

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

Hierarchy of evidence

Pfizer's 2 month data report, Dec 31 2020

- [ARR vs RRR explained - VIDEO](#)
- [Early unblinding of Pfizer's randomized control trial](#)

Pfizer's 6 month data report, Sep 15 2021

- [Increased risk of illness](#)
- [Increased risk of death](#)

The Pfizer Trials - What went wrong

- [Pfizer did not follow established protocols](#)
- [Misleading demographics - Wrong age](#)
- [Misleading demographics - Tested on healthy, given to sick](#)
- [Inadequate control groups](#)
- [Did not track biomarkers](#)
- [Wrong clinical endpoints](#)
- [Not tested for spread reduction](#)
- [Subjective testing](#)
- [Missing data - Lost to follow up and Suspected, but unconfirmed](#)

- [Failure to test - Why it matters](#)
- [12 - 15 trial - All risk, no benefit](#)
- [12 - 15 trial - Failure to report serious adverse events](#)
- [5 - 11 year olds - Risking their health](#)
- [Myocarditis is serious](#)
- [The FDA abandons "First, do no harm"](#)
- [5 - 11 year olds - No informed consent](#)
- [The BMJ Pfizer trial whistleblower article](#)

A critical eye on the Sep 15 2020 report

- [6 month data manipulation - Mixed cohorts](#)
- [The Pfizer trials did not prove safety - they proved harm](#)

How this is playing out in the real world

- [Roll out surveillance - You don't find what you don't look for](#)
- [Rising incidents of heart issues in young people \(Ontario Public Health Report\)](#)
- [This is not normal - High incidences of deaths in athletes \(German, Israeli news articles\)](#)

- [This is supposed to be rare - VIDEO of athletes collapsing](#)
- [Pfizer's post marketing pharmacovigilance report](#)

Considerable evidence of conflict of interest

- [Pfizer is making billions](#)
- [The public record of Pfizer's corporate culture](#)
- [Links to articles on Pfizer's past behaviour](#)
- [Conflicts of interest among Pfizer report authors](#)
- [The CDC has redefined "vaccine"](#)
- [The media has been captured - VIDEO](#)

This is no way to manage a supplier

The inoculations should be withdrawn immediately

Recommended reading & viewing



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

Level	Example of Evidence
Level 1	Meta-analysis of Homogenous RCTs Randomized Control Trial
Level 2	Meta-analysis of Level 2 or Heterogenous Level 1 Evidence Prospective Comparative Study
Level 3	Review of Level 3 Evidence Case-control Study Retrospective Cohort Study
Level 4	Uncontrolled Cohort Studies Case Series
Level 5	Expert Opinion Case Report Personal Observation
Foundational Evidence	Animal Research <i>In Vitro</i> Research Ideas, Speculation



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.

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.

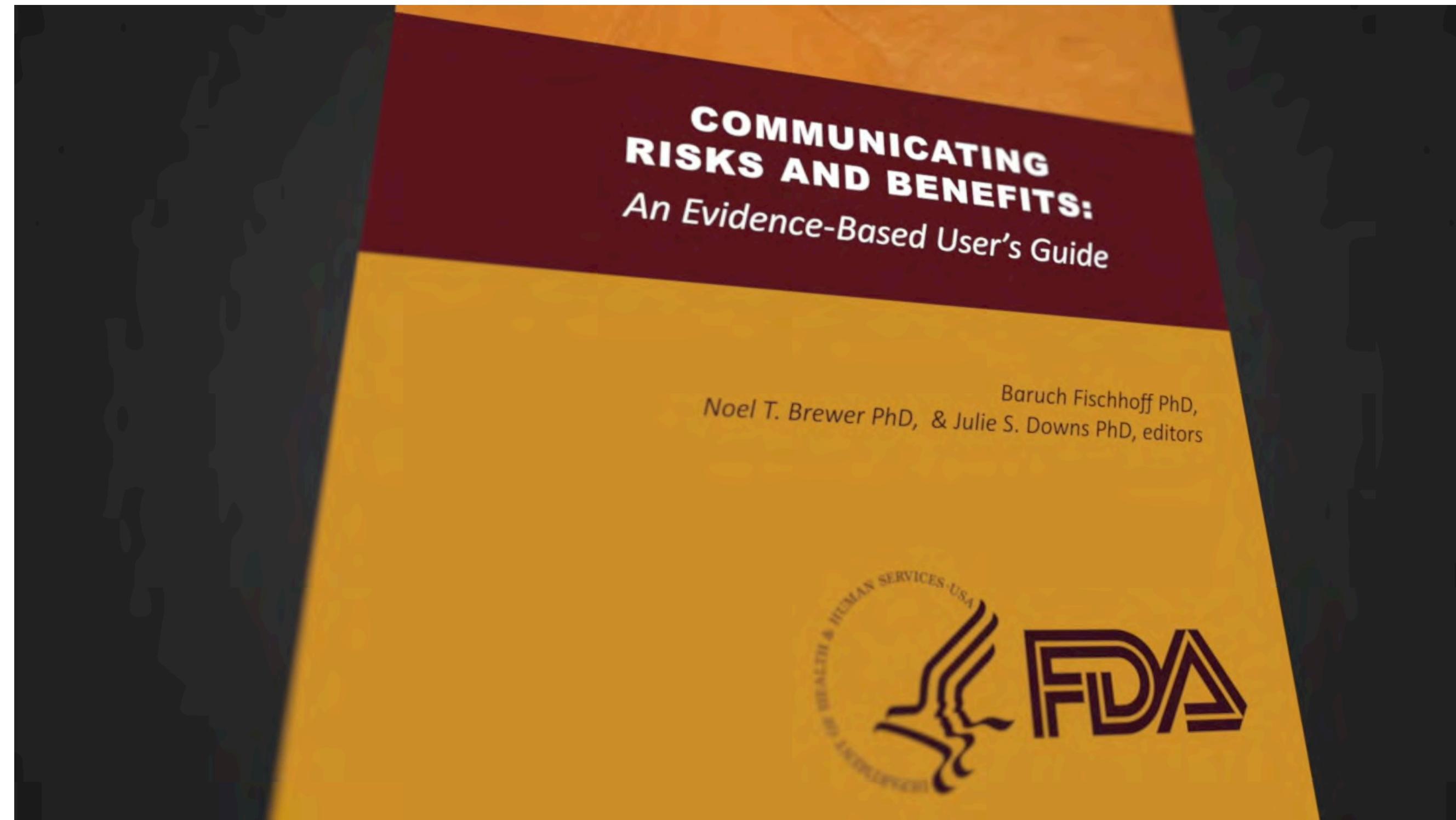
Links: Full article | Quick Take | Editorial

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

Copyright © 2020 Massachusetts Medical Society



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

	INOCULATED GROUP	PLACEBO GROUP	
2020			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.
2021			
2022			
2023			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

	INOCULATED GROUP	PLACEBO GROUP	
2020			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 .
2021			Dec 31 2020 Release 2 month data report. The trial is unblinded early.
2022			Crossover Occurs The participants from the Placebo Group are given the opportunity to take the inoculation and by early 2021, <u>the majority of them have crossed over to the inoculated group</u> . It's no longer a randomized control trial, as control group is gone.
2023			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

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. French, 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- μ g 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
Copyright © 2021 Massachusetts Medical Society.

CME
at NEJM.org

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

The New England Journal of Medicine

Downloaded from nejm.org on November 10, 2021. For personal use only. No other uses without permission.

Copyright © 2021 Massachusetts Medical Society. All rights reserved.

1761



INCREASED RISK OF ILLNESS

Screen capture from Pfizer 6 Month Supplementary Appendix

Adverse Event	BNT162b2 (N=21,926) n^b (%)	Placebo (N=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 ^a	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
<i>Shigella</i> 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
<p>"After unblinding" means when the Placebo participants were given the opportunity to "cross over" and take the BNT162b2 inoculation.*</p> <p>...3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died.</p> <p>Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months</p>		
Concerning Causes of Death		
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.)

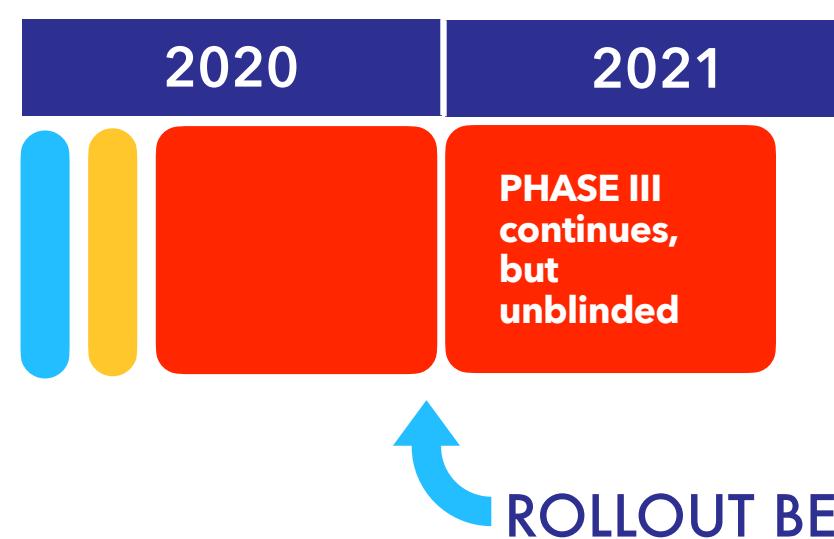
NORMALLY, VACCINE DEVELOPMENT LOOKS LIKE THIS, WITH A TIMELINE OF 5 TO 10 YEARS.



