNA transcribed, but the LNP “vessel” components ALC-0315 and ALC-0159 were retained in the liver and in the plasma for at least 12.5 days. The fate of the Luciferase mRNA was not discussed.

With respect to degradation of the mRNA component, we learn from “2.4 Nonclinical Overview” that Pfizer/Acutas did not study at all the degradation of the synthetic mRNA in BNT162b2. Similarly, there was no analysis by Pfizer of protein products from BNT162b2 provided.

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p.20.]

The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins. RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. Therefore, no RNA or protein metabolism or excretion studies will be conducted.

Several serious questions are raised by these results:

1. How long does the BNT162b2 mRNA persist in human tissues? Where does it go in the host cell? How long does it persist inside the cell? What proteins does it produce, and for how long?
2. Is there any possibility that the BNT162b2 mRNA can be transcribed into DNA, then incorporate into the host genome? If this happens what are the implications?
3. What are the toxicities from the lipid nanoparticle coating?
4. Was Pfizer obligated to answer these questions prior to human testing?
5. Doesn't proper informed consent require answers to these questions?

Fortunately, answers to these important questions are beginning to appear:

1a. Duration of mRNA in tissues:

In a July 19, 2022, article, the essayist Joomi reviews the topic of how long BNT162 b2 containing mRNA stabilized by a synthetic nucleotide 1N-methyl pseudouridine persists in human tissues.

[https://joomi.substack.com/p/were-still-being-misled-about-how?r=chkp3&s=r&utm_campaign=post&utm_medium=web]

A January 2022 human lymph node biopsy study from Stanford University found that the mRNA from both Pfizer and Moderna persists for at least two months, which was the duration of the study.

[<https://www.cell.com/action/showPdf?pii=S0092-8674%2822%2900076-9>]

1b. Proteins produced from BNT162b2 mRNA:

Spike protein is produced after the mRNA is transcribed, and has been found in vivo for at least four months after inoculation.

[https://joomi.substack.com/p/were-still-being-misled-about-how?r=chkp3&s=r&utm_campaign=post&utm_medium=web]

Proteins transcribed from the mRNA have not been completely characterized yet. SARS-CoV-2-like Spike protein has been identified as long as four months after inoculation with LNP/mRNA in human

exosomes. Toxicity of Spike protein has been described and is reviewed in the essay “We’re still being misled about how long the mRNA vaccines last in the body.”

[https://joomi.substack.com/p/were-still-being-misled-about-how?r=chkp3&s=r&utm_campaign=post&utm_medium=web]

2. What is the fate of BNT162b2 mRNA?

We were informed that “RNA is required for protein synthesis, does not integrate into the genome, is transiently expressed, and is metabolized and is eliminated by the body’s natural mechanisms and, therefore is considered safe.” [Alberer, M. et al. *Safety and immunogenicity of a mRNA rabies vaccine in healthy adults: an open-label, non-randomized, prospective, first-in-human phase I clinical trial. Lancet* 90, 1511-1520 (2017).] [Sahin, U. et al. *Personalized RNA mutanome vaccines mobilize poly-specific therapeutic immunity against cancer. Nature* 547, 222-226 (2017).]

However, Alden, et. al., reporting in *Current Issues in Molecular Biology* 2022, 44, 1115-1126, found BNT162b2 mRNA is reverse transcribed into host DNA beginning six hours after contact with BNT162b2:

“In the BNT162b2 toxicity report, no genotoxicity nor carcinogenicity studies have been provided. Our study shows that BNT162b2 can be reverse transcribed to DNA in liver cell line Huh7, and this may give rise to the concern if BNT162b2-derived DNA may be integrated into the host genome and affect the integrity of genomic DNA, which may potentially mediate genotoxic side effects. At this stage, we do not know if DNA reverse transcribed from BNT162b2 is integrated into the cell genome. Further studies are needed to demonstrate the effect of BNT162b2 on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as tissues from human subjects who received BNT162b2 vaccination.” [<https://www.mdpi.com/1467-3045/44/3/73/htm>]

This study did not identify DNA transcribed from BNT162b2 mRNA in the host genome following transcription.

However, Zhang et. al., working at Massachusetts Institute of Technology, demonstrated fragments of SARS-CoV-2 mRNA integrated in host DNA in “Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues,” published in 2021 in *PNAS*, vol. 118, no. 21:

“We show here that SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of the infected cell and be expressed as chimeric transcripts fusing viral with cellular sequences. Importantly, such chimeric transcripts are detected in patient-derived tissues.” [<https://www.pnas.org/doi/10.1073/pnas.2105968118>]

So, scientists are getting close to knowing whether BNT162b2, with its synthetic mRNA, is translated into host DNA and is now a permanent part of human genetic material. If so, the next step is to determine what the implications are.

3. What are the toxicities from the lipid nanoparticle coating?

More research is required to understand the implications of LNP concentration in various organ tissues. It is thought that the PEG component (the polyethylene glycol that coats the LNP) is responsible for anaphylaxis, an often rapid-onset major physiologic event that requires emergency treatment.

4. Was Pfizer obligated to answer these questions prior to human testing?

5. Doesn’t proper informed consent require answers to these questions?

The answers to questions 4 and 5 are “yes,” and the reasons should be obvious now. Basic information about functioning of this mRNA product, BNT162b2, was not known at the time of mass inoculation;

and, therefore, a proper risk, benefits and complications discussion was compromised by lack of information. Informed consent is not possible in such a situation.

In conclusion, many negatively consequential shortcuts were made in the development of BNT162b2.

Many omissions in basic research evaluation of BNT162b2 were kept hidden, and there was outright misinformation regarding some of the work that was done.

Assumptions rather than actual research to determine where BNT162b2 goes, what it does, and how long it lasts were made that proved to be false and constitute intentional mis/dis/mal information. We were told that the prodrug, BNT162b2, consisting of a lipid nanoparticle coating of synthetic messenger ribonucleic acid (modRNA), would be deposited in muscle tissue at the injection site and would be migrate to local lymphatics prior to rapid degradation producing Spike antigens for a limited period of time that would produce a desired immune response.

However, Pfizer in its very early Phase 1 trial with mice, rats, and rhesus non-human primates learned that the LNP/mRNA is rapidly disseminated throughout the body and remained in tissues for as long as it was studied, 48 hours for BNT162b2 and 12.5 days for the LNP/Luciferase mRNA test product. No effort was expended to determine what proteins are produced by the modRNA, what their physiological actions are and how long they are produced as well as what toxicities and adverse events might be anticipated with widespread usage of the LNP/mRNA prodrug.

FOIA requests for internal documents from federal health care agencies, independent review board members, approximately 140 clinical investigators and Pfizer personnel should be made. Billions of doses were administered to billions of people. The scale of this potentially massive medical misstep is large.

Ten months to develop novel gene therapy for a novel virus is well short of the five to 10 years usually required to develop, test and refine such a product. After billions of doses have been given to children and adults around the world, possibly altering the course of human evolution, the public is now seeing the unfortunate consequences of cutting corners.

Report 36: “Pfizer, FDA, CDC Hid Proven Harms to Male Sperm Quality, Testes Function, from mRNA Vaccine Ingredients” by Amy Kelly

When the COVID-19 vaccine rollout to the public began in late 2020, medical professionals, public health agencies, and government spokespeople all assured the American public that the novel mRNA vaccines did not cause negative systematic effects to human bodies. They promised the public, many of whom were skeptical about the safety of a drug brought to market at “warp speed,” that the vaccines were “safe and effective.” [“Operation Warp Speed: Accelerated Covid-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges.” Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address *Manufacturing Challenges* | U.S. GAO, U.S. Government Accountability Office, 11 Feb. 2021, <https://www.gao.gov/products/gao-21-319>.] [“Safety of Covid-19 Vaccines.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 8 Aug. 2022, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>.]

As we know, those who questioned or challenged the “safe and effective” assurances were dismissed as “anti-vaxxers” and accused of wanting to kill others, especially the elderly. [Gostin, Lawrence O., and Eric A. Friedman. “This Is the Best Evidence Yet That Anti-Vaxxers Kill.” *Yahoo! News*, Yahoo!, 23 June 2022, <https://news.yahoo.com/best-evidence-yet-anti-vaxxers-225950487.html>.]

Due to this pressure, during the push to vaccinate everyone against COVID-19, few medical and public health experts spoke out about the need for long-term studies to protect Americans against possible catastrophic vaccine-related outcomes, including against possible negative impacts on fertility.

This attack on challengers to public health’s all out push, and the resulting censorship of the emerging problem, resulted in catastrophic harms to male fertility.

Pfizer’s own documents and other medical studies show:

1. mRNA vaccine ingredients can be transferred from one person to another via skin-to-skin contact, inhalation and via “sexual intercourse,” through bodily fluids. That is to say, vaccine “shedding” can occur via sexual contact, including via exposure to semen. [“A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals,” Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c45_91001-interim-mth6-protocol.pdf, pp. 213, 246, 398, 431, 575, 607, 751, 783, 918, 948, 1073, 1103, 1226, 1255, 1378, 1406, 1522, 1549, 1663, 1688, 1813, 1836, 1949, 1969, 2081, 2100, 2211, 2228, and 2337.] In other words, according to Pfizer’s own internal documents, a vaccinated man can expose his sexual partner to the vaccine ingredients, via ejaculation.
2. Pfizer did not test “male reproductive toxicity”. Male reproductive toxicity is defined as adverse effects (negative impacts) related to sexual function and fertility in adult male [“Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech.” *GOV.UK*, <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine>.]
3. Pfizer also did not test for adverse effects from vaccinated men’s semen, on the development of their offspring. [“Reproductive Toxicity March 2017 – SCHC.” *org*, SCHC-OSHA Alliance GHS/HazCom Information Sheet Workgroup, Mar. 2017, https://www.schc.org/assets/docs/ghs_info_sheets/schc_oshareproductive_toxicity_4-4-16.pdf.]
4. mRNA vaccine ingredients travel throughout the body and gather in organs, including in the testes. [“A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats,” https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_1_85350.pdf, p. 24.]

5. mRNA vaccines resulting in “anti-sperm antibodies” – that is to say, antibodies that treat sperm as an “invader”, and damage or kill it – is a known adverse event related to this form of vaccination. [“5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021,” https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, p. 30.] [Salvador, Zaira, and Sandra Fernández. “What Are Antisperm Antibodies? – Causes & Treatment.” *InviTRA*, 8 Jan. 2019, <https://www.invitra.com/en/antisperm-antibodies/>.]
6. mRNA vaccines cause a staggering drop in semen concentration and total motile count. [Gat, Itai, et al. “Covid-19 Vaccination BNT162B2 Temporarily Impairs Semen Concentration and Total Motile Count among Semen Donors.” *Wiley Online Library, Andrology*, 17 June 2022, <https://onlinelibrary.wiley.com/doi/10.1111/andr.13209>.]
7. By suppressing discussion of this information, public health agencies, medical professionals, and governments globally denied and continue to deny men true informed consent.

Transfer of mRNA Vaccine Ingredients Between Humans

We stated above that Pfizer knew that men can transmit the vaccine ingredients to their partners via sexual intercourse. Pfizer’s clinical trial protocol shows the company suspected that negative fertility impacts may occur in men, from its vaccine. Male trial participants had to follow specific “Male Participant Reproductive Inclusion Criteria.” These were spelled out in all fourteen versions of Pfizer’s protocol:

“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)”

The inclusion criteria requirements stated that men must:

- Refrain from donating sperm.

In addition, the men in the Pfizer trials must either:

- Abstain from heterosexual intercourse with a female of childbearing potential as their preferred and usual lifestyle. They must be abstinent from heterosexual intercourse with a female of childbearing age on a long-term and persistent basis and they must agree to remain abstinent.

OR the men in the Pfizer trial:

- 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 (women of childbearing age) partners of male participants." ["A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals," Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c45_91001-interim-mth6-protocol.pdf, pp. 213, 246, 398, 431, 575, 607, 751, 783, 918, 948, 1073, 1103, 1226, 1255, 1378, 1406, 1522, 1549, 1663, 1688, 1813, 1836, 1949, 1969, 2081, 2100, 2211, 2228, and 2337.]

In other words, the men in the Pfizer trial agreed to abstain from heterosexual intercourse with childbearing age women or else, if they did have intercourse with women who could bear children, they agreed to use a condom and were advised to add an effective additional method of contraception. Reassuring, right? The Pfizer study constructs regarding total abstinence from sex with women who could bear children, or else the use of both condoms and other contraception, suggest that Pfizer suspected that vaccinated men's ejaculate could affect both women and unborn children conceived during the trial or after.

Pfizer's protocol documents also explain:

"An EDP (Exposure During Pregnancy) occurs if:

- ...A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.

- A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
 - ...A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception." [Protocol Amendment 14, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_535_1_c4591001-interim-mth6-protocol.pdf, pp. 111, 319, 501, 677, 848, 1009, 1162, 1314, 1461, 1603, 1747, 1889, 2023, 2153, 2279, and 2346]

Clearly, Pfizer showed strong concern about and precautions against exposure to the "study intervention" – that is, the mRNA vaccine – via bodily fluids contact such as exposure to ejaculate, and via skin-to-skin contact.

Yet as recently as July 2022, the Centers for Disease Control and Prevention (CDC) assured Americans that COVID-19 mRNA vaccine shedding – "the release or discharge of any of the

vaccine components in or outside of the body” – is a “myth.” [“Myths and Facts about Covid-19 Vaccines.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 20 July 2022, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>.] Indeed a recent FOIA via America First Legal reveals that Carol Crawford of the CDC coordinated with Twitter employees to target tweets (including one by Dr. Naomi Wolf) about “shedding,” as an example, as CDC put it, of “misinformation.” But it was not, per Pfizer’s own documents, disinformation at all. According to the manufacturer, “shedding” was a real concern.

mRNA Vaccine’s Adverse Effects on Male Reproduction

National Institutes of Health (NIH) boldly stated on February 1, 2022, “COVID-19 vaccination does not reduce chances of conception...” [“Covid-19 Vaccination Does Not Reduce Chances of Conception, Study Suggests.” *National Institutes of Health*, U.S. Department of Health and Human Services, 1 Feb. 2022, <https://www.nih.gov/news-events/news-releases/covid-19-vaccination-does-not-reduce-chances-conception-study-suggests>.] However, the NIH’s statement was and is false.

Pfizer did not initially evaluate its vaccine’s male “reproductive toxicity” – i.e., adverse effects on fertility in adult males – during clinical trials because the company was in a rush: “The absence of reproductive toxicity data is a reflection of the speed of development to first identify and select COVID-19 mRNA Vaccine BNT162b2 for clinical testing and its rapid development to meet the ongoing urgent health need.” [“Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech.” *GOV.UK*, GOV.UK, <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine>.]

But when Pfizer eventually did look at the mRNA vaccine’s impact on male fertility, the company used “untreated male” rats for its “Reproductive and Developmental Toxicity” studies. The untreated males mated with female rats that had been dosed with BNT162b2, Pfizer’s mRNA vaccine. [2.4 *Nonclinical Overview*, https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 29.]

In other words, Pfizer tested fertility effects on female mammals dosed with its mRNA product but left the males undosed.

Throughout the Pfizer documents, the issue arises that studies were constructed so that Pfizer (and the FDA) did not find what it chose not to look for.

How do scientists determine a new drug's adverse effects on male fertility if they give only one-half of the reproducing population – the females – the treatment in question?

That same Pfizer document goes on to say, "Macroscopic and microscopic evaluation of male and female reproductive tissues from the repeat-dose toxicity studies with BNT162b2 showed no evidence of toxicity."

[https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf, p. 30.]

This statement seems to indicate that the study sought to evaluate whether the vaccine was passed through bodily fluids and/or skin contact during intercourse between the treated females and untreated males.

But how convenient – the male rats' reproductive tissues were declared free of toxicity; but the male rats had never been vaccinated at all.

2.4.4.6. Reproductive and Developmental Toxicity

Reproductive and developmental toxicity assessments were made with BNT162b2 (V9) (Study 20256434). BNT162b2 was administered by IM injection at the human clinical dose (30 µg RNA/dosing day) to 44 female Wistar Han rats (F0) 21 and 14 days prior to mating with untreated males and on GD 9 and 20, for a total of 4 dosing days. A separate control group of 44 F0 females received saline by the same route and regimen.

Following completion of a mating phase with **untreated males**, 22 rats/group underwent caesarean-section on GD 21 and were submitted to routine embryo-fetal development evaluations. The remaining 22 rats/group were allowed to litter and development of the offspring was observed until PND 21.

There were no BNT162b2-related deaths during the study. IM administration of BNT162b2 before and during gestation to female Wistar rats resulted in nonadverse clinical signs and macroscopic findings localized to the injection site as well as transient, nonadverse body weight and food consumption effects after each dose administration. These maternal findings are all consistent with administration of a vaccine and an inflammatory/immune response.

There were no BNT162b2-related effects on any mating or fertility parameters. There were no BNT162b2-related effects on any ovarian, uterine, or litter parameters, including embryo-fetal survival, growth, or external, visceral, or skeletal malformations, anomalies, or variations. There were no effects of BNT162b2 administration on postnatal offspring (F1) development, including postnatal growth, physical development (pinna unfolding and eye

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opening), reflex ontogeny (pre-weaning auditory and visual function tests), macroscopic observations, and survival.

Figure 1: Untreated Male Rates in Pfizer's 2.4. Nonclinical Overview.

Since there were no vaccinated male rats at all in the Pfizer reproductive studies during its internal trials, it appears Pfizer, and since the human males in the Pfizer study had to promise to abstain from intercourse with childbearing age women or else use a condom PLUS another effective contraceptive – it appears that Western public health agencies decided to test the effects of mRNA vaccines on men's reproduction simply by using the "intervention" – the mRNA vaccine – on human subjects, male as well as female, during a mass vaccination campaign.

mRNA Vaccine Ingredients Travel Throughout the Body and Gather in Organs

As we have seen in other DailyClout/War Room Pfizer Documents Research Volunteer Reports, medical and public health agency professionals assured the U.S. public that the COVID vaccine ingredients remained in the deltoid muscle when injected and did not disperse throughout the body. [Chandler, Robert W. "Pfizer Used Dangerous Assumptions, Rather than Research, to Guess at Outcomes." *DailyClout*, DailyClout, 9 Aug. 2022, <https://dailyclout.io/pfizer-used-dangerous-assumptions-rather-than-research-to-guess-at-outcomes/>.]

