PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

In accordance with RCW 34.05.330, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at http://apps.leg.wa.gov/wac/default.aspx?cite=82-05.

CONTACT INFORMATION *(please type or print)*

Petitioner's Name: Kenneth Harp

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COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: _____

☐ **1. NEW RULE - I am requesting the agency to adopt a new rule.**

☐ The subject (or purpose) of this rule is: _____

☐ The rule is needed because: _____

☐ The new rule would affect the following people or groups: _____

☒ **2. AMEND RULE - I am requesting the agency to change an existing rule.**

List rule number (WAC), if known: WAC 246-105-070

☒ I am requesting the following change: See attached (Petition to Amend Rule letter, 2 pages).

☒ This change is needed because: Fully Informed Consent is not being obtained from Covid-19 mRNA product recipients (see attached Affidavit, 127 pages).

☒ The effect of this rule change will be: To ensure Fully Informed Consent is being obtained from recipients of products under EUA and/or which have not completed Stage III Clinical Safety Trials.

☐ The rule is not clearly or simply stated: _____

☐ **3. REPEAL RULE - I am requesting the agency to eliminate an existing rule.**

List rule number (WAC), if known: _____

(Check one or more boxes)

☐ It does not do what it was intended to do.

☐ It is no longer needed because: _____

☐ It imposes unreasonable costs: _____

☐ The agency has no authority to make this rule: _____

☐ It is applied differently to public and private parties: _____

☐ It conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known: _____

☐ It duplicates another federal, state or local law or rule. List duplicate law or rule, if known: _____

☐ Other (please explain): _____

Date: May 16th, 2022

To: The Washington State Board of Health Members

From: Kenneth Harp

Subject: Petition to Amend Rule modifying Chapter 245-105-070 WAC to include specific language requiring a health care provider administering immunizations to obtain Fully Informed Consent for any product or medical formulation that is Emergency Use Authorized and/or has not completed Stage III Safety Trials.

Dear Board of Health Members:

I am requesting the WA State Board of Health amend Chapter 245-105-070 WAC to include specific language requiring a health care provider administering immunizations to obtain Fully Informed Consent for any product or medical formulation that is Emergency Use Authorized and/or has not completed Stage III Safety Trials.

Current text of WAC 246-105-070:

"Duties of health care providers or organizations.

- A health care provider administering immunizations, or the organizations he or she works for, either public or private, shall furnish each person immunized, or their parent, with a medically verified immunization record containing information required by this chapter."

Recommended amendment to WAC 246-105-070 (recommend adding the following paragraphs):

- "A health care provider administering immunization, or the organizations he or she works for, either public or private, shall ensure Fully Informed Consent is attained from each person immunized with an Emergency Use Authorized product and/or any product that has not completed Stage III Clinical Safety Trials, or their parent, consistent with the Nuremburg Code, UNESCO, the World Medical Association's Declaration of Helsinki, the guidelines of the Council for International Organizations of Medical Services and the International Covenant on Civil and Political Rights which categorically forbid medical experimentation without consent.

  Information provided to each person to achieve informed consent shall at a minimum consist of:
  (1) The regulatory status of the *specific immunization lot number* they are receiving, including:
      (a) Approval status (Emergency Use Authorized, fully FDA approved, other)
  (2) Clinical trial status. The current status of clinical trials for the immunization, including whether the clinical trial has been properly blinded or unblinded. If clinical trials are

incomplete and/or being performed in parallel with deployment a notice shall be provided that clearly communicates this to the person immunized.

(3) Whether or not the immunization prevents infection and transmission.

(4) All known potential side effects, both short term and long term.

(5) Clearly identification of the party(s) financially responsible for any adverse health impacts that may occur as a result of the immunization, including legal and lawful recourse for injuries sustained from any adverse events associated with the immunization and any legal indemnification afforded to the product manufacturer, the health care provider administering the immunization, or the organization he or she works for, either public or private.

A copy of the above information shall be provided to the product recipient prior to immunization."

Summary of rational for new WAC 246-105-070 paragraph:

I am requesting this rule amendment out of concern that Fully Informed Consent is not being obtained from Covid-19 mRNA product recipients, in particular that risks and benefits are not being fully and accurately communicated to product recipients. The attached "Health and Safety Concerns with respect to Covid-19 novel mRNA and recumbent DNA products" is provided as supporting information.

The proposed amendment to WAC 246-105-070 is necessary to ensure Fully Informed Consent is being obtained from product recipients. This rule modification would have a documentation recording and reporting impact on health care providers providing immunizations in WA State.

Respectfully,

Kenneth Harp

SWORN STATEMENT AND AFFIDAVIT

State of WASHINGTON

County of KING

PERSONALLY came and appeared before me, the undersigned Notary, the within named Kenneth Henry Harp III, who is a resident of King County, State of Washington, and makes this his Statement and General Affidavit upon oath and affirmation of research, personal knowledge and belief that the following matters, facts and things set forth are true and correct to the best of his knowledge:

RE: **Health and Safety Concerns with respect to Covid-19 novel mRNA and recumbent DNA products**

Given the historically very short timeframe in which the novel coronavirus mRNA therapies and recombinant DNA gene therapies were developed, the history of failed vaccine development attempts for SARS-CoV-1, MERS-CoV and related coronaviruses that resulted in increased sensitivity and enhanced disease, and the lack of extended clinical trial safety data, the long-term safety of these novel therapies cannot be currently ascertained.

Specifically of concern:

1) the rapid pace at which these novel mRNA therapy and recumbent DNA gene therapy products have been developed and rushed to market relative to traditional vaccine development timelines,
2) the specific and significant risk of resultant Antibody Dependent Enhancement (ADE) of disease and history of failed vaccine development attempts for SARS1, MERS and related coronaviruses,
3) the long-term risk of resultant auto-immune conditions,
4) the long-term risk of degradation of innate adaptive immune system response,
5) other potential long-term risks and adverse effects related to these novel medical products,
6) the incomplete and unblinded long-term Safety and Efficacy trials (scheduled to complete in 2023),
7) the de facto experimental nature of these products given (1) through (6) above,
8) the already high and growing number of short-term adverse reactions and deaths reported,
9) the growing incidence of myocarditis in young adults and athletes observed post-vaccination,
10) recent medical journal research indicating the SC2 spike protein alone may trigger adverse events,
11) recent medical journal research indicating these novel products do not prevent or reduce the transmission of, or infection from, the SARS-CoV-2 virus,
12) recent medical journal research indicating these novel products do not reduce SARS-CoV-2 viral load in the vaccinated,
13) the ambiguity surrounding the FDA approval announcement for the BioNTech “Corminaty” and Moderna “SpikeVax” products. These products are currently unavailable in Washington State. All currently available products, including the Pfizer BNT162b2 and Moderna mRNA-1273 product, are still under Emergency Use Authorization (EUA) and as such voluntary under Federal Law.

The long-term effects of these products are unknown. Until long term costs, benefits and side-effects are properly established, the mRNA and recumbent DNA gene therapy roll outs remain an experiment without conclusions. Coercing, mandating or manipulating people into medical experiments without fully informed consent is a crime.

Rapid pace in which these products were rushed to market relative to traditional development timelines

A typical vaccine development timeline takes 5 to 10 years, and sometimes longer, to assess whether the vaccine is safe and efficacious in clinical trials, complete the regulatory approval processes, and manufacture sufficient quantity of vaccine doses for widespread distribution. Figure 1 illustrates a typical vaccine development timeline (10 years) with the accelerated timeline (5 years) and Covid-19 product development timeline (1 year) for comparison. The rapid development timeline for these novel Covid-19 gene therapy "vaccines" is historically unprecedented.

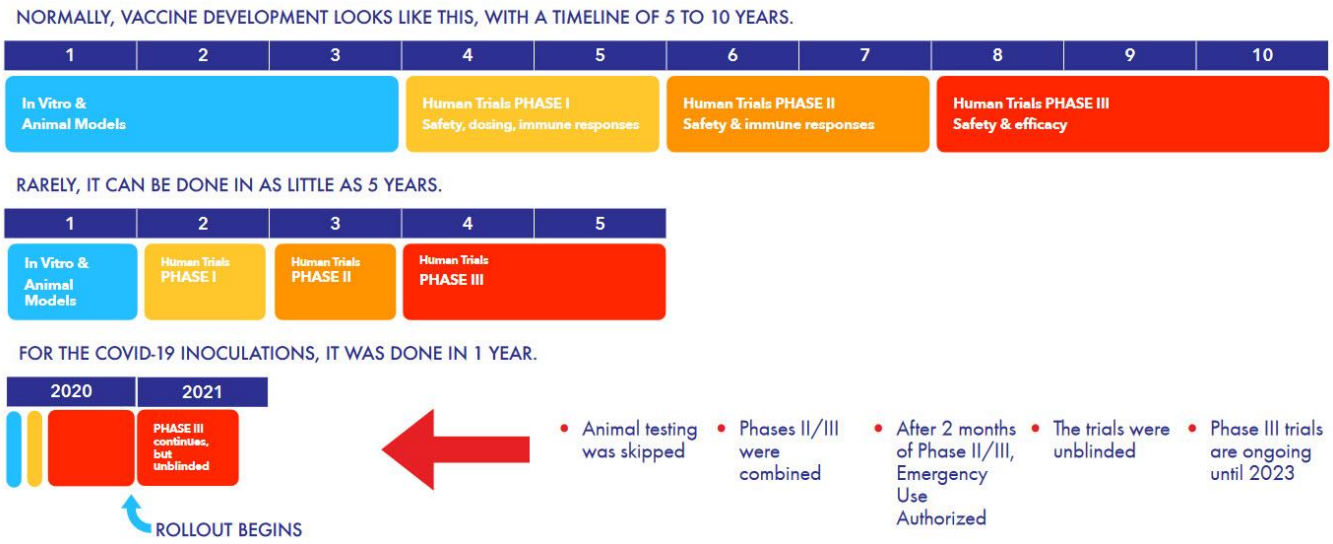

Figure 1: Rapid development timeline of Covid-19 mRNA and recumbent DNA therapies [1]

These products do not meet the Revised Code of Washington State definition of a "Vaccine"

From the Revised Code of Washington State, RCW 70.290.010, Definitions Section (10), "Vaccine" "means a preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity that protects against disease and is approved by the federal food and drug administration as safe and effective and recommended by the advisory committee on immunization practices of the centers for disease control and prevention for administration to children under the age of nineteen years." [2]

The available Pfizer, Moderna and Johnson & Johnson Covid-19 products do not meet the Washington State definition of a Vaccine. These products are not traditional vaccines, they are novel messenger RNA gene therapies [3] [4] and novel recombinant DNA gene therapies [5]. These novel technologies have never been tested nor deployed in a wide scale manner on human subjects. The clinical trial process is being performed in parallel with mass deployment. As such long-term risks and side-effects of these novel products are unknown.

Risk of Antibody Dependent Enhancement (ADE) and a History of Failed Vaccine Development

Antibody Dependent Enhancement of disease is, in simple terms, when vaccine-induced antibodies enhance, or make worse, a viral infection when exposed to the virus after being vaccinated for it.

Previous vaccine trials for SARS-CoV-1 and MERS-CoV (coronaviruses similar to SARS-CoV-2) never made it past pre-clinical (or animal test stage) due to ADE.

ADE is a response to the wild virus in which vaccinated people (or animals) experience a hyper-immune response which sets off dangerous inflammatory processes of disease – basically, and ironically, creating the worst outcome for the disease among those who have been vaccinated. At least 130 children died in the Philippines in 2017 when an experimental vaccine against Dengue fever resulted in an explosive immune ADE reaction killing the children when they were exposed to wild Dengue virus after vaccination [6]. The fiasco led to government health officers being indicted and the pharmaceutical giant, Sanofi, yanking its vaccine – but not before more than 800,000 children had already been given the shots and left in danger of an ADE response to the circulating virus.

“COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE). This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.” [7]

Multiple studies [8] had warned of the repeated failures and dangers of a coronavirus vaccine that created an ADE response when vaccinated individuals encountered a wild virus. Yet there is no evidence that the deaths from COVID-19 in the fully vaccinated have been investigated to determine if they suffered from an ADE response to a wild coronavirus” [9]. Current monitoring methods would treat ADE as a Covid infection leading to a self-reinforcing cycle. Monitoring protocols should be adjusted to screen for ADE.

“It is not clear from the CDC data if the people who have become seriously ill, including those who have died of COVID infection following vaccination, are not experiencing a known side-effect of coronavirus vaccination that was warned about before the rollout began: antibody dependent enhancement” [7].

“There are several vaccine types currently being pursued including mRNA, DNA, recombinant protein, virus-like particle, and live-attenuated or killed virus. With the potential exception of live, attenuated virus vaccines, the general goal is to induce adaptive immune response resulting in high-affinity IgG against S (spike) or N (nucleotide) viral capsid proteins. However, unless care is taken to modify the protein sequences to remove or inactivate regions highly associated with ADE, if this is even possible, we may produce vaccines that enhance, rather than protect against, severe SARS-CoV-2 infection. This could be particularly problematic in children, with their reduced risk of severe infection.” [7]

Vaccine associated disease enhancement has been identified as an “important potential risk” in Pfizer’s most recent Cumulative Analysis of Post-EUA Adverse Event Reports (BNT162B2), specifically identifying Vaccine-Associated Enhanced Disease (VAED) and Vaccine-Associated Enhanced Respiratory Disease (VAERD) [10].

If ADE is occurring one result would be an increase in disease occurrence and/or severity among the vaccinated population. Note that an increase in disease occurrence coupled with non-sterilizing products (which do not prevent infection or transmission) places both vaccinated and unvaccinated at increased health risk.

“The specific and significant COVID-19 risk of ADE should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent.” [11]

The risks of Antibody Dependent Enhancement of disease should be fully disclosed as part of informed consent.

Risk of Resultant Autoimmune Conditions

The risk of long-term Auto-Immune conditions resulting from mRNA or recumbent DNA gene therapies or traditionally based COVID 19 vaccines is currently unknown.

For reference, an antigen is a substance (protein) that causes the immune system to produce antibodies and trigger an immune response. An epitope is a localized region on the surface of an antigen capable of eliciting an immune response and of combining with a specific antibody to counter that response. Full-length SARS-CoV-2 spike proteins contain epitopes that have moderate to strong cross-reactivity with a variety of human tissues.

“Razim et al. concluded that before considering a protein as a vaccine antigen, special care should be taken in analyzing the sequence of tissue cross-reactive epitopes in order to avoid possible future side effects. We agree with Razim et al., and we feel that our own findings that 21 out of 50 (human) tissue antigens had moderate to strong reactions with the SARS-CoV-2 antibodies are a sufficiently strong indication of cross-reaction between SARS-CoV-2 proteins and a variety of tissue antigens beyond just pulmonary tissue, which could lead to autoimmunity against connective tissue and the cardiovascular, gastrointestinal, and nervous systems.” [12]

“At the moment, scientists are frantically trying to develop either a definitive cure, neutralizing antibodies, or a vaccine to protect us from contracting the disease in the first place, and they want it right now. We must consider that finding a vaccine for a disease may normally take years. There are reasons for all the precautions involved in developing a vaccine, not the least of which are unwanted side-effects. In light of the information discussed above about the cross-reactivity of the SARS-CoV-2 proteins (antigens) with human tissues and the possibility of either inducing autoimmunity, exacerbating already unhealthy conditions, or otherwise resulting in unforeseen consequences, it would only be prudent to do more extensive research regarding the autoimmune-inducing capacity of the SARS-CoV-2 antigens.” [12]

The Pfizer BNT162B2, Moderna mRNA-1273 and Janssen Ad26.COV2.S products all encode for and produce full-length spike proteins.

The risk of resultant autoimmune conditions should be fully disclosed as part of informed consent.

Risk of degradation of innate immune system response

Recent medical research findings reveal that the SARS-CoV-2 full-length spike protein may impair adaptive immunity by inhibiting DNA damage repair. The Pfizer BNT162B2, Moderna mRNA-1273 and Janssen Ad26.COV2.S products all encode for and produce full-length spike proteins.

“Adaptive immunity plays a crucial role in fighting against SARS–CoV–2 infection and directly influences the clinical outcomes of patients. Clinical studies have indicated that patients with severe COVID–19 exhibit delayed

and weak adaptive immune responses; however, the mechanism by which SARS–CoV–2 impedes adaptive immunity remains unclear. Here, by using an in vitro cell line, we report that the SARS–CoV–2 spike protein significantly inhibits DNA damage repair, which is required for effective V(D)J recombination in adaptive immunity." [13]

"Our findings provide evidence of the spike protein hijacking the DNA damage repair machinery and adaptive immune machinery in vitro. We propose a potential mechanism by which spike proteins may impair adaptive immunity by inhibiting DNA damage repair. Although no evidence has been published that SARS–CoV–2 can infect thymocytes or bone marrow lymphoid cells, our in vitro V(D)J reporter assay shows that the spike protein intensely impeded V(D)J recombination. Consistent with our results, clinical observations also show that the risk of severe illness or death with COVID–19 increases with age, especially older adults who are at the highest risk. This may be because SARS–CoV–2 spike proteins can weaken the DNA repair system of older people and consequently impede V(D)J recombination and adaptive immunity. In contrast, our data provide valuable details on the involvement of spike protein subunits in DNA damage repair, indicating that full–length spike–based vaccines may inhibit the recombination of V(D)J in B cells, which is also consistent with a recent study that a full–length spike–based vaccine induced lower antibody titers compared to the RBD–based vaccine. This suggests that the use of antigenic epitopes of the spike as a SARS–CoV–2 vaccine might be safer and more efficacious than the full–length spike. Taken together, we identified one of the potentially important mechanisms of SARS–CoV–2 suppression of the host adaptive immune machinery. Furthermore, our findings also imply a potential side effect of the full–length spike–based vaccine." [13]

Note that a degradation of the innate immune system response may place the product recipient at increased risk for disease beyond Covid-19.

The risk of degradation of innate immune system response should be fully disclosed as part of informed consent.

Risk of Myocarditis, Pericarditis and/or other Acute Coronary Syndrome conditions

A recent JAMA study has shown that the 7-day risk of myocarditis following mRNA COVID vaccination is around 133 times greater than the background risk in young males [14].