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



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



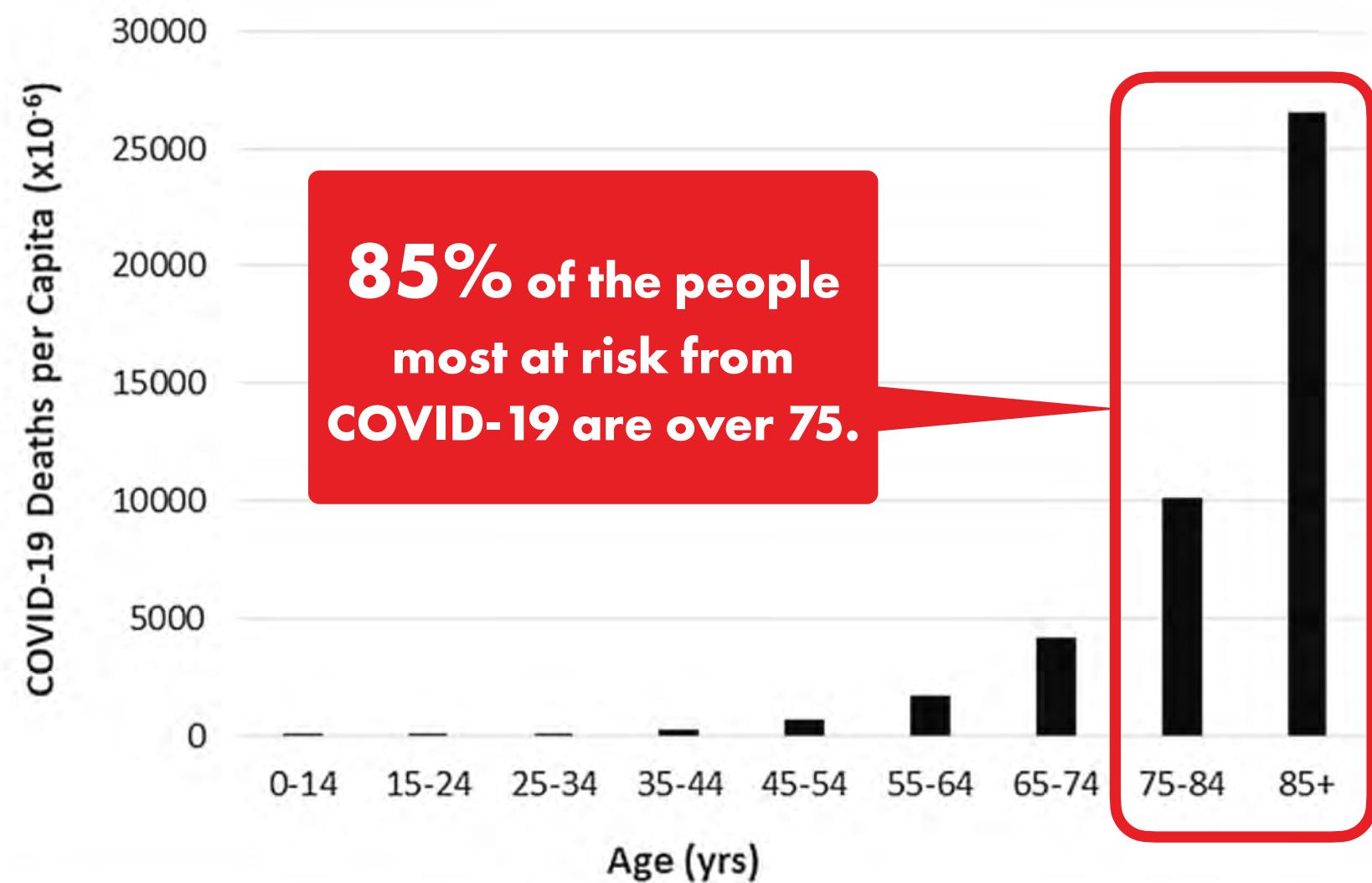
- Animal testing was skipped
- Phases II/III were combined
- After 2 months of Phase II/III, Emergency Use Authorized
- The trials were unblinded
- Phase III trials are ongoing until 2023



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



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.

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>

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>



PFIZER'S INOCULATIONS FOR COVID-19 / MORE HARM THAN GOOD

MISLEADING DEMOGRAPHICS TESTED ON HEALTHY, GIVEN TO SICK

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-
mordities.**

[https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?
fbclid=IwAR3-wrg3fTK5-9tOHPGAHWFVO3DfsIkJ0KsDEPQpWmPbKtp6EsoVV2Qs1Q#Comorbidities](https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm?fbclid=IwAR3-wrg3fTK5-9tOHPGAHWFVO3DfsIkJ0KsDEPQpWmPbKtp6EsoVV2Qs1Q#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.

PF-0732048 (INT132 RNA-based COVID-19 Vaccine)
Protocol CTP-0101
Protocol CTP-0101

PF-0732048 (INT132 RNA-based COVID-19 Vaccine)
Protocol CTP-0101
Protocol CTP-0101

PF-0732048 (INT132 RNA-based COVID-19 Vaccine)
Protocol CTP-0101
Protocol CTP-0101

Type of Participant and Disease Characteristics:

- Participants who are willing and able to comply with all scheduled visits, vaccination plans, laboratory tests, telephone consultations, and other study procedures.
- Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.
- Note: Healthy participants with preexisting stable disease, defined as disease no longer requiring treatment, longer than 3 months, asymptomatic, and stable during the 6 weeks before enrollment may be included. Specific criteria for phase 4 participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), and/or tuberculosis (TB) will be specified.
- Phase 2/3 only:** Participants who, in the judgment of the investigator, are at higher risk for acquiring COVID-19 (including, but not limited to, risk of mass transportation, relevant comorbidities, and frontline essential workers).

Informed Consent:

- Given by the participant signed informed consent form (either in English or Spanish) establishing signed informed consent is described in Appendix 1, which includes compliance with the requirements and responsibilities listed in the ICD and this protocol.
- Exclusion Criteria:**

Participants are excluded from this study if any of the following criteria apply:

- Medical Conditions:**

 - Other medical or psychiatric condition, including mental health, within the past year or active and/or planned or planned or laboratory ascertainable that may interfere with the ability of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
 - Phase 1 and 2 only:** Current infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).
 - History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study investigation.
 - Receipt of medications intended to prevent COVID-19.
 - Prior recent travel to or COVID-19 symptoms/clinical course. If a SARS-CoV-2 NAAT test result is available from the participant, then a COVID-19 symptomatology, and a positive NAAT-CoV-2 XAAT result) diagnosis of COVID-19.

- Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

 - Hypertension
 - Diabetes mellitus
 - Chronic heart failure
 - Chronic pulmonary disease
 - Asthma
 - Cancer (any stage)
 - Cancer vaping or smoking
 - History of chronic smoking within the prior year
 - Chronic liver disease
 - Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min)
 - Resident in a long-term facility
 - BMI >30 kg/m²
 - Anticipating the need for immunosuppressive treatment within the next 6 months

- Phase 1 only:** Individuals currently working in occupations with high risk of exposure to COVID-19, including food service workers, healthcare workers, and first responders.
- Phase 1 only:** Immunocompetent individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.
- Phase 1 only:** Individuals with a history of autoimmune disease or an active autoimmune disease, including, but not limited to, systemic lupus erythematosus, sarcoidosis, vasculitis, Guillain-Barré syndrome, multiple sclerosis, Sjögren's syndrome, idiopathic thrombocytopenic purpura, pemphigus, pemphigoid, sarcoidosis, Hashimoto's thyroiditis (hypothyroidism), porphyria, and insulin-dependent diabetes mellitus (type 1).
- Phase 1 only:** Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular bleeding.
- Phase 1 only:** Women who are pregnant or breastfeeding.
- Prior/Concomitant Therapy:**

 - Previous vaccination with any coronavirus vaccine.
 - Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents, monoclonal antibodies, or cancer or an autoimmune disease, and planned receipt throughout the study. If systemic corticosteroids have been administered short term (<14 days) for treatment of an acute illness, participants should not be enrolled into the study.

- Other Exclusions:**

 - Investigator site staff or Pfizer BioNTech employees directly involved in the conduct of the study, site staff who were supervised by the investigator, and their respective family members.