However, the FDA received the Pfizer document, "A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," on November 9, 2020, over a month before Pfizer's vaccine received Emergency Use Authorization (EUA) and began to be injected into humans worldwide. The document shows shocking biodistribution results. ["A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.]

"Biodistribution" is a method of tracking where given ingredients travel in the body of an experimental animal or a human subject. The document clearly demonstrates that Pfizer's mRNA vaccine contents – including lipid nanoparticles – enter the bloodstream, travel throughout the body, and accumulate in organs, including in the testes. Reference Table 1, "Mean (Sexes-Combined) Concentration of Total Radioactivity in Whole Blood, Plasma and (Continued) Tissues Following Single Intramuscular Administration of [3H]-08-A01-C01 to Wistar Han Rats – Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal – Results expressed as total lipid concentration (µg lipid equiv/g (mL)) and % of administered dose," shown below. ["A Tissue Distribution Study of a [3H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats," https://www.phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf, p. 24.]

Table 1 Mean (Sexes-Combined) Concentration of Total Radioactivity in Whole Blood, Plasma and Tissues Following Single Intramuscular Administration of [³H]-08-A01-C01 to Wistar Han Rats
 (Continued)

Target Dose Level: 50 µg mRNA/Animal; 1.29 mg Total Lipid/Animal

Results expressed as total lipid concentration (µg lipid equiv/g (mL)) and % of administered dose

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))							% of Administered Dose						
	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
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472	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	2.471	7.734	10.296	22.091	20.080	23.353	0.013	0.093	0.325	0.385	0.982	0.821	1.030
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	1.000	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	1.970	4.369	5.401	3.049	1.314	0.909	0.420	-	-	-	-	-	-	-
Plasma	3.965	8.132	8.903	6.503	2.360	1.783	0.805	-	-	-	-	-	-	-
Blood:plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540	-	-	-	-	-	-	-

-=Partial tissue taken therefore not applicable/not applicable

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How did medical and public health leaders remain so staunchly firm in their position that mRNA vaccination did *not* impact male fertility, even as they had access to Pfizer’s biodistribution study?

These experts who were swearing that the mRNA vaccine ingredients did not leave the injection site also had access to a 2018 NIH-published paper that clearly shows that nanoparticles — of which lipid nanoparticles are subtype [Murthy, Shashi K. “Nanoparticles in Modern Medicine: State of the Art and Future Challenges.” *International Journal of Nanomedicine*, Dove Medical Press, June 2007, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2673971/>.] — could pass into the testes from the blood and cause male reproductive harm. The 2018 study showed that NPs accumulate in the testes to damage sperm quality and amount, as well as their “motility”, or ability to move effectively, a requirement of conception:

“NPs [nanoparticles] can pass through the blood-testis barrier...then accumulate in reproductive organs. NP accumulation damages organs (testis, epididymis...) by destroying Sertoli cells, Leydig cells, and germ cells, *causing reproductive organ dysfunction that adversely affects sperm quality, quantity, morphology, and motility...*” [Wang, Ruolan, et al. “Potential Adverse Effects of Nanoparticles on the Reproductive System.” *International Journal of Nanomedicine*, U.S. National Library of Medicine, 11 Dec. 2018, <https://pubmed.ncbi.nlm.nih.gov/30587973/>.]

To appreciate fully how NPs harm key components of healthy male sexual development and function, one must understand the roles of the damaged organs and cells, all crucial to male sexual health and even to male sexual development, mentioned above.

- The “epididymis” is involved in transporting sperm from the testes. [Boskey , Elizabeth. “Anatomy and Function of the Epididymis.” *Verywell Health*, Verywell Health, 30 June 2022, <https://www.verywellhealth.com/epididymis-anatomy-4774615>.]
- “Sertoli cells” are vital to the development of the testes. “Sertoli cells are of critical importance for testis development...[and] are the master regulators of testis development...” [Pelosi, Emanuele, and Peter Koopman. “Development of the Testis.” *Sertoli Cell – an Overview | ScienceDirect Topics*, Science Direct, 2017, <https://www.sciencedirect.com/topics/engineering/sertoli-cell>.] “During [the sperm developmental process], developing sperm cells are closely linked with the Sertoli cells.” [Carlson, Bruce. “Gametogenesis.” *Sertoli Cell – an Overview | ScienceDirect Topics*, Science Direct, 2014, <https://www.sciencedirect.com/topics/engineering/sertoli-cell>.]
- “Leydig cells” are present in the testicular interstitial tissue. Their main function is to produce *testosterone for the maintenance of sperm creation and development and male body development*. [Huhtaniemi, Ilpo, and Katja Teerds. “Leydig Cell.” *Leydig Cell – an Overview | ScienceDirect Topics*, Science Direct, 2018, <https://www.sciencedirect.com/topics/neuroscience/leydig-cell>.] Thus, when Leydig cells are damaged, one could say that physical masculinity itself is damaged. This is especially urgent to consider when we reflect on the fact that small boys and teenagers, who have not reached or completed puberty, are being injected with mRNA vaccines containing lipid nanoparticles.
- “Germ cells” “are...precursors of...sperm cells. [“Germ Cells – Definition, Embryonic to Gametes, vs Somatic Cells.” *MicroscopeMaster*, MicroscopeMaster.com, <https://www.microscopemaster.com/germ-cells.html>.]

Thus, these excerpts and citations show that:

1. lipid nanoparticles gather in human organs including the testes,
2. nanoparticles are detrimental to normal male reproduction, and
3. Big Pharma and public health agencies knowingly gambled with harms to boys' and male teens' sexual development, and with all ages of males' testosterone levels, older males' sperm counts, and male fertility.

A Sperm-Related mRNA Vaccine Adverse Event That Causes Male Infertility

An alarming mRNA vaccine-induced reproductive Adverse Event of Special Interest (AESI) came to light at the end of February 2021. Pfizer's own document lists "anti-sperm antibody positive" among its 1,290 AESIs. ["5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, p. 30.]

What is an "ASA"?

According to *inviTRA*, a certified medical magazine created by doctors and fertility experts, "The presence of antisperm antibodies (ASA) in the ejaculate is an immune cause of male infertility. The adhesion of antibodies to sperm affects their motility, making the sperm's journey to the egg highly difficult or even impossible." [Salvador, Zaira, and Sandra Fernández. "What Are Antisperm Antibodies? – Causes & Treatment." *InviTRA*, 8 Jan. 2019, <https://www.invitra.com/en/antisperm-antibodies/>.]

This late February 2021 Pfizer document confirming anti-sperm antibodies is the first documented indication I found within the Pfizer records that Pfizer's mRNA COVID-19 vaccine negatively impacts male fertility.

Note that Pfizer knew about this male infertility AESI almost *12 months* prior to the clearly false NIH statement from February of 2022: "COVID-19 vaccination does not reduce chances of conception..." ["Covid-19 Vaccination Does Not Reduce Chances of Conception, Study Suggests," 1 Feb. 2022.] The Food and Drug Administration (FDA) knew about this AESI by April 30, 2021. ["5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021," https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf]

For nearly a year, then, the FDA, public health agencies, and medical organizations ignored this "cause of male infertility" contained in the Pfizer documents – all of which were sent to the FDA. Then they lied about it.

They kept silent for a year and then misled the public, rather than alerting the public. The mass vaccination campaign continued, without even a brief pause, and again, men were denied informed consent.

The Suspension of Informed Consent for Men Continues

Contrary to established medical ethics, Pfizer and public health agencies did not disclose the true impacts of mRNA gene therapy vaccines on male fertility and, thus, as noted above, denied men informed consent. ["Informed Consent – Definition, Examples, Cases, Processes." *Legal Dictionary*, Legal Dictionary, 7 Dec. 2015, <https://legaldictionary.net/informed-consent/>.]

In fact, the medical establishment, governments, public health agencies worldwide, Big Pharma, and Big Tech colluded to suppress COVID vaccine facts, risks, and alternatives. [Tucker, Jeffrey A, and Debbie Lerman. "Besties: Twitter, Facebook, Google, CDC, NIH, WHO." *Brownstone Institute*, Brownstone Institute, 3 Aug. 2022, <https://brownstone.org/articles/besties-twitter-facebook-google-cdc-nih-who/>.]

In January of 2021, the American Society for Reproductive Medicine posted the “Joint Statement Regarding COVID-19 Vaccine in Men Desiring Fertility from the Society for Male Reproduction and Urology (SMRU) and the Society for the Study of Male Reproduction (SSMR)” encouraging COVID vaccination for men, including for male fertility treatment patients, despite their having no data about its impact on male reproductive health:

“As of January 9, 2021, there are no data about the impact of the COVID-19 vaccine on male...fertility. [...] the American Society for Reproductive Medicine does not recommend withholding the vaccine from patients who are planning to conceive, and emphasizes that patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria.” [“Update No. 11 Covid-19 Vaccination December 16, 2020 – ASRM.” *American Society for Reproductive Medicine*, American Society for Reproductive Medicine, 9 Jan.

2021, <https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf>.]

Additionally, for men, SMRU and SSMR recommended:

- The COVID-19 vaccine should not be withheld from men desiring fertility who meet criteria for vaccination.
- COVID-19 vaccines should be offered to men desiring fertility, similar to men not desiring fertility, when they meet criteria for vaccination.

The organization went on to blame declines in sperm production on COVID-19 vaccine-related fevers. [“Joint Statement Regarding Covid-19 Vaccine in Men Desiring Fertility from the Society for Male Reproduction and Urology (SMRU) and the Society for the Study of Male Reproduction (SSMR).” *ASRM*, American Society for Reproductive Medicine, 9 Jan.

2021, <https://www.asrm.org/news-and-publications/covid-19/statements/joint-statement-regarding-covid-19-vaccine-in-men-desiring-fertility-from-the-society-for-male-reproduction-and-urology-smru-and-the-society-for-the-study-of-male-reproduction-ssmr/>.]

The ASRM, SMRU, and SSMR – all reproductive societies – stated in unison in 2021 that there were no data about fertility impacts *and* that men “desiring fertility” should take the drug for which fertility impacts are unknown.

But how could they advise that men take the vaccine if there were no data proving that it would not affect fertility?

The slanted messaging continued when the “Semen Analysis Parameters Following Pfizer’s COVID-19 Vaccine” clinical study said, “Unfounded claims in the popular media linked a possible correlation between the COVID-19 vaccine and potential...male infertility. Currently, there is no information in the medical literature which examined semen analysis parameters following the COVID-19 vaccine.” [“Semen Analysis Parameters Following Pfizer’s COVID-19 Vaccine.” Full Text View – *ClinicalTrials.gov*, *ClinicalTrials.gov*, 2 Mar. 2021, <https://clinicaltrials.gov/ct2/show/NCT04778033>.]

Again, how exactly could public speculation about potential mRNA vaccine-induced infertility be “unfounded” when those leading the study admit that, as of February 2021, there were no data to show that such a concern was invalid?

The push to brush off fertility concerns continued throughout 2021.

In September 2021, *Fertility and Sterility* journal published a study which concluded, “After receiving the two doses of the vaccines, we did not observe a clinically significant sperm parameter decline within the cohort, suggesting the vaccines do not negatively impact male fertility potential.”

However, the study was flawed. It went on to admit: “The limitations of the study include the small number of men enrolled; limited generalizability beyond young, healthy men; short follow-up; and lack of a control group.” [Gonzalez, Daniel C., et al. “Sperm Parameters before and after COVID-19 mRNA Vaccination.” *JAMA*, *JAMA Network*, 20 July

2021, <https://jamanetwork.com/journals/jama/fullarticle/2781360>.] [Gonzalez, Daniel, et al. "Effect of COVID-19 Mrna Vaccines on Sperm Quality." *Fertility and Sterility*, Published by Elsevier Inc., 17 Sep. 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8446925/>.]

True experiments always include at least one control group that does not receive the experimental treatment. Without a control group, a study's outcome cannot be certain. Yet, despite long-established scientific norms being cast aside, "the science" told men in this case that COVID vaccines would not negatively affect their fertility.

At the end of 2021, a Chinese study published truths that previous Western studies had refused to acknowledge. The study validated fertility-related vaccine concerns: "Although several fertility societies have announced that COVID-19 mRNA vaccines are unlikely to affect fertility, there is no denying that the current evidence is very limited, which is one of the reasons for vaccine hesitancy..." The Chinese study went on to say, "...given the potential damage of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to the reproductive system, some individuals suspect that the vaccine which mimics the virus (mRNA vaccine) may also affect fertility via the same mechanism." It even addressed the fact that COVID vaccines were rushed to market: "Admittedly, data on COVID-19 mRNA vaccines are incomplete when compared with traditional vaccines based on long-term studies with large samples." [Chen, Fei, et al. "Effects of COVID-19 and Mrna Vaccines on Human Fertility." *Human Reproduction (Oxford, England)*, Oxford University Press, 27 Dec. 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8689912/>.]

Finally, cracks were appearing in mRNA vaccine and fertility information dam, and those cracks prefaced a stunning revelation that was about to drop.

Pfizer's mRNA COVID-19 Vaccine in Fact Cause an Astonishing Drop in Male Fertility

On June 22, 2022, *Andrology* published a bombshell study, "Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors." The study, which did not even include the effects of additional booster injections, showed a staggering drop in male fertility, with an average decrease of 22.1% across the

study group, from the initial injections alone. The study concluded, "Systemic immune response after BNT162b2 vaccine is a reasonable cause for transient semen concentration and TMC (total motile count) decline." [Gat, Itai, et al. "Covid-19 Vaccination BNT162B2 Temporarily Impairs Semen Concentration and Total Motile Count among Semen Donors." *Wiley Online Library, Andrology*, 17 June 2022, <https://onlinelibrary.wiley.com/doi/10.1111/andr.13209>.]

Each study participant provided multiple semen samples throughout the study's duration as follows:

- T0 = pre-vaccination baseline
- T1 = 15-45 days post-vaccination
- T2 = 75-120 days post-vaccination
- T3 = 150+ days post-vaccination

The investigators studied participants for five months (T1-T3 above) after they received Pfizer's vaccine. Table 2 below demonstrates the troubling results, which have a 95% confidence interval. T3 collection averaged a time frame of 174 (+/- 26.8) days.

So, at close to six months post-vaccination, sperm concentration, motility, and total motile count were all still in significant states of decline versus pre-vaccination levels. Sperm concentration had not recovered at all and was, in fact, at its lowest point yet.

TABLE 2 Percentage and absolute change¹ compared to T0 as reference measured by repeated measures analysis (total samples)

		Change ¹	95% CI		p-Value
Semen volume	T0 ²	Ref			
	T1	10%	-3.9%	25.8%	0.214
	T2	-4.5%	-14.7%	7%	
	T3	9%	-6.3%	26.8%	
Sperm concentration	T0	Ref			
	T1	-14.5%	-27.9%	1.4%	0.044
	T2	-15.4%	-25.5%	-3.9%	
	→ T3	-15.9%	-30.3%	1.7%	
Sperm motility	T0	Ref			
	T1	2.7	-1	6.6	0.058
	T2	-1.9	-4.9	1.7	
	→ T3	-4.1	-8.2	0.1	
Total motile count	T0	Ref			
	T1	-2%	-19.9%	20.1%	0.027
	T2	-22.1%	-35%	-6.6%	
	→ T3	-19.4%	-35.4%	0.6%	

¹Volume, concentration and TMC are presented as *percentage change* compared to T0 while motility change is presented as *absolute change*.

²T0 - pre-vaccination baseline control; T1, T2 and T3 - short, intermediate and long-term evaluations after 15-45, 75-125 and over 145 days after vaccination date, respectively.

Figure 3: From

“Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors,” p. 4.

Despite these alarming outcomes, the published study went on to encourage vaccination: “Since misinformation about health-related subjects represents a public health threat our findings should support vaccinations programs. Further studies concentrating on different

vaccines and populations (ex. subfertile patients) are urgently required.” [Gat, Itai, et al., 17 June 2022, <https://onlinelibrary.wiley.com/doi/10.1111/andr.13209>, p. 6.]

Alarming, men continue to receive incomprehensibly contradictory messages, being told to keep injecting the mRNA vaccines even when the study that contains these exhortations, clearly demonstrates adverse fertility results – to men.

The Public Is Left with More Questions Than Answers

This review of documents and studies, culminating with one that shows shocking data about mRNA vaccines conclusively reducing men’s fertility, gives rise to important questions:

- When, if at all, do men’s fertility fully recover from such a drastic decline after a two-dose vaccination course?
- Do boosters, which twenty-nine percent of the world’s population have received as of July 31, 2021, have an even stronger negative impact on men’s fertility? [Holder, Josh. “Tracking Coronavirus Vaccinations around the World.” *The New York Times*, The New York Times, 29 Jan. 2021, <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>.]
- Does giving mRNA COVID-19 vaccines to pre-pubescent and adolescent males affect their normal sexual development and ability to reproduce, as the implication of the study on NPs in testes suggest it may?
- Is the decline in birth rates being seen in highly vaccinated countries [Chudov, Igor. “Igor’s Newsletter.” *Substack*, Igor Chudov, <https://igorchudov.substack.com/>.] at least in part due to how mRNA vaccines have conclusively affected male fertility?

- What factors in the well-documented “baby die-off” being seen around the globe may come from the effects of men being vaccinated with mRNA vaccines? [Wolf, Naomi. “Dear Friends, Sorry to Announce a Genocide.” *Substack*, Outspoken with Dr Naomi Wolf, 30 May 2022, <https://naomiwolf.substack.com/p/dear-friends-sorry-to-announce-a>.]
- Why did pharmaceutical companies, public health officials, medical professionals, and governments tell the public that mRNA COVID-19 vaccines did not affect men’s fertility when they had no data to support such a conclusion?
- Why, when health officials, doctors, and governments received data confirming mRNA vaccines negatively impact men’s fertility, did they not raise the alarm and fight to give men informed consent?

The public must demand answers to these questions from pharmaceutical companies, world governments, public health agencies, and the medical establishment. Those entities blocked men from having the ability to give informed consent and made them unwitting participants in an ongoing clinical trial of a novel gene therapy.

Such assaults on humanity and its ability to reproduce, and especially, the potential harms to boys, youths, and unborn babies, must be challenged. Those responsible for human experimentation that demonstrably harmed male fertility, must be held accountable.

Amy Kelly is the Program Director for the War Room/DailyClout Pfizer Documents Analysis Project.