The study, conducted by researchers from the U.S. Centers for Disease Control (CDC) as well as from several U.S. universities and hospitals, examined the effects of vaccination with products manufactured by Pfizer-BioNTech and Moderna. The study's authors used data obtained from the CDC's VAERS reporting system which were cross-checked to ensure they complied with CDC's definition of myocarditis; they also noted that given the passive nature of the VAERS system, the number of reported incidents is likely to be an underestimate of the extent of the phenomenon.

Table 2. Reports to VAERS After mRNA-Based COVID-19 Vaccination That Met the CDC's Case Definition for Myocarditis Within a 7-Day Risk Interval per Million Doses of Vaccine Administered

	Reported cases of myocarditis within a 7-d risk interval per million doses of vaccine administered (95% CI)[a]				Expected cases of myocarditis in a 7-d risk interval per million doses (95% CI)[c]
	Vaccination with BNT162b2		Vaccination with mRNA-1273[b]		
	First dose	Second dose	First dose	Second dose	
Males					
Age group, y					
12-15	7.06 (4.88-10.23)	70.73 (61.68-81.11)			0.53 (0.40-0.70)
16-17	7.26 (4.45-11.86)	105.86 (91.65-122.27)			1.34 (1.05-1.72)
18-24	3.82 (2.40-6.06)	52.43 (45.56-60.33)	10.73 (7.50-15.34)	56.31 (47.08-67.34)	1.76 (1.58,1.98)
25-29	1.74 (0.78-3.87)	17.28 (13.02-22.93)	4.88 (2.70-8.80)	24.18 (17.93-32.61)	1.45 (1.21-1.74)
30-39	0.54 (0.20-1.44)	7.10 (5.26-9.57)	3.00 (1.81-4.97)	7.93 (5.61-11.21)	0.63 (0.54.0.73)
40-49	0.55 (0.21-1.48)	3.50 (2.28-5.36)	0.59 (0.19-1.82)	4.27 (2.69-6.78)	0.78 (0.67-0.90)
50-64	0.42 (0.17-1.01)	0.68 (0.33-1.43)	0.62 (0.28-1.39)	0.85 (0.41-1.79)	0.77 (0.68-0.86)
≥65	0.19 (0.05-0.76)	0.32 (0.10-1.00)	0.18 (0.05-0.72)	0.51 (0.21-1.23)	
Females					
Age group, y					
12-15	0.49 (0.12-1.98)	6.35 (4.05-9.96)			0.17 (0.11-0.29)
16-17	0.84 (0.21-3.37)	10.98 (7.16-16.84)			0.42 (0.27-0.66)
18-24	0.18 (0.03-1.31)	4.12 (2.60-6.54)	0.96 (0.31-2.96)	6.87 (4.27-11.05)	0.38 (0.30-0.49)
25-29	0.26 (0.04-1.84)	2.23 (1.07-4.69)	0.41 (0.06-2.94)	8.22 (5.03-13.41)	0.48 (0.35-0.65)
30-39	0.72 (0.32-1.60)	1.02 (0.49-2.14)	0.74 (0.28-1.98)	0.68 (0.22-2.10)	0.47 (0.39-0.57)
40-49	0.24 (0.06-0.97)	1.73 (0.98-3.05)	0.18 (0.02-1.25)	1.89 (0.98-3.63)	0.89 (0.77-1.04)
50-64	0.37 (0.15-0.88)	0.51 (0.23-1.14)	0.65 (0.31-1.36)	0.43 (0.16-1.15)	1.00 (0.89-1.13)
≥65	0.08 (0.01-0.54)	0.35 (0.13-0.92)		0.26 (0.08-0.81)	

Figure 2: Reports to VAERS after mRNA-Based Covid-19 Vaccination That Met the CDC's Case Definition for Myocarditis Within a 7-day Risk Interval per Million Doses of Vaccine Administered [14]

From Figure 2 above (Table 2: Reports to VAERS after mRNA-Based Covid-19 Vaccination that met the CDC's case definition for myocarditis withing a 7-day risk interval per million doses of vaccine administered)

Males, Age Group 12-15, vaccination with BNT162b2 (Pfizer):

- Second Dose: 70.73 (Reported cases of myocarditis per million doses administered)
- Expected Cases : 0.53 (background rate of myocarditis in this age/sex group, 2017-2019)

70.73/0.53 = 133.45 or 133 times the background rate

A recent study suggests that the presence of the full-length spike protein alone may be sufficient to cause cardiovascular damage.

"It was found that the treatment of cultured primary human pulmonary artery smooth muscle cells (SMCs) or human pulmonary artery endothelial cells with the recombinant SARS-CoV-2 spike protein S1 subunit is sufficient to promote cell signaling (cellular changes) without the rest of the viral components [15]. Furthermore, our analysis of the postmortem lung tissues of patients who died of COVID-19 has determined that these patients exhibited pulmonary vascular wall thickening, a hallmark of pulmonary arterial hypertension (PAH) [15]. Based on these results, we proposed that the SARS-CoV-2 spike protein (without the rest of the viral

components) triggers cell signaling events that may promote pulmonary vascular remodeling and PAH as well as possibly other cardiovascular complications [15], [16].” [17]

“Recent observations suggest that the SARS-CoV-2 spike protein can by itself trigger cell signaling that can lead to various biological processes. It is reasonable to assume that such events, in some cases, result in the pathogenesis of certain diseases.

Our laboratory only tested the effects of the SARS-CoV-2 spike protein in lung vascular cells and those implicated in the development of PAH. However, this protein may also affect the cells of systemic and coronary vasculatures, eliciting other cardiovascular diseases such as coronary artery disease, systemic hypertension, and stroke. In addition to cardiovascular cells, other cells that express ACE2 have the potential to be affected by the SARS-CoV-2 spike protein, which may cause adverse pathological events. Thus, it is important to consider the possibility that the SARS-CoV-2 spike protein produced by the new COVID-19 vaccines triggers cell signaling events that promote PAH, other cardiovascular complications, and/or complications in other tissues/organs in certain individuals (Figure 3). We will need to monitor carefully the long-term consequences of COVID-19 vaccines that introduce the spike protein into the human body.” [17]

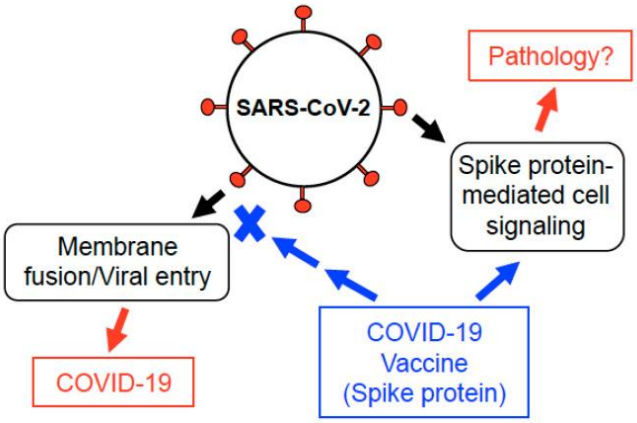

Figure 3: Possible actions of the SARS-CoV-2 spike protein. [17]

“The SARS-CoV-2 spike protein of the intact virus targets ACE2 of the host cells to facilitate the membrane fusion and the viral entry. The SARS-CoV-2 spike protein also elicits cell signaling in human cells [15], [18]. COVID-19 vaccines introduce the spike protein into the human body. In addition to eliciting an immune response that suppresses the viral entry, the spike protein produced by the COVID-19 vaccines may also affect the host cells, possibly triggering adverse events. Further investigations addressing this possibility are warranted [16].” [17]

The Pfizer BNT162B2, Moderna mRNA-1273 and Janssen Ad26.COV2.S products all encode for and produce full-length spike proteins.

A recent presentation by the Canadian Covid Care Alliance, a group of over 500 independent Canadian doctors, scientists and health care practitioners echoed these concerns about myocarditis in youth and athletes. That presentation is attached as Appendix B.

The risk of developing heart inflammation, and associated heart muscle damage, should be fully disclosed as part of informed consent.

Risk of other Short- and Long-Term Side Effects

Established in 1990, the Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

The following short-term adverse events have been reported via the Vaccine Event Reporting System (VAERS) as related to novel COVID 19 mRNA and recumbent gene therapies as of February 25, 2022 [19]:

- Total Covid Vaccine Data Reports (1,151,448)
- Deaths (24,827)
- Hospitalizations (135,783)
- Urgent Care Visits (121,670)
- Doctor Office Visits (178,014)
- Severe Allergic Reaction (40,382)
- Life Threatening (28,349)
- Heart Attack (12,731)
- Myocarditis/Pericarditis (35,303)
- Bell's Palsy (14,364)
- Anaphylaxis (9,335)
- Thrombocytopenia/Low Platelet (5,812)
- Miscarriages (4,209)
- Shingles (12,701)
- Permanent Disability (45,615)

Adverse events are underreported VAERS as typically only a fraction of total adverse events are entered into VAERS. "VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting. Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed." [20]

Given the level of under reporting that is known to occur in VAERS [20] the question is raised: Do the adverse events reported above [19] represent the extent of these issues or are they simply the tip of an iceberg?

Figure 4 illustrates annual deaths reported to VAERS since its inception in 1990.

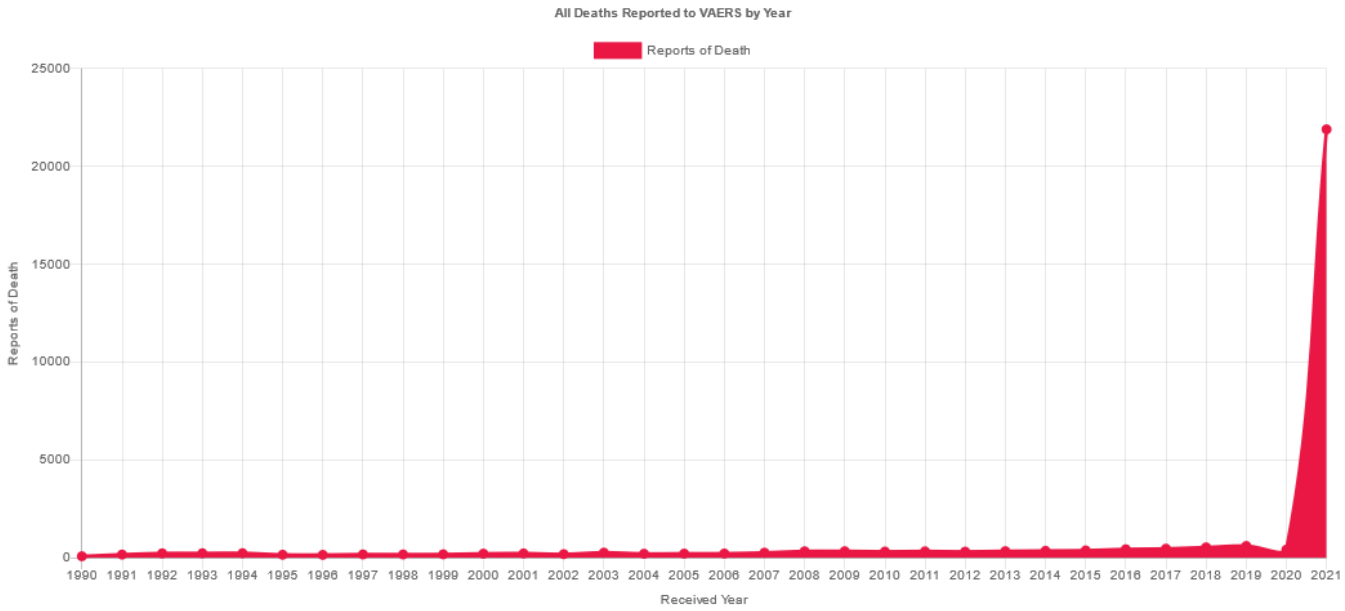

Figure 4: All Deaths Reported to VAERS by Year [19]

Figure 5 illustrates VAERS Covid Vaccine reports of death as a function of days to death onset post vaccination. Note that the majority of deaths occur within the first 3 days post vaccination. This implies a causal relationship.

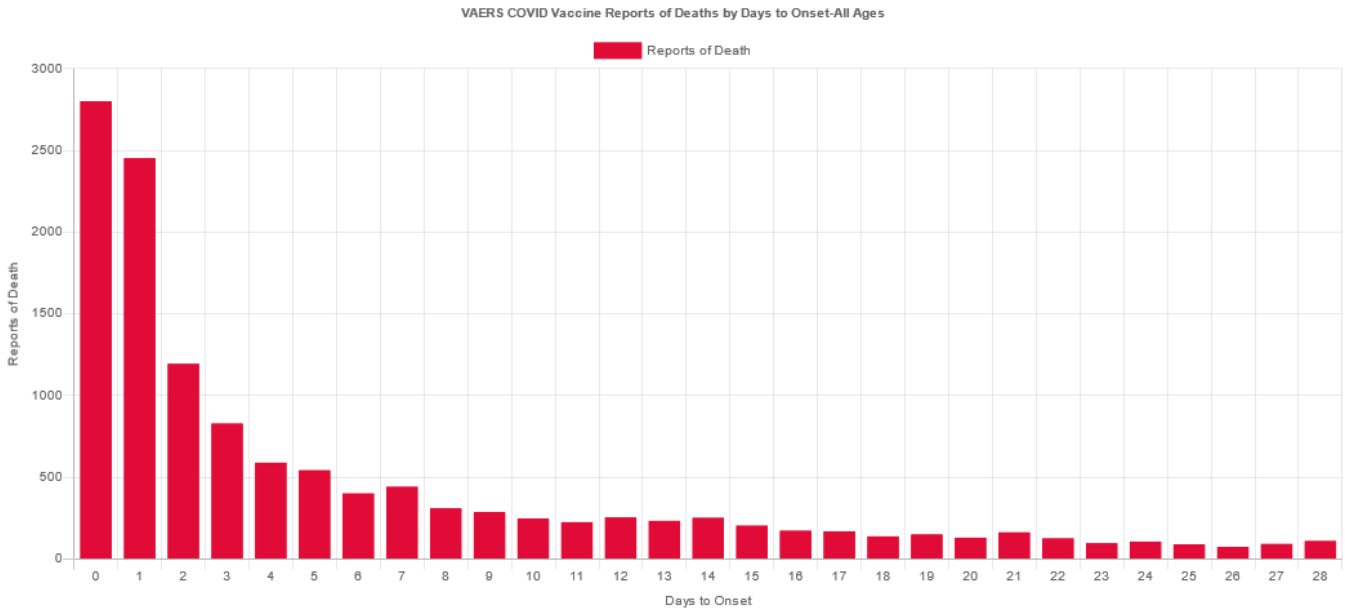

Figure 5: VAERS COVID Vaccine Reports of Deaths by Days to Onset – All Ages [19]

A collection of medical journal articles associated with adverse events observed to date associated with these novel Covid-19 products is included as Appendix A: Sampling of Covid-19 vaccination associated Adverse Events (AEs). Note that these Adverse Events are short-term. The Long-Term safety profiles of these novel products have not been determined.

The risk of short-term adverse events should be fully disclosed as part of informed consent.

Novel products do not prevent infection or transmission of SARS-CoV-2

A recent report published in the European Journal of Epidemiology evaluating cases per million people across 68 countries shows a slightly increase in new Covid-19 cases associated with countries having a higher percentage of population fully vaccinated [21]. For a sterilizing vaccine (one that prevents infection and transmission) a decreasing trend in cases with increasing vaccination rates would be expected.

"At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 6). In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people. Notably, Israel with over 60% of their population fully vaccinated had the highest COVID-19 cases per 1 million people in the last 7 days." [21]

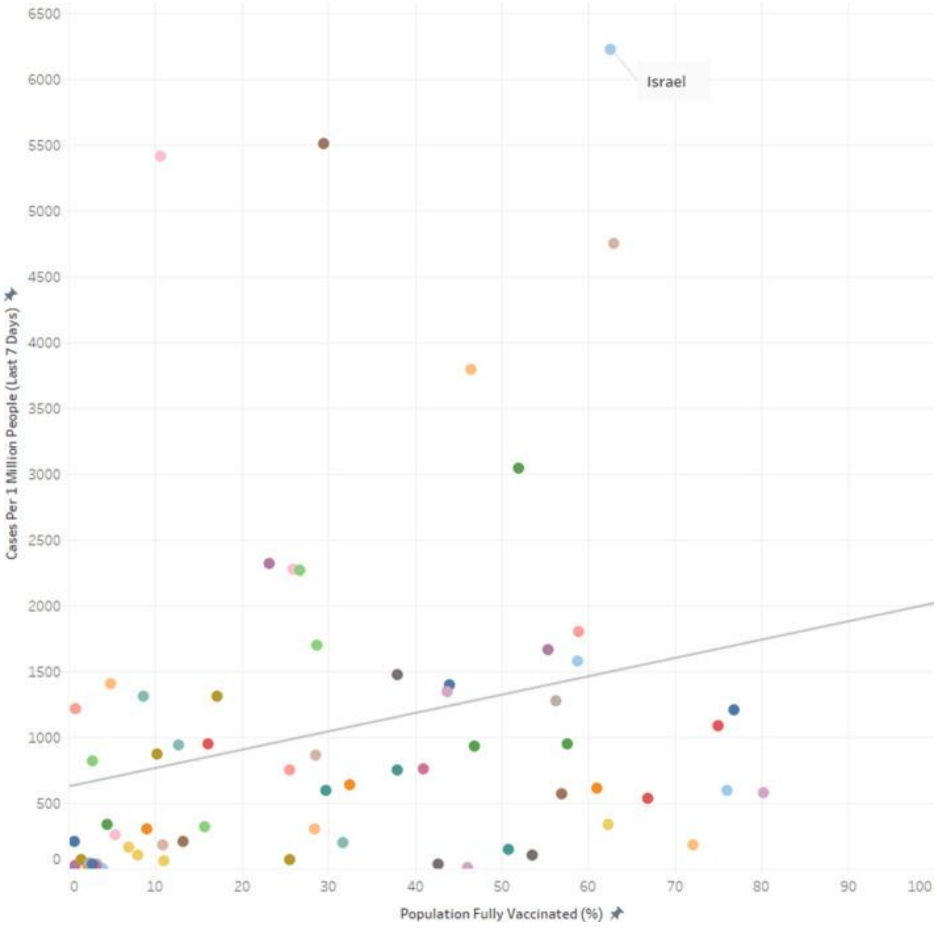

Figure 6: Relationship between cases per 1 million people (last 7 days) and percentage of population fully vaccinated across 68 countries as of September 3, 2021 [21].