Pfizer Trial Protocols - Exclusions



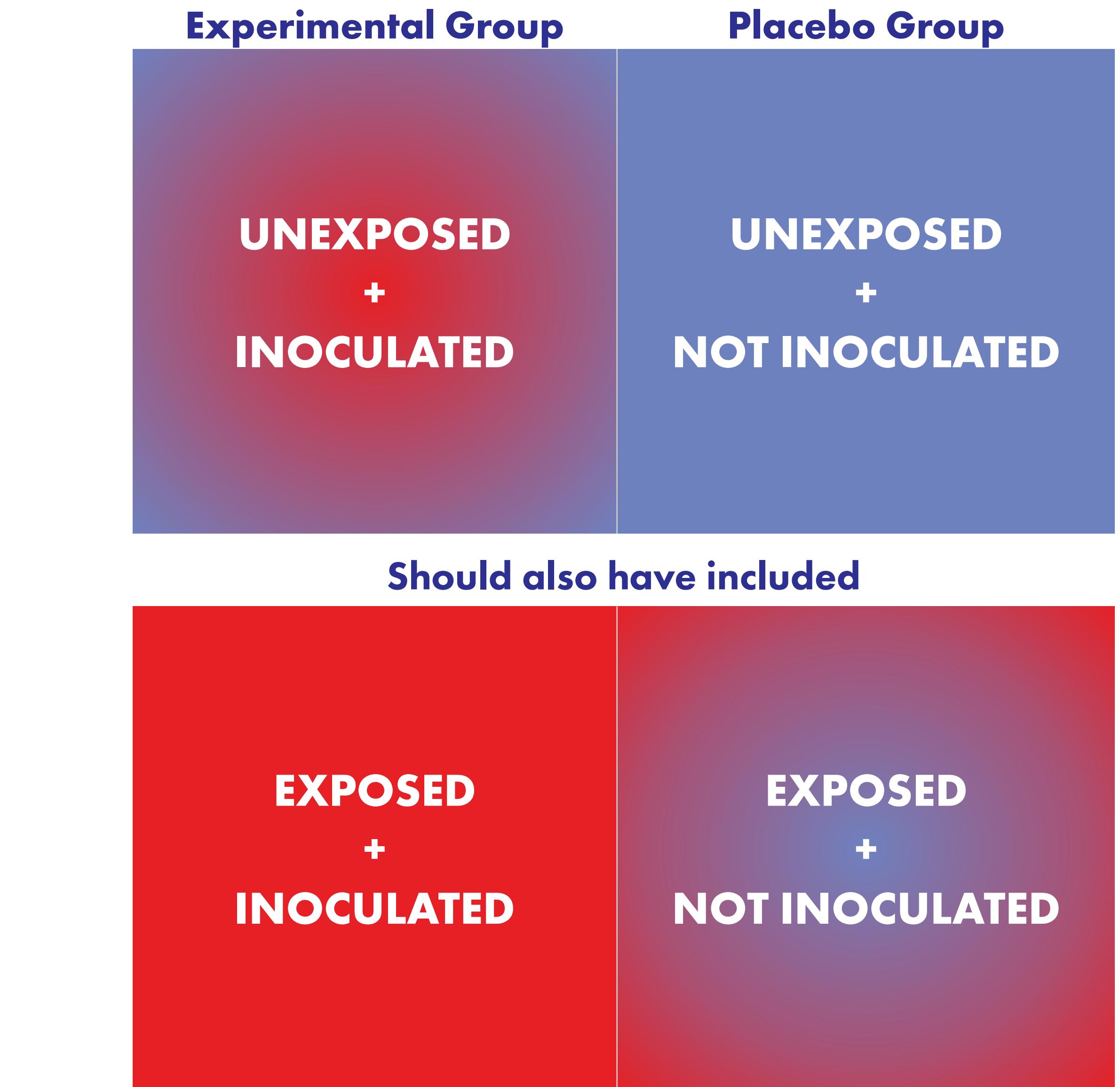
INADEQUATE CONTROL GROUPS

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.**

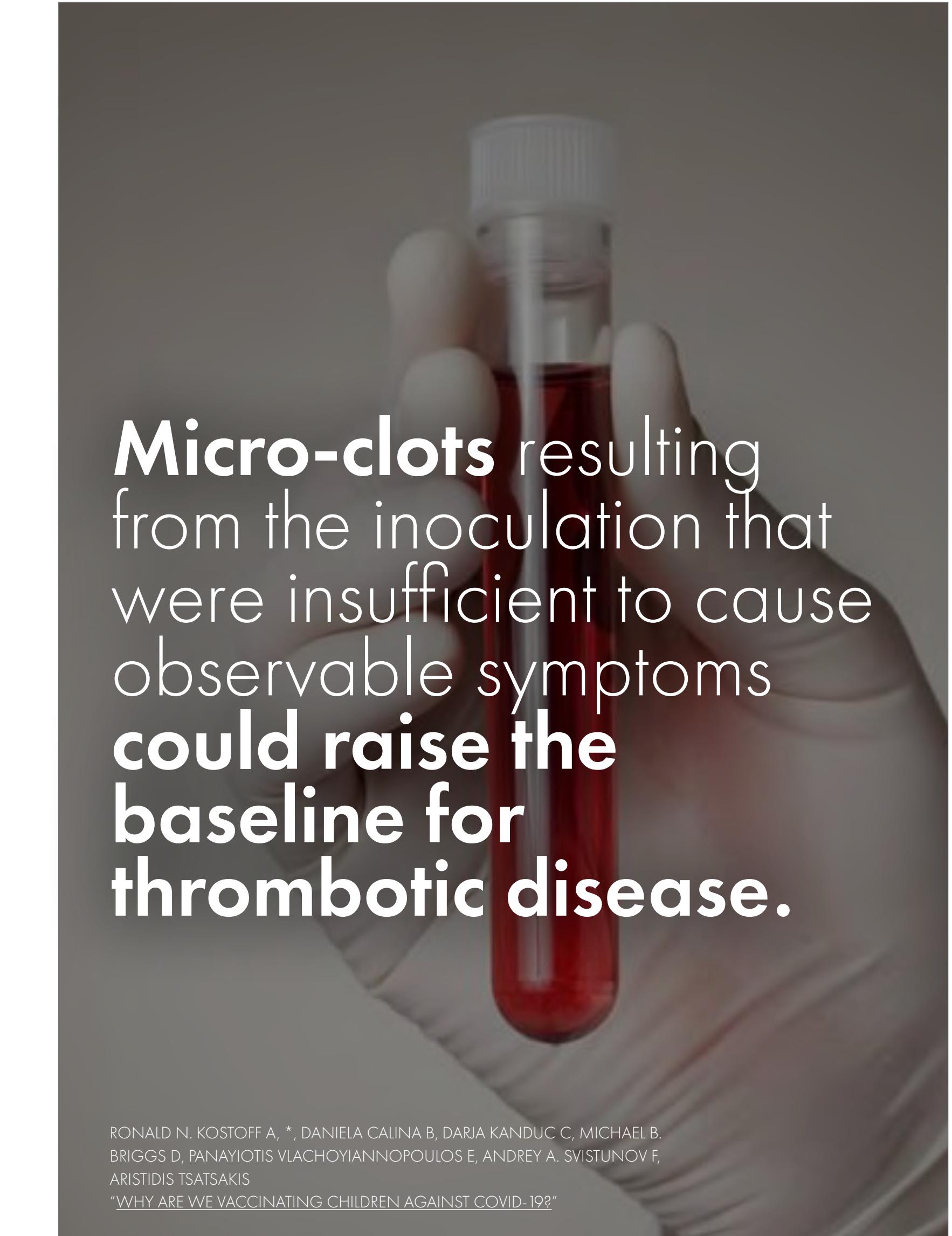
This was extremely unsafe, because **symptoms/diseases are typically end points of processes** that can take months, years, or decades to surface. By the time you get to symptoms, things can have gone pretty wrong. (Think diabetes or high blood pressure, where the disease can be quite advanced before 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.

Micro-clots resulting from the inoculation that were insufficient to cause observable symptoms could raise the baseline for thrombotic disease.