Report 37: [“Women Have Two and a Half Times More Risk of Adverse Events Than Men. Risk to Female Reproductive Functions Is Higher Still.”](#) by Robert Chandler, MD, MBA – Team 5

The Pfizer documents demonstrate a strong signal that women have far more adverse events than males, particularly when considering reproductive organs and function. Primary source material from Pfizer shows a strong, sex-linked Adverse Event (AE) difference. Two major data collections, Reissue of Pfizer’s [“5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 \(BNT162B2\) Received Through 28-FEB-2021”](#) and [“APPENDIX 2.1 Cumulative Number of Case Reports \(Serious and Non-Serious, Medically Confirmed and Non Medically-Confirmed\) from Post-Marketing Data Sources, Overall, by Sex, Country, Age Groups and in Special Populations and Summary Tabulation by Preferred Term and MedDRA System Organ Class,”](#) show substantially greater numbers of Adverse Events in women contrasted with men. This signal is particularly strong for the reproductive organs and their functions. Women have approximately three times the risk of Adverse Events than do males, and the specific risk to the reproductive organs and their functions is even stronger.

Two large data sets in the [Pfizer confidential document collection](#), released pursuant to a court order, report consistent sex differences in the absolute number and percentage of Adverse Events (AEs) and Adverse Events of Special Interest (AESI). This report will examine primary source documents that collect Adverse Events at two points in time – February 28, 2021, the end of first two and a half months [following widespread inoculation with Pfizer’s COVID-19 vaccine](#), and then at a second time ending on March 15, 2022.

Most AEs appear to have been spontaneously reported through a mechanism the public is still waiting to learn about, which means they were not part of a well-regulated and proactive surveillance program and may underestimate the actual frequency of such events.

Many people having a complication related to Pfizer’s Lipid Nanoparticle Messenger Ribonucleic Acid (LNP/mRNA) prodrug, BNT162b2 (the Pfizer COVID-19 vaccine), are not

aware of how to report or are unable to report in cases of a severe complication. Alternatively, reporting may be being actively suppressed.

As a review of the entries in Appendix 2.1, the 170-page registry of 4,563,770 Adverse Events logged in by April 15, 2022, shows that over-reporting and, in some cases, questionable relevance of the reporting in some disease categories is a possibility.

**Sex Differences Example 1:
Reissue of Pfizer's 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of
PF-07302048 (BNT162B2) Received Through 28-FEB-2021**

The FDA reissued Pfizer's 5.3.6 Adverse Events document on April 1, 2022, and it offers a summary of Adverse Events and Adverse Events of Special Interest after injection of BNT162b2, Pfizer's LNP/mRNA vaccine.

This data set comprises 42,086 subjects from the first two and a half months following the [Emergency Use Authorization \(EUA\) issued by the Food and Drug Administration \(FDA\) on December 11, 2020](#).

[Table 1](#) below shows a tally of Adverse Events and Adverse Events of Special Interest by organ system from the 5.3.6 Reissue document, although it must be pointed out that some cases were reassigned to organ categories by the author.

For instance, myopericarditis was moved from Pfizer's Autoimmunity assignment to Cardiac based on the organ involved rather than the assumed disease process.

Table 1: AEs and ASEIs up to 2/28/2021

In every category, females substantially outnumber males. Charts 1 and 2 are graphical representations of this data.

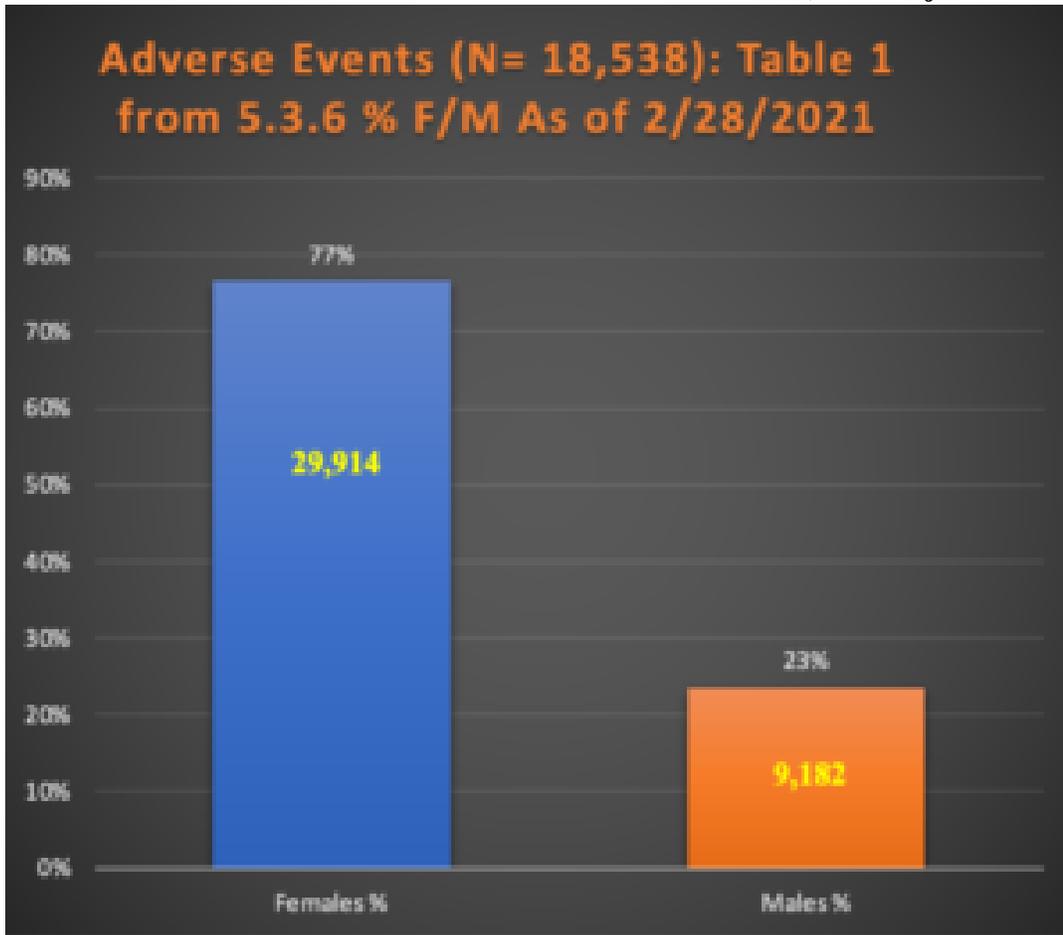
Study	Females %	Males %	F	M	N =	Unk	p
Table 1 from 5.3.6	77%	23%	29914	9182	42086	2990	p < 0.001
Table 7 from 5.3.6							
Autoimmune	81%	19%	682	156	838	N/A	p < 0.001
Cardiac	77%	21%	1076	291	1403	36	p < 0.04
Covid-19	66%	34%	1650	844	3067	573	p < 0.001
Dermatologic	94%	6%	17	1	19	1	See note below Chart 1
Hematologic	75%	25%	676	222	898	0	p = 0.385
Hepatic	61%	37%	43	26	70	0	p =0.019
Musculoskeletal	80%	20%	2760	711	3471	0	p < 0.001
Neurologic	69%	31%	623	283	927	21	p < 0.001
Other (Pyrexia and Herpes)	76%	24%	5969	1860	7829	0	p = 0.527

Renal	67%	33%	46	23	69	0	p = 0.085
Respiratory	55%	45%	72	58	130	0	p < 0.001
Stroke	67%	33%	182	91	273	0	p = 0.001
Thromboembolic event	62%	38%	89	55	144	0	p < 0.001
Vasculitis	81%	19%	26	6	32	0	p = 0.549
Total excl. Unknown	75%	25%	13911	4627	18538		

Chart 1 illustrates this finding with 29,914 females with AEs compared with only 9,182 for males. (i.e., $p < 0.001$).

It should be noted that “p,” as shown in $p < 0.001$ above, indicates the level of significance. Commonly, $p < 0.05$ is the minimal level of acceptance, meaning there is a 95% chance that the number is the true number with a certain confidence interval. Therefore, $p < 0.001$ indicates a 99.999% probability that the number did not occur by chance. “p” values this low are rarely seen in clinical medical studies.

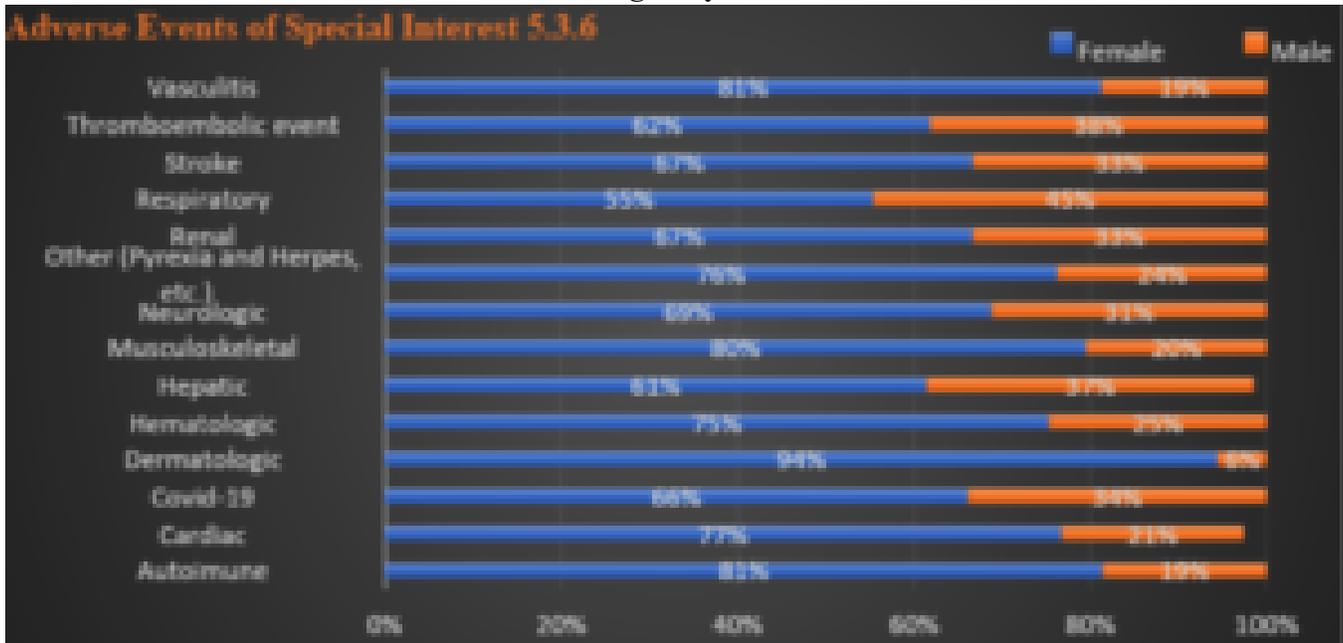
Chart 1: Female/Male Ratio in 39,096 Subjects



This trend follows through [Table 7](#) (AESI), from 5.3.6 Reissue. Chart 2 shows the female-to-male ratio as percentages for each organ system as reported. Note that females substantially outnumber males in all categories and by more than a factor of three overall.

There is no category in which the number of cases for males outnumber females. Statistical significance exists at $p < 0.05$ in comparison of the rates of particular types of AEs in females versus males. Hematologic, Dermatologic, Other (Pyrexia and Herpes), Renal and Vasculitis all appear as exceptions with p values > 0.05 . **Note:** Dermatologic was evaluated using Fisher exact test due to small sample size, $p = 0.093$.

Chart 2: Organ System Detail



Sex Differences Example 2: Appendix 2.1

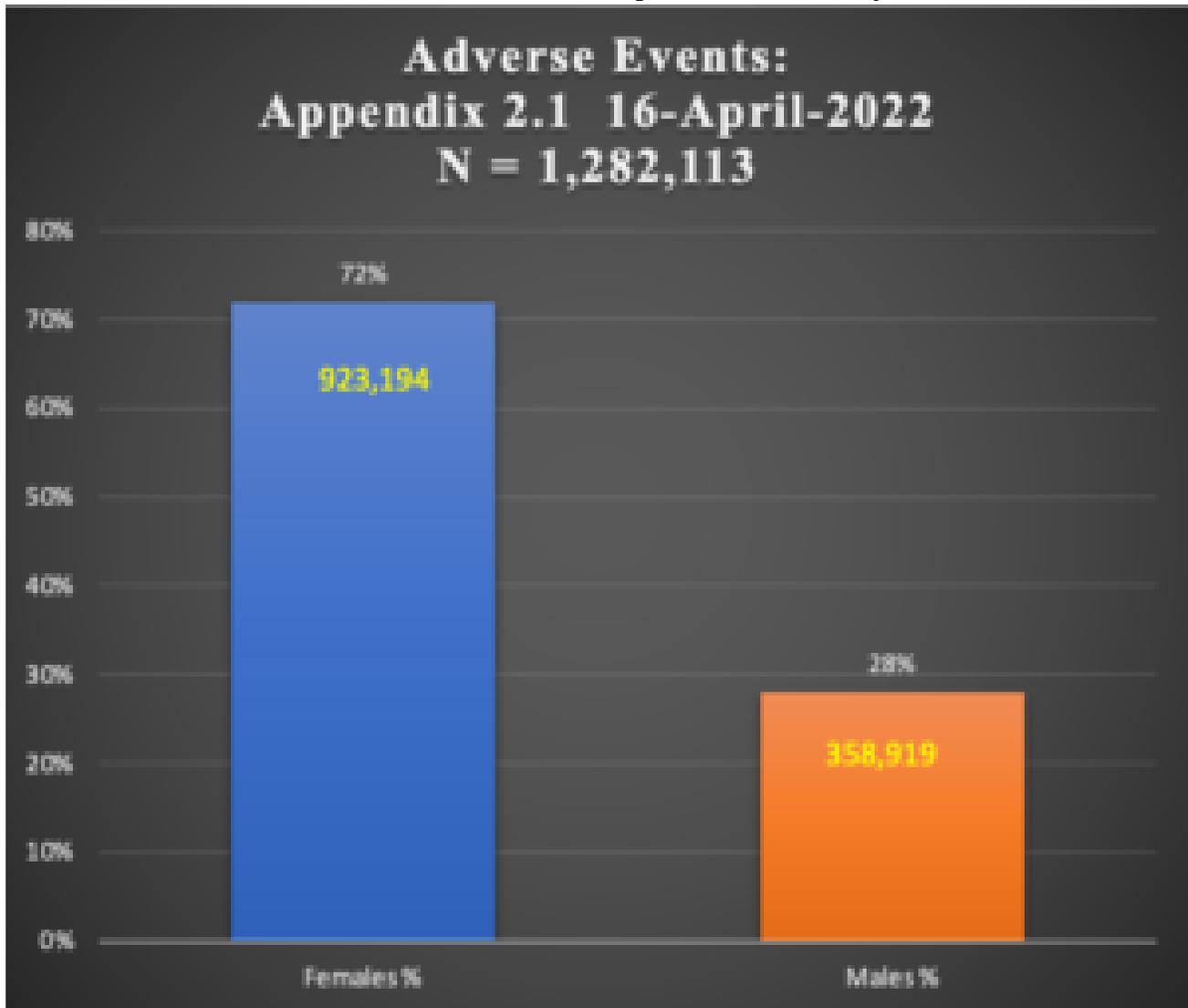
A second large series of Adverse Events associated with Pfizer’s BNT162b2 vaccine document trove, Appendix 2.1, recently surfaced following a FOIA request from the Australian Therapeutic Goods Administration (TGA) and consists of a 170-page document that tallies Adverse Events by diagnosis in 1,348,079 subjects (i.e., patients). The sex was known in 1,282,113 cases – 923,194 women (72% of those with known sex and 68% of total series including unknown sex) and 358,919 men. Data capture ended on April 15, 2022.

The total number of Adverse Events reported in this document is 4,563,770 for an average of 3.4 AEs per case. The disproportionate representation of AEs in females presents again strongly here, as it did in Pfizer’s 5.3.6 Reissue document.

Table 2: Female:Male Difference in 1,282,113 Cases of Adverse Events

Study	Females %	Males %	Females	Males	N =	
2.1 Appendix 16-April- 2022	72%	28%	923194	358919	1282113	

Chart 3: Female:Male Comparison in AEs Subjects

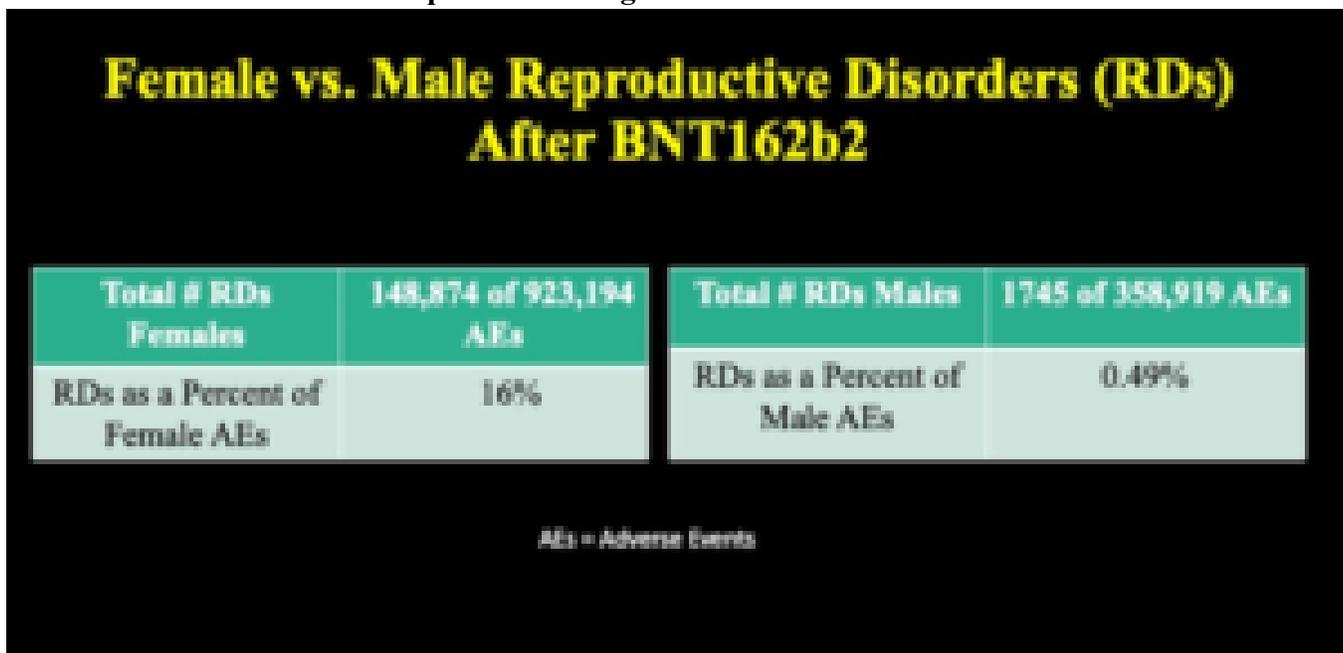


Adverse Events occur two and a half times more in women than men as shown in Chart 3 above. This is the same pattern seen in the earlier reporting of a smaller series from Document 5.3.6, $p < 0.001$.