The risk of infection and transmission post-vaccination should be fully disclosed as part of informed consent.

Waning product efficacy and "booster" doses

A recent study out of Israel illustrates that immune escape variants readily spread among a highly vaccinated population only 4 to 6 months post vaccination.

"A nosocomial (hospital) outbreak of SARS-CoV-2 Delta variant infected 42 patients, staff and family members; 39 were fully vaccinated. The attack rate was 10.6% (16/151) among exposed staff and reached 23.7% (23/97) among exposed patients in a highly vaccinated population, 16–26 weeks after vaccination (median: 25 weeks). All cases were linked and traced to one patient. Several transmissions occurred between individuals wearing face masks. Fourteen of 23 patients became severely sick or died, raising a question about possible waning immunity" [22]

The mitigation strategy for waning product efficacy thus far has been to focus on additional "booster" doses of the original Pfizer, Moderna and Johnson & Johnson products, products that were developed to induce an immune response to target the initial "Wuhan" strain spike proteins of SARS-CoV-2. As a result of this selective immune pressure the early Wuhan strains have effectively gone extinct (Figure 7, B.1.1.7, B.1.526 and P.1) while the immune escape variants (Delta strains, B.1.617.2 and AY.3) largely bypass the initial protection afforded by these products. Note that this all happened over a period of just 3 months. "Boosting" again with the product formulations for the Wuhan strain appears to be a case of chasing diminishing returns when Delta has already achieved immune escape against this formulation. Unless a vaccine is sterilizing the virus will continue to mutate and spread. This process is repeating with Omicron now rapidly replacing Delta as the dominant strain.

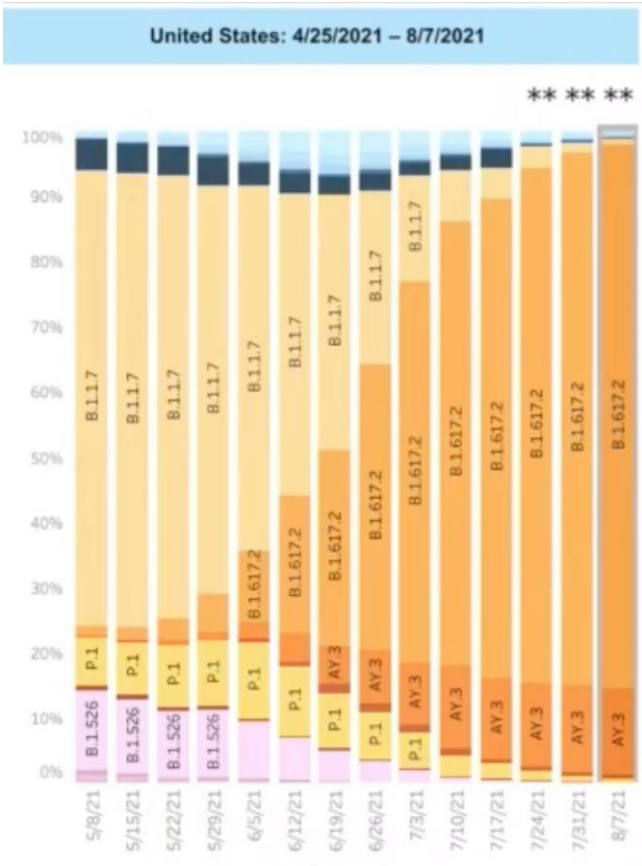

Figure 7: Delta strain immune escape variant becomes dominate in the U.S. (B.1.617.2) (credit P.M., MD)

Non-sterilizing products (which do not prevent infection or transmission) coupled with an increase in disease occurrence driven by immune escape variants place both vaccinated and unvaccinated at increased health and safety risk of contracting Covid-19.

Waning product efficacy post-vaccination should be fully disclosed as part of informed consent.

Novel products do not reduce viral load of SARS-CoV-2

A recent study out of Wisconsin compared RT-PCR cycle threshold (Ct) data from 699 test-positive anterior nasal swab specimens from fully vaccinated (n = 310) and unvaccinated (n=389) individuals. They focused on low cycle thresholds (less than 25 cycles). RT-PCR cycle threshold values less 25 have previously been associated with shedding of infectious SARS-CoV-2.

"We observed low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Low Ct values were detected in vaccinated people regardless of symptoms at the time of testing. Ct values <25 were detected in "158 of 232 unvaccinated (68%, CI: 62-74%) and 156 of 225 fully vaccinated (69%; CI: 63-75%) symptomatic individuals." [23]

The viral loads they observed were effectively the same regardless of vaccination status.

As these studies show no reduction in infection rates, transmission rates or symptomatic viral load between vaccinated and unvaccinated, they illustrate little if any collective benefit associated with these novel products.

Incomplete and compromised long-term Safety and Efficacy trials

Clinical trials are ongoing and not scheduled to complete until 2023 [24], [25], [26].

In several trials the control subjects have been unblinded and offered the novel products. This has effectively tainted the control group and compromised the validity of these trails [24], [25].

"Participants who originally received placebo will be offered the opportunity to receive BNT162b2 (Pfizer-BioNTech) at defined points as part of the study" [24].

"Participants who were previously enrolled in the mRNA-1273-P301 (Moderna) study, and chose to be unblinded. [25]"

This unblinding of the placebo (control) groups is illustrated in Figures 8 and 9 for the Pfizer trial.

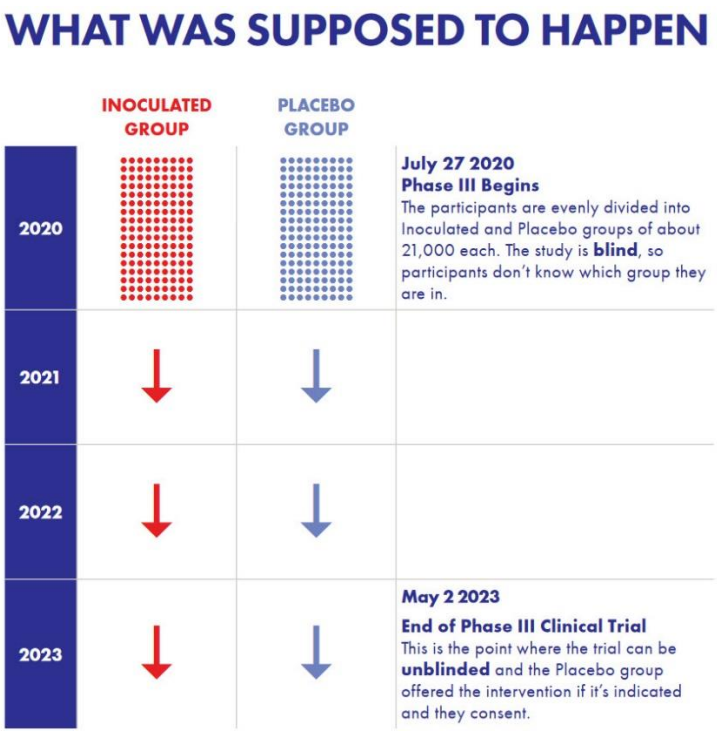

Figure 8: Pfizer clinical trial as originally planned [27]

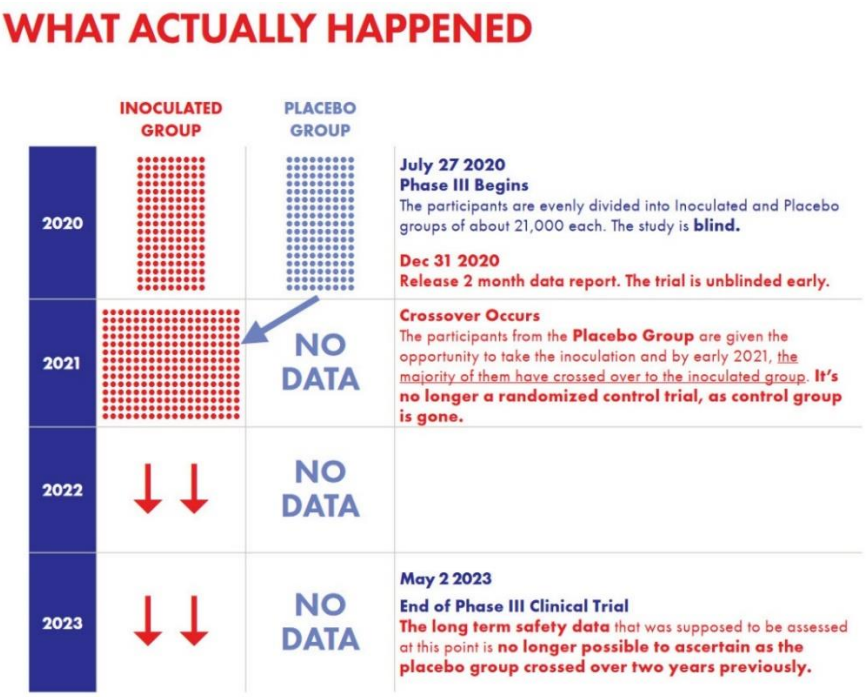

Figure 9: Pfizer clinical trial as executed [27]

The unblinding of the Randomized Clinical Trials (RCTs) should be fully disclosed as part of informed consent.

FDA Approved Comirnaty versus the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA

By approving BioNTech product Comirnaty, which is currently available in Europe but unavailable in the Washington State [28] the FDA may have inadvertently given the impression that the available Pfizer (BNT162b2) product is FDA approved when in fact it's EUA has simply been extended.

"The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series. The licensed vaccine 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.* [1] "

From the FDA Letter of Authorization to Pfizer dated January 3, 2022, Section I [28]:

> Criterion for Issuance of Authorization, Paragraph C: "There is no adequate, approved, and available alternative[19] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19."
>
> Note 19: "Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no COVID-19 vaccines that are approved to provide: COVID-19 vaccination in individuals 5 through 15 years of age; a third primary series dose to certain immunocompromised populations described in this EUA; a homologous booster dose to the authorized population described in this EUA; or a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine."

The legal difference is that "Comirnaty" is FDA approved for interstate commerce and marketing while the Pfizer (BNT162b2) product is still under Emergency Use Authorization (EUA). Under the 2005 Public Readiness and Emergency Preparedness (PREP) Act vaccine manufacturers have full legal and financial immunity from any injury or damages incurred resulting from an EUA product [29]. From a legal perspective this means that all of the other EUAs issued for Moderna, J&J, etc. can remain in force as the EUA nullification conditions of (a) FDA approval and (b) product availability in the US have not been met with the BioNTech Corminaty product. If an FDA Approved and *available* product to treat Covid-19 were to come onto the US market it would legally nullify all other active EUAs [30]. This also means that currently all of the EUA products retain full legal and financial immunity for their manufacturers.

At this time the Moderna product is being approved under the trade name "SpikeVax". It is anticipated that this product will not be made initially available in the US market in a similar fashion to Corminaty, and that the available Moderna product will remain under EUA for the foreseeable future.

Lack of FDA Approved and Licensing for products currently available in Washington State

None of these novel products currently available in the Washington State are FDA approved nor licensed, rather these have been authorized under Emergency Use Authorization (EUA). An EUA is a legal designation that allows

for the distribution of an experimental treatment or other medical agent prior to completion of clinical safety and efficacy trials and thus prior to formal FDA Approval. An EUA is not the same as an FDA approval or FDA Licensing [30].

As long-term clinical safety trials are incomplete and compromised (unblinded), and as the long-term (multi-year) safety profiles have yet to be established, these novel medical products are, by definition, experimental in nature.

The Nuremburg Code and Voluntary Informed Consent

"The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a code that is now accepted worldwide.

This judgment established a new standard of ethical medical behavior for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of voluntary informed consent of the human subject. *The principle of voluntary informed consent protects the right of the individual to control his own body*." [31]

1. "The voluntary consent of the human subject is *absolutely essential.*

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to *exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion*; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; *all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment*.

The duty and responsibility for ascertaining the quality of the consent rests upon *each individual who initiates, directs or engages* in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity." [32]

United Nations (UNESCO) Universal Declaration on Bioethics and Human Rights

From the UN Universal Declaration of Human Rights, Article 6, Section 1 [33]."Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice."

Summary

In summary the following concerns are raised with respect to these novel mRNA and recumbent DNA gene therapy products:

1) These novel Covid-19 products do not prevent Covid-19 infection.

2) These novel Covid-19 products do not prevent SARS-CoV-2 transmission.

3) What personal (non-collective) benefit these products do provide wanes rapidly over the course of months necessitating booster doses. The boosters are currently still "tuned" to the original formula for the Wuhan strain of SARS-CoV-2, which is now effectively extinct in the wild. Boosting against new variants (Delta, Omicron) that have already immune escaped the initial strain protection stands to be a case study in diminishing returns. Boosting with updated formulation(s) against these immune escape variants will drive new variants (wash, rinse, repeat).

4) Significant severe short term adverse effects (including death) have been reported via VAERS [19], medical journals (see Appendix A, attached) and are documented in the Pfizer Post-Authorization Analysis (which includes 9 pages of Adverse Events of Special Interest) [10]. Repeated doses may have a cumulative effect (majority of myocarditis cases in young men occur within 7 days of the 2nd dose of Covid-19 mRNA product administration) [14]. The concern is raised that these novel products place recipients at risk of significant health and financial harm based on the observed short term side effects and a history of failed vaccine development attempts for this family of viruses.

5) Long term side effects are unknown, however early evidence is suggestive of Antibody Dependent Enhancement of Disease (ADE), Vaccine Associated Enhanced Disease (VAED), downgrading of the innate immune system in favor of spike protein specific antibody development (original antigenic sin) which viral variants have already found a way around (immune escape) and the potential of long term consequences of vaccine induced endotheliitis (myocarditis and pericarditis).

6) The concern is raised that the vaccinated population may be at increasing risk of catching and transmitting SARS-CoV-2 variants due to ADE/VAED [10], [11]. Non-sterilizing products (products which do not prevent infection or transmission) coupled with an increase in disease occurrence driven by immune escape variants place both vaccinated and unvaccinated at increased risk of Covid-19.

7) Under EUA law [29] the product manufacturers are immune from legal and financial responsibility for any adverse health effects or associated damages. Legal and financial liability for any short or long-term adverse events associated with the incentivization of these novel products is unclear, and may ultimately fall on those individuals and organizations incentivizing, coercing and/or mandating their usage.

8) Given the observed short-term adverse events and the lack of long-term safety data, the mandating of novel Covid-19 gene therapies for students as a condition of public school attendance may ultimately be adjudicated as medical coercion in violation of Informed Consent.

9) The concern is raised that Fully Informed Consent is not being provided and attained during the administration of these experimental EUA products, and that legal and lawful action may be brought against those who fail to adequately and fully disclose the risks identified in this document as a necessary part of Fully Informed Consent [30]. The same applies to individuals or organizations that

initiate or direct people to engage in these medical experiments. Where this is medical risk there must be free choice (Nuremburg, UNESCO).

Dated this the 8TH day of MARCH, 2022.

Kenneth D. Kay III

Signature of Affiant

SWORN to and subscribed before me, this the 8 day of March, 2022.

DIANE C FULTON
NOTARY PUBLIC
STATE OF WASHINGTON
COMMISSION EXPIRES
33920
04-02-25

Diane C Fulton

Notary Public

My commission expires April 2, 2025.

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Appendix A

Sampling of Covid-19 vaccination associated Adverse Events (AEs) observed to date

1. Cerebral venous thrombosis after COVID-19 vaccination in the UK: a multicentre cohort study: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01608-1/
2. Vaccine-induced immune thrombotic thrombocytopenia with disseminated intravascular coagulation and death after ChAdOx1 nCoV-19 vaccination: https://www.sciencedirect.com/science/article/pii/S1052305721003414
3. Fatal cerebral hemorrhage after COVID-19 vaccine: https://pubmed.ncbi.nlm.nih.gov/33928772/
4. Myocarditis after mRNA vaccination against SARS-CoV-2, a case series: https://www.sciencedirect.com/science/article/pii/S2666602221000409
5. Three cases of acute venous thromboembolism in women after vaccination against COVID-19: https://www.sciencedirect.com/science/article/pii/S2213333X21003929
6. Acute thrombosis of the coronary tree after vaccination against COVID-19: https://www.sciencedirect.com/science/article/abs/pii/S1936879821003988
7. US case reports of cerebral venous sinus thrombosis with thrombocytopenia after vaccination with Ad26.COV2.S (against covid-19), March 2 to April 21, 2020: https://pubmed.ncbi.nlm.nih.gov/33929487/
8. Portal vein thrombosis associated with ChAdOx1 nCov-19 vaccine: https://www.thelancet.com/journals/langas/article/PIIS2468-1253(21)00197-7/
9. Management of cerebral and splanchnic vein thrombosis associated with thrombocytopenia in subjects previously vaccinated with Vaxzevria (AstraZeneca): position statement of the Italian Society for the Study of Hemostasis and Thrombosis (SISET): https://pubmed.ncbi.nlm.nih.gov/33871350/
10. Vaccine-induced immune immune thrombotic thrombocytopenia and cerebral venous sinus thrombosis after vaccination with COVID-19; a systematic review: https://www.sciencedirect.com/science/article/pii/S0022510X21003014
11. Thrombosis with thrombocytopenia syndrome associated with COVID-19 vaccines: https://www.sciencedirect.com/science/article/abs/pii/S0735675721004381
12. Covid-19 vaccine-induced thrombosis and thrombocytopenia: a commentary on an important and practical clinical dilemma: https://www.sciencedirect.com/science/article/abs/pii/S0033062021000505
13. Thrombosis with thrombocytopenia syndrome associated with COVID-19 viral vector vaccines: https://www.sciencedirect.com/science/article/abs/pii/S0953620521001904
14. COVID-19 vaccine-induced immune-immune thrombotic thrombocytopenia: an emerging cause of splanchnic vein thrombosis: https://www.sciencedirect.com/science/article/pii/S1665268121000557
15. The roles of platelets in COVID-19-associated coagulopathy and vaccine-induced immune thrombotic immune thrombocytopenia (covid): https://www.sciencedirect.com/science/article/pii/S1050173821000967
16. Roots of autoimmunity of thrombotic events after COVID-19 vaccination: https://www.sciencedirect.com/science/article/abs/pii/S1568997221002160
17. Cerebral venous sinus thrombosis after vaccination: the United Kingdom experience: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01788-8/fulltext

18. Thrombotic immune thrombocytopenia induced by SARS-CoV-2 vaccine: https://www.nejm.org/doi/full/10.1056/nejme2106315
19. Myocarditis after immunization with COVID-19 mRNA vaccines in members of the US military. This article reports that in "23 male patients, including 22 previously healthy military members, myocarditis was identified within 4 days after receipt of the vaccine": https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601
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Appendix B

More Harm Than Good

Presentation by the Canadian Covid Care Alliance, December 16, 2021

www.canadiancovidcarealliance.org

THE PFIZER INOCULATIONS FOR COVID-19

MORE HARM
THAN GOOD

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

Contact us
info@canadiancovidcarealliance.org
www.canadiancovidcarealliance.org

WHO WE ARE

Our alliance of **over 500 independent Canadian doctors, scientists, and health care practitioners** is committed to providing quality, balanced, evidence-based information to the Canadian public about COVID-19 so that hospitalizations can be reduced, lives saved, and our country safely restored to normal as quickly as possible.