RONALD N. KOSTOFF A, *, DANIELA CALINA B, DARJA KANDUC C, MICHAEL B. BRIGGS D, PANAYIOTIS VLACHOYIANNOPoulos E, ANDREY A. SVISTUNOV F, ARISTIDIS TSATSAKIS
["WHY ARE WE VACCINATING CHILDREN AGAINST COVID-19?"](#)





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.**

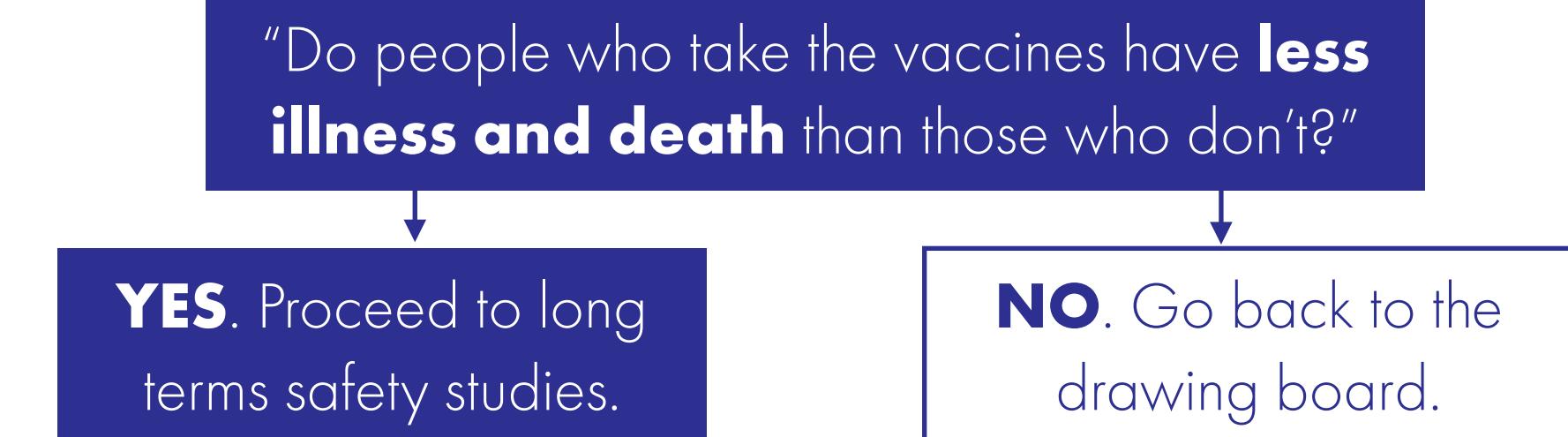
So any COVID-19 vaccine clinical trial should set out to ask the question "**Do people who take the vaccines have less illness and death than those who don't?**"

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](#).)

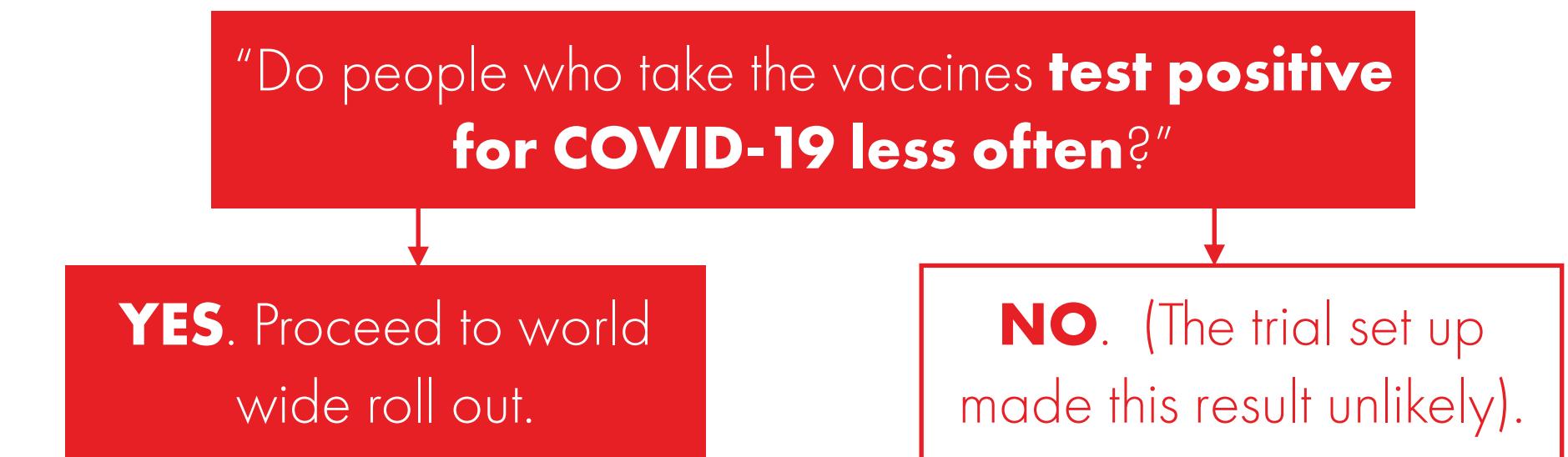
WHAT SHOULD HAVE HAPPENED

(After the proper early safety phases of development were completed.)



WHAT ACTUALLY HAPPENED

(Without the proper early safety phases of development having been completed.)





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.**

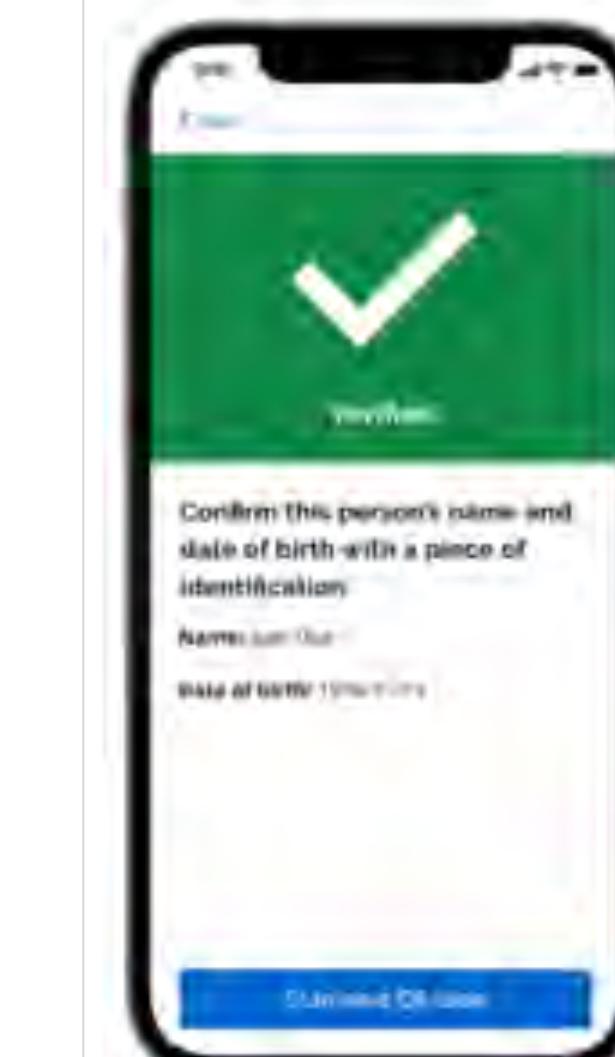
LIMITATIONS AND REMAINING QUESTIONS

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.

Verify Ontario:

Ontario's official app for verifying COVID-19 vaccine certificates.



When a business or organization scans a visitor's digital or paper QR code, this app will:

- protect user privacy by only reading certificates that are trusted and secure
- check if a certificate is valid and the visitor can enter
- show a visitor's name and date of birth so their identity can be verified
- work offline (without an internet connection)



Download the Verify Ontario app at:
ontario.ca/verify

Ontario



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.