Chart 4 illustrates this same disparity in the specific data referable to female and male reproductive organ and organ function disorders with much higher absolute numbers for women as well as in terms of percent of adverse events.

A striking difference is shown here with 148,874 women reporting Reproductive System AEs contrasted with only 1,745 males, $p < 0.001$.

Chart 4: Reproductive Organ and Function Sex Differences

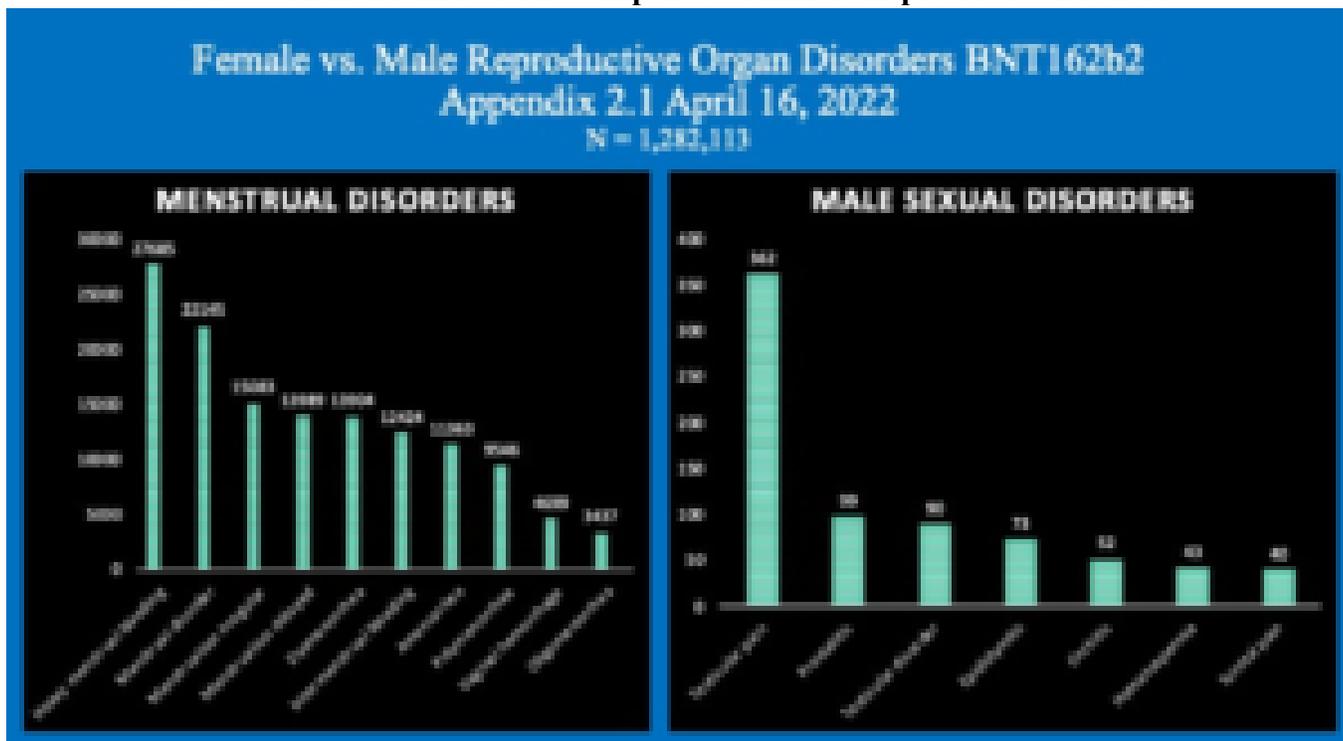


As seen in Chart 5, below left, females appear to have fewer diagnostic categories than males but only because there are so many for women that a charting of them is too busy if all are plotted.

For comparison of the sexes see Appendix 2 (females) and Appendix 3 (males) that list the reported reproductive organ and organ function disorders by sex following injection of Pfizer's BNT162b2. This tally lists diagnoses with reporting frequency of ten or more.

Chart 5 shows the numbers of the just the top ten *menstrual* dysfunctions contrasted with the much smaller number of reproductive issues in men.

Chart 5: Menstrual Disorders compared with Male Reproductive Disorders



Why do Women Have So Many More Adverse Events than Males?

No immediate answer to this question exists. However, the signal is strong.

Is there some distortion in the reporting mechanism that might explain such a wide difference? Perhaps. Is there some kind of systematic reporting bias? We can only speculate at present.

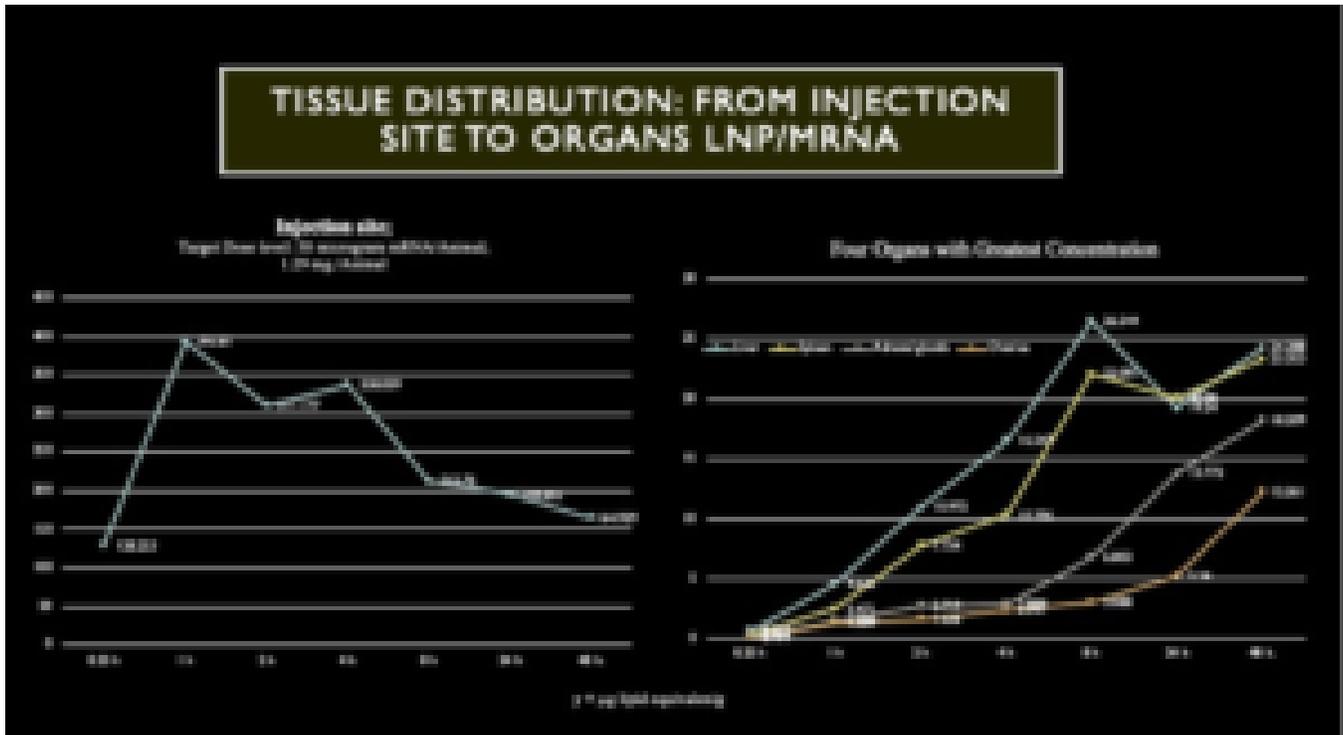
Alternatively, are there true sex differences in reaction to Pfizer's LNP/mRNA injections? Are women more prone to having complications after receiving Pfizer's BNT162b2 vaccine? Perhaps. Is there something about the LNP/mRNA concentration in ovaries that leads to production of more mRNA transcribed Spike or Spike-related proteins that have been shown to be toxic in multiple studies.

We have seen from the preclinical animal studies, Chart 6 following, that ovaries are one of the top four organs as far as concentration of LNP/mRNA is concerned. [But, unfortunately, this study in Wistar Han Rats only ran for two days and no longer-term studies were performed.](#) Furthermore, the ovaries – like liver, spleen and adrenal glands – had LNP/mRNA concentrations that were steeply rising at the time of animal sacrifice.

Had autopsies had been performed in a systematic manner following widespread human inoculation in individuals dying in the weeks following injection of Pfizer's BNT162b2, we may have had the answer by now and would certainly know more about gross and microscopic changes occurring in organs following the injection. Spike and related protein levels in the various organ systems would be of great interest.

Chart 6 illustrates deposition of LNP/mRNA at the injection site, left chart, followed by rapid dissemination throughout the body with concentration in four organs, liver, spleen, adrenal glands and ovaries, right chart.

Chart 6: Distribution of LNP/mRNA in Wistar Han Rats

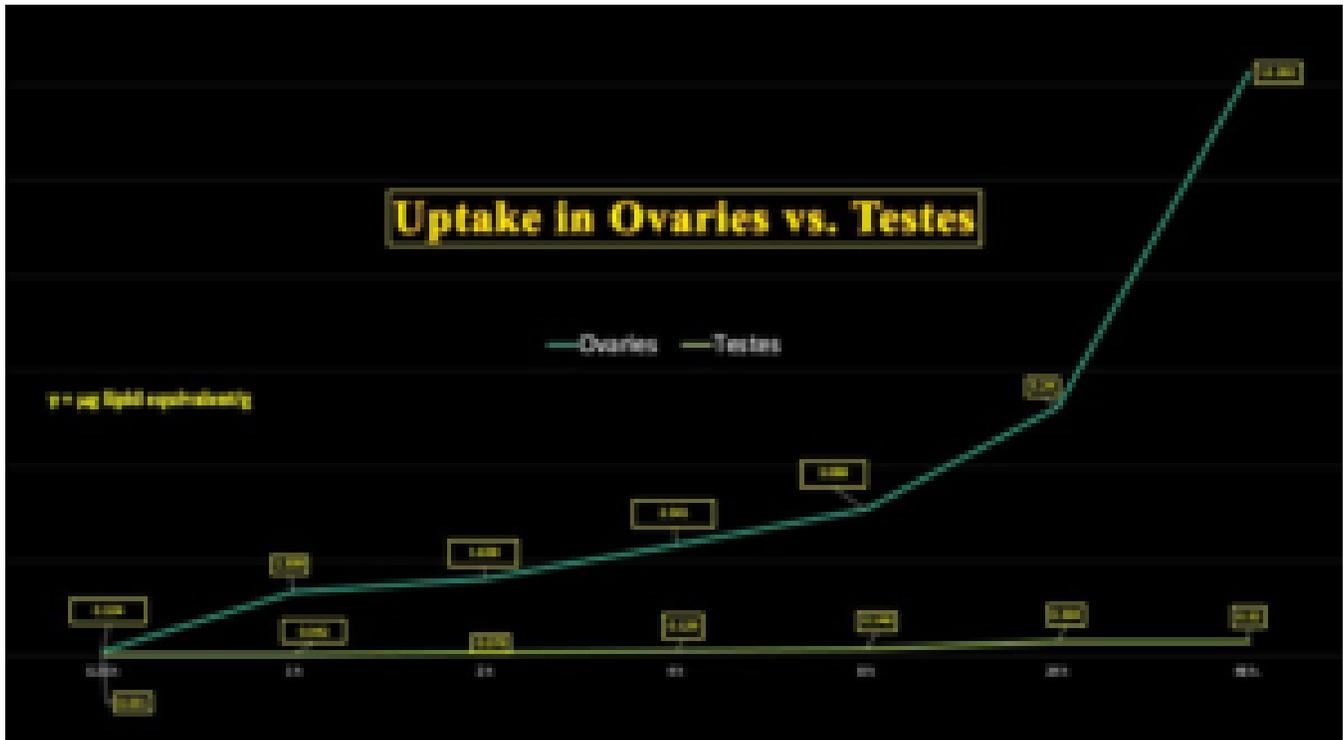


LNP/mRNA concentrates in ovaries as shown in Chart 6 illustrating data from preclinical studies performed in Wistar Han Rats. Note: The X-axis is nonlinear in Charts 6 and 7. Interpret the data accordingly.

Caution is needed here as animal studies may be misleading. There is such a thing as species-specific reactions, and humans may have different findings.

Chart 7 illustrates the disparity between ovaries and testes with respect to LNP/BNT162b2 uptake showing more than 38 times more concentration in ovaries than testes, as shown in these animal studies.

Chart 7: Tissue Concentration of LNP/mRNA Ovaries vs. Testes



Why do ovaries concentrate lipid nanoparticles and mRNA contained therein so much more effectively than testes?

And does this account for the large disparity in the incidence of Adverse Events and Adverse Events of Special Interest following injection of BNT162b2 in women as opposed to men?

Or are these differences in AEs overall and with respect to the dysfunction in the Reproductive Systems specifically a result of some methodological quirk?

We cannot definitively answer that question at present. For now, we must interpret these data as showing women are at increased risk for Adverse Events from Pfizer's LNP/mRNA product than are men, both in terms of many or all organ systems but especially with respect to reproductive organ systems and their functions.

Assuming this differential is caused by the disproportionate impact of BNT162b2 on women and their reproductive systems and organs, the implications could be profound.

Appendix 1: Female Reproductive AEs Following Inoculation with BNT162b2

148,874 reproductive organ AEs occurred in women which represents ~16% of the total number of Adverse Events in women. The list below gives the diagnoses reported 10 or more times.

Total AEs N =	923194
Heavy menstrual bleeding	27685
Menstrual disorder	22145
Menstruation irregular	15083
Menstruation delayed	13989
Dysmenorrhea	13904
Intermenstrual bleeding	12424
Amenorrhea	11363
Polymenorrhea	9546
Breast pain	4800
Vaginal hemorrhage	4699
Oligomenorrhea	3437
Hypomenorrhea	2643
Postmenopausal hemorrhage	2456

Abortion spontaneous	1809
Breast swelling	1339
Menstrual discomfort	1199
Premenstrual syndrome	998
Breast tenderness	792
Menometrorrhagia	632
Adnexa uteri pain	609
Premenstrual pain	585
Breast enlargement	483
Vaginal discharge	480
Breast discomfort	443
Mastitis	392
Ovulation pain	347
Endometriosis	337
Menstrual cycle management	308
Anovulatory cycle	273
Uterine pain	270
Abnormal withdrawal bleeding	265
Uterine hemorrhage	231
Vulvovaginal pain	191
Ovulation delayed	181
Premature baby	181

Vulvovaginal mycotic infection	173
Breast cancer	147
Fetal death	147
Fetal growth restriction	124
Vulvovaginal candidiasis	122
Breast cyst	115
Genital hemorrhage	115
Breast edema	113
Abnormal uterine bleeding	100
Pelvic venous thrombosis	98
Labor pain	95
Uterine leiomyoma	91
Polycystic ovaries	82
Breast discharge	71
Vulvovaginal pruritus	71
Breast disorder	68
Uterine contracture during pregnancy	68
Ectopic pregnancy	67
Premature labor	64
Morning sickness	62
Vaginal infection	60
Vulvovaginal discomfort	59

Abortion	58
Premature menopause	58
Vulval ulceration	56
Stillbirth	56
Vulvovaginal dryness	54
Coital bleeding	46
Ovarian cyst rupture	44
Premature delivery	44
Endometrial thickening	42
Genital burning syndrome	42
Adenomyosis	41
Breast abscess	41
Fetal heart rate abnormal	41
Menarche	40
Premenstrual headache	40
Uterine contractions abnormal	40
Breast induration	39
Premature rupture of membranes	37
Uterine polyp	37
Vulvovaginal swelling	37
Abortion induced	36
Uterine inflammation	36

Vulval hemorrhage	34
Pelvic inflammatory disease	33
Pregnancy	32
Pelvic discomfort	30
Premature menarche	27
Premature ovulation	27
Breast hematoma	26
Infertility female	26
Postpartum hemorrhage	26
Uterine disorder	26
Pelvic hemorrhage	25
Noninfective oophoritis	23
Vaginal ulceration	23
Dyspareunia	22
Ovarian disorder	22
Unintended pregnancy	22
Vaginal order	22
Vulvovaginal inflammation	21
Breast cancer	20
Breast disorder female	20
Hemorrhagic ovarian cyst	20
Placental disorder	20

Gestational diabetes	19
Abortion early	19
Endometrial disorder	18
Nipple inflammation	18
Endometrial hyperplasia	18
Ovarian hemorrhage	17
Ovarian failure	16
Vulvovaginal erythema	16
Ovarian vein thrombosis	15
Polymenorrhagia	15
Threatened labor	14
Fibrocystic breast disease	13
Ovarian enlargement	13
Uterine enlargement	13
Cervix hemorrhage uterine	12
Breast atrophy	11
Breast hemorrhage	11
Breast neoplasm	11
Cesarean section	11
Cervical dysplasia	11
Pelvic girdle pain	11
Vaginal disorder	11

Vulval disorder	11
Bartholin's cyst	10
Decidual cyst	10
Fetal cardiac disorder	10
Fetal growth abnormality	10
Fetal vascular malperfusion	10
Vaginal cyst	10
Small for dates baby	10
Vaginal cyst	10

Appendix 2: Male Reproductive Disorders Following Inoculation with BNT162b2

1,745 reproductive organ AEs were reported in men which represents 0.49% of the total number of Adverse Events in men. AEs list occurred 10 or more times.

Males	
Total AEs =	358919
Testicular pain	362
Prostatitis	99
Testicular disorder	90
Epididymitis	73
Orchitis	52
Hemospermia	43
Scrotal pain	40
Penile pain	31
Penis disorder	31
Benign prostatic hypertrophy	26
Penile swelling	25
Scrotal swelling	24
Erection increased	23
Testicular disorder	22
Orchitis noninfective	20
Ejaculation disorder	18
Ejaculation failure	18
Prostatomegaly	18

Priapism	17
Testes discomfort	16
Spontaneous penile erection	15
Penile edema	13
Prostatic disorder	13
Penile hemorrhage	11
Penile erythema	10
Penile vein thrombosis	10
Scrotal erythema	10

Author: Robert W. Chandler, MD, MBA, Team 5

Media Summaries of the Volunteers' Findings in the Pfizer Documents

Today's Lucky # is 2400

By Etana Hecht

April 6, 2022

That's the number of unexpected employees secretly hired by Pfizer to process a flood of adverse events reports.