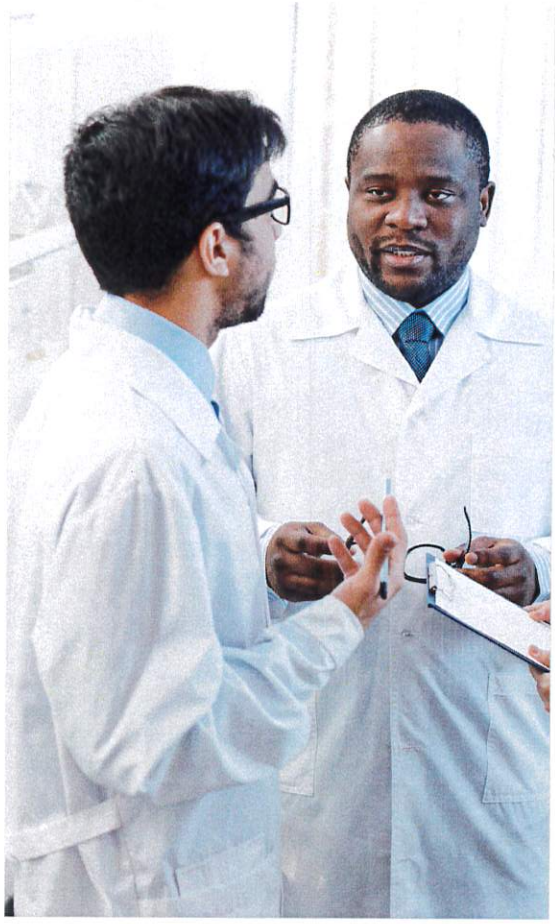
WE SUPPORT

The doctor/patient relationship and personalized care

Informed consent and treatment options

Free and open **scientific discourse**

Safe & effective vaccines

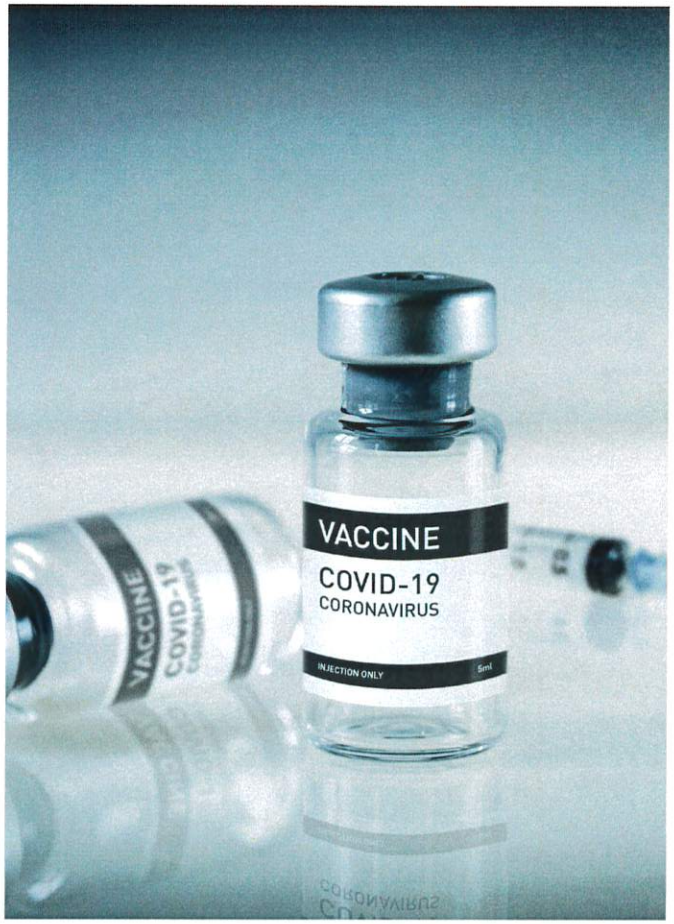


FIRST, DO NO HARM

The federal, provincial and municipal governments in Canada have a **responsibility to protect the health of Canadians as well as our Charter Rights and Freedoms. Any medical interventions approved by Health Canada must first be PROVEN SAFE.**

Due diligence in research, as well as **adherence to established protocols of the doctor/patient relationship, informed consent and scientific inquiry** are essential to carrying out that responsibility.

Deviating from those practices, causing harm and failing to disclose risks of harm is negligent at best.

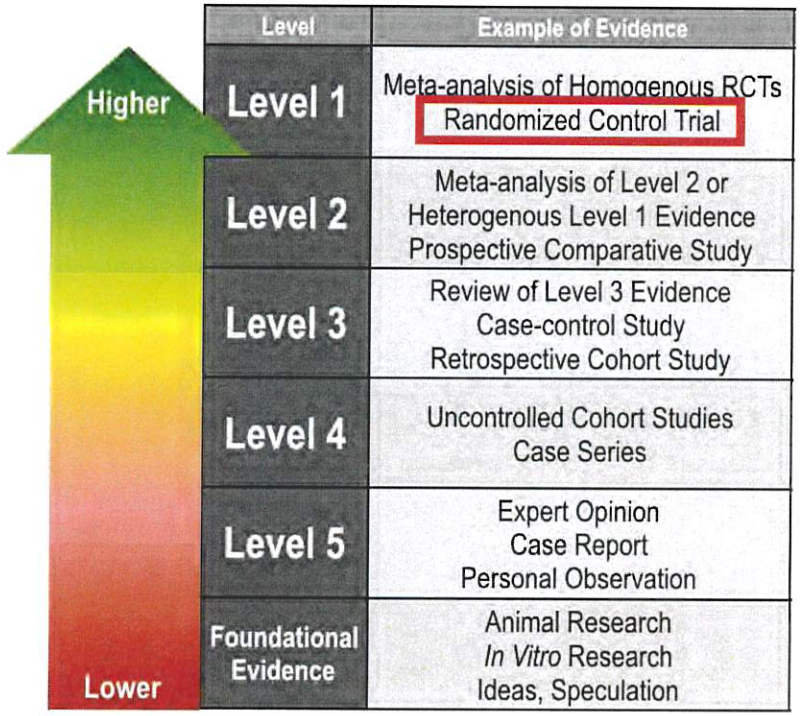


OVERVIEW

THE HIERARCHY OF EVIDENCE

- **A randomized control trial is LEVEL 1 Evidence**, the highest form of evidence there is. It is considered the Gold Standard and is the only way to prove something is true.
- **Models are LEVEL 5 or lower** as they are expert opinion/speculation.
- **Policy should be determined by the highest level of evidence available, LEVEL 1.**

Levels of Scientific Evidence



PFIZER'S ORIGINAL TRIAL REPORT DECEMBER 31 2020

- Published in New England Journal of Medicine
- Showed **2 months worth of safety & efficacy data**
- Described starting with 43,548 people divided into:
  1. **Treatment group** (received inoculation)
  2. **Control group** (received saline)
     for 2 months to see who developed COVID-19
- The claim was that the inoculations were safe and showed **95% efficacy 7 days after the 2nd dose**. But that 95% was actually **Relative Risk Reduction. Absolute Risk Reduction** was only **0.84%.**

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

F.P. Polack, et al. DOI: 10.1056/NEJMoa2034577

CLINICAL PROBLEM

Safe and effective vaccines to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and Covid-19 are urgently needed. No vaccines that protect against betacoronaviruses are currently available, and mRNA-based vaccines have not been widely tested.

CLINICAL TRIAL

A randomized, double-blind study of an mRNA vaccine encoding the SARS-CoV-2 spike protein.

43,548 participants ≥16 years old were assigned to receive the vaccine or placebo by intramuscular injection on day 0 and day 21. Participants were followed for safety and for the development of symptomatic Covid-19 for a median of 2 months.

RESULTS

Safety:
Vaccine recipients had local reactions (pain, erythema, swelling) and systemic reactions (e.g., fever, headache, myalgias) at higher rates than placebo recipients, with more reactions following the second dose. Most were mild to moderate and resolved rapidly.

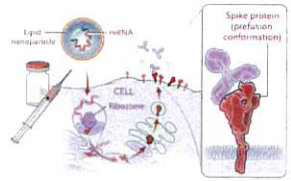
Efficacy:
The vaccine showed protection 7 days after the second dose; 95% efficacy was observed.

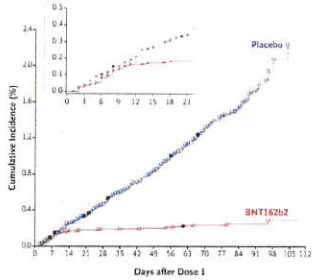
LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

Links: Full article | Quick Take | Editorial



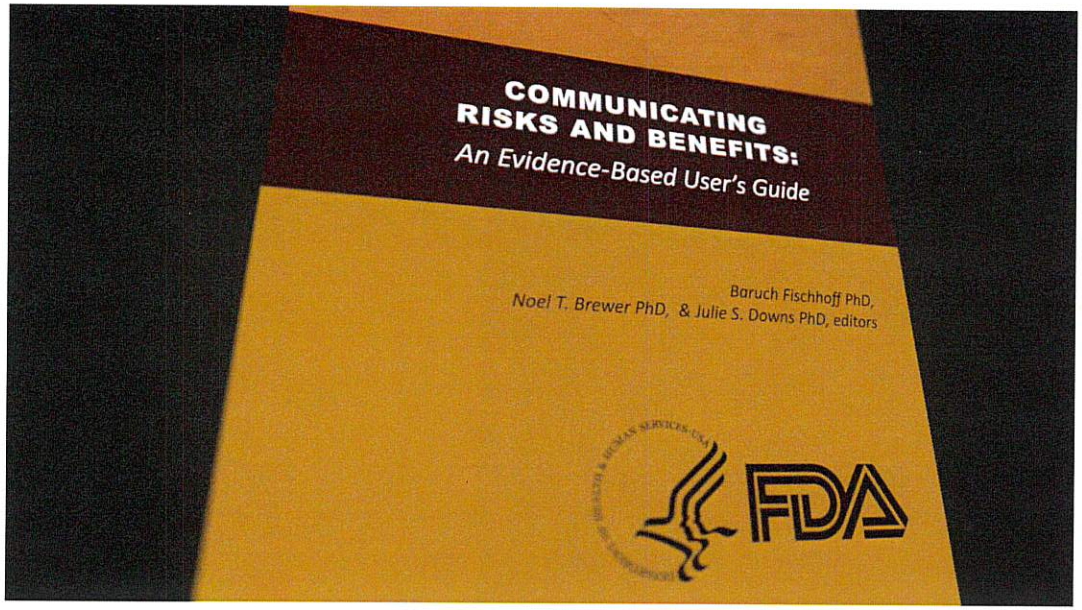


Vaccine efficacy of 95% (95% credible interval, 90.3 –97.6%)

CONCLUSIONS

Two doses of an mRNA-based vaccine were safe over a median of two months and provided 95% protection against symptomatic Covid-19 in persons 16 years of age or older.

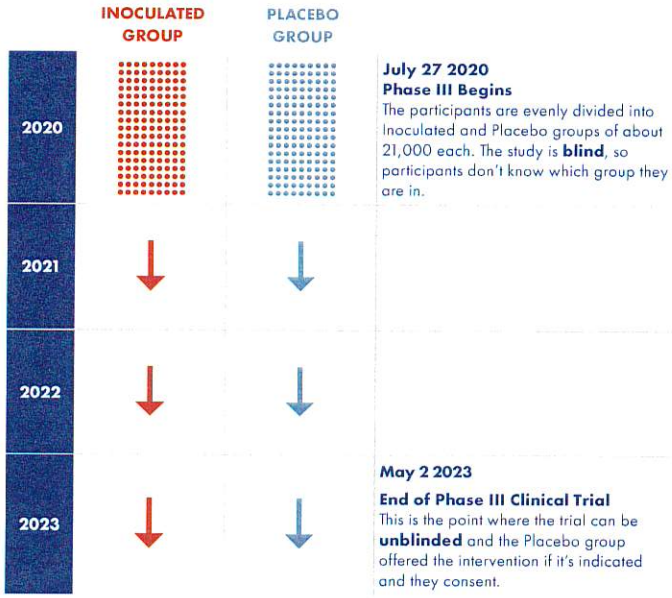
ABSOLUTE RISK REDUCTION VS RELATIVE RISK REDUCTION



https://rumble.com/vobcg5-relative-vs-absolute-risk-reduction.html

EARLY UNBLINDING OF RANDOMIZED CONTROL TRIAL = NO LONG TERM SAFETY DATA

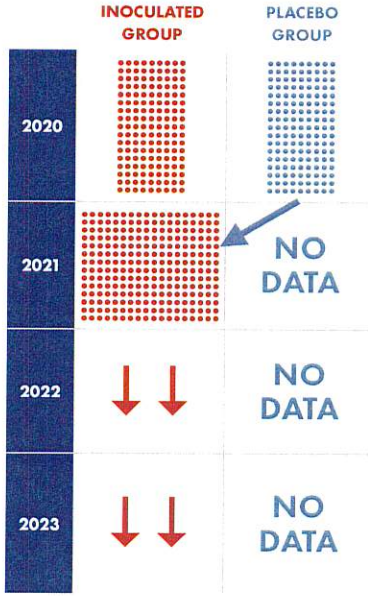
WHAT WAS SUPPOSED TO HAPPEN



July 27 2020
Phase III Begins
The participants are evenly divided into Inoculated and Placebo groups of about 21,000 each. The study is **blind**, so participants don't know which group they are in.

May 2 2023
End of Phase III Clinical Trial
This is the point where the trial can be **unblinded** and the Placebo group offered the intervention if it's indicated and they consent.

WHAT ACTUALLY HAPPENED



July 27 2020
Phase III Begins
The participants are evenly divided into Inoculated and Placebo groups of about 21,000 each. The study is **blind.**

Dec 31 2020
Release 2 month data report. The trial is unblinded early.

Crossover Occurs
The participants from the **Placebo Group** are given the opportunity to take the inoculation and by early 2021, the majority of them have crossed over to the inoculated group. **It's no longer a randomized control trial, as control group is gone.**

May 2 2023
End of Phase III Clinical Trial
The long term safety data that was supposed to be assessed at this point is **no longer possible to ascertain as the placebo group crossed over two years previously.**

PFIZER'S 6 MONTH REPORT DATA
LEVEL 1 EVIDENCE OF HARM

- Pfizer's most recent report indicates an **Efficacy of 91.3%**. (Which means **a reduction in positive cases** compared to placebo group.)
- **But it also showed**, compared to the placebo group, **an increase in illness and deaths.**
- There is **no benefit to a reduction in cases** if it comes at the cost of **increased sickness and death.**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

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ABSTRACT

BACKGROUND
BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS
In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS
BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS
Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Dormitzer can be contacted at philip.dormitzer@pfizer.com or at Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

*A list of the investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on September 15, 2021, at NEJM.org.

N Engl J Med 2021;385:1761-73.
DOI: 10.1056/NEJMoa2110345

CME at NEJM.org

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110345?articleTools=true

INCREASED RISK OF ILLNESS

Screen capture from Pfizer 6 Month Supplementary Appendix

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥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 ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months - Supplementary Appendix

*A **significant increase in illness,** which the Pfizer inoculations were supposed to reduce.*

	BNT162b2	Placebo	Risk Change
Efficacy (Meaning number of people diagnosed with COVID-19.)	77	850	**-91%**
Related Adverse Event (Meaning an investigator has assessed it as related to the BNT162b2 injection.)	5,241	1,311	**+300%**
Any Severe Adverse Event (Interferes significantly with normal function.)	262	150	**+75%**
Any Serious Adverse Event (Involves visit to ER or hospitalization.)	127	116	**+10%**

INCREASED RISK OF DEATH

Screen capture from Pfizer 6 Month Supplementary Appendix

Reported Cause of Death*	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months - Supplementary Appendix

	BNT162b2	Placebo
Deaths before unblinding (In Table S4 of Supplementary Appendix)	15	14
Deaths after unblinding (Not in table, but mentioned in text of 6 month report. See quote below.)	5	
Total Deaths	**20**	**14**

"After unblinding" means when the Placebo participants were given the opportunity to "cross over" and take the BNT162b2 inoculation.*

"...3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died."

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

Concerning Causes of Death

	BNT162b2	Placebo
Total COVID-19 Related Deaths	1	2
Deaths Related to Cardiovascular Events	9	5

* A total of 19,525 subjects originally randomized to placebo received at least one dose of BNT162b2 after unblinding (Dose 3 and Dose 4) and before the March 13, 2021 data cutoff

THE PFIZER TRIALS

WHAT WENT WRONG

PFIZER DID NOT FOLLOW ESTABLISHED PROTOCOLS

Regarding the persistent claim that the COVID-19 inoculation products do not need to be tested, because mRNA technology has already undergone testing: mRNA technology is the delivery mechanism, not the inoculation. That's like saying that since we've used syringes safely before, anything injected via syringe is safe. (And in fact, there are still a lot of unknowns about the effects of the mRNA delivery mechanism.)

NORMALLY, VACCINE DEVELOPMENT LOOKS LIKE THIS, WITH A TIMELINE OF 5 TO 10 YEARS.