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

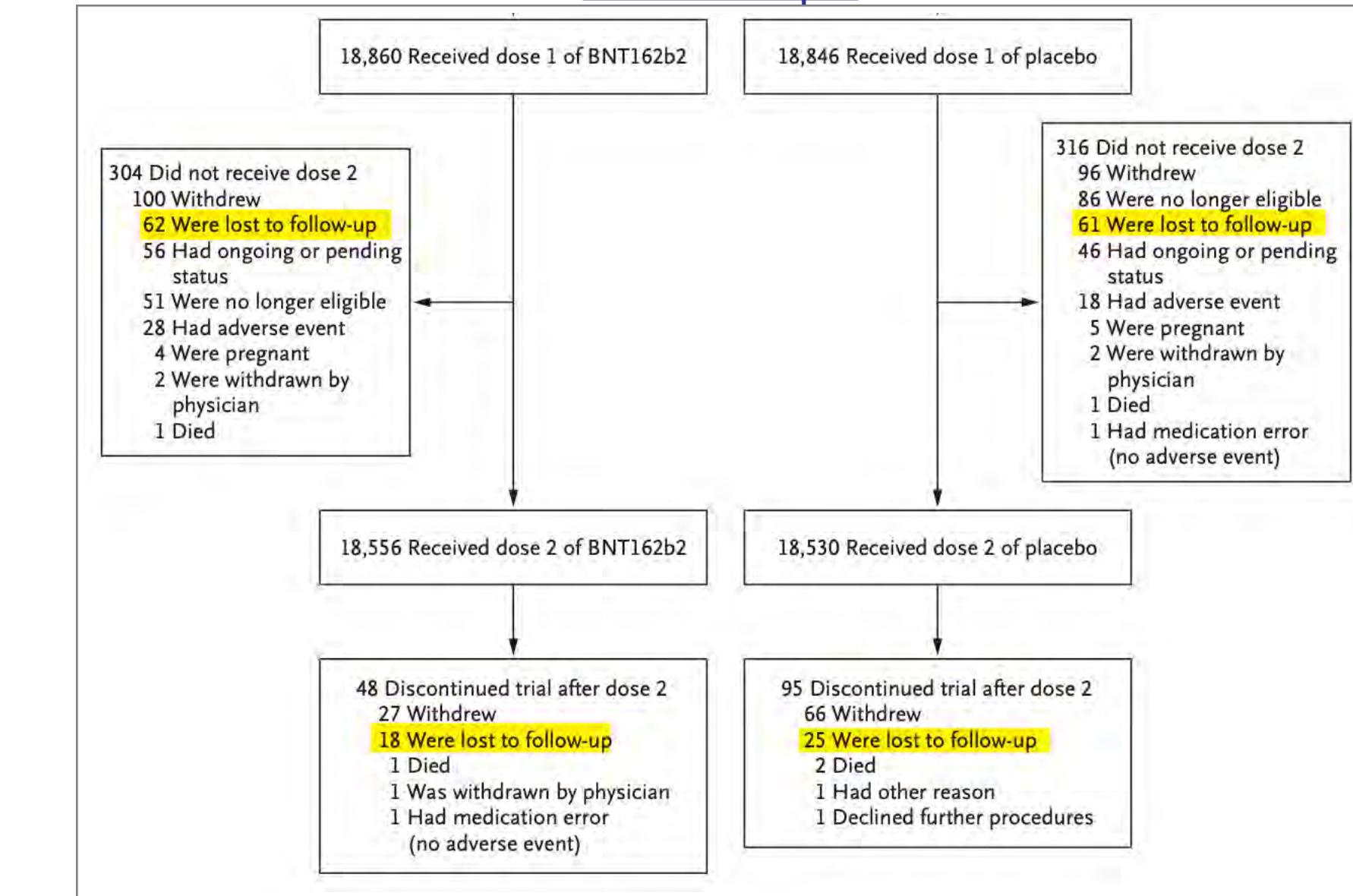
Dec 31 2020 Report

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)†		
Overall	No. of Cases 8	Surveillance Time (No. at Risk)* 2.214 (17,411)	No. of Cases 162	Surveillance Time (No. at Risk)* 2.222 (17,511)	95.0 (90.0–97.9)

Lost to Follow Up

Dec 31 2020 Report



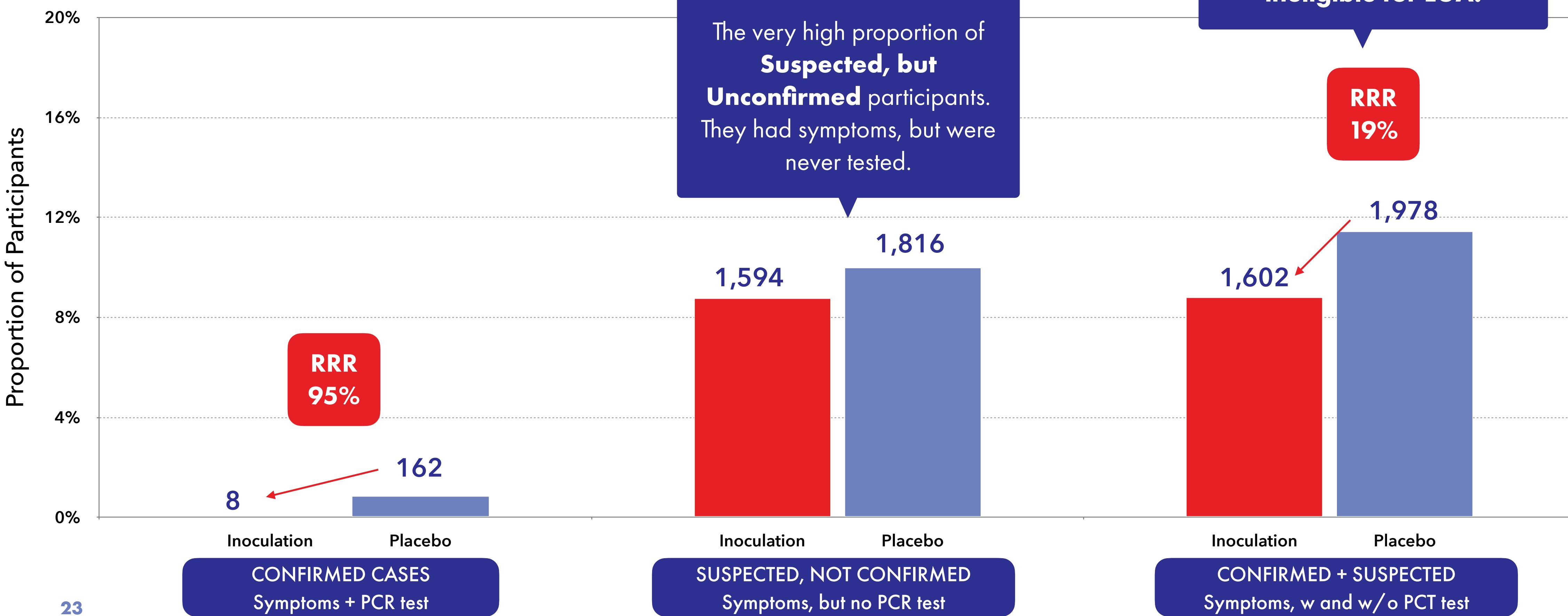
Suspected but Unconfirmed

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





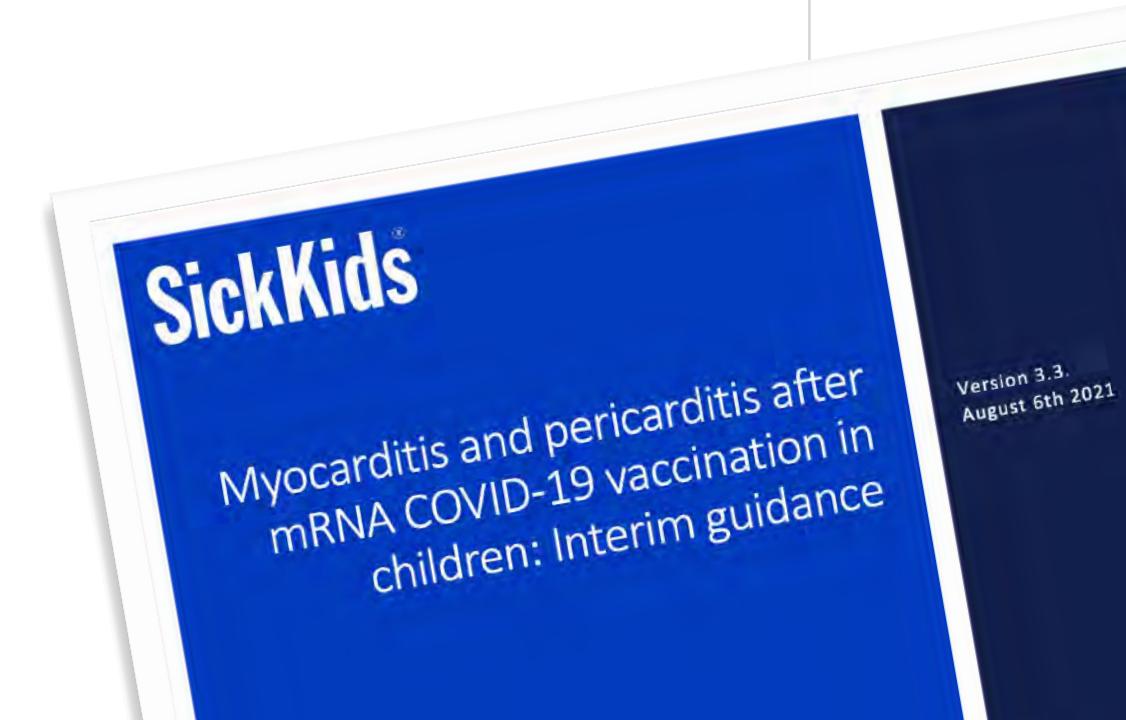
5 - 11 YEAR OLDS RISKING THEIR HEALTH

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

Sex	Benefits					Risks			
	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	

Scenario 1: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
 Scenario 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% vs. COVID-19 hospitalization.
 Scenario 3: COVID-19 incidence as of nadir in June 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
 Scenario 4: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization.
 Scenario 5: COVID-19 case incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization, COVID-19 death rate 300%, and 300% excess myocarditis cases.
 Scenario 6: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization, COVID-19 death rate 300%, and 50% excess myocarditis cases.