Dr. Naomi Wolf has assembled an army of warriors to study the information that Pfizer and the FDA have seemed dead set against us learning about.

Thanks to a [court order](#), the Pfizer documents are being released to the public in monthly batches, revealing to the public information that belonged to us all along. The findings are vast, and it's becoming increasingly clear why Pfizer + The FDA had no intention of letting us see these documents in our lifetimes.

The April batch came out earlier this week, and Mr. Stevan Looney, a civil trial and appellate attorney of the DailyClout team, has made a [pretty shocking discovery](#). There was one document that was released on Nov 17, 2021 (Dated Feb 28, 2021) with 2 pieces of redacted information. That document showed up as "re-issued" in the April 1 release, with those 2 missing facts now unredacted:

1. The total number of BNT162b2 (Pfizer) doses that were shipped worldwide as of Feb 28, 2021 was "approximately **126,212,580**". An important figure to have for any independent scientist or data analyst who's trying to study the data.
2. The first 3 months of the vaccine rollout generated a "large number" of adverse events reported to Pfizer. Pfizer hired a number of new employees to manage the incoming flood of reports, and that number was just released. At the end of Feb 2021, they had hired 600 new employees, with the expectation of an additional 1800 joining by the end of June, 2021. A total of **2400** employees were hired in a ~6 month span to deal with an unexpected flow of reports.

events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately 600 additional full-time employees (FTEs). More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately 126,212,580 doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

RESULTS

1. Safety Database

1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining

[Link to Unredacted Version. Page 6.](#)

Watch Dr. Wolf explain it herself on [Warroom](#), along with updates on the horrific ongoing practice of masking small children that Mayor Eric Adams is personally responsible for.



[Link to](#)

[Video](#)

Why didn't we know about this at the time? If there was a sudden need to bring on additional resources to deal with a sudden influx of reports, maybe there should have been an equally sudden response by those tasked with ensuring "do no harm"?

Dr. Wolf maintains that serious fraud has occurred at the hands of both Pfizer and the FDA based on what her team is finding in the Pfizer documents. They hid, concealed, and redacted the fact that they had to hire an army of new employees to deal with the volume of bad outcomes that they didn't previously have the manpower to process.

There are already hundreds of findings by Dr. Wolf's team that have potential actionability. Anyone can help her team, or even just go through the data they've already pulled, over at [DailyClout](#). It's an overwhelming amount, but slowly the signals will emerge, and we'll get more pieces of this insane puzzle.

Meanwhile, today the FDA will be holding a [live virtual meeting](#) regarding future boosters. If you haven't yet, check out Toby Roger's post for how to express concern for approving more boosters, or under 5 doses.

https://tobyrogers.substack.com/p/urgent-call-to-action-2-tell-the?utm_source=substack&utm_campaign=post_embed&utm_medium=web

Bonus: Dr. Vinay Prasad interviewed an Infectious Disease specialist named [Dr. Katie Sharff](#). She runs the vaccine safety program for a region in the Northwest, and she wrote 2 papers based on studies that she ran, showing that the rate of myocarditis that was detected by the CDC is significantly lower than what she's detecting on a much tighter timeline.

[We Deserved to Know](#)

Myocarditis/Vaccine Effectiveness

By Etana Hecht

April 10, 2022

Hindsight has finally arrived, and while still very murky, the fog of Covid is beginning to clear. As a flood of Pfizer documents is released from the FDA, we'll learn in more detail how 2021 unfolded, who knew what when, and how harmful the vaccines actually are.

The DailyClout/War Room Pfizer Document Review team of analysts from medical, statistics, pharmaceutical research, and medical fraud backgrounds, organized by Dr Naomi Wolf, Project Manager Amy Kelly, and the team at DailyClout are [studying the documents](#) and sharing their findings with the public as quickly and accurately as possible. There will be a full interim report released in the coming weeks, and they're also managing to publicize important pieces of information as they emerge. It seems that Pfizer has a recurring theme of keeping highly relevant data to themselves, only to reluctantly publicize it months later. As a quick reminder, they also colluded with the FDA in a failed attempt to continue to conceal this data for our lifetimes.

Known Myocarditis Risk

Dr. Chris Flowers MBBS, FRCR, FSBI is a retired Associate Professor of Radiology at the University of South Florida. He was previously an Associate Professor of Radiology and Biomedical Imaging at the University of California, San Francisco. He is also a retired academic cancer radiologist, author, and scientific paper reviewer for multiple radiology journals.

On April 7, Dr. Chris Flowers published a [post on DailyClout](#) with an educated assumption that the FDA was aware of the risk of myocarditis far earlier than they publicized. The timeline is as follows:

May 10, 2021: The FDA issued an [Emergency Use Authorization](#) approval for the Pfizer Covid-19 vaccine for ages 12 and over. That EUA made no mention of the risks of myocarditis in young men.

June 2021: ACIP (Advisory Committee on Immunization Practices) [published a report](#) regarding the risks of myocarditis, and concluded that for all ages the benefits of receiving the Covid vaccine outweigh the risk of myocarditis.

August 2021: The FDA put out a [press release](#) that included myocarditis as a known side effect of the vaccine and updated the datasheet with a warning.

Theory: Dr Flowers' hypothesis that the FDA knew before Aug 2021; I am reporting his hypothesis that the FDA must have been aware of the emerging myocarditis signal at the time the EUA was issued in May, yet made no mention of it. That theory comes from the fact that the June 2021 report was based on studies that would have been already internally published by May 2021, and available for the FDA to review.

If they were aware of the myocarditis signal in May 2021, yet authorized millions of young men to get the vaccine without mentioning it as a risk at the time, they're guilty of yet another example of failing to give proper informed consent.

Known Vaccine Ineffectiveness

Vicki Goldstein, RN, JD, and the DailyClout team have [discovered another example](#) of deceit by Pfizer.

Dec 2020-Feb 2021: [Internal Pfizer documents](#) clearly indicate a degree of vaccine ineffectiveness and vaccine failure.

- Example 1: Their own report shows 16 cases of vaccine failure, and on the same page fails to detect new safety signals for lack of efficacy.

Table 6. Description of Missing Information

Topic	Description
Missing Information	<p>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</p> <p>2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness.</p> <p>Vaccination failure cases (16)</p> <ul style="list-style-type: none"> • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: <ul style="list-style-type: none"> ○ Within 7 and 13 days: 8 subjects; ○ Within 15 and 29 days: 6 subjects. <p>COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases.</p> <p>Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.</p>

From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed

- Example 2: In the report for Adverse Events of Special Interest for the Pfizer vaccine, there were 3067 cases of Covid-19 reported as an adverse event.

Table 7. AESIs Evaluation for BNT162b2

AESIs ^a Category	Post-Marketing Cases Evaluation ^b Total Number of Cases (N=42086)
	<ul style="list-style-type: none"> • Relevant event outcome^c: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue</p>
<p>COVID-19 AESIs <i>Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia</i></p>	<ul style="list-style-type: none"> • Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant^d and Adolescent (2 each), Child (1);

September 17, 2021: In an [FDA advisory meeting](#), studies were presented that showed a decline in the efficacy of the vaccines.

March 29, 2022: The FDA [authorized a 2nd booster dose](#) of the Covid-19 vaccine for older and immunocompromised individuals.

All we heard throughout 2021 was how the vaccines were “safe and effective”. Neither is true and yet somehow the vaccines are continuously being pushed by the FDA and Co, while the tremors of an earthquake caused by their own lies rumble under the surface.

Dr. Wolf and her team put out a call to journalists everywhere to dig into the publicly available data that tells the story of the biggest scandal humanity has ever experienced:



+ - 719 rumbles

EMBED ↗

Our Whole Health Apparatus 'Colluded' With Big Pharma To Experiment On Americans

[Link to Video](#)

[Show Us the Data](#)

10 Members of Congress demand that the FDA immediately release ALL of the Covid vaccine data in their possession.

By Etana Hecht

April 14, 2022

Distrust in governments around the world is high. Average citizens are becoming increasingly aware of the deep corruption and [regulatory capture](#) that's been ruling their lives for decades. Through the fog of propaganda and outright lies, it's important to detect signals that matter to the current state of events.

In a refreshing move that represents the manner in which government is meant to function, [The Daily Clout reports](#) that 10 members of Congress have penned a letter to the Commissioner of the FDA, Robert Califf. The letter requests immediate access to ALL the data that they possess related to the Covid-19 vaccines, from both before and after the EUA was issued.

Highlights:

- The more information, the better. Doctors, scientists, elected officials, parents, and all other members of the public should have as much access to information as possible in order to make proper risk/benefit assessments.
- Concealing this data has resulted in the loss of countless independent reviews that could have added value and perspective to the pandemic response. The lack of access to this data is “appalling”.
- Extreme disappointment in the usage of the courts by the FDA to attempt to conceal the data for 75 years.
- Request that the FDA publicly produce all data that they receive related to the Covid-19 products within 14 days of receiving it.
- Vaccine mandates should not have been allowed while the products were under the EUA and information was not made available to the public.
- Informed consent is a legal requirement, and simultaneously impossible with limited information.
- Vaccine manufacturers have been granted [legal immunity from liability](#) for injuries their products cause. The FDA must release the data immediately in order to enable independent review, the “gold standard” for evaluating the safety and efficacy of a medical product.

The letter ends off by requesting an immediate response in order to address the deficiencies mentioned. Thanks to the 10 Congressmen and women who put their names on this letter: Bill Posey, Louie Gohmert, Thomas Massie, Vicky Hartzler, Mo Brooks, Ralph Norman, Madison Cawthorne, Mary E. Miller, Clay Higgins, and Thomas P. Tiffany.

Congress of the United States
Washington, DC 20515

April 11, 2022

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

As the FDA continues to consider issues relating to the safety and efficacy of COVID-19 vaccines and therapeutics, Americans also continue to evaluate the benefits and risks associated with these vaccines and therapeutics in the midst of the changing dynamics of the pandemic. Nothing is more important to physicians, parents, patients, public health officials and elected officials than having access to as much information as possible when evaluating immediate and long-term responses to the pandemic.

Although we have been responding to the COVID-19 pandemic for two years, most of the information in the FDA's possession relating to EUA products, and now approved COVID-19 vaccines— including vaccines that have been mandated for tens of millions of Americans, has not been made available for independent review and evaluation. Broader access to this data early on in the pandemic could have been beneficial in making better public health decisions by enabling thousands of additional reviewers to evaluate the data and identify potential risks and risk factors. The fact that the data in the FDA's possession has remained behind an FDA firewall for more than 18 months is appalling.

There is absolutely no reason for failing to fully disclose pre- and post-EUA data in the FDA's possession for those products which have now been approved. We are extremely disappointed that Pfizer and the FDA used the courts to obstruct and delay the release of efficacy and safety information. The FDA even requested that the court to allow it to slowly release this information over a course of 75 years. Failure to be more forthcoming with this important safety and efficacy data undermines public confidence.

We write to request that the FDA immediately release all safety and efficacy data in its possession for EUA COVID-19 products which have now been approved by the FDA. This request applies to pre- and post-EUA approval data. We also request that all safety and efficacy data submitted to the FDA for future and ongoing evaluation of EUA, and subsequently approved, COVID-19 products be made publicly available within 14 days of the FDA receipt of such information. Delays in the release of efficacy and safety data of medical treatments fail to serve the public interest.

It is particularly noteworthy that the FDA already requires that most of this information be submitted by the manufacturers in redacted and releasable form, so as to protect manufacturer trade secrets and clinical trial participant information, according to §5.65 Exemption four, Federal Regulation 21 C.F.R. § 601.51(e), and 21 C.F.R. § 20.63(b). Therefore, the FDA should have been preparing to immediately release data once licensure was granted, and should not have allowed vaccine mandates while the products were under EUA and the data remained unavailable to the public.

Lastly, the manufacturers of COVID-19 vaccines and other products have been granted immunity under the Public Readiness and Emergency Preparedness and Act (PREP) from liability for injuries caused by their products. Tens of billions of U.S. taxpayer dollars have been spent to purchase, distribute and administer these EUA COVID-19 products.

The "gold standard" for evaluating safety and effectiveness of medical treatments is rigorous independent review. To enable independent review, the FDA must allow for immediate release of this information.

Thank you for your immediate attention to this request and we look forward to hearing from you how the FDA will address this deficiency in a timely manner.

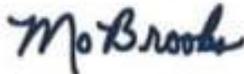
Sincerely,



Bill Posey
Member of Congress



Vicky Hartzler
Member of Congress



Mo Brooks
Member of Congress



Madison Cawthorn
Member of Congress



Clay Higgins
Member of Congress



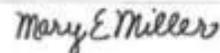
Louie Gohmert
Member of Congress



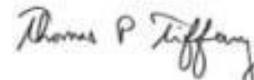
Thomas Massie
Member of Congress



Ralph Norman
Member of Congress



Mary E. Miller
Member of Congress



Thomas P. Tiffany
Member of Congress

It seems like the two parallel realities are only drifting further apart from each other, as more people's lives are destroyed by the vaccine on one hand, and on the other hand, the FDA is [authorizing yet another shot](#) for 50+. That age wasn't even on the [formal request](#) from Pfizer, who requested the booster be approved for 65+.

On Team Reality, it gets more obvious every day that the Covid-19 vaccines are, at the very least, not "safe and effective" as advertised, and at the worst, a slow-moving, ongoing societal catastrophe. The reasons for that perspective are many and can be found all over Substack, but as a quick summary, here are some of the main bombshells:

- **[Athletes](#)**: The number of [vaccinated athletes](#) who have suffered cardiac arrest since the vaccine campaign began approaches 800.
- **[Excess Mortality Rates](#)**: For updates on signals that point to high mortality rates and high injury rates, follow Ed Dowd on Twitter and [Gettr](#):
- **[Military DMED data](#)**: There's a lot of funny business going on in the military healthcare system. There's a new [piece of information](#) that came out yesterday, claiming that medics in the military were actively ordered to refrain from reporting vaccine injuries to VAERS.
- **[Fraudulent Trials](#)**: [Brooke Jackson](#) managed an arm of clinical trials for Pfizer vaccines, and she's carefully recorded and reported many examples of outright fraud that took place within the trials.
- **[Pfizer Data Dump](#)**: [Dr. Naomi Wolf](#), her team at [Daily Clout](#) and the [Warroom Posse](#) are running an impressive operation to extract relevant findings from the tens of thousands of documents that the FDA released under court order. They've already broken a few pieces of news, and I recommend signing up for the site so you can stay updated on what they're finding.
- **[Bait and Switch](#)**: Pfizer and the FDA played a nasty trick by approving a version of the vaccine that conveniently is unavailable in the US. The vast majority of the vials used in the US were and still are legally under the EUA.

It seems like it can't possibly be more obvious that the Covid vaccines haven't exactly been a success. There are so many question marks and red flags, that it honestly surprises me when I meet people who are still proponents of the vaccines. This is some crazy storm we're in the middle of, and the only way we lose is if we stop fighting.

[The Arc of a Fraud](#)

Bombshell conversation between Dr. Naomi Wolf and Edward Dowd

By Etana Hecht

April 20, 2022

[Dr. Naomi Wolf](#) of the [Daily Clout](#) hosted [Mr. Edward Dowd](#), former Blackrock portfolio manager for a 2nd conversation yesterday. Watching the two of them piece together this insane vaccination puzzle is an amazing thing to observe. We must appreciate that while big players on the Internet have forced people like them mostly underground, the Internet itself is still a miraculous tool without which the public would have no chance of pulling back the curtain of propaganda and figuring things out for ourselves.

Mr. Dowd presented his theory regarding the mass vaccination program that he arrived at using a combination of factors and sources. Dr. Wolf and her team have been able to back Mr. Dowd's theories with evidence of fraud and coverups that they've begun to uncover in the trove of FDA documents that have been released so far. The two of them together are a powerhouse that is shifting the Overton Window with herculean efforts.

The Current Fraud is "Trust the Science"

Mr. Dowd spent 10 years at BlackRock where he and his team managed to take 2 billion dollars and turn it into 14 billion dollars by capturing a large portion of the market share. He's seen many frauds perpetrated throughout the years, along with a mass psychosis that allowed the fraud to go on as long as it did. He gave 3 main examples of frauds that he worked through and had been able to anticipate:

1. The dotcom bubble
2. Housing and financial crisis of '08
3. Trust the Science

Thesis of the current scientific fraud: The clinical data of the Covid-19 vaccines is corrupt and fraudulent. Attempting to conceal the data for 75 years is another form of fraud as well.

The Arc of a Fraud

There's an arc to every fraud. The fraud grows and those responsible for it profit, until they eventually reach what Mr. Dowd calls an "inflection point" and then the tide turns. He's ahead of the herd with this thesis, as he was with theses in the past which led to his professional success. In his world of financial forecasts and data analysis, he doesn't need to wait for journalists at the New York Times to report on an event in order to formulate a thesis and act on it.

While we all know that the mainstream media is still completely ignoring what many would consider the greatest humanitarian scandal in history, Wall Street IS beginning to think about acknowledging this unfolding disaster.

Mr. Dowd explained that while Pfizer's stock seems to be resilient, he believes it's at its peak and it will eventually break its prior low of 46. Over the course of their conversation, Dr. Wolf repeatedly expressed the disbelief and confusion that a lot of us are feeling. It's hard to stop asking "But WHY" over and over when we think about what possessed so many people to knowingly push leaky and harmful vaccines to as many people as they possibly could, knowing the potential repercussions. Mr.

Dowd did a great job filling that gap by explaining the way a fraud functions, the way a criminal mind operates, and the possible reasons behind it from a few different perspectives:

- **Albert Bourla**, the CEO of Pfizer had multiple interviews recently. In some, he distanced himself from the mRNA tech and expressed his surprise that “they” used it.

Mr. Dowd’s seen this kind of behavior over and over in his 30-year career, where a CEO with a looming fraud scandal will pump up his stock as much as he can and then get out right before it breaks. In Bourla’s case, this kind of trading isn’t even illegal because the “pre-sale” is already set, and the merchandise has a fixed sale via government contracts.