RARELY, IT CAN BE DONE IN AS LITTLE AS 5 YEARS.

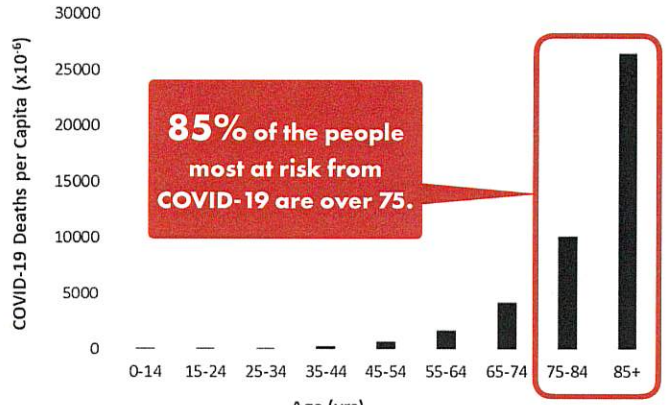
FOR THE COVID-19 INOCULATIONS, IT WAS DONE IN 1 YEAR.

- Animal testing was skipped
- Phases II/III were combined
- After 2 months of Phase II/III, Emergency Use Authorized
- The trials were unblinded
- Phase III trials are ongoing until 2023

MISLEADING DEMOGRAPHICS
WRONG AGE FOR TARGET POPULATION

When designing a trial for the efficacy and safety of a potential treatment, **the focus should be on the target population who could most benefit from that treatment.** Instead Pfizer chose participants from younger demographic that would be a) less likely to need a vaccine, b) less likely to suffer an adverse event during a trial, c) more likely to respond well to a vaccine, as the elderly have comparatively poor immune responses.

Actual Risk of Death by Age from COVID-19



COVID-19 Deaths per capita by age in the United States (as of Jun 5, 2021). Population-based on U.S. CDC WONDER Bridge-Race Population Estimate 2019. Data obtained from https://wonder.cdc.gov/bridged-race-v2019.html

Pfizer Trial Demographics

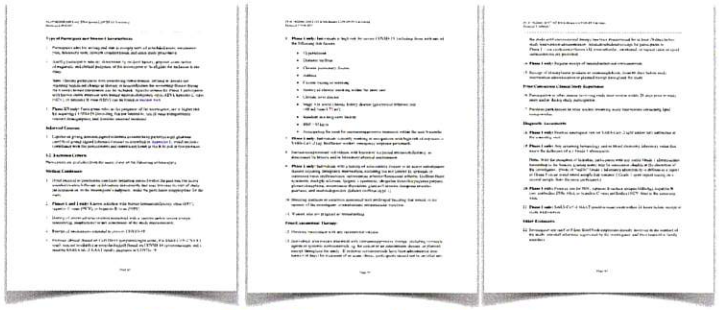
Demographics (population for the primary efficacy endpoint). The number of participants who received vaccine and placebo, stratified by age.

AGE GROUP	Pfizer-BioNTech COVID-19 Vaccine (N = 18,242) n (%)	Placebo (N = 18,379) n (%)
≥12 through 15 years[b]	46 (0.3 %)	42 (0.2 %)
≥16 through 17 years	66 (0.4 %)	68 (0.4 %)
≥16 through 64 years	14,216 (77.9 %)	14,299 (77.8 %)
≥65 through 74 years	3176 (17.4 %)	3226 (17.6 %)
≥75 years	804 (4.4 %)	812 (4.4 %)

Yet 75+ year olds represent only 4% of trial subjects.

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS) EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) https://labeling.pfizer.com/ShowLabeling.aspx?id=14471

MISLEADING DEMOGRAPHICS
TESTED ON HEALTHY, GIVEN TO SICK



Pfizer Trial Protocols - Exclusions

REAL WORLD CO-MORBIDITIES

95% of people who have died with COVID-19 have had **at least 1 co-morbidity** listed as cause of death. The **average is 4 co-morbidities**.

https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR3-wrgJtTKK5-9tOHFGAHWFVO3DhJlJ0KsDEPQpWmPbKtp6EsoVV2Qs1Q#Comorbidities

PFIZER TRIAL CO-CONDITIONS

Only **21% had a co-existing condition.**

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2034577?articleTools=true

IMPLICATIONS FOR ROLL OUT

- We are told the inoculations are "safe." Yet **many health conditions** - in fact a list several pages long - **were excluded from the trials**, including pregnant or breastfeeding women, people with allergies, with psychiatric conditions, immunocompromised people, people with bleeding disorders, people who had previously tested positive for COVID-19, people who had been prescribed steroids, etc., so there has never been any data to make safety claims about those people. Yet **they are also not excluded from mandates and vaccine passports.**
- The vaccines were **tested on the healthy**, and then immediately **given to the frailest members of the society** - the elderly with multiple health conditions. This is unscientific and unethical.

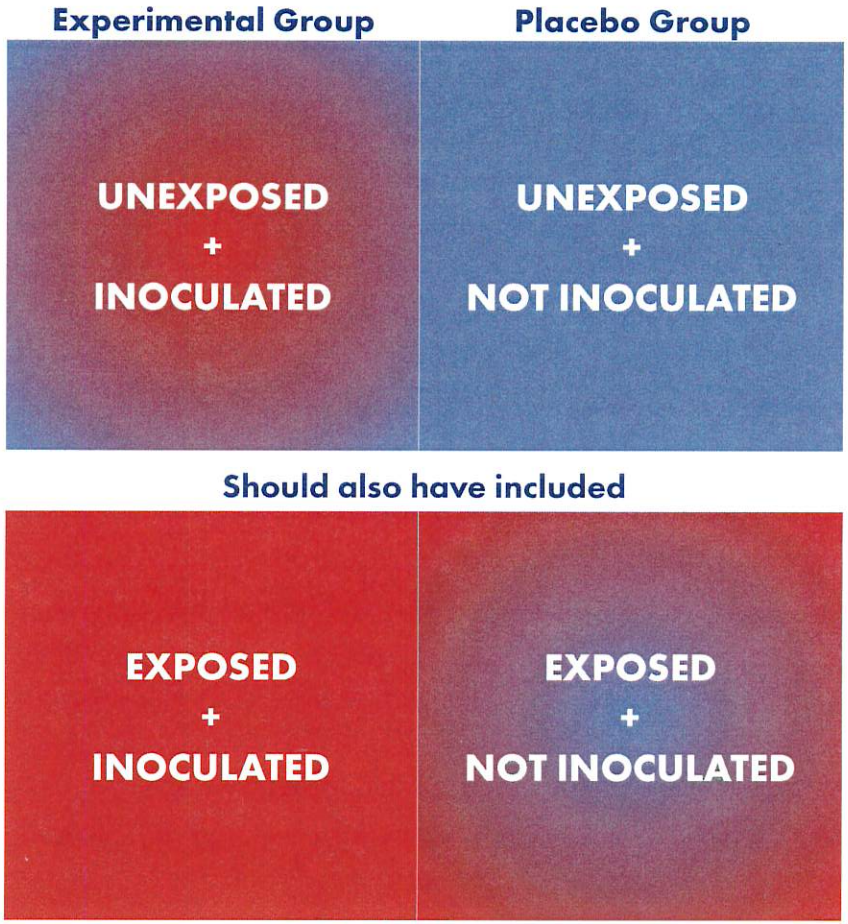
INADEQUATE CONTROL GROUPS

Pfizer only observed 2 groups:

- **UNEXPOSED** & **INOCULATED**
- **UNEXPOSED** & **NOT INOCULATED**

They should have included two more groups:

- **EXPOSED** & **INOCULATED**, people who had recovered, then got the inoculation, to see if the inoculation was safe for them
- **EXPOSED** & **NOT INOCULATED** people who were recovered and not inoculated to see how the inoculations stacked up against natural immunity



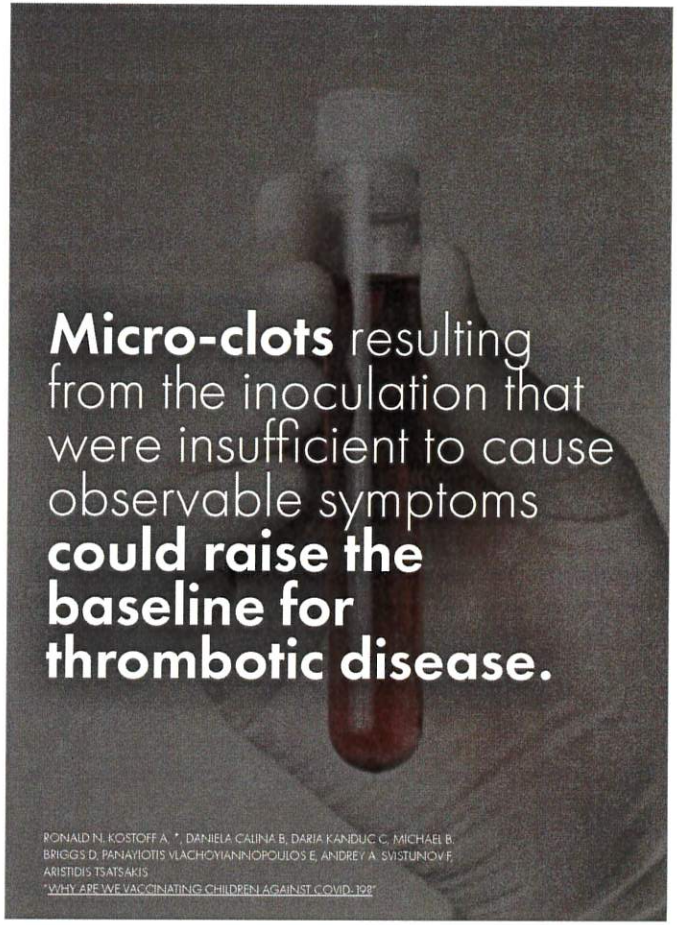
LOW QUALITY SAFETY SCIENCE DIDN'T TRACK BIOMARKERS

As Kostoff *et al.* highlighted in a recent paper, "Why are we vaccinating children against COVID-19?" (highly recommended), that while the Pfizer trials tested for antibodies and tracked adverse events in terms of symptoms, **they didn't test for adverse events at the subclinical (pre-symptom) level.**

This was extremely unsafe, because **symptoms/diseases are typically end points of processes** that can take months, years, or decades to surface. By the time you get to symptoms, things can have gone pretty wrong. (Think diabetes or high blood pressure, where the disease can be quite advanced before any symptoms occur.) **Pfizer should have been tracking biomarkers that would have been early warning indicators for disease caused by the inoculations.**

High quality safety science would have meant they should have tested before & after inoculation for:

- d-dimers for evidence of enhanced **coagulation/clotting** *(several of our doctors have noticed increased levels of d-dimers in inoculated patients presenting with stroke like symptoms - video available **here**)*
- C-reactive protein for evidence of enhanced **inflammation**
- troponins for evidence of **cardiac damage**
- occludin and claudin for evidence of enhanced **barrier permeability**
- blood oxygen levels for evidence of enhanced **hypoxia**
- amyloid-beta and phosphorylated tau for evidence of increased **predisposition to Alzheimer's** disease
- Serum HMGB1, CXCL13, Dickkopf-1 for evidence of an **increased disposition to autoimmune disease**, etc.



WRONG CLINICAL ENDPOINTS
SHOULD HAVE FOCUSED ON ALL CAUSE MORTALITY & ILLNESS

The fear with COVID-19, was that it was going to **a) kill people, b) make them sick.**

So any COVID-19 vaccine clinical trial should set out to ask the question **"Do people who take the vaccines have less illness and death than those who don't?"**

Illness + Death should be the CLINICAL ENDPOINTS. And not just illness + death with COVID-19, but **any and all illness and death,** in order to make sure that the vaccines are not causing harm.

This is well known. It was learned decades ago with cancer drug trials. At first, they used a clinical endpoint of "Did the drug shrink the cancer?" If it did, they called it effective. **But it turned out the drugs were not only killing cancer, they were killing patients.** They were forced to change the design of their trials and switch to "all cause mortality" as the primary endpoint instead and show that people receiving the drug actually live longer than those who don't. (J.Bart Classen has written an excellent research article on the subject. Read **here**.)

NOT TESTED FOR SPREAD REDUCTION
VACCINE PASSPORTS UNJUSTIFIED

Although vaccine passports are now being used to ostensibly prevent or reduce transmission of COVID-19, this outcome was never studied in the trial and it is inappropriate to assign that capability to these inoculations. **There is no evidence at all that they reduce the spread of disease and transmission was never one of the study's endpoints.**

LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

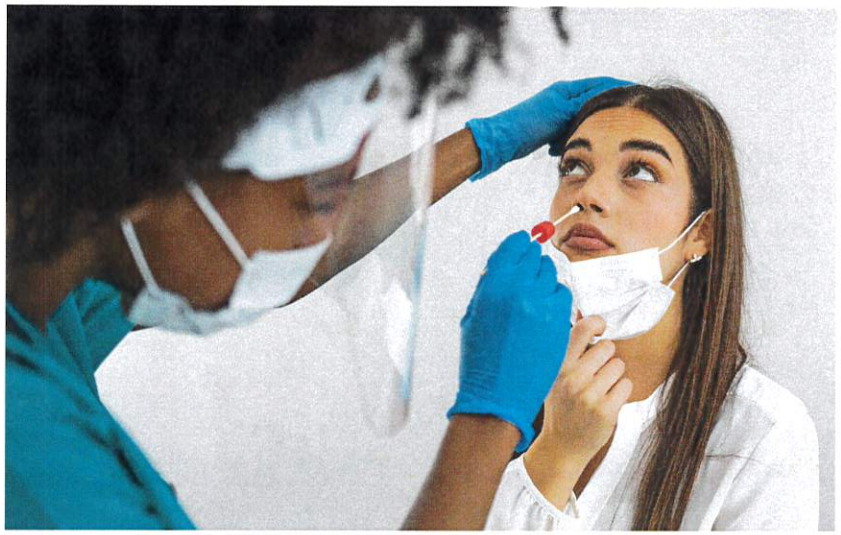
- Safety and efficacy beyond 2 months and in groups not included in this trial (e.g., children, pregnant women, and immunocompromised persons).
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to deal with those who miss the second vaccine dose.

TESTING FAILURES
SUBJECTIVE TESTING

The Pfizer trials DID NOT test all participants for COVID-19. Instead, they instructed their investigators to test only those with a COVID-19 symptom and **left it up to their discretion** to decide what those were.

This means that:

- **Asymptomatic infection would be missed entirely**
- A high level of **subjectivity was introduced to the study - an investigator had the ability to sway the results**
- The lack of objective systematic testing **makes results unreliable**



All participants should have been tested.

CCCA

MISSING DATA

- LOST TO FOLLOW UP
- SUSPECTED, BUT UNCONFIRMED

	INOCULATED GROUP	PLACEBO GROUP
ENDPOINT DATA - Confirmed COVID Cases	8	162
Participants Lost to Follow Up	80	86
Suspected, but Unconfirmed Cases	1,594	1,816

The basis for the Emergency Use Authorization was the Confirmed COVID cases of 8 vs 162, which meant a Relative Risk Reduction of 95%. But **when dealing with such a small number of cases, any change can impact the results significantly.**

Lost to follow up means **they lost touch with those subjects** and can't confirm whether they got sick or not. They don't know.

Suspected, but unconfirmed means these people were **symptomatic for COVID-19,** but were **never tested**. (Discretion for testing was left up to the investigator.)

The fact that the Lost to Follow Up and Suspected but Unconfirmed numbers are higher - and here they are even significantly higher - than the End Point numbers means that **this data is unreliable. The study should not have been accepted in this state.** In normal scientific practice they should have returned to investigate further.

Confirmed Cases

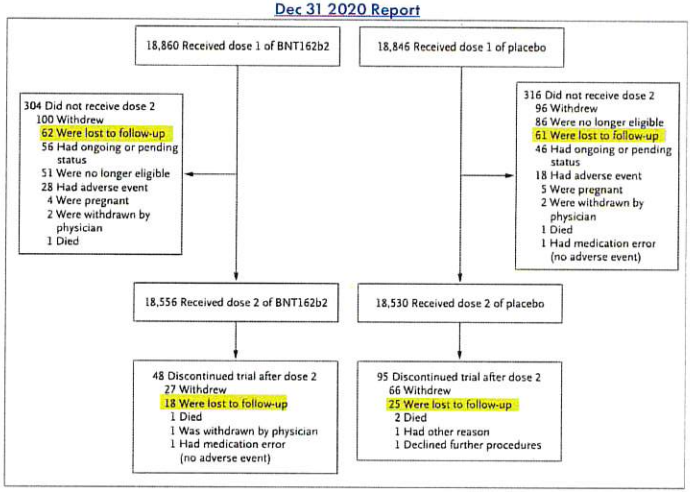
Dec 31 2020 Report

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198)		Placebo (N=18,325)		Vaccine Efficacy, % (95% CI)†
	No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*	
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)

Lost to Follow Up

Dec 31 2020 Report



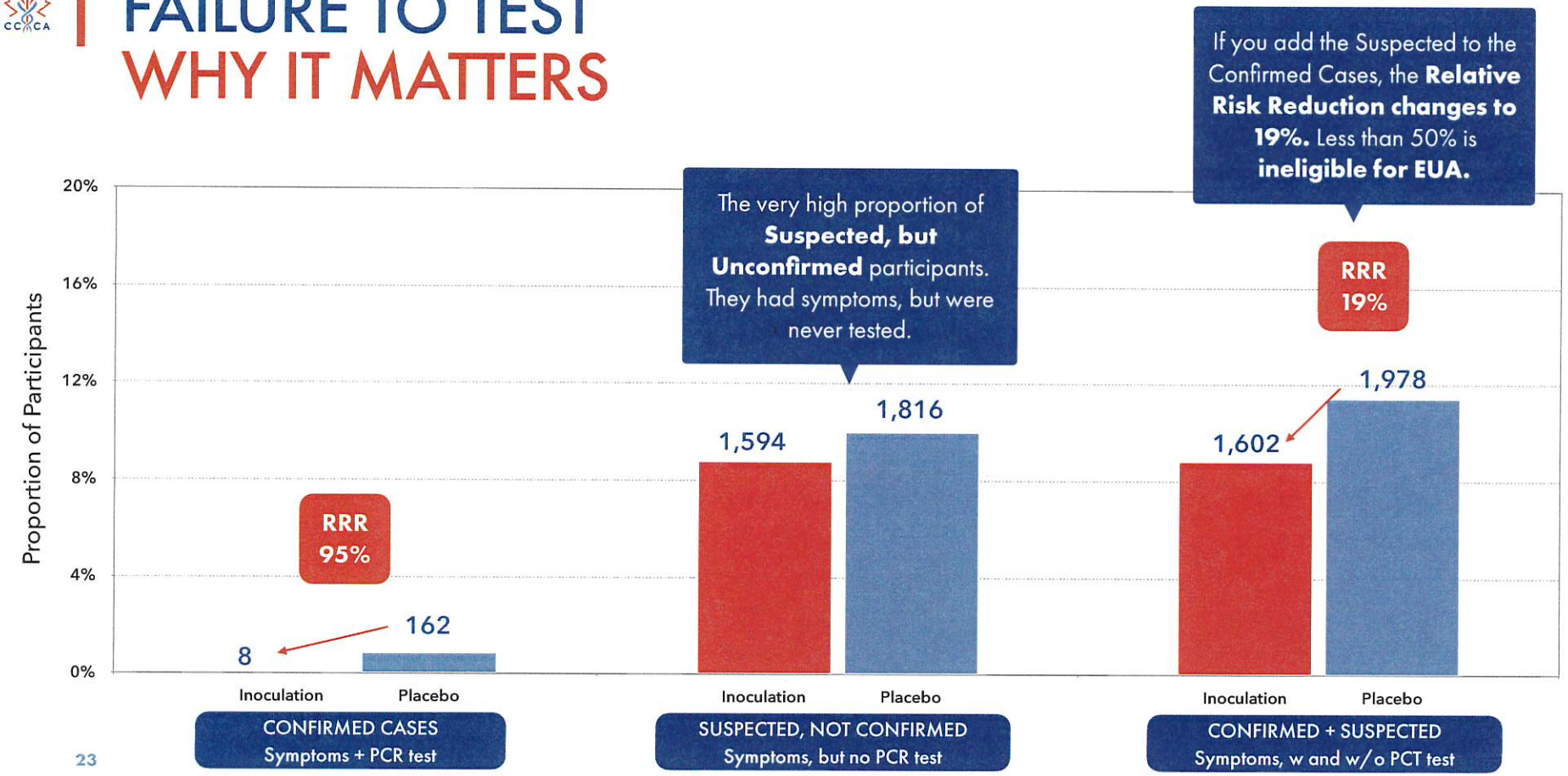
Suspected but Unconfirmed

Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020

FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine

Among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.