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



MYOCARDITIS IS SERIOUS

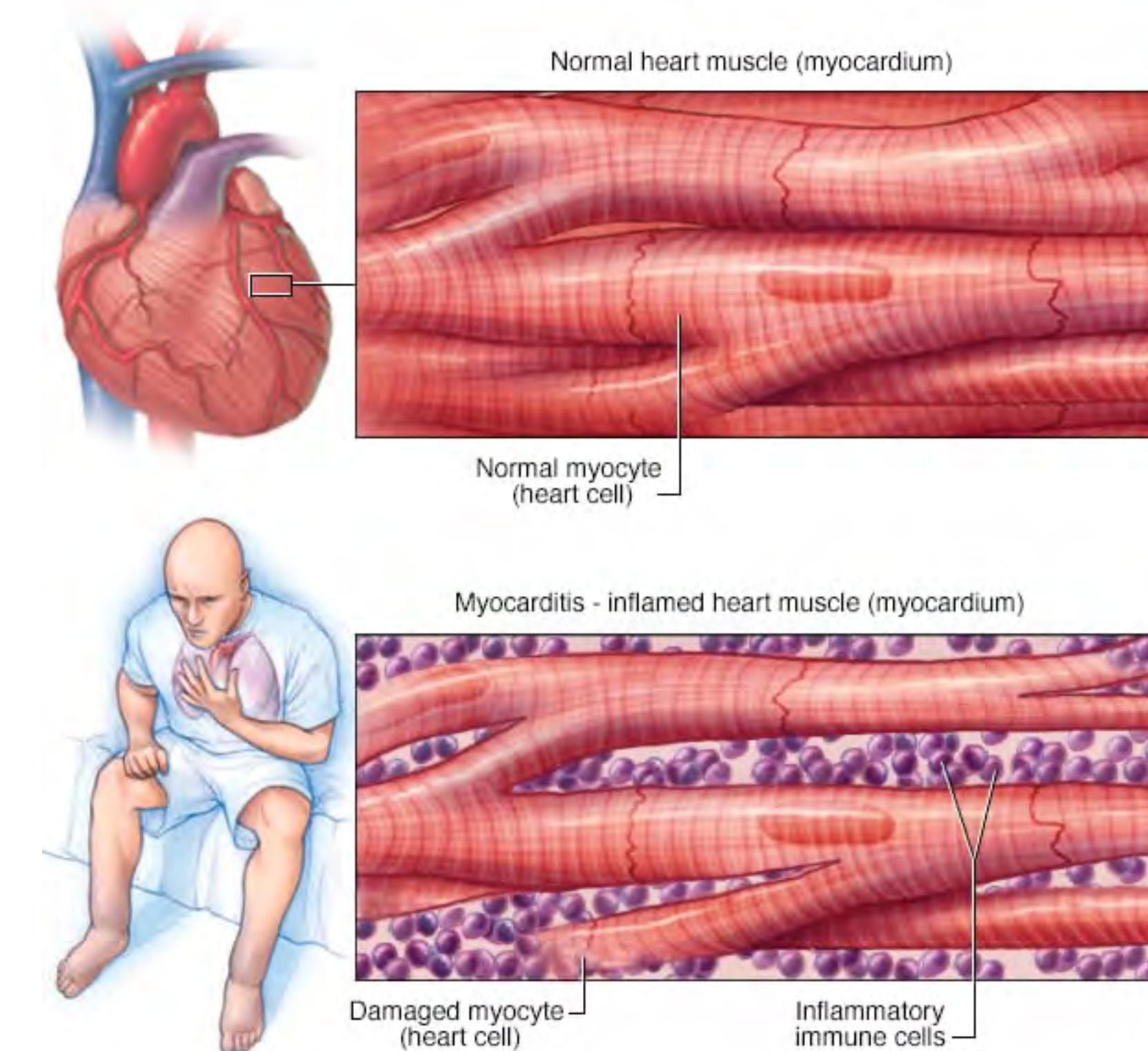
MYOCARDITIS

"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>



© MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH. ALL RIGHTS RESERVED.

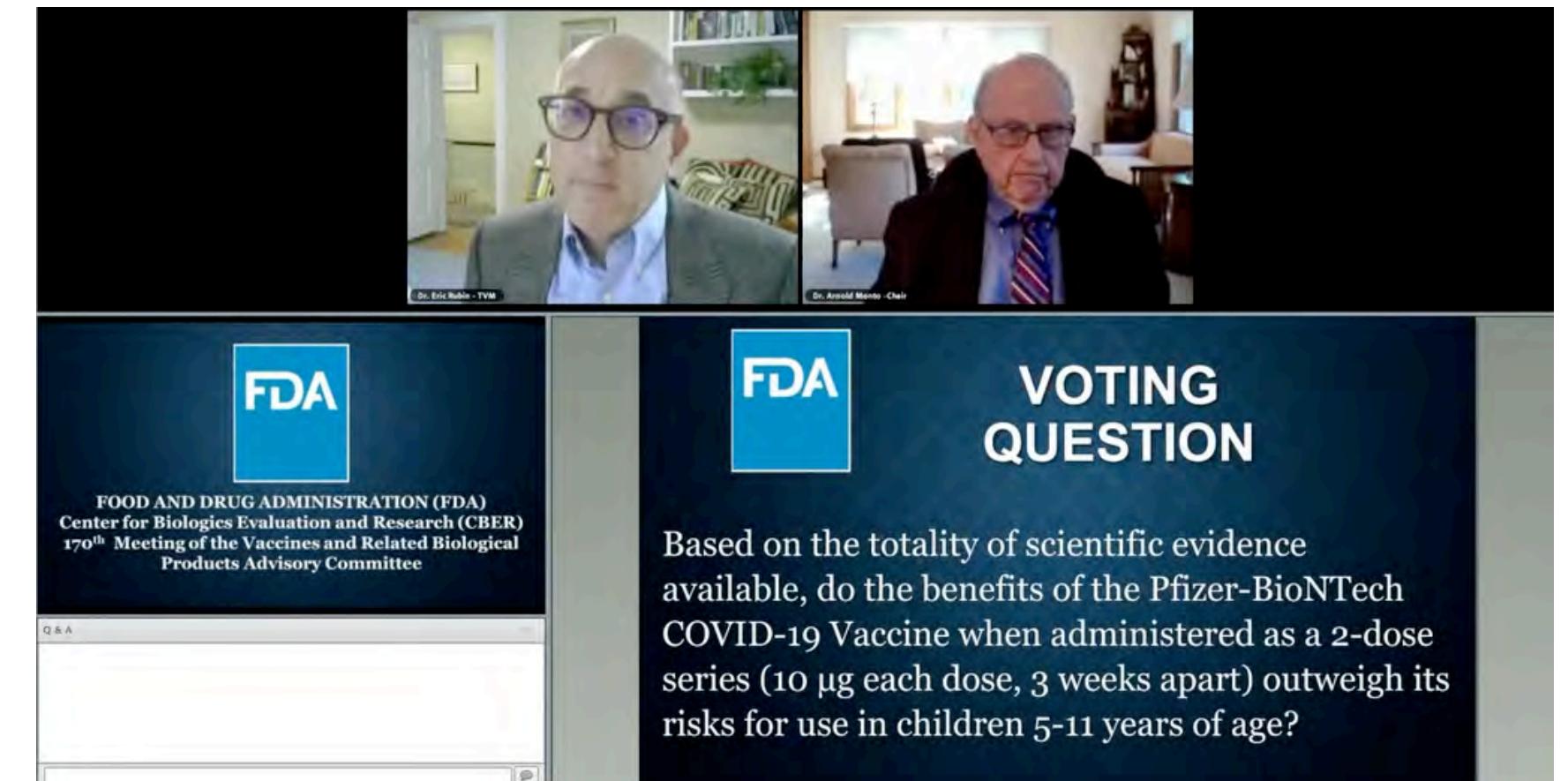


THE FDA ABANDONS FIRST, DO NO HARM

Medical interventions are supposed to be **PROVEN SAFE BEFORE** they 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.**