- **Health Agencies and Universities:** Why would they push additional injections, and by doing so hop onto a train that’s headed for litigation? This is the biggest example of [Asymmetric Information](#) Mr. Dowd’s ever seen in his life. He categorized high information people such as the Warroom audience as “Smart Money”. With the continuous output of information, eventually, enough people move into the Smart Money group and it begins to have real-world effect until it reaches the inflection point. The universities have not yet crossed over into Smart Money, partly because by solely relying on the CDC recommendations the policymakers remain low-information. [Steve Kirsch discussed](#) a doctor on staff at UCLA who warned the dean against mandating the vaccines and he was told that CDC data is where they get policy information. That doctor is going to leave the University rather than get the booster.
- **Rochelle Walensky** is the director of the CDC which is a [named defendant](#) in a [grand jury investigation](#) demand by Dr. Henry Ealy, and State Senators Thatcher and Linthicum. She’s facing potential criminal charges.

ON BEHALF OF ALL CONCERNED CITIZENS

Formal Grand Jury Petition Overview¹⁻⁸

This petition is presented by [elected officials representing American citizens](#) with professional expertise in medicine, law, statistics, and death certificate reporting that have come together [to investigate irregularities in COVID-19 data and Federal Law](#). Irregularities that played a significant role in justifying emergency executive orders. Irregularities that were used to establish excessive and ineffective health policies. Irregularities that have [led to major collateral damage including: \(1\) historic economic collapse, \(2\) dramatic rises in mental illness, and \(3\) unnecessary loss of life.](#)

Why at this late stage is the CDC still sticking with its monotonous false lines instead of scrambling to cover itself? Dr. Walensky tried to deflect a few weeks ago on a show by mentioning that [she gets her information from CNN](#), but why is she continuing to push boosters when she absolutely must know that parents are getting extremely litigious? It boggles the rational mind.

The Criminal Mind

The bottom line in the above examples is that when a criminal is caught, he keeps tripling down and pretending everything’s fine while hoping it goes away quickly and that something else comes along to capture public attention.

The Very Big Issue for the perpetrators of this particular criminal fraud is that the consequences of their complicity are too horrible to truly comprehend. The victims of their fraud and those who don't yet know that they're victims will be going through stages of grief: Many are still in the denial phase, but Pfizer better buckle up because anger is coming, and many people on Team Vaccine will never be able to walk back the horrible ways they treated and spoke about the unvaccinated.

Note: Mr. Dowd has publicly declared he has no financial stake in Pfizer because he doesn't want to be accused of speaking out for ulterior motives. However, he encourages anyone who's listening to use the information that he's giving us to make some money, which will also help move the needle towards the tipping point. The Overton window is moving, but we all should do our part to make it move faster, as people's lives are on the line.

DailyClout Efforts

After Mr. Dowd explained the criminal mind and the arc of a fraud, Dr. Wolf detailed the 5 main findings that her highly credentialed research team has found that begin to tell a picture of the magnitude of the fraud. The team is made up of Drs, RNs, medical researchers, medical fraud investigators, biological scientists, and statisticians. The reports are signed off by the team's professionals:

1. DailyClout Team 5 found that the Pfizer vaccines are broken down by dose:
 - 3 micrograms -ages 5-11
 - 10 micrograms -ages 12-17
 - 30 micrograms- ages 18+
 - Doses were based on age. This means that a small 11-year-old right before her 12th birthday would get 3 micrograms, and if they waited a few days, it would be more than tripled to 10, for the same body size, simply based on age. A 90-pound 12-year-old girl would get the same dose as a 200-pound 17-year-old boy.
 - Dr. Wolf has been looking at many reports of teenagers dropping dead to investigate if there's a correlation between serious adverse events happening and tiny teens who were given high doses.
2. [DailyClout volunteers found](#) that the material that was doubled or tripled based on the dose were the following: Lipid Nanoparticles, mRNA, and spike protein.
 - The public claim was that the injection stayed in the injection sites. Internal documents have shown that the companies and health agencies knew early on that this wasn't true. They knew that within 48 hours, the material goes right into the bloodstream and ends up in the liver, spleen, adrenals, and ovaries. Mr. Dowd questions if the research and reporting regarding how long the ingredients remain in the bloodstream were capped at 48 hours in a classic "you don't find what you don't look for" move. That appears to be the case based on this internal Pfizer document that tested the length of time the materials were found in the bloodstreams of animals:

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

**Test Article: [³H]-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

- o Moderna micrograms are more than triple Pfizer’s doses. Pfizer understood how toxic a high dose was early on with a high rate of adverse reactions. Pfizer then quietly dropped the 100 microgram dose from its clinical trials due to “[reactogenicity](#)”. Meanwhile, anyone who got their first dose of Moderna was injected with 100 micrograms of material and no informed consent.

3. [Stevan Looney discovered](#) Pfizer had to ramp up their staff and made plans to hire up to 2400 additional staff to handle a flood of adverse events reports in the first 6 months of the vaccine rollout.
4. Dr. Chris Flowers [pointed out](#) that in May of 2021, the FDA and Pfizer would have known about the myocarditis risk. 35 teens had heart damage within one week of receiving the vaccine. Nonetheless, they issued the EUA in June of 2021, after which hundreds of thousands of teens got the injection before an August 2021 [press release](#) came out that added myocarditis as an adverse event.
5. [DailyClout Team 1 found](#) that early on Pfizer’s internal trials showed vaccine failure and lack of efficacy. One listed side effect of the vaccine was Covid itself! By December of 2020, Pfizer knew it waned and didn’t say anything about waning efficacy until Spring of 2021 when Israeli studies were published about it.

Dr. Wolf: “Litigation has Just Begun”

- Mr. Stevan Looney of the DailyClout team found that the side effects that were disclosed by Pfizer don’t match the side effects that were reported early on in the [internal documents](#). Particularly muscle pain and joint pain are huge categories they knew about that weren’t disclosed. It was recently [updated](#) to include muscle pain and joint pain, but again, they knew this internally far before they disclosed it to the public. This too fits the definition of fraud- they withheld information that would change the course of the consumer’s decision.

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- Lawyers are preparing letters to send to State Attorney Generals warning them that there's a lot of false advertising currently occurring, as the FDA and pharma companies continue to state that the vaccine is safe and effective.

How and Why?

Dr. Wolf asked for Mr. Dowd's opinion on how and why the FDA has gone along with this. At this point, it's clear that they're in deep and it would be difficult to suddenly reverse course. However, why did the FDA go along with this at the beginning? In Dec of 2020 and into the next year, how did they continuously approve a product that's both ineffective and harmful, while claiming the exact opposite? Mr. Dowd responded that the FDA was corrupted over a timeline of many years. 50% of the FDA budget comes in the form of "fees" from the very companies they're meant to regulate. The industry evolved over time into an interconnected structure between the drug companies and the regulators. Professional success is achieved by letting things slide for the drug companies, then eventually getting hired by them. Occasionally, executives of pharmaceutical companies also have an open door back into the public health agencies. It became culturally acceptable to work for a few years at government health agencies and then shift to private companies. Coupled with pressure from then-President Trump and Operation Warp Speed, the institutions went along with the fast pace, recognizing there was a fortune to be made on the other side. The blind spots created by industry dynamics are tremendous and dangerous.

How were the agencies so confident that the criminal and murderous results of the clinical trials would never come to light? In a normal drug approval, everything goes through the FDA, and rarely would others ask for the data. They were naive. When the data was [requested by America's Front Line Doctors](#), they asked for 75 years to produce it, and that was the beginning of the end for them.

Where Are We Now?

Mr. Dowd's been approaching this insane issue from multiple angles, and he has experience with interpreting real-world data and supplementing it with information from other sources to stay ahead of the curve.

- 10 members of Congress have [written a letter to the FDA](#) demanding that all the vaccine data be immediately released.
- CEOs can no longer claim they didn't know the vaccine doesn't work, based on the internal documents we've seen proving that they did know, and they knew early. Within the arc of this fraud, the excuse of ignorance is gone.
- There have been 2 phases of death spikes:
 - **Phase 1** - at the beginning of Covid-19, it was the elderly and the ill who died at excess rates. The insurance companies weren't fazed by this, as most of the excess deaths would have been likely to occur within a short time frame of when they would have otherwise died. They were prepared for those deaths, and it did nothing to their bottom line.
 - **Phase 2**- From early 2021 until today, young and otherwise healthy people are dying at an accelerated rate with a high rate of cardiac arrests. They're also starting to see long-term disability claims spike. This is NOT something the insurance companies were prepared for. Mr. Dowd's take on the data is that the vaccine is the likeliest cause for this sudden rise in deaths.
- It's all over Wall Street. The question is starting to be asked. On a recent call at an insurance company, a ratings agency asked about vaccine effects.

- Mr. Dowd believes we're approaching an inflection point. He thinks if we compare the arc of the pharma fraud to the arc of the '08 bubble, we're at about Nov '07, that is, the peak right before the fallout. In this case, the peak is the end of an era in which the public suffered from a broad lack of knowledge, and into a tipping point of unavoidable information about the vaccine risks and fallout.
- Anecdotes are starting to become common knowledge. In an Australian news broadcast, vaccine reaction as a cause of injury was mentioned, and one of the hosts himself had clear physical signs of what he acknowledged was [Bell's Palsy](#) as a direct result of the Covid vaccine.
- Financially, there's an industry that's about to wake up. Long-term disability insurance claims are rumored to be up for Q1 of 2022, although that's as yet unconfirmed.
- The loss of life years in the form of young sudden deaths, coupled with the concerning spike in people with long-term disabilities suddenly dropping out of the workforce is almost incomprehensible. This will have a huge cost on every aspect of our economy and society. Breadwinners and industry workers disappearing from the family life and workforce is devastating, and as Smart Money is already aware, we're watching a slow-moving disaster unfold in front of our eyes, while the bodies pile up and lives are ruined.
- [Kelly Brown](#) is a finance professional in Canada who's been in contact with Mr. Dowd since he went public because he's been doing the same work and coming to similar conclusions. Kelly recreated a chart for ages 0-44 and found similar death spikes in the fall of 2021. Death data lags but what's showing so far is that the 2 most populated and updated regions show excess mortalities hitting new highs into the end of 2021.

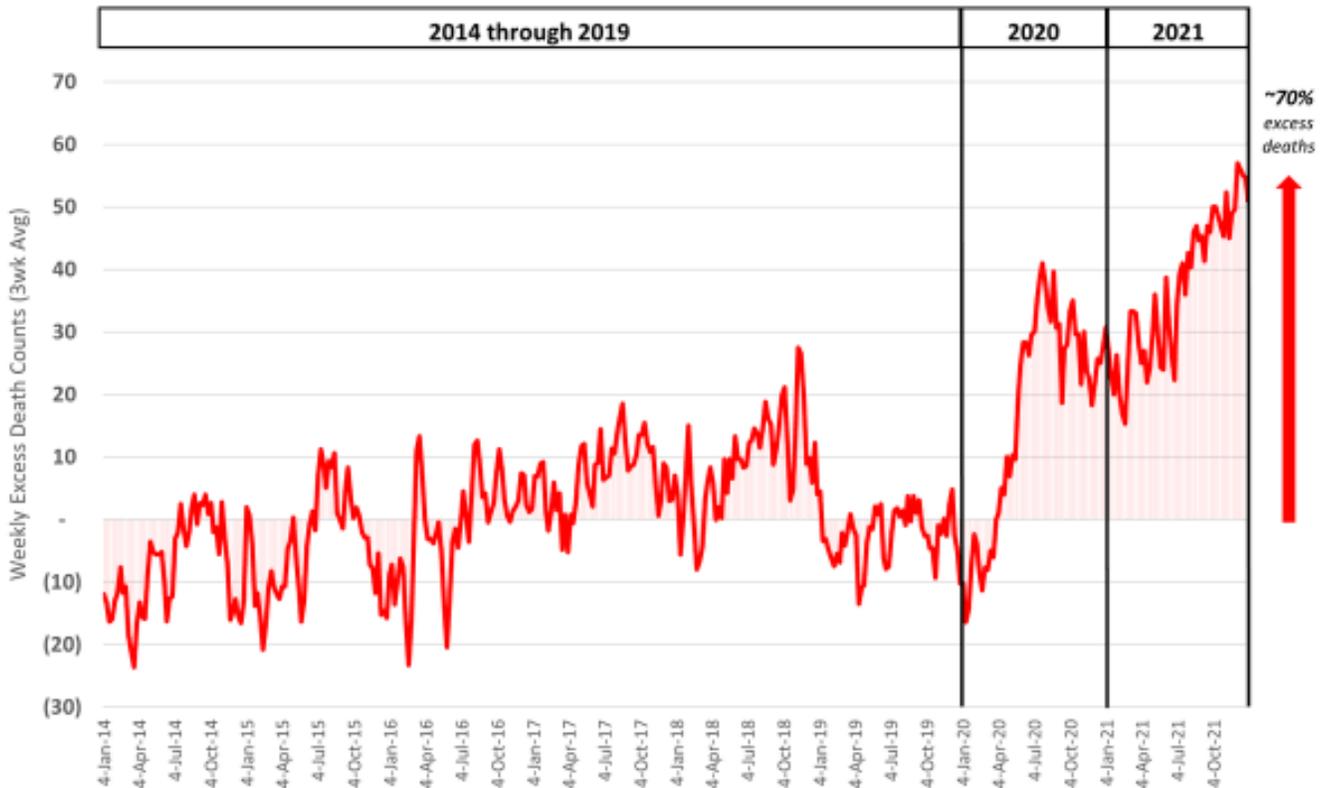


[Kelly Brown @rubiconcapital](#)

[What is going on in Alberta and British Columbia? From Stats !\[\]\(43052ab27641c1af21e94ff3e0d2d7d4_img.jpg\) data, excess deaths in ages 0-44 as of Dec. '21 are MORE THAN 70% of expected deaths, since accelerating in Jul '21. This is the real "tsunami of death", and a public health emergency that must be investigated ASAP.](#)

Source: StatsCanada

Alberta and British Columbia (Ages 0-44) WEEKLY EXCESS DEATHS (2014 - 2021)



[April 11th 2022](#)

[1,703 Retweets](#)[3,070 Likes](#)

Dr. Wolf maintains that the Covid-19 vaccines are an open experiment on society. It's important to remember that global multi-national corporations such as Pfizer will never have American citizens' well-being as their top priority. The toxicity of the vaccines is becoming more clear by the day. We're living in a time when multi-national corporations can be weaponized against citizens and used in geopolitical warfare, and this is clearly shaping up to be the battle of our generation.

The inflection point is looming closer, and the sooner it arrives, the more lives will be saved, and the more people who were injured will be able to get help.

[Steve Bannon: Dr. Naomi Wolf Nails It](#)

Pfizer And BioNTech's Exposed: Unsettling Alignment with The Chinese Communist Party: Dr. Naomi Wolf [VIDEOS]

Posted By *Zach Heilman* On April 28, 2022 @ 7:51 am In News and Commentary, Politics | [3 Comments](#)

The COVID-19 pandemic started over two years ago. Throughout that time, Americans and people all around the world were subject to outlandish mandates that included wearing masks indoors and outdoors, distancing from loved ones, and being forced to endure lockdowns. On top of that, the highly debated COVID-19 drug was not only promoted, but in America, the Biden administration tried to force it on the workforce. Not to mention the untold side effects that have been reported pertaining to the drug. Still, as numerous governments continue to spend trillions fighting the virus, Dr. Naomi Wolf uncovered a rather interesting alignment between pharmaceutical companies like Pfizer and BioNTech with the Chinese Communist Party.

Speaking with Steve Bannon on The War Room, Dr. Wolf, as can be seen below, explained the history between the drug companies and the CCP. "Pfizer opened a Research and Development hub in 2009 in three Chinese cities, one of them was Wuhan. And that was with the support of the Chinese Communist Party's research and development entity organization. Okay, so Pfizer partnered with BioNTech in 2020, right as the pandemic was rolling out. Very timely to acquire their mRNA vaccine technology for them to produce the mRNA vaccines in March of 2020."

<https://rumble.com/v12otut-pfizer-and-biontechs-disturbing-alignment-with-the-chinese-communist-party-.html>

Not only did the doctor admit that in 2020, but Fosun pharmaceuticals invested \$100 into its joint venture. At the same time, BioNTech agreed they would provide their exclusive patent technology if Fosun built the factories. Dr. Wolf added, "So let's fast forward to June of this year and the SEC filing that I reported on yesterday. It shows, as I mentioned, a tech transfer being completed from BioNTech, which has in the last two years produced the mRNA vaccine in alignment with Fosun pharmaceuticals. The Wuhan hub is described in the pharmaceutical press as Pfizer's Regional Base for global partnerships, global distribution, and global R&D. Okay, so now at the end of last year, the SEC has been informed that there has been a completed 100% tech transfer from BioNTech, which by now has injected you with this vaccine at scale of millions. In fact, Fosun said that they produced a billion doses of the vaccine. And that Tech has now gone back to China."

Although Dr. Wolf has done a significant amount of research, she admitted, "So I don't yet know exactly what this means. But what I do know is that it casts the damages and the harms that are at such massive scale in a very alarming light. Because it's certainly not an American company that's just bungling or concealing side effects from an American rollout of an American vaccine. This is a global company with a hub in Wuhan and a strong alliance with the Chinese Communist Party and at least some of its regional research and development and distribution centers with a joint venture sharing data. And so this needs to have questions asked about it."

URL to

article: <https://www.redvoicemedia.com/2022/04/pfizer-and-biontechs-exposed-unsettling-alignment-with-the-chinese-communist-party-dr-naomi-wolf-videos/>

[The Pfizer Documents - Part One](#)

The Wolf Team Findings So Far

Joe Giannotti

May 5, 2022



So, in part one of this new series, I am going to post videos, tweets and documents that have been release thus far. These are materials and documents that Pfizer wanted hidden for 55-75 years. The first data dump occurred in March 2022 and will continue with 10,000+ pages per month until all of the documents have been released to the public.

I know that science is very difficult to understand, especially during this pandemic. This Substack will post materials that are easy for the average person to understand, which is why I prefer posting videos, social media threads and the occasional podcast from those who have been on the forefront for Medical Freedom around the world. However, if there are questions with an interesting post, I will post that here as well.