FAILURE TO TEST
WHY IT MATTERS



12-15 ADOLESCENT TRIAL
ALL RISK, NO BENEFIT

- This study was severely underpowered, as **a study this small will not show up risk**.
  - Inoculated group - **1,005** (**0** tested positive for COVID-19)
  - Placebo group - **978** (**18** tested positive for COVID-19)

- Pfizer claimed these were great results, but since adolescents are at statistically 0% risk of death from COVID-19, and very low risk of severe illness, **the inoculation is of little benefit to them.** Instead, it presents a very real risk of adverse events.

- But the adolescent Pfizer study wasn't actually designed to find those. **A serious adverse event**, including death, that occurred at a 1/800 rate **might not even show up in a sample of 1,005** people.

- But in this case, it did. **Among the 1,005 adolescents, there WAS at least one serious adverse event - Maddie de Garay.**

"For children without a serious medical condition, the danger of severe Covid is so low as to be difficult to quantify."
-COVID AND AGE, Oct 12, 2021, New York Times

12 -15 ADOLESCENT TRIAL FAILURE TO REPORT SERIOUS ADVERSE EVENTS

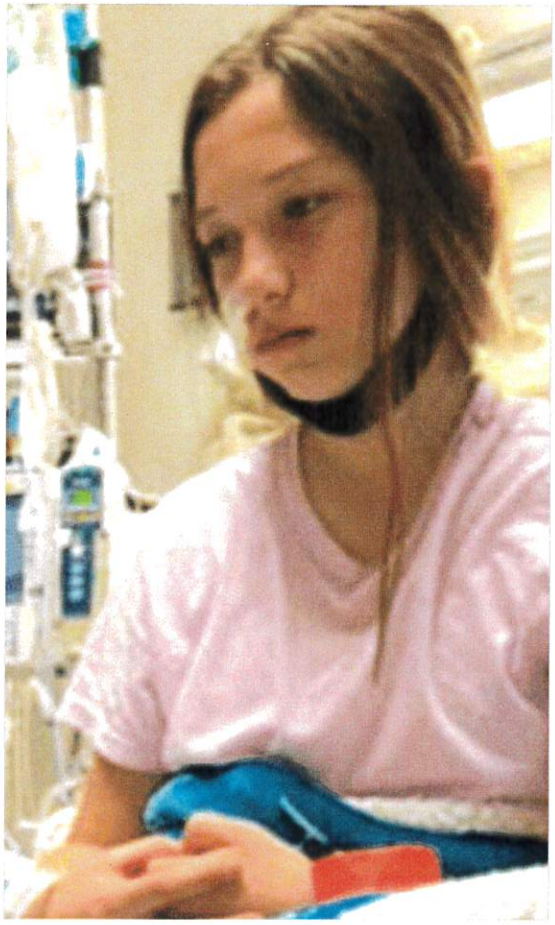
Maddie de Garay is a 12 year old trial participant who developed a serious reaction after her second dose and was hospitalized within 24 hours.

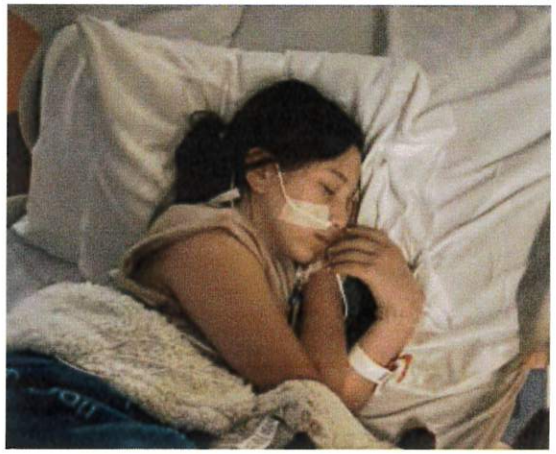
Maddie developed gastroparesis, nausea and vomiting, erratic blood pressure, memory loss, brain fog, headaches, dizziness, fainting, seizures, verbal and motor tics, menstrual cycle issues, lost feeling from the waist down, lost bowel and bladder control and had an nasogastric tube placed because she lost her ability to eat. She has been hospitalized many times, and for the past **10 months she has been wheelchair bound and fed via tube.**

In their report to the FDA, **Pfizer described her injuries as "functional abdominal pain."**

- One participant experienced an SAE reported as generalized neuralgia, and also reported 3 concurrent non-serious AEs (abdominal pain, abscess, gastritis) and 1 concurrent SAE (constipation) within the same week. The participant was eventually diagnosed with functional abdominal pain. The event was reported as ongoing at the time of the cutoff date.

Emergency Use Authorization Amendment





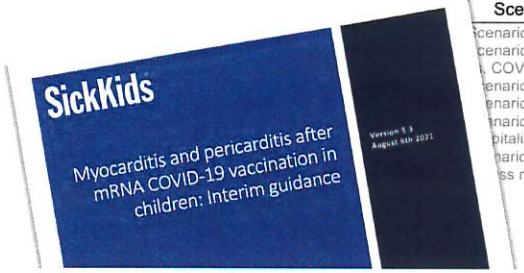
5 - 11 YEAR OLDS RISKING THEIR HEALTH

Re: the 5 to 11 year old cohort

In this table, **Pfizer, using predictive modelling acknowledges that their inoculations WILL cause myocarditis**, but optimistically **claims there will be zero deaths** from myocarditis in any of their modelled (speculation, level 5 evidence) scenarios.

But **even if it were true,** there is no justification for causing harm to children this way. **FIRST, DO NO HARM.**

There is now such a high expectation of heart problems from the inoculations among children that **Sick Kids is putting out brochures on how to deal with them.**



FDA BRIEFING DOCUMENT
EUA AMENDMENT REQUEST FOR PFIZER-BIONTECH COVID-19 VACCINE
FOR USE IN CHILDREN 5 THROUGH 11 YEARS OF AGE

Table 14. Model-Predicted Benefit-Risk Outcomes of Scenarios 1-6 per One Million Fully Vaccinated Children 5-11 Years Old

	Benefits				Risks			
Sex	**Prevented COVID-19 Cases**	**Prevented COVID-19 Hospitalizations**	**Prevented COVID-19 ICU Admissions**	**Prevented COVID-19 Deaths**	**Excess Myocarditis Cases**	**Excess Myocarditis Hospitalizations**	**Excess Myocarditis ICU Admissions**	**Excess Myocarditis Deaths**
Males & Females								
Scenario 1	45,773	192	62	1	106	58	34	0
Scenario 2	54,345	250	80	1	106	58	34	0
Scenario 3	2,639	21	7	0	106	58	34	0
Scenario 4	58,851	241	77	1	106	58	34	0
Scenario 5	45,773	192	62	3	106	58	34	0
Scenario 6	45,773	192	62	1	53	29	17	0
Males only								
Scenario 1	44,790	203	67	1	179	98	57	0
Scenario 2	54,345	250	82	1	179	98	57	0
Scenario 3	2,639	21	7	0	179	98	57	0
Scenario 4	57,857	254	83	1	179	98	57	0
Scenario 5	44,790	203	67	3	179	98	57	0
Scenario 6	44,790	203	67	1	89	49	29	0
Females only								
Scenario 1	45,063	172	54	1	32	18	10	0
Scenario 2	54,345	250	78	2	32	18	10	0
Scenario 3	2,639	21	7	0	32	18	10	0
Scenario 4	57,938	215	67	2	32	18	10	0
Scenario 5	45,063	172	54	4	32	18	10	0
Scenario 6	45,063	172	54	1	16	9	5	0

cenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
cenario 2: COVID-19 incidence at peak of U.S. Delta variant surge at end of August 2021, VE 70% vs. COVID-19 cases and 80%
, COVID-19 hospitalization.
enario 3: COVID-19 incidence as of nad
enario 4: COVID-19 incidence as of Se
nario 5: COVID-19 case incidence as
pitalization, COVID-19 death rate 300%
ario 6: COVID-19 incidence as of Se
ss myocarditis cases 50% of Scenari

Low Level (Level 5 Evidence)
SPECULATION - A Predictive Model

MYOCARDITIS IS SERIOUS

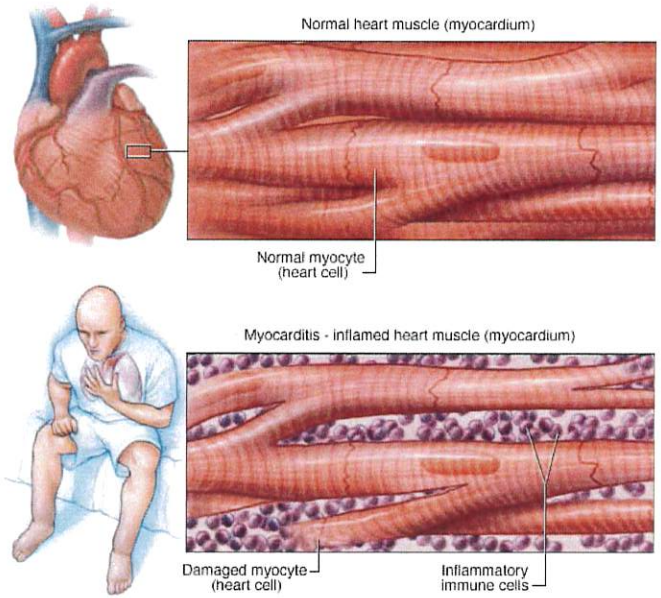
MYOCARDITIS

"Myocarditis is an inflammatory process of the myocardium. (Heart muscle.) **Severe myocarditis weakens your heart** so that the rest of your body doesn't get enough blood. Clots can form in your heart, **leading to a stroke or heart attack."**

THE US NATIONAL CENTRE FOR BIOTECHNOLOGY INFORMATION

"The mortality rate is up to 20% at 6.5 years."

https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7

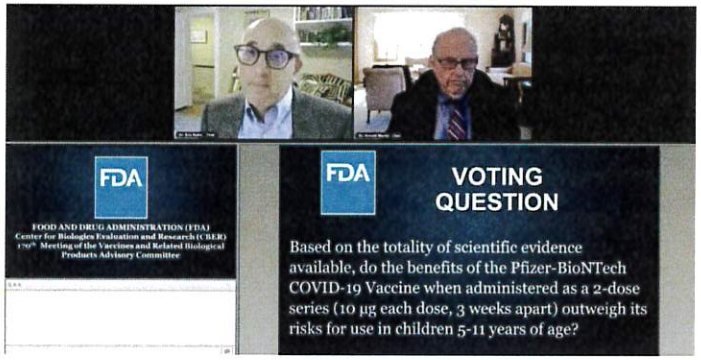


THE FDA ABANDONS FIRST, DO NO HARM

Medical interventions are supposed to be **PROVEN SAFE BEFORE** the are rolled out in the population.

Yet **Dr. Eric Rubin**, one of the 18 members of the **FDA advisory panel** who voted, to approve the inoculations for children 5 - 11, actually said the opposite, and suggested that **a population level roll out was an appropriate way to test for adverse events.**

It's worth noting that Dr. Eric Rubin is the **editor-in-chief of the New England Journal of Medicine, which publishes the Pfizer trial reports.**



"We're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes. That's how we found out about rare complications of other vaccines like the rotavirus vaccine. And I do think we should vote to approve it."

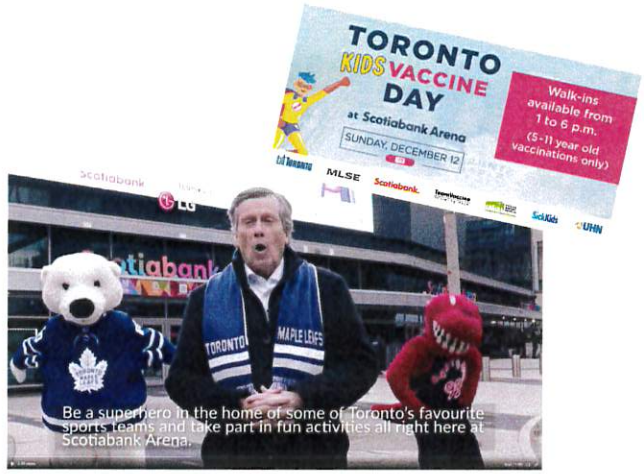
Dr. Eric Rubin, FDA advisory panel member,
Harvard professor & editor-in-chief of the New England Journal of Medicine
Vaccines and Related Biological Products Advisory Committee – 10/26/2021

5 - 11 YEAR OLDS
NO INFORMED CONSENT

- **Direct-to-consumer advertising of prescription drugs is illegal in Canada,** yet politicians from all levels of government are marketing inoculations to children, using cartoons and mascots.

- **They are proclaiming the inoculations to be safe, yet the data is not there to back that up.** In addition to admitting that their inoculations can cause myocarditis, Pfizer also admits, right in their report, that **their long term immune response, efficacy & safety data is limited and that their studies weren't powered to find "rare" side effects** as only 1,517 kids got the inoculation.

- How many parents would take their kids to get this shot if they were informed of this? **The law of informed consent says they should be, but it's not happening.**



of a Covid-19 vaccine in this population; trials of other vaccines are under way. Limitations of the study include the lack of longer-term follow-up to assess the duration of immune responses, efficacy, and safety. However, longer-term follow-up from this study, which will continue for 2 years, should provide clarification. This study was also not powered to detect potential rare side effects of BNT162b2 in 5-to-11-year-olds. However, the safety of BNT162b2 observed in the study com-

https://www.nejm.org/doi/full/10.1056/NEJMoa2116298

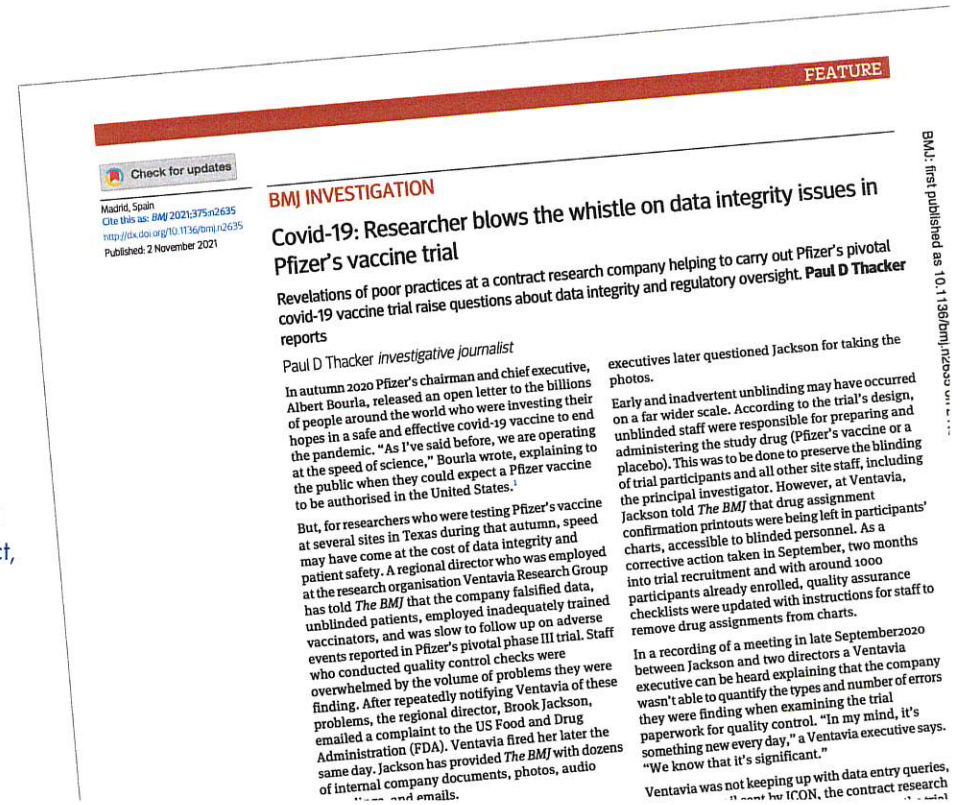
THE BRITISH MEDICAL JOURNAL PUBLISHES WHISTLEBLOWER STORY

On November 2nd, the British Medical Journal released an article about their investigation into Ventavia, one of the research companies Pfizer hired to conduct the trials.