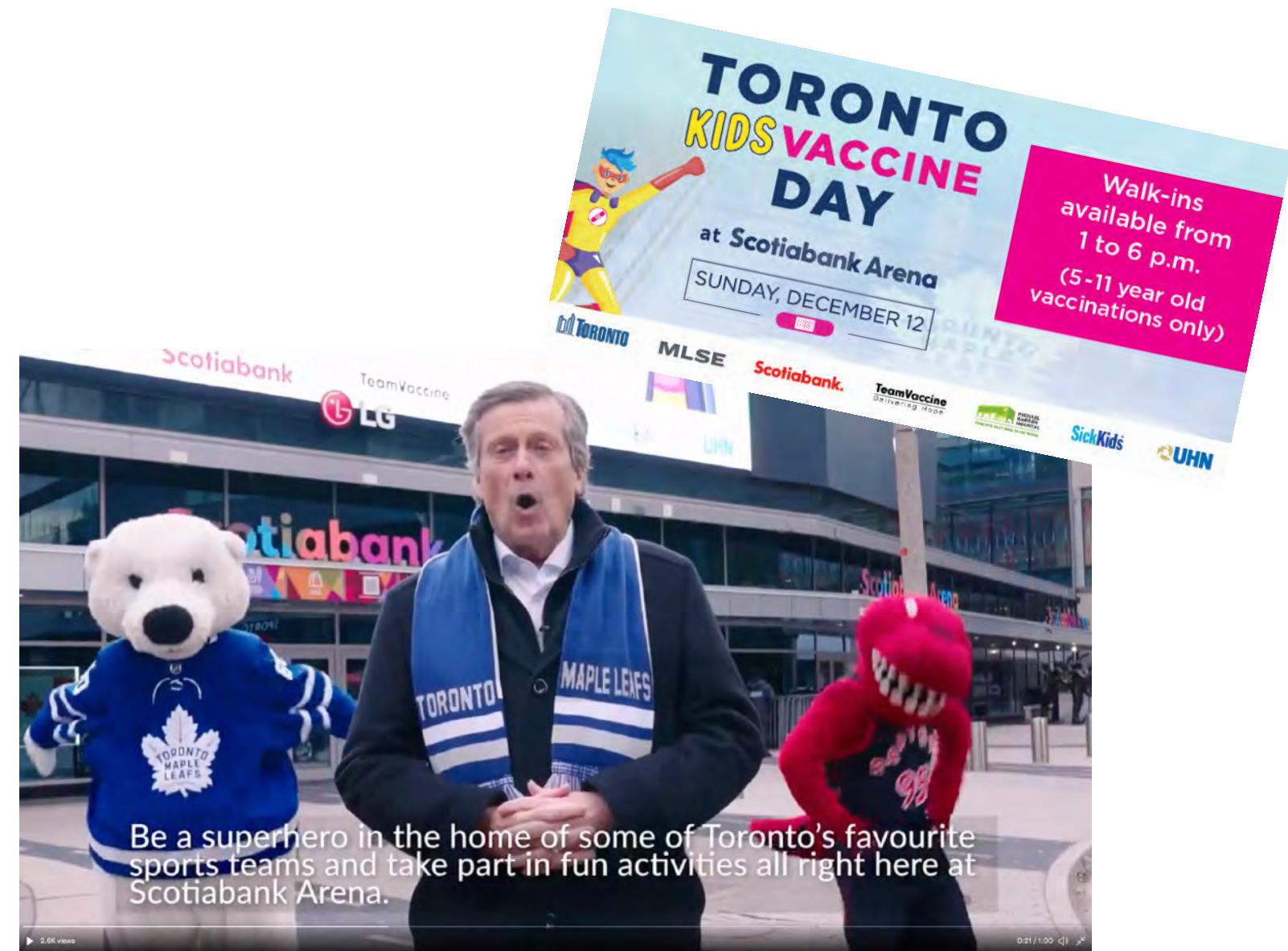
"We're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes. That's how we found out about rare complications of other vaccines like the rotavirus vaccine. And I do think we should vote to approve it."

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-



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**

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 recordings, 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 September 2020 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, and the trial was not being run by ICON, the contract research



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. French, 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- μ g 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
The New England Journal of Medicine

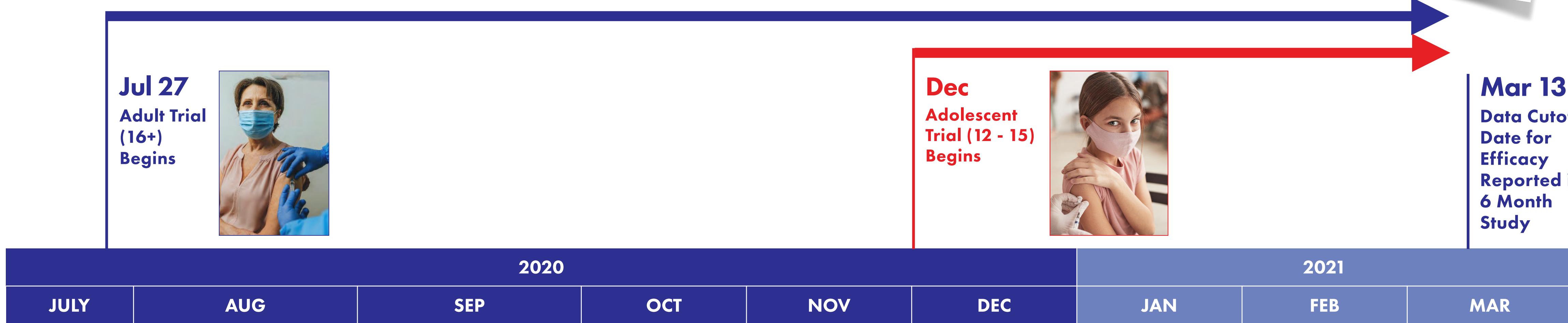
Downloaded from nejm.org on November 10, 2021. For personal use only. No other uses without permission.
Copyright © 2021 Massachusetts Medical Society. All rights reserved.



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.



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- μ g 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
 Downloaded from nejm.org on November 10, 2021. For personal use only. No other uses without permission.
 Copyright © 2021 Massachusetts Medical Society.
 DOI: 10.1056/NEJMoa2110345
 CME at NEJM.org



PFIZER TRIALS DID NOT PROVE SAFETY THEY PROVED HARM

ILLNESS				DEATHS
	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%	
	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



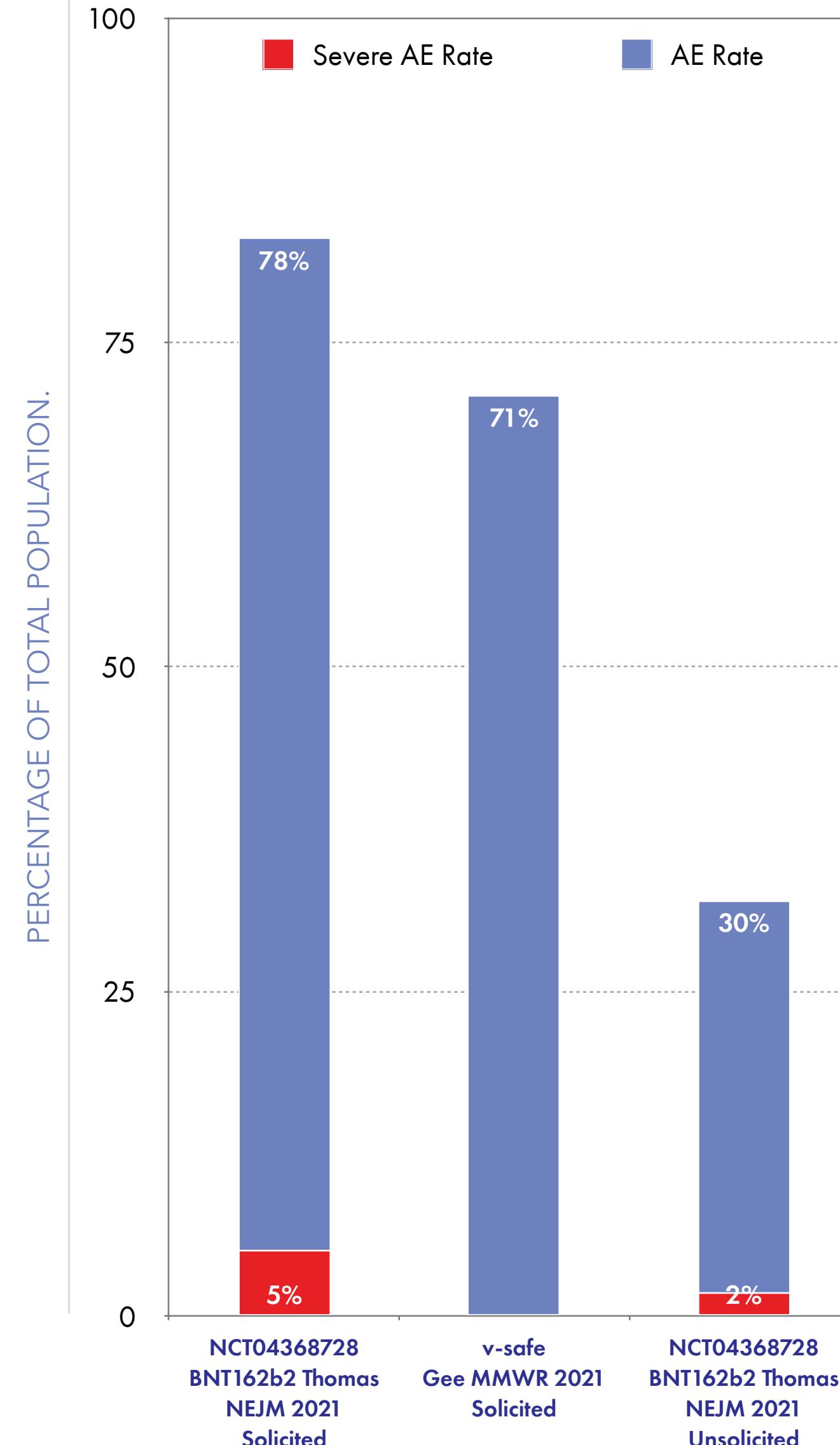
ROLL OUT SURVEILLANCE YOU DON'T FIND WHAT YOU DON'T LOOK FOR

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.