In part one, I am going to post a series of the video links about the findings that the team led by Naomi Wolf have uncovered so far. Naomi Wolf, who is not a medical doctor, has done an outstanding job in organizing a team of 2500+ volunteers from different backgrounds, such as biostatisticians, lawyers, researchers. I am only going to post the Naomi Wolf updates since the Pfizer documents started getting released on March 1, 2022. I will be posting more interview link of Dr. Wolf in the coming weeks. However, I will continue this list and will occasionally repost it.

Updated: May 6, 2022

1. [The Pfizer Documents Bombshell w/ Dr. Naomi Wolf](#) - March 5, 2022

2. [Joint Campaign Combs Through Thousands of Pfizer Documents](#) - March 7, 2022
3. [Dr. Naomi Wolf Updates on Pfizer Document Dump](#) - March 9, 2022
4. ['161 Lawyers' Working On Pfizer's 'Crimes Of Extraordinary Scale'](#) - March 12, 2022
5. [Dr. Wolf: Covid Dosages and Variance Amongst Batches](#) - March 14, 2022
6. [Dr. Wolf - Lack of Discernment in Covid Vaccine Dosing](#) - March 16, 2022
7. [Dr. Wolf: "They Are Counting Wrong - You Can't Verify the Data Sets."](#) - March 19, 2022
8. [Pfizer Documents Review: Revelations Continue](#) - March 23, 2022
9. [Dr. Wolf in the WarRoom Talks Pfizer Investigations and Her New Book, The Bodies of Others](#) - March 29, 2022
10. ['An Experiment On Millions Of People': Naomi Wolf On Covid Vaccine Data](#) - March 31, 2022
11. [Dr. Naomi Wolf on Pfizer: "They hid. They concealed. They redacted."](#) - April 5, 2022
12. [Our Whole Health Apparatus 'Colluded' With Big Pharma To Experiment On Americans](#) - April 8, 2022
13. [Dr. Wolf: The Continued Uncovering of the Pfizer Reports](#) - April 18, 2022
14. [The Pfizer Investigation: COVID Vaccine Lacked Proper Quality Controls](#) - April 23, 2022
15. [The Pfizer Report Raises More Questions Than It Answers](#) - April 23, 2022
16. [COVID Vaccine Side Effects in Children and Youths](#) - April 25, 2022
17. [Dr. Wolf: Pfizer's Vaccine, BioNTech and China](#) - April 26, 2022
18. [Big Pharma-CCP Alignment](#) - April 27, 2022
19. [COVID Vaccine Deceptions](#) - April 28, 2022
20. [Dr. Wolf: COVID Vaccines and Pregnancy](#) - April 29, 2022
21. [Naomi Wolf's Explosive Reveal On The Pfizer Investigation](#) - May 2, 2022
22. [Naomi Wolf On Pfizer Reporting Record Profits](#) - May 4, 2022
23. [Naomi Wolf: 'The Lies Of Pfizer'](#) - May 4, 2022
24. [Naomi Wolf: The Pfizer Report](#) - May 5, 2022
25. [Dr. Wolf On The FDA's Late Restrictions On Covid Vax's](#) - May 5, 2022
26. [Dr. Naomi Wolf Reports on COVID Vaccine Data in Pregnancy, Lactation](#) - May 17, 2022

If you want to become part of the team of volunteers, go to [Daily Clout](#). We will delve into more of their finding in coming Medical Freedom posts.

Note: At the end of the day, Medical Freedom is about personal choice, and it is up to each individual to decide what is the best decision for them. However, the public deserves to be properly informed.

Vaccinated Women

Fertility signals are coming through.

By **Etana Hecht**

May 25, 2002

The topic of pregnant and nursing moms getting vaccinated under encouragement and coercion is painful. It's painful to research, painful to write about, and painful to learn how carelessly the most precious among us are being treated. The very essence of life and nature live within pregnant and nursing mothers. Reflecting on how little regard was paid to that life is upsetting, and everything I have to report in this post is done so with a heavy heart and a hope that we'll get through this with a renewed sense of personal autonomy when it comes to medical decisions.

Notes to Keep in Mind:

1. **The FDA + Pfizer actively worked to keep this data hidden from sight for our lifetimes.**
2. **Academic institutions, Medical institutions, and public health agencies are all still recommending that pregnant women take the Covid-19 vaccines as a precaution against Covid.**

Dr. Naomi Wolf, Project Manager Amy Kelly, and the WarRoom/ DailyClout Pfizer Documents Volunteer Research Team have uncovered so many new important pieces of information that it's getting difficult to keep up. I highly recommend pinning DailyClout to your homepage and checking their updates often. Their team of thousands of volunteers including hundreds of lawyers is working quickly, thoroughly, and efficiently.

A lot of information and serious concerns have emerged surrounding pregnant and nursing mothers and the possible effect that the Covid vaccines are having on their babies. Dr. Naomi Wolf has been appearing on Warroom regularly to provide us with updates on the findings of her and her team. On one appearance last week Dr. Wolf broke down some of the main red flags that have emerged, with the help of a female physician who studied the data:

- Pregnant women were **excluded** from clinical trials when they were declared safe and effective for pregnant women. Pfizer, the FDA, the CDC, the entire "medical community" and your local employer who declared that you couldn't come to work if you're not vaccinated have concluded that this was safe and effective for pregnant women based on trials that were done on rats in France. There have not been any human clinical trials that have been concluded by Pfizer or other pharmaceutical companies to find out if these vaccines are safe for use during pregnancy or breastfeeding. There is currently one that's still active, has no posted results and won't conclude until July, 2022.

No Study Results Posted on ClinicalTrials.gov for this Study

About Study Results Reporting on ClinicalTrials.gov

Recruitment Status ⓘ :	Active, not recruiting
Estimated Primary Completion Date ⓘ :	July 26, 2022
Estimated Study Completion Date ⓘ :	July 26, 2022

- o The animal studies that were conducted for the trial that the NIH based their conclusions on included 44 rats and were done over a period of 42 days. There are 2 main issues with this study:
 0. This doesn't fulfill the requirement to ensure that the drug will do no harm to the next generation
 1. The doctors conducting the trials have all either been employed by or owned shares of Pfizer or BioNTech. There was an attempt to hide this fact by using their initials instead of full names on the study.

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Abstract

BNT162b2 is a vaccine developed to prevent coronavirus disease 2019 (COVID-19). BNT162b2 is a lipid nanoparticle formulated nucleoside-modified messenger RNA (mRNA) encoding the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein locked in its prefusion conformation. A developmental and reproductive toxicity study was conducted in rats according to international regulatory guidelines. The full human BNT162b2 dose of 30 µg mRNA/dose (>300 times the human dose on a mg/kg basis) was administered intramuscularly to 44 female rats 21 and 14 days prior to mating and on gestation days 9 and 20. Half of the rats were subject to cesarean section and full fetal examination at the end of gestation, and the other half were allowed to deliver and were monitored to the end of lactation. A robust neutralizing antibody response was confirmed prior to mating and at the end of gestation and lactation. The presence of neutralizing antibodies was also confirmed in fetuses and offspring. Nonadverse effects, related to the local injection site reaction, were noted in dams as expected from other animal studies and consistent with observations in humans. There were no effects of BNT162b2 on female mating performance, fertility, or any ovarian or uterine parameters nor on embryo-fetal or postnatal survival, growth, physical development or neurofunctional development in the offspring through the end of lactation. Together with the safety profile in nonpregnant people, this ICH-compliant nonclinical safety data supports study of BNT162b2 in women of childbearing potential and pregnant and lactating women.

Keywords: BNT162b2; COVID-19 vaccine; Developmental toxicity; Fertility; Pregnancy; Rat.

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Conflict of interest statement

CJB, NRC, GDC, SNC, MWC, CMR, RS are currently employed by and hold stock in Pfizer, Inc. CL and JD are currently employed by and hold stock in BioNTech SE. MB is currently employed by Charles River Laboratories.

- All Emergency Use Authorization excludes pregnant women.

- Pregnant and nursing mothers were NOT ALLOWED to participate in phases 1,2, and 3 of human clinical trials. They were included on a list of 21 conditions that were not allowed to be recruited for trials. Page 33

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Exclusion Criteria				
#	Exclusion Number	Criterion Description	Criterion met?	Criterion ID: (For Pfizer use only)
2.a	1	Other medical or psychiatric condition incl. recent (within past year) or active suicidal deation/behavior/lab abnormal ty that may increase the risk of study participation		EX01A00
2.b	2	Known infection w th human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)		EX02A00
2.c	3	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)		EX03A00
2.d	4	Receipt of medicat ons intended to prevent COVID-19		EX04A00
2.e	8	Immunocompromised indiv duals w th known or suspected immunodeficiency, as determined by history and/or laboratory/phys cal examination		EX08A00
2.f	9	Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention		EX09A00
2.g	10	Bleeding diathesis or condition associated w th prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular inject on		EX10A00
2.h	11	Women who are pregnant or breastfeeding		EX11A00
2.i	12	Previous vaccinat on with any coronavirus vaccine		EX12A00
2.j	13	Individuals who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids. Inhaled/nebulized, Intra-art ular, intrabursal, or topical cort costeroids are permitted		EX13A00
2.k	14	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervent ion administrat on or planned receipt throughout the study		EX14A00
2.l	15	Participation in other studies involving study intervent ion w thin 28 days pr or to study entry and/or during study participation		EX15A00
2.m	16	Previous part cipation in other studies involving study intervent on containing lip d nanopart cles		EX16A00
2.n	21	Investigator s te staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members		EX21A00

- The Department of Defense data is showing that female soldiers are having an astronomical rate of abnormalities and fetal problems. (NOTE- Mathew Crawford of RoundingtheEarth Substack has stated that he does not believe ANY of the DOD data is reliable, as it's been demonstrably tampered with. Having said that, there are whistleblowers on the ground who corroborate that the rates of a variety of serious medical issues have indeed skyrocketed in 2021).

Adverse Events

In the Pfizer documents that were released thanks to legal force, there is data on reported adverse events since the rollout of the vaccine. On pages 12-13 of the document labeled “postmarketing-experience” Dr. Wolf’s Team 5 found:

- 28% of the 270 pregnancies + 4 fetus/baby cases of adverse events were categorized as serious, including:
 - o Miscarriages
 - o Fetal deaths
 - o Uterine contractions
 - o Pre-term deliveries
 - o Premature rupture of membranes
 - o Fetal growth restrictions
- Breastfed babies were reported to have effects such as:
 - o Infantile vomiting
 - o Fever
 - o Rash
 - o Agitation
 - o Allergy to the vaccine

- 4 nursing women reported adverse events such as:
 - Partial paralysis
 - Suppressed lactation
 - Breastmilk discoloration
 - Breast pain
 - Migraines

The document concludes that no serious adverse events have been detected. Dr. Wolf again questions whether we, as citizens of the United States of America, must begin to consider if all of these signs put together point to a serious national security breach. She has never seen anything as bad as what we're seeing today in her 30 years in journalism.

There is a strong case that the potential risks for pregnant women from taking the Covid vaccine far outweigh the potential benefits.

On May 17, Dr. Wolf re-appeared on War Room shortly after the FDA and the CDC authorized the Pfizer Covid-19 booster for 5-11-year-olds. In this segment, Dr. Wolf revealed some new information about data on the vaccine for pregnant and nursing mothers:

- In Scotland there is an investigation happening right now that was triggered by a threshold that was crossed regarding the number of neonatal deaths. Its double the baseline amount, and this is the 2nd time in 7 months that the rate triggered an investigation.
- Contrary to BBC claims (partially funded by Pfizer) that the rise in neonatal deaths cannot be connected to the vaccine, Dr. Wolf's team, specifically Project Manager Amy Kelly, has found conclusive evidence to the contrary in Pfizer's own documents.
- Pfizer defined exposure to the vaccine as breastfeeding. This was not disclosed to pregnant women. A research team in Germany has confirmed to Dr. Wolf that breastmilk can deliver elements of the vaccine
- A baby born to a vaccinated mother died after being born bleeding from the nose and mouth.
- A mother received her 2nd vaccine dose on March 17, and within 24 hours her breastfed infant developed a rash and became inconsolable. The baby died 2 days later, with evidence of liver damage and a rare blood disorder.

The history of the claims of safety and efficacy regarding the Covid-19 vaccines for pregnant and nursing mothers will hopefully result in individuals who will be held criminally liable.

Missing Data

DailyClout's expert Team 5 research team has reported some alarming numbers from Pfizer's documents regarding missing information. In one group of 270 pregnancies, there were "no known outcomes" for 238 of the cases.

That leaves us with 36 known outcomes. Of those 36 known outcomes, 28 babies died before or at birth. It would be really helpful to know the outcome of the remaining 238 cases.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)
Use in Pregnancy and lactation	<ul style="list-style-type: none"> • Number of cases: 413^a (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. <p>Pregnancy cases: 274 cases including:</p> <ul style="list-style-type: none"> • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.

Pieces of the Puzzle - A Timeline

March 2021 - 50 participants in a clinical trial reported becoming pregnant, with some of them subsequently being dismissed from the trials. Cindy L. Weis of the DailyClout found that those 50 women have still not had their profiles updated to include pregnancy outcomes.

2.5.5.7.2. Pregnancies

At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2. In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo

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FDA-CBER-2021-5683-0002700

BNT162b2
2.5 Clinical Overview

who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 54). These participants continue to be followed for pregnancy outcomes. No births have been reported from individuals who have become pregnant in Study C4591001 as of the time of this submission.

In the same March 2021 document, we can see that Pfizer themselves admits the following:

1. Available data are insufficient to inform vaccine-related risks in pregnancy.
2. Adverse effects from the vaccine on a breastfed child are a possibility.

BNT162b2
2.5 Clinical Overview

There were no pregnancies reported in Study BNT162-01 as of the data cutoff date for the BNT162-01 Phase 1 Interim CSR. At the time of the most recent data cutoff in Study C4591001 (13 March 2021), a total of 50 participants had reported pregnancies in the safety database (Section 2.5.5.7.2). These participants continue to be followed for pregnancy outcomes.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on BNT162b2 administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. In a DART study, no vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for vaccination with BNT162b2 and any potential adverse effects on the breastfed child from BNT162b2 or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

July 2021- In Waterloo, Ontario between the months of January - July 2021, there were 86 babies who were born dead, otherwise known as stillbirths. The baseline rate is usually 5-6 per YEAR. One brave

MP named Rick Nicholls raised the issue in a parliamentary session with great concern and passion. In response, the Minister of Health gave the answer we're all used to. The vaccine is Safe and Effective. Just to note, there was no noticeable rise in stillbirths in 2020, the year of Covid.

September 2021 - Scotland launched its first investigation into an abnormal spike in newborn baby deaths that was triggered by surpassing a threshold in infant deaths that hadn't been seen since the 1980's. (Note- this spike did not occur in 2020, the Year of Covid)

Ashmedai over at Resisting the Intellectual Literati wrote an extensive report on fertility issues and the vaccine back in September 2021.



[Resisting the Intellectual Illiterati](#)

Is There a Plausible Basis For Fertility Concerns?

In my own community, the most prominent concern on the minds of many of the vaccine hesitant, especially young women of childbearing age, is the fear of an adverse effect on fertility. Possibly because of this, fertility concerns have also been derisively dismissed by the doctors with more passion and vengeance than for any other type of adverse effect...

[Read more](#)

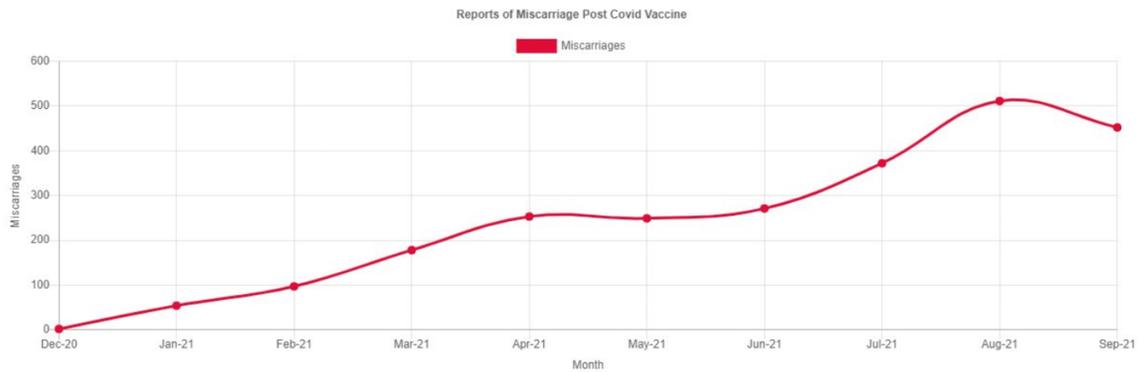
8 months ago · 49 likes · 40 comments · Ashmedai

August 2021- NPR reported on a survey out of the University of Chicago to investigate reports of changes in menstrual cycles after the vaccine. They received 140,000 responses.,

October 2021- VAERS looked like this:

VAERS COVID Vaccine Reproductive Health Related Reports

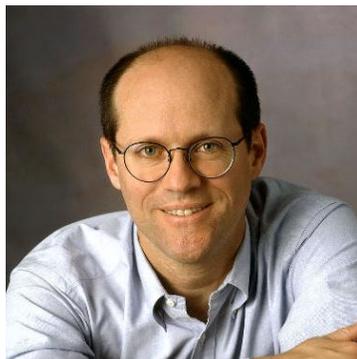
Through October 08, 2021



I ran my own [VAERS report](#) using only a few pregnancy-related keywords. The list is 769 events long, and here's a screenshot of just a few from the first page:

ABORTION SPONTANEOUS	PFIZERBIONTECH	Life Threatening	1216055-1	Yes	I received the vaccine and was unknowingly pregnant. My first shot was on 1/6/2021 and my second shot was on 1/27/2021. I conceived on 1/25/2021. I ended up miscarrying the child and when they sent it in for testing it had 2 abnormal chromosomes. One of which they said is very rare and they have no idea how or why the baby had this. I was told that the vaccine was supposed to be safe for pregnant people but with no family history of anything like this happening and no history of any children being born with mutations I believe this happened from the vaccine. Possibly caused by the spike in temperature I experienced after the second shot. I should have been due to deliver 10/2021.
ABORTION SPONTANEOUS	PFIZERBIONTECH	Life Threatening	1267942-1	Yes	Received 1st dose approx 6 weeks gestation. Fetal development stopped later same week. Missed miscarriage discovered at 8 week 3 days. Complete miscarriage at 8 weeks 5 days.
ABORTION SPONTANEOUS	PFIZERBIONTECH	Life Threatening	1279405-1	Yes	miscarriage of the 16-17 week fetus; This is a spontaneous report from a contactable consumer (patient). A 30-year-old female patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number : ER8730), via an unspecified route of administration, administered in the left arm on 26Mar2021 at 16:30 as a single dose for COVID-19 immunization. The patient had no medical history and no known allergies. The patient's concomitant medications included unspecified prenatal vitamins. The patient did not have other vaccines in four weeks prior to the COVID vaccine. On an unspecified date in Mar2021, the patient had a miscarriage of the 16-17 week fetus. The patient had surgery to remove the fetus and tissue. The mother was due to deliver on 09Sep2021. The outcome of the event was recovering. The patient had a nasal swab COVID-19 test on 22Apr2021 with a result of negative. The event was reported as life-threatening.
ABORTION SPONTANEOUS	PFIZERBIONTECH	Life Threatening	1360595-1	Yes	Late miscarriage at 18 weeks gestation. Fetal demise.; This is a spontaneous report from a contactable nurse. A 30-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as unknown, single for COVID-19 immunisation. The patient medical history was not reported. There were no concomitant medications. The patient experienced late miscarriage at 18 weeks gestation. fetal demise on 11May2021 12:00. The mother was 18 weeks pregnant at the onset of the event. The mother was due to deliver on 10Oct2021. The mother delivered the pregnancy on 11May2021. Patient had Nasal swab (NP and rapid) on 17May2021 and the result was negative. Treatment: Delivery of fetus, D&C of remaining undelivered placenta. Event resulted to doctor or other healthcare professional office/clinic visit, prolongation of existing hospitalization (vaccine received during existing hospitalization), life threatening illness (immediate risk of death from the event). The outcome of the event was recovering. Information about the Lot/batch number has been requested.; Sender's Comments: A contributory role of BNT162B2 to event late miscarriage at 18 weeks gestation. fetal demise cannot be excluded based on temporal association and available information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Authorities, Committees and Investigators, as appropriate.
ABORTION SPONTANEOUS	PFIZERBIONTECH	Life Threatening	1371940-1	Yes	I experienced a miscarriage a week after having the Pfizer to vaccine and I'm not being given much information from the vaccine facility they gave me a piece of paper with a phone number to vaers in this doesn't even look like a phone number

December 2021 - IVF clinics reported unusual issues after the mass vaccination campaign began. Steve Kirsch covered it thoroughly.