It's quite damning. **The whistleblower is a Regional Director** who actually reported her company to the FDA for:

- **Falsifying data**
- **Unblinding participants**
- **Not following up and testing participants who reported symptoms**
- **Mislabelling specimens**

Several other employees backed up her account. Despite all this, **neither Pfizer, nor the FDA ever audited or investigated** the research company, Pfizer never disclosed the problems in its EUA application, and in fact, Pfizer has now hired that same Researcher, Ventavia, to run four more COVID-19 clinical trials.



FEATURE

Check for updates

Madrid, Spain
Cite this as: *BMJ* 2021;375:n2635
http://dx.doi.org/10.1136/bmj.n2635
Published: 2 November 2021

BMJ INVESTIGATION

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight. Paul D Thacker reports

Paul D Thacker *investigative journalist*

In autumn 2020 Pfizer's chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective covid-19 vaccine to end the pandemic. "As I've said before, we are operating at the speed of science," Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the United States.[1]

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio [illegible] and emails.

executives later questioned Jackson for taking the photos.

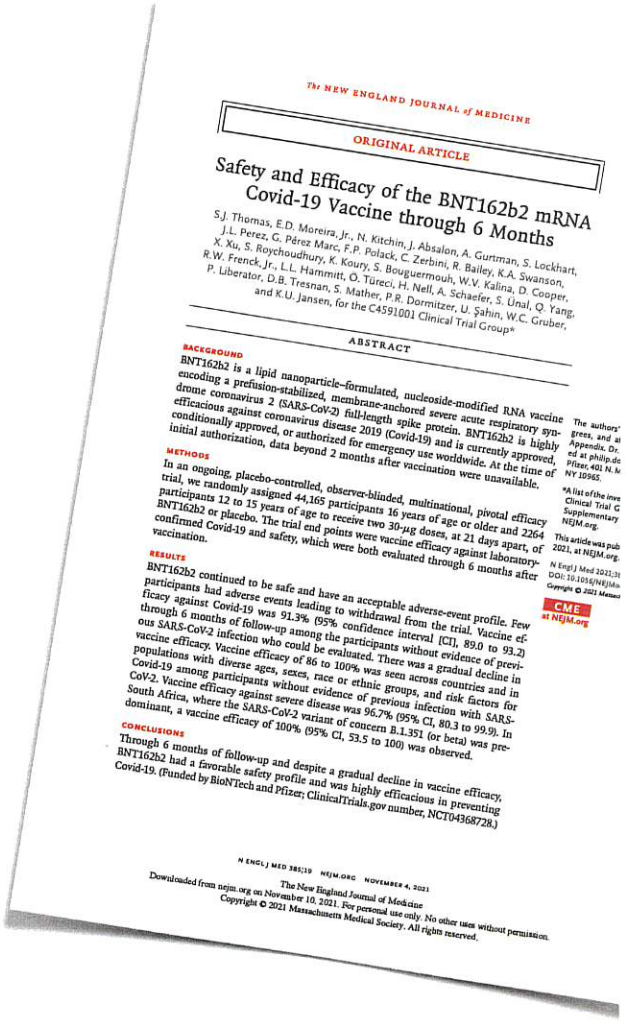
Early and inadvertent unblinding may have occurred on a far wider scale. According to the trial's design, unblinded staff were responsible for preparing and administering the study drug (Pfizer's vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told *The BMJ* that drug assignment confirmation printouts were being left in participants' charts, accessible to blinded personnel. As a corrective action taken in September, two months into trial recruitment and with around 1000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

In a recording of a meeting in late September2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. "In my mind, it's something new every day," a Ventavia executive says. "We know that it's significant."

Ventavia was not keeping up with data entry queries, [illegible] sent by ICON, the contract research [illegible]

BMJ: first published as 10.1136/bmj.n2635 on 2 November 2021

A CRITICAL EYE BACK ON
THE SEP 15 2021 REPORT



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

S.J. Thomas, E.D. Moreira, Jr., N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J.L. Perez, G. Pérez Marc, F.P. Polack, C. Zerbini, R. Bailey, K.A. Swanson, X. Xu, S. Roychoudhury, K. Koury, S. Bouguermouh, W.V. Kalina, D. Cooper, R.W. Frenck, Jr., L.L. Hammitt, Ö. Türeci, H. Nell, A. Schaefer, S. Ünal, Q. Yang, P. Liberator, D.B. Tresnan, S. Mather, P.R. Dormitzer, U. Şahin, W.C. Gruber, and K.U. Jansen, for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS

In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS

BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

N ENGL J MED 385;19 NEJM.ORG NOVEMBER 4, 2021

6 MONTH DATA MANIPULATION
MIXED COHORTS

Pfizer took the results from their adult trial, which started July 27, 2020, and then added the results from the 12 - 15 year olds' trial, **despite the fact that the adolescent trial started four months later.**

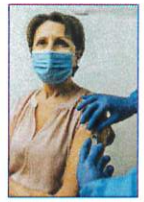
Since it's well known that the efficacy of the inoculations wanes over time, **this gives a false boost to the efficacy numbers.** The efficacy for these two cohorts should have been reported separately, not presented as one combined result. Without this boost, their efficacy number would likely have fallen.


THE NEW ENGLAND JOURNAL of MEDICINE

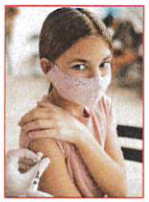
ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

ABSTRACT



Jul 27
Adult Trial (16+) Begins



Dec
Adolescent Trial (12 - 15) Begins

Mar 13
Data Cutoff Date for Efficacy Reported in 6 Month Study

2020						2021		
JULY	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR

PFIZER TRIALS DID NOT PROVE SAFETY
THEY PROVED HARM

ILLNESS

	BNT162b2	Placebo	Risk Change
Efficacy (Meaning number of people diagnosed with COVID-19.)	77	850	**-91%**
Related Adverse Event (Meaning an investigator has assessed it as related to the BNT162b2 injection.)	5,241	1,311	**+300%**
Any Severe Adverse Event (Interferes significantly with normal function.)	262	150	**+75%**
Any Serious Adverse Event (Involves visit to ER or hospitalization.)	127	116	**+10%**

DEATHS

BNT162b2	Placebo
20	14

These are the results of Pfizer's own randomized control trial.

LEVEL 1 EVIDENCE OF HARM.

HOW THIS IS PLAYING OUT IN THE REAL WORLD

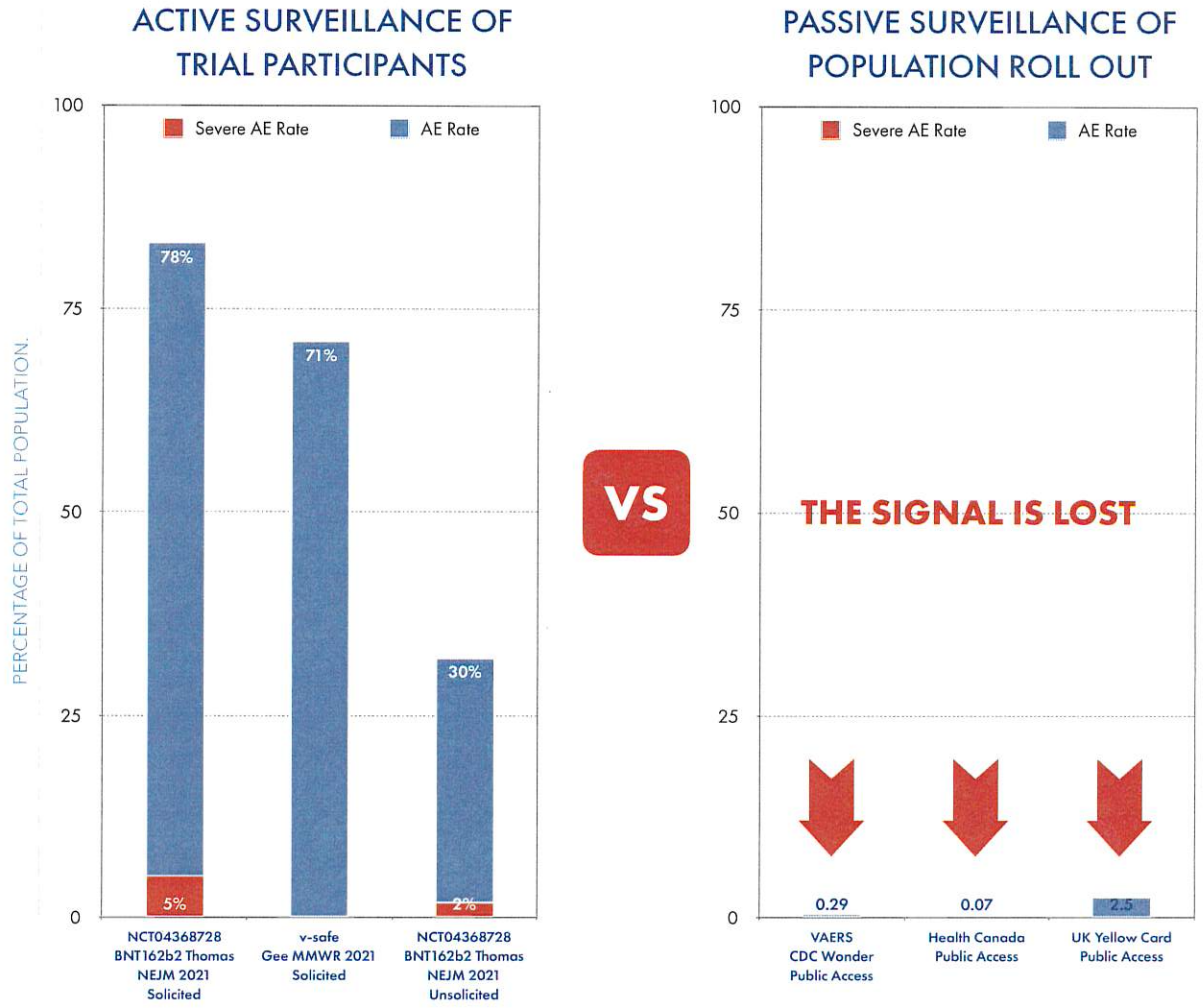
ROLL OUT SURVEILLANCE YOU DON'T FIND WHAT YOU DON'T LOOK FOR

There is a dramatic difference between passive vs active monitoring of adverse events

1. When participants were **actively** followed for adverse events (AEs) in the trials, high percentages of adverse events were reported.

2. Once the vaccine was rolled out at the population level, **passive** surveillance was used with Health Canada, VAERS or the European Yellow Card system.

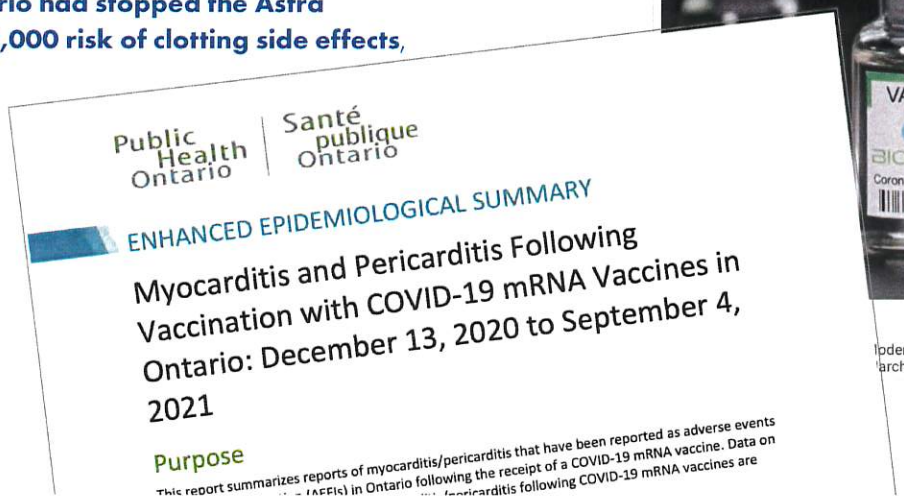
When that happened, the **signal was completely lost**.



RISING INCIDENTS OF HEART ISSUES IN YOUNG PEOPLE

Ontario Public Health is well aware of this, as they published a report on it, but they seem inconsistent in their concerns.

- On Sep 29, 2021, Ontario Public Health recommended **young men 18-24** not take the **Moderna shot**, because of a **1 in 5,000 risk of myocarditis.** They suggested **Pfizer shot** instead, which has a **1 in 28,000 risk of myocarditis.**
- But as recently as May 8, 2021, **Ontario had stopped the Astra Zeneca shot because of a 1 in 60,000 risk of clotting side effects**, which was considered too high.
- **Their priorities are inconsistent.**


Public Health Ontario | Santé publique Ontario

ENHANCED EPIDEMIOLOGICAL SUMMARY

Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021

Purpose

This report summarizes reports of myocarditis/pericarditis that have been reported as adverse events ... (AEFIs) in Ontario following the receipt of a COVID-19 mRNA vaccine. Data on ... pericarditis following COVID-19 mRNA vaccines are

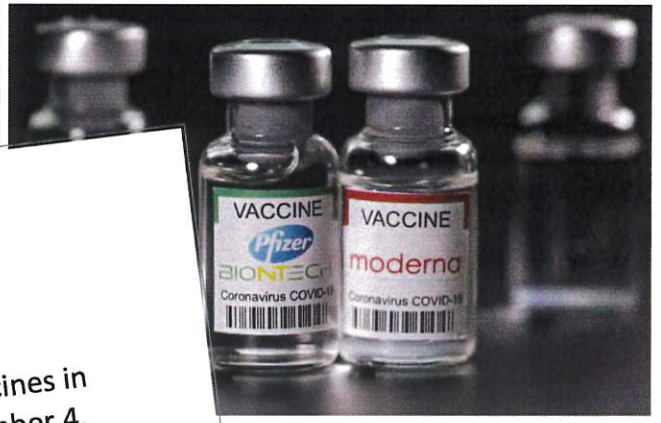
TORONTO SUN

Ontario

More than 100 Ontario youth sent to hospital for vaccine-related heart problems: Report

There were 54 persons aged 25-39 included in the tally and 44 persons aged 40 and over

Anthony Furey
Sep 03, 2021 • September 3, 2021 • 2 minute read • 314 Comments



oderna coronavirus disease (COVID-19) vaccine labels are seen arch 19, 2021. PHOTO BY DADO RUVIC /REUTERS

THIS IS NOT NORMAL

Health News · Vaccine Injury Stories · Vaccines

Grieving Father Ernest Ramirez Shares Heartbreaking Story of His Teen Son's Death 5 Days After Pfizer Vaccine

Isaiah Harris Aged 18 – Pfizer May 2021

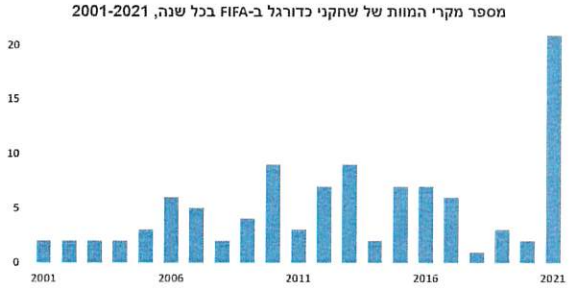
Severe Adverse Reaction: Myocarditis (Inflammation of the Heart) Resulting in a Heart Attack

A German news site put together a list of over **75 known cases of athletes collapsing - and even dying - in the last 5 months.**

https://report24.news/ab-13-jahren-lange-liste-ploetzlich-verstorbener-oder-schwerkranker-sportler/

An Israeli news site analyzed the number of sudden deaths "on the pitch" of members of the International Football Association (FIFA) over the past 20 years.

The average number of FIFA sudden deaths between 2000 - 2020 was 4.2. In 2021, it was 21.



https://www.rtnews.co.il/?view=article&id=49&catid=22

THIS IS SUPPOSED TO BE RARE

https://rumble.com/vpnxkr-are-these-side-effects-extremely-rare.html

PFIZER'S POST MARKETING PHARMACOVIGILANCE REPORT

- On Nov 17, 2021, the FDA released the first batch of what will ultimately be **329,000 pages** they were ordered by a court to provide to satisfy a Freedom of Information request by a group called Public Health and Medical Professionals for Transparency who want access to the **data used by the FDA to approve Pfizer's COVID-19 inoculations**. (The FDA asked in court to have over 50 years to release the documents.)

- One **post marketing pharmacovigilance report** submitted to the FDA, where Pfizer tracked real world adverse events occurring in the first 2.5 months after Emergency Use Authorization, was particularly disturbing.
  - **Over 1,200 deaths**
  - **Over 25,000 nervous system adverse events**
  - Under "Safety concerns" Pfizer listed **Anaphylaxis** and **Vaccine-Associated Enhanced Disease**

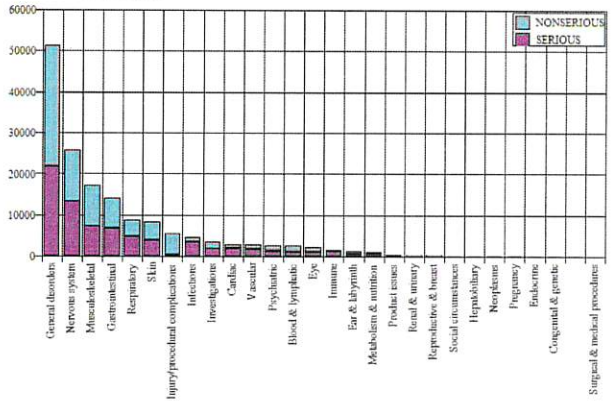
- **This document should be incriminating for any agency who saw it and called these inoculations "safe."**

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

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

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

Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness



3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

CONSIDERABLE EVIDENCE OF CONFLICT OF INTEREST

PFIZER IS MAKING BILLIONS

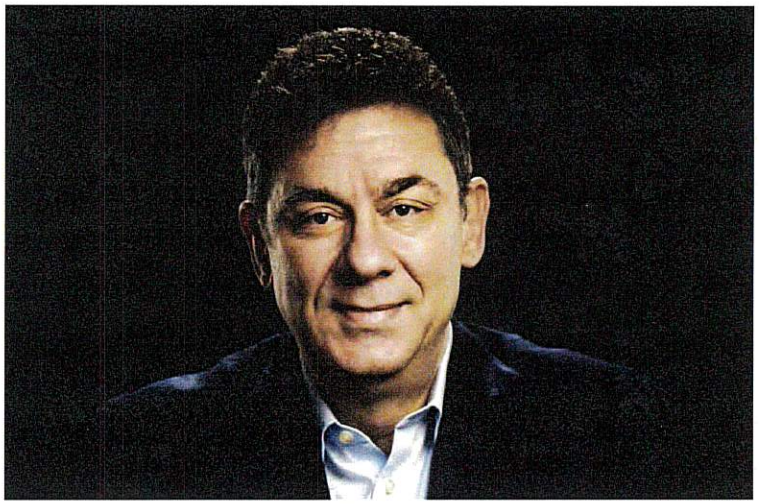
$33.5B+ in 2021 alone.