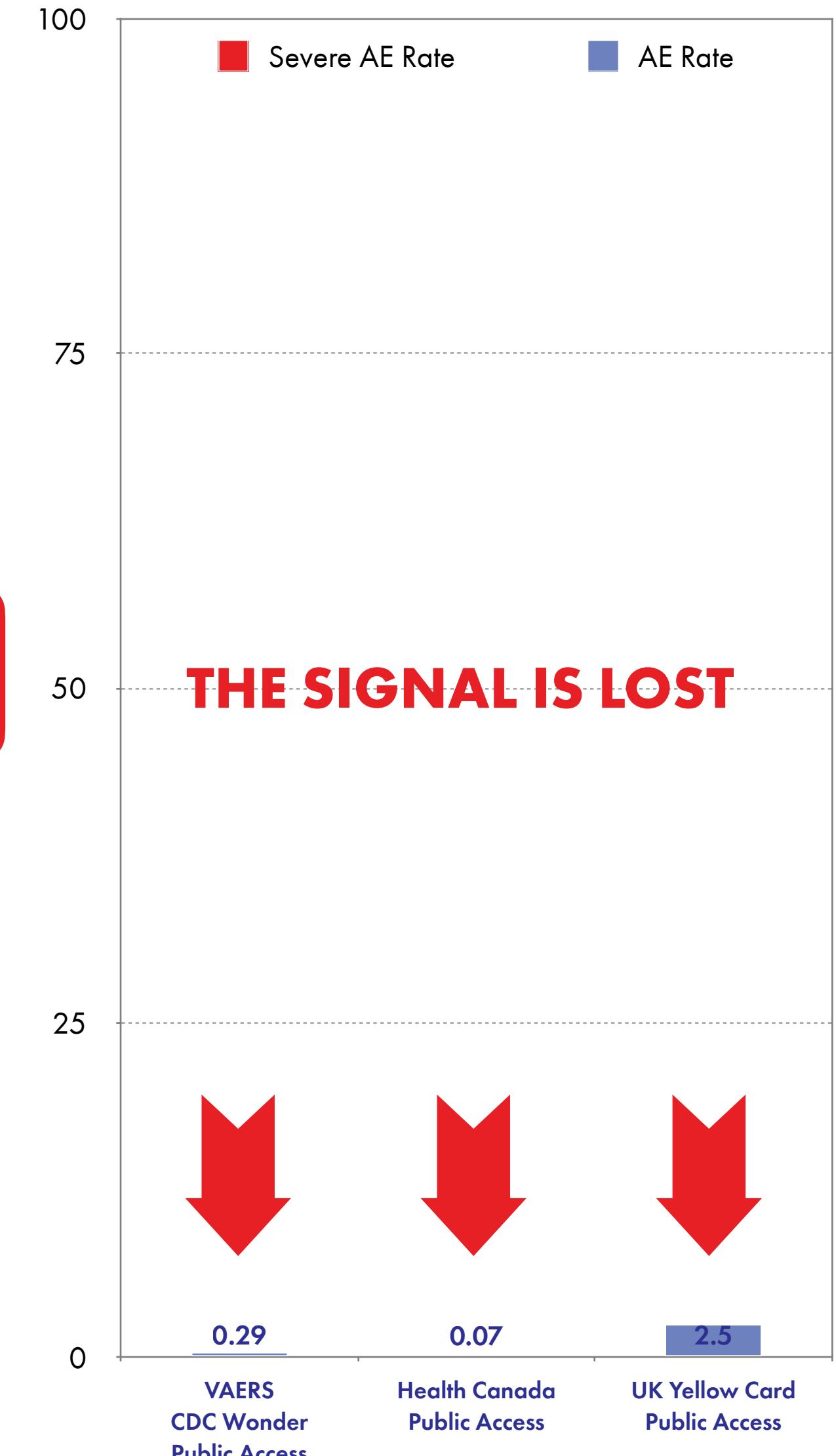
When that happened, the **signal was completely lost.**

ACTIVE SURVEILLANCE OF TRIAL PARTICIPANTS



VS

PASSIVE SURVEILLANCE OF POPULATION ROLL OUT





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 following vaccination (AEFVs) in Ontario following the receipt of a COVID-19 mRNA vaccine. Data on myocarditis and 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



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

Ernest Ramirez

Health News , Vaccine Injury Stories , Vaccines

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

Sign in
Contribute →

The Guardian
For 200 years

Barcelona
Sergio Agüero out for three months following 'cardiological evaluation'

- Striker admitted to hospital after draw with Alavés
- 33-year-old to undergo 'diagnostic and therapeutic process'

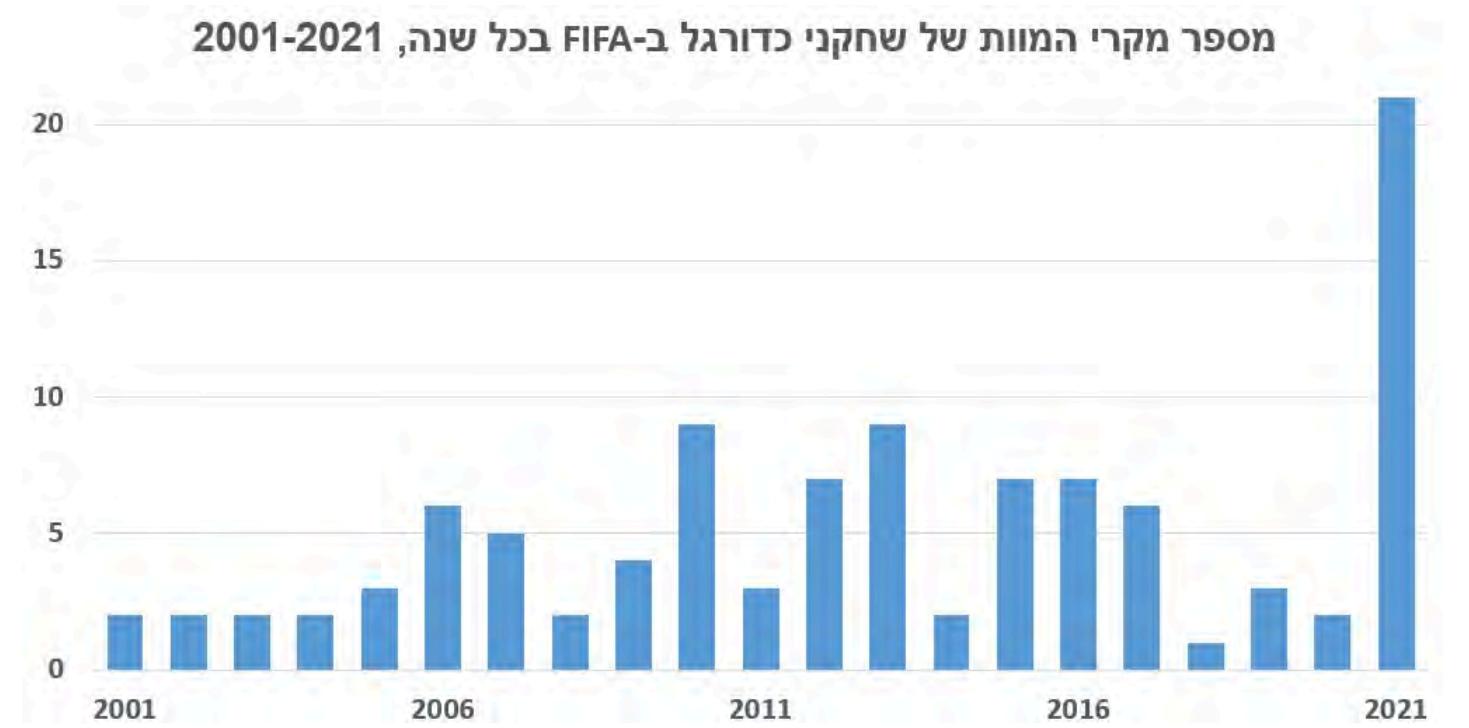
THIS IS NOT NORMAL

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-schwerranker-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.



SN

USPORTS Men's Football Men's Basketball Women's Basketball Men's Hockey Women's

EN MÉMOIRE DE IN MEMORY OF FRANCIS PERRON 1996 - 2021

Gee-Gees football player Francis Perron dies shortly after season opener

PFIZER/BIONTECH, USA

Isaiah Harris – Pfizer Severe Adverse Reaction

06/09/2021 / 1,139 views

Isaiah Harris Aged 18 – Pfizer May 2021

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

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



THIS IS SUPPOSED TO BE RARE



<https://rumble.com/vpxnkr-are-these-side-effects-extremely-rare.html>



PFIZER'S POST MARKETING PHARMACOVIGILANCE REPORT