Steve Kirsch's newsletter

IVF clinics started having serious problems right after the vaccines started rolling out

I just got off the phone with a woman who works at a large IVF clinic. She has to remain nameless to avoid being fired for speaking out. Nobody is supposed to know about the serious problems happening in the IVF clinics. Let me tell you what is really going on and the scientific study that explains it...

[Read more](#)

5 months ago · 498 likes · 457 comments · Steve Kirsch

January 2022- NIH funded a study that was released that reported a slight causal relationship between the Covid-19 vaccines and a lengthier menstrual cycle.

Release: COVID-19 vaccination associated with a small, temporary increase in menstrual cycle length, suggests NIH-funded study

Thursday, January 6, 2022



Credit: Stock Image

Women receiving one dose of a COVID-19 vaccine during a single menstrual cycle had an increase in cycle length of nearly one day, compared to unvaccinated women, according to a study funded by the National Institutes of Health. The increase in cycle length—a longer time between bleeding—was not associated with any change in the number of days of menses (days of bleeding). The study appears in *Obstetrics & Gynecology*.

February 2022- An EU health agency announced an investigation between Covid-19 and disruptions in menstrual cycles based on reports coming in.

Menstrual disorders

Further assessment started

In October 2021, PRAC concluded that there was insufficient evidence to suggest a causal relationship between vaccination with Comirnaty and menstrual disorders ([Safety Update for Comirnaty of 6 October 2021](#)).

A further assessment has started following published studies² suggesting there may be short-lived changes in menstrual patterns, including absence of menstrual bleeding (amenorrhoea) and heavier than usual menstrual bleeding following vaccination with Comirnaty or Spikevax. Further information can be found in the [PRAC highlights of February 2022](#).

Information on how Comirnaty and Spikevax work is provided in their respective medicine overviews: [Comirnaty](#) and [Spikevax](#) (in all EU/EEA languages). Full information on the vaccines, including all identified side effects and advice on how to use them, is available in their respective product informations: [Comirnaty](#) and [Spikevax](#) (in all EU/EEA languages). The product information will be updated to reflect the latest safety assessment outcomes.

Josh Guetzkow reported on data from Rambam Hospital in Haifa, Israel. Vaccinated mothers were experiencing spontaneous abortions/miscarriages/stillbirths at a rate that's 34% higher than their unvaccinated counterparts.



Jackanapes Junction

Stillbirths, Miscarriages and Abortions in Vaccinated vs. Unvaccinated Women

Data from Rambam hospital in Haifa reveal a stillbirth, miscarriage and abortion (SBMA) rate of 6% among women who never received a COVID-19 vaccine, compared to 8% among women who were vaccinated with at least one dose (and never had a SARS-Cov-2 infection...

[Read more](#)

3 months ago · 58 likes · 62 comments · [Josh Guetzkow](#)

March 2022- A 2nd investigation was launched in Scotland due to the high rate of infant deaths, totaling 18 for the month of March.



Chief Nerd @chiefnerd · May 16

...

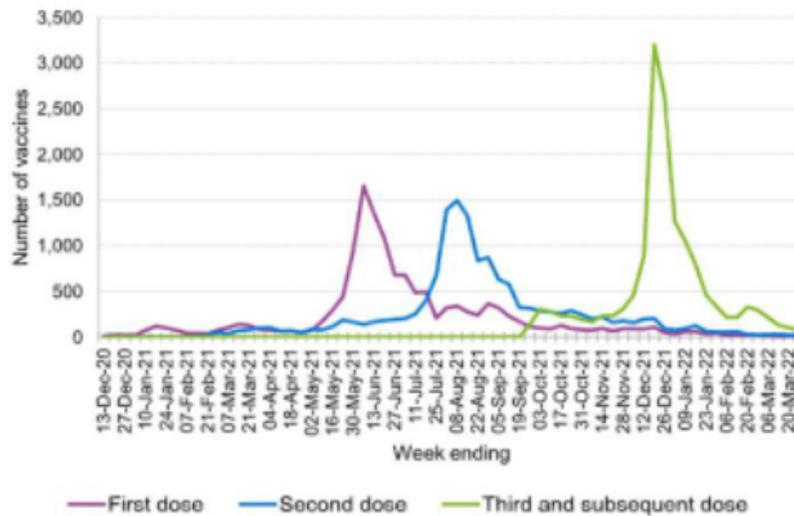
Scotland Neonatal Deaths (top) vs. COVID-19 Vaccines in Pregnancy (bottom)

Notice the corresponding spikes in May/June (Dose 1), August (Dose 2), and January (Dose 3)? 🤔

Source: Public Health Scotland



Figure 26: Number of COVID-19 vaccines given in pregnancy by dose, December 2020 to March 2022, Scotland



Chief Nerd @chiefnerd · May 16



"At least 18 babies under four weeks old died in March, a rate of 4.6 per 1,000 births. Infant death rates vary widely from month to month, but the increase is larger than expected from chance alone...."

Pfizer, what say you?

After spending days reading reports about the horrible negative effects of fertility that are coming out in droves, I had to at least try and get some sort of response from Pfizer. After sitting on hold for a while, a gentleman named Ron got on the line. When I asked if the Covid-19 vaccine is safe for a pregnant woman to take, he read me the entire safety warning from Pfizer's website. I then told him that I know many women who have had serious disruptions to their menstrual cycle, as well as numerous women who experienced miscarriages late term, shortly after getting one of the Pfizer vaccines. I asked him what he knows about the safety and efficacy of the vaccine, given all the new information that's come out from the FOIA requests.

He responded that he can pass me along to his managers, but first he has to read another statement, this time from the CDC. He proceeded to verbally read it for 10 minutes while I waited patiently. When he finished, surprised that I was still on the line, he asked if I had any more questions. I said yes and asked if he wanted to be a whistleblower. He said he noted my response and passed me along to Olivia, which was pretty much a repeat of the first conversation.

I left contact information with both of them just in case, but somehow I highly doubt we'll get a response. I did note to both of them that should they want to get on the right side of this scandal and begin to help those who are suffering, they should do so before the entire thing crumbles down.

Now What?

We're now in May 2022. The claims of safety and efficacy don't match their own internal documents that they tried to hide for 75 years. Yet academic institutions and public health agencies continue to insist it's recommended for pregnant women to receive Covid-19 vaccines and boosters. Until when? Until the wave of misery gets so large that it's no longer deniable? No one is coming to save us. Groups like DailyClout, VSRF, America's Frontline Doctors, Children's Health Defense, and ICAN are sources of inspiration that there are still good men out there, as well as a source of hope that through their strength and efforts, we'll come out of the other side of this with some integrity still left in some medical professionals.

[Raising the Red Flags](#)

Dr. Naomi Wolf and Mr. Steve Bannon connect the vaccine dots.

By Etana Hecht

[Dr. Naomi Wolf](#), [Steve Bannon](#), The Warroom Posse, and the DailyClout team have been on fire. Dr. Wolf has been featured on Warroom every day this week, and with each appearance, she brings more information that answers some questions while raising others. Details about the web woven between US Federal health agencies, pharmaceutical companies, foreign entities, and the Chinese govt, alongside the accelerating societal disaster of vaccine fallout should be the most widely discussed and investigated scandal of our time, and it's mind-boggling that this conversation is still mostly limited to our little corner of the Internet. Here are Dr. Wolf's Warroom segments from this week, I recommend watching all of them for the full picture, but below the links are some highlights:

[April 25](#) [April 26](#) [April 27](#) [April 28](#)

Background

Scott Gottlieb, former head of the FDA now sits on the board at Pfizer. He discussed applying for an EUA for kids Covid boosters while admitting they will not reach an efficacy rate of 50%. His bio is a revolving door of the FDA, Pfizer, MSNBC, CBS, and the NYT.



Near The Edge @NearTheEdge1

[More lipstick.... Pfizer Board Member Dr. Scott Gottlieb Says Pediatric Vaccines Will Miss 50% Efficacy Target, However Still Recommends the "Value" They Offer](#)

[rumble.com/v1296m5-pfizer...](https://www.rumble.com/v1296m5-pfizer...)

April 25th 2022

1 Retweet 2 Likes

It's shameless - he's admitting the vaccines don't work, but he still advocates injecting children in order to achieve a "baseline immunity" that he doesn't even claim will protect them from symptoms. Lawyers theorize he's laying a paper trail to try and claim they disclosed the information. Meanwhile, the CDC was forced to issue a correction stating that they'd overcounted kids dying from covid by a factor of 26%. Their entire narrative of kids dying from covid was manufactured and effective at convincing parents to vaccinate their kids, from which there's no turning back. It must be mentioned repeatedly that the FDA and Pfizer fully planned on hiding the vaccine data for 75 years, and went to great lengths in a failed attempt to keep it concealed.

BioNTech SEC Filing

Dr. Wolf has been studying a [SEC filing by BioNTech](#) from 2021, alongside documents and news reports surrounding joint ventures between Pfizer, BioNTech, and a Chinese company called [Fosun Pharma](#). The filing raised numerous red flags:

- Two unnamed US citizens hold most of the BioNTech shares along with one Hong Kong-based individual. That individual transferred over 5 million shares back into the company in exchange for \$0 right before the pandemic began.
- On Page 22 of the SEC filing, BioNTech listed its accomplishments for 2021. Along with administering over 3 billion vaccine doses, they proudly listed new headquarters in Singapore and China, and a joint venture plus tech transfer with a Chinese company called Fosun Pharma. They noted that for strategic reasons they chose not to implement the tech transfer with China at the end of 2021 until after marketing approval has been granted.

	Performance Targets 2021 Financial Year	Relative Weighting	Achievement
	Release and sell / distribute 3 billion COMIRNATY® doses	15%	100%
Company Goals	Develop explicit transformation plans and implement quick wins:	40%	100%
	• Manufacturing network plan		
	• Integrated oncology acceleration plan		
	• Integrated infectious disease acceleration plan		
	• Integrated digitalization plan		
	• Integrated automation plan		
	Establish Singapore and China Headquarter and China Joint Venture (JV) + Tech Transfer	10%	100%
	Reach a specified number of clinical trials milestones	15%	100%
ESG	Achieve C+ rating for ESG (Environment / Social / Governance)	20%	100%
	Total	100%	100%

- Fosun Pharma, a CCP-aligned Shanghai-based company, will inject \$100M into this joint venture with BioNTech. The German company will provide the patent, tech, and know-how, and the Chinese company will provide the vaccine facilities.
- In the SEC filing, there's a list of side effects and adverse events that consumers are supposed to be informed of. Included in that list are fainting, falling, and heart disease. The CDC public list of adverse events is a watered-down version of the full list in the SEC.

Dr. Wolf and the rest of us have some questions about the above information. These findings are the background to the questions that have been swirling about the immense harm we're seeing from the vaccine. What does "Tech Transfer" mean in the context of BioNTech sending over technology to China?

Timeline

Dr. Wolf laid out a timeline with the following events as it stands:

2009: Pfizer opened Research and Development hubs in 3 Chinese cities, one of them being Wuhan, with the support of the CCP R&D organization.

2020: Pfizer partnered with BioNTech to acquire mRNA technology to manufacture the Covid vaccines.

March 2020: BioNTech launched a formal joint venture with Fosun in Shanghai, who injected 100M dollars into it. The Chinese provide the vaccine facilities, and the Germans provide the technology.

June 2021: **SEC filing** shows Tech transfer being complete from BioNTech to China. Pfizer's regional base for global distribution has been listed as its Wuhan headquarters.

This entire twisted timeline casts a dark shadow over the vaccine fallout we're seeing at an increasing rate. This can no longer be considered a US bungling of clinical trials and attempting to cover themselves as harms emerge from their negligence. This must be treated as a potential national security threat from foreign entities who feel no allegiance to US citizens at best, and would actively like to see the US harmed at worst.

Institutional Failures

Institutions that society has tasked with specific responsibilities have failed spectacularly. It can't be overstated that those responsible for Covid/Vaccine fallout must be held accountable. If they are not, there's nothing to stop bad actors from running this playbook all over again to various ends. The work that private citizens like Dr. Naomi Wolf, Del Bigtree, Aron Siri, and many others are doing to ensure that information that belongs to all of us is accessible to all of us, and then acting upon that information to hold people in power to account is invaluable.

- **Government:** Congress, US Intelligence Communities, and the FDA are the ones who are meant to be protecting us from foreign entities who intend to cause us harm. Instead, with a handful of exceptions, they're either ignoring the calls for help or actively trying to assist Pfizer with long-term data concealment.
- **Media:** Where are the journalists? There are thousands of actively engaged private citizens doing research, studying documents, and sharing information. Unfortunately, the Old Mainstream Media has been institutionally captured by pharmaceutical industries and govt regulators (Hello, Scott Gottlieb) for a long time. These are puppets, not journalists:



jseths @jseths

[@DrAseemMalhotra_@MaajidNawaz](#)

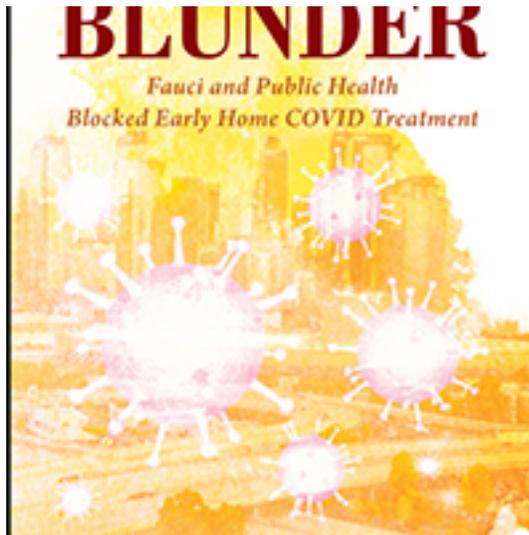
November 3rd 2021

188 Retweets **336** Likes

- **Academia:** With over 1000 universities still mandating the vaccine, and over 1/3 of those still mandating the booster for millions of healthy young men and women, there are numerous examples that demonstrate the negligence of critical thinking among those tasked to think. University administrators openly admit to deferring to official CDC guidance for all Covid-related matters, even as official CDC guidance seems more absurd by the day.

So just to take a quick recap: Pfizer, the FDA, and the CDC knew very early on that the vaccine was neither safe nor effective. With billions of dollars, government mandates, no informed consent, and a media campaign the likes of which we've never seen before, the above agencies declared quite definitively, with zero room for discussion that indeed the vaccines ARE safe and effective. Hundreds of millions of people ages 5+ have now taken an experimental injection with brand new technology and zero long-term studies.

We're now well into the second year since vaccines have been in circulation. Here's a great but horrific summary of where that's led- so far.



[Pandemic Blunder Newsletter](#)

[Latest COVID vaccine adverse events data](#)

The Centers for Disease Control and Prevention (CDC) the other day released new data showing a total of 1,226,314 reports of adverse events following COVID vaccines were submitted between Dec. 14, 2020, and April 8, 2022, to the Vaccine Adverse Event Reporting System (VAERS). VAERS is the primary government-funded system for reporting adverse vaccine re...

[Read more](#)

2 months ago · 13 likes · 4 comments · Joel S Hirschhorn

Denmark apparently is waking up. Stay tuned for more, as the unspeakable becomes inevitable.



Igor's Newsletter

Denmark Halts COVID Vaccination, in Ominous Sign for the Boosted

Hat tip to Steve Kirsch, who wrote about Denmark stopping its COVID vaccination program. The original article is [here](#). And [here](#). And [here](#). Rejoice. A formerly pro-vaccine country halting vaccination is a very ominous sign. It means that Denmark is scared of Covid vaccines...

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Finally, this is an absolute must-read by Dr. Wolf. So many of us are experiencing similar roller-coaster emotions, and reading it in her words is therapeutic.

[Outspoken with Dr Naomi Wolf](#)

Oh, Ok, It's Over

For the last two days I've felt an uneasy sense of grief, or of a heavy pressure on my heart. At first I could not figure out the cause of it. Nothing unusual was wrong in my personal life. My loved ones were safe and well, thank God. The battle for liberty was ongoing, as it has been for over two years, but I was used to the rigors and stress...

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[Dr. Naomi Wolf's Appearances on "Steve Bannon's War Room Pandemic"](#)

[Dr. Naomi Wolf: New Fears for Vaccinated Pregnant Mothers](#)