When the incentive is such an astronomical sum of money, it only makes sense to **ensure rigorous oversight** of the process and to ensure **as many safeguards as possible** are in place.

Their agenda is **their shareholders and their bottom line**, not public health.

Forbes

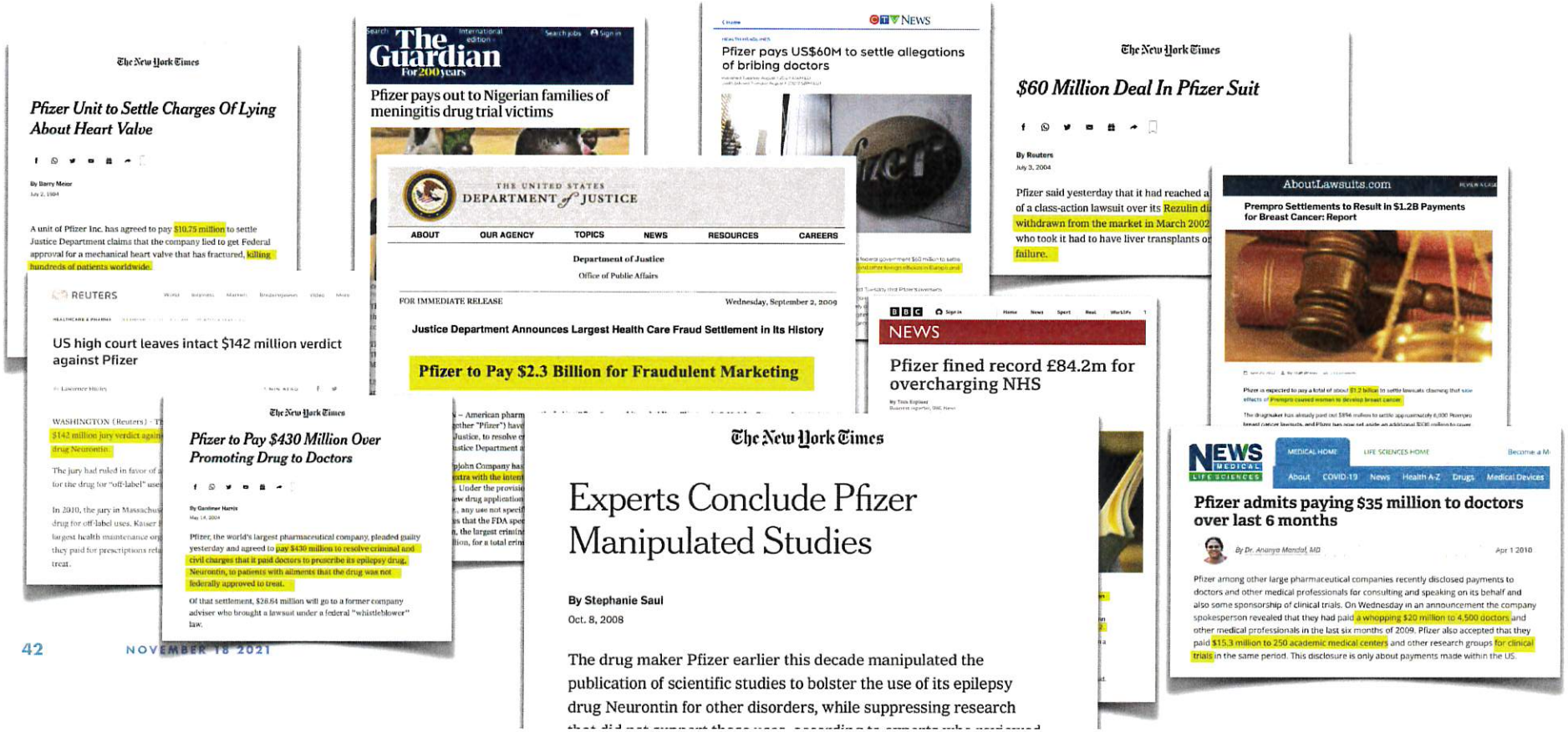
Pfizer Expects $33.5 Billion In Vaccine Revenue In 2021



Albert Bourla, CEO of Pfizer, photographed in June 2020 JAMEL TOPPIN FOR FORBES

Biotech giant Pfizer expects to generate $33.5 billion in Covid-19 vaccine sales in 2021, up from previous estimates of $26 billion, according to its second quarter earnings reports. These projections are based on the 2.1 billion doses of the Pfizer/BioNTech vaccine which the company expects to manufacture and deliver by the end of the year.

THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE



The New York Times

Pfizer Unit to Settle Charges Of Lying About Heart Valve

By Barry Meier

July 2, 1994

A unit of Pfizer Inc. has agreed to pay $10.25 million to settle Justice Department claims that the company lied to get Federal approval for a mechanical heart valve that has fractured, killing hundreds of patients worldwide.

The Guardian

For 200 years

Pfizer pays out to Nigerian families of meningitis drug trial victims

CTV NEWS

Pfizer pays US$60M to settle allegations of bribing doctors

The New York Times

$60 Million Deal In Pfizer Suit

By Reuters

July 3, 2004

Pfizer said yesterday that it had reached a

of a class-action lawsuit over its Rezulin di

withdrawn from the market in March 2002

who took it had to have liver transplants or

failure.

THE UNITED STATES DEPARTMENT of JUSTICE

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Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 2, 2009

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

AboutLawsuits.com

Prempro Settlements to Result in $1.2B Payments for Breast Cancer: Report

REUTERS

US high court leaves intact $142 million verdict against Pfizer

WASHINGTON (Reuters) - T

$142 million jury verdict agains

drug Neurontin.

The jury had ruled in favor of a

for the drug for "off-label" use

In 2010, the jury in Massachus

drug for off-label uses. Kaiser

largest health maintenance org

they paid for prescriptions refu

treat.

BBC NEWS

Pfizer fined record £84.2m for overcharging NHS

The New York Times

Pfizer to Pay $430 Million Over Promoting Drug to Doctors

By Gardiner Harris

May 14, 2004

Pfizer, the world's largest pharmaceutical company, pleaded guilty yesterday and agreed to pay $430 million to resolve criminal and civil charges that it paid doctors to prescribe its epilepsy drug, Neurontin, to patients with ailments that the drug was not federally approved to treat.

Of that settlement, $268.64 million will go to a former company adviser who brought a lawsuit under a federal "whistleblower" law.

The New York Times

Experts Conclude Pfizer Manipulated Studies

By Stephanie Saul

Oct. 8, 2008

The drug maker Pfizer earlier this decade manipulated the publication of scientific studies to bolster the use of its epilepsy drug Neurontin for other disorders, while suppressing research

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About COVID-19 News Health A-Z Drugs Medical Devices

Pfizer admits paying $35 million to doctors over last 6 months

By Dr. Ananya Mandal, MD

Apr 1 2010

Pfizer among other large pharmaceutical companies recently disclosed payments to doctors and other medical professionals for consulting and speaking on its behalf and also some sponsorship of clinical trials. On Wednesday in an announcement the company spokesperson revealed that they had paid a whopping $20 million to 4,500 doctors and other medical professionals in the last six months of 2009. Pfizer also accepted that they paid $15.3 million to 250 academic medical centers and other research groups for clinical trials in the same period. This disclosure is only about payments made within the US.

LINKS TO THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE

- **Pfizer Unit to Settle Charges Of Lying About Heart Valve, Jul 2, 1994** https://www.nytimes.com/1994/07/02/business/pfizer-unit-to-settle-charges-of-lying-about-heart-valve.html
- **Pfizer to Pay $430 Million Over Promoting Drug to Doctors, May 14, 2004** https://www.nytimes.com/2004/05/14/business/pfizer-to-pay-430-million-over-promoting-drug-to-doctors.html
- **$60 Million Deal In Pfizer Suit over Rezulin, July 3, 2004** https://www.nytimes.com/2004/07/03/business/60-million-deal-in-pfizer-suit.html
- **Experts Conclude Pfizer Manipulated Studies, Oct 8, 2008** https://www.nytimes.com/2008/10/08/health/research/08drug.html
- **Pfizer to Pay $2.3 Billion for Fraudulent Marketing, Sep 2, 2009** https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history
- **Pfizer Admits Paying $35 Million to Doctors Over Last 6 Months, Apr 1, 2010** https://www.news-medical.net/news/20100401/Pfizer-admits-paying-2435-million-to-doctors-over-last-6-months.aspx
- **Pfizer Pays Out to Nigerian Families of Meningitis Drug Trial Victims, Aug 12, 2011** https://www.theguardian.com/world/2011/aug/11/pfizer-nigeria-meningitis-drug-compensation
- **Pfizer Pays US$60M to Settle Allegations of Bribing Doctors, Aug 7, 2012** https://www.ctvnews.ca/health/health-headlines/pfizer-pays-us-60m-to-settle-allegations-of-bribing-doctors-1.906216
- **SEC Charges Pfizer with FCPA Violations, Aug 7, 2012** https://www.sec.gov/news/press-release/2012-2012-152htm
- **US High Court Leaves Intact $142 million Verdict Against Pfizer, Dec 9, 2013** https://www.reuters.com/article/us-usa-court-pfizer-idUSBRE9B80K020131209
- **Pfizer Fined Record £84.2m for Overcharging NHS, Dec 7, 2016** https://www.bbc.com/news/business-38233852
- **Sonofi, FSK, Pfizer, Boehringer Must Face Zantac Class-Action Lawsuits: Court Oct 15, 2021** https://medicaldialogues.in/news/industry/pharma/sanofi-gsk-pfizer-boehringer-must-face-zantac-class-action-lawsuits-court-83138

CONFLICTS OF INTEREST AMONG PFIZER REPORT AUTHORS

6 MONTH REPORT AUTHORS

Employment + Stock
N. Kitchin
J. Absalon — Corresponding Author
S. Lockhart
R. Bailey
K.A. Swanson — Last Author
S. Roychoudhury
K. Koury
W.V. Kalina
D. Cooper,
D.B. Tresnan
S. Mather
P.R. Dormitzer
U. Şahin — BioNTech founders whose stock value increased by $9 billion
W.C. Gruber
K.U. Jansen
Ö. Türeci — BioNTech founders whose stock value increased by $9 billion

Employment
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J.L. Perez
S. Bouguermouh
P. Liberator
X. Xu

Grant/Consultant/ Clinical Trial
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S. Ünal
S.J. Thomas — Lead Author
G. Pérez Marc
F.P. Polack

No Conflict
E.D. Moreira, Jr
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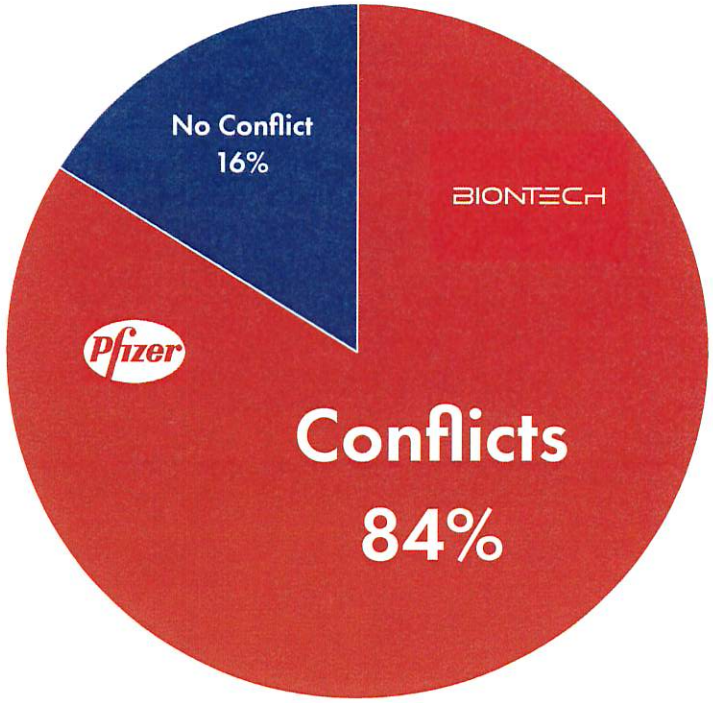
A. Schaefer
C. Zerbini
Q. Yang



THE CDC HAS REDEFINED "VACCINE" TO SUIT POLITICAL & PHARMACEUTICAL INTERESTS

For many years	Jul 27, 2021	Aug 18, 2021	Starting Sep 2, 2021
CDC Definition of VACCINE *"A product that stimulates a person's immune system* ***to produce immunity to a specific disease, protecting the person from that disease."***	Head of CDC Rochelle Walensky went on CNN and admitted the COVID-19 vaccines do not provide immunity - they don't stop people from catching or transmitting COVID-19. 	Joe Biden announced booster shots for all Americans. 	**CDC Definition of VACCINE CHANGED** *"A preparation that is used* ***to stimulate the body's immune response against diseases."*** **This looks like fraud.**

THE MEDIA HAS BEEN CAPTURED

https://rumble.com/voz64j-brought-to-you-by-pfizer.html

THIS IS NO WAY TO MANAGE A SUPPLIER

Pfizer has been **indemnified for damages** in case their inoculations hurt and kill people, and Pfizer **profits to the tune of billions** if the trials are successful.

No reasonable, responsible person would have given Pfizer carte blanche in such a situation.

Instead, **you would engage in rigorous oversight** and **hold them to the highest scientific standards**. This was not done.

THE INOCULATIONS SHOULD BE WITHDRAWN IMMEDIATELY

- It's clear that Pfizer - and the agencies overseeing their trials - failed to follow established, high quality safety and efficacy protocols right from the beginning.
- We have presented **Level 1 evidence of harm from Pfizer's own trial data**. Any government which has approved these inoculations, much less mandated them, **knew or should have known from the available data that harm would be caused to its citizens.**
- Any government that approved this medical intervention for its citizens should have ensured that the trial had used the **appropriate clinical endpoints** and **high quality safety science**.
- **Any government official who possesses this evidence and continues to allow its citizens to be inoculated with a toxic agent is, at the very least, negligent.**

RECOMMENDED READING/VIEWING

PUBLISHED PAPERS REFUTING PFIZER INOCULATIONS

- Why Are We Vaccinating Children Against COVID-19? https://www.sciencedirect.com/science/article/pii/S221475002100161X
- US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity" https://www.scivisionpub.com/pdfs/us-covid19-vaccines-proven-to-cause-more-harm-than-good-based-on-pivotal-clinical-trial-data-analyzed-using-the-proper-scientific--1811.pdf

PFIZER'S NEJM PUBLISHED RESULTS

- Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine https://www.nejm.org/doi/full/10.1056/nejmoa2034577
- FDA Briefing Document, Dec 10, 2020 https://www.fda.gov/media/144245/download
- Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months https://www.nejm.org/doi/full/10.1056/NEJMoa2110345
- The 6 Month Supplementary Appendix https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl_file/nejmoa2110345_appendix.pdf

BRITISH MEDICAL JOURNAL

- Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial https://www.bmj.com/content/375/bmj.n2635

ONTARIO PUBLIC HEALTH EPIDEMIOLOGICAL SUMMARY

- Myocarditis and Pericarditis Following Vaccination with COVID-19 mRNA Vaccines in Ontario: December 13, 2020 to September 4, 2021 https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en

SHORT VIDEOS

- Informed Consent - It's Your Right (3 minutes) https://rumble.com/vleq43-informed-consent-its-your-right.html
- Brought to You by Pfizer (1 minute) https://rumble.com/voz64j-brought-to-you-by-pfizer.html
- Why Do We Need Vaccine Passports? (2 minutes) https://rumble.com/vn1zof-why-do-we-need-vaccine-passports.html
- COVID-19 Vaccines and D-Dimer levels (9 minutes) https://rumble.com/voeisj-dr-rochagn-kilian-blowing-the-whistle-on-covid-19-vaccines-and-d-dimer-leve.html
- How Reliable Is the PCR Test? (2 minutes) https://youtu.be/gL7Z5JmRIM4

WE NEED YOU TO HOLD THEM ACCOUNTABLE

- This evidence is a tool you can use. It represents a real opportunity to hold our leaders accountable as it is not opinion, or modelling, or real world evidence that can be dismissed or manipulated, but LEVEL 1 EVIDENCE from a randomized control trial. As such, it has high evidentiary value.
- We're asking that you call your MP and MPP and that you ask for a 1 hour meeting. Preferably in person, but Zoom will work too.
- During the meeting, play them the video and provide them with the PDF version. Ask them questions, like whether or not they were aware of all the issues with the Pfizer trial. Or what they plan to do now that they are. Get them to agree to a follow up meeting where they will provide you with answers.
- Share this video with friends and family. Have group viewing sessions on Zoom and discuss it.
- Share this video and the PDF on social media. When you do, please use the hashtags #CCCA and #MoreHarmThanGood
- Please join our mailing list at www.canadiancovidcarealliance.org and we will update you with additional evidence as we have it.
- Follow us on social media. This linktree has all our social accounts.
- This presentation is available in PDF and video format on our website at www.canadiancovidcarealliance.org

THE PFIZER INOCULATIONS FOR COVID-19

MORE HARM
THAN GOOD

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

Contact us
info@canadiancovidcarealliance.org
www.canadiancovidcarealliance.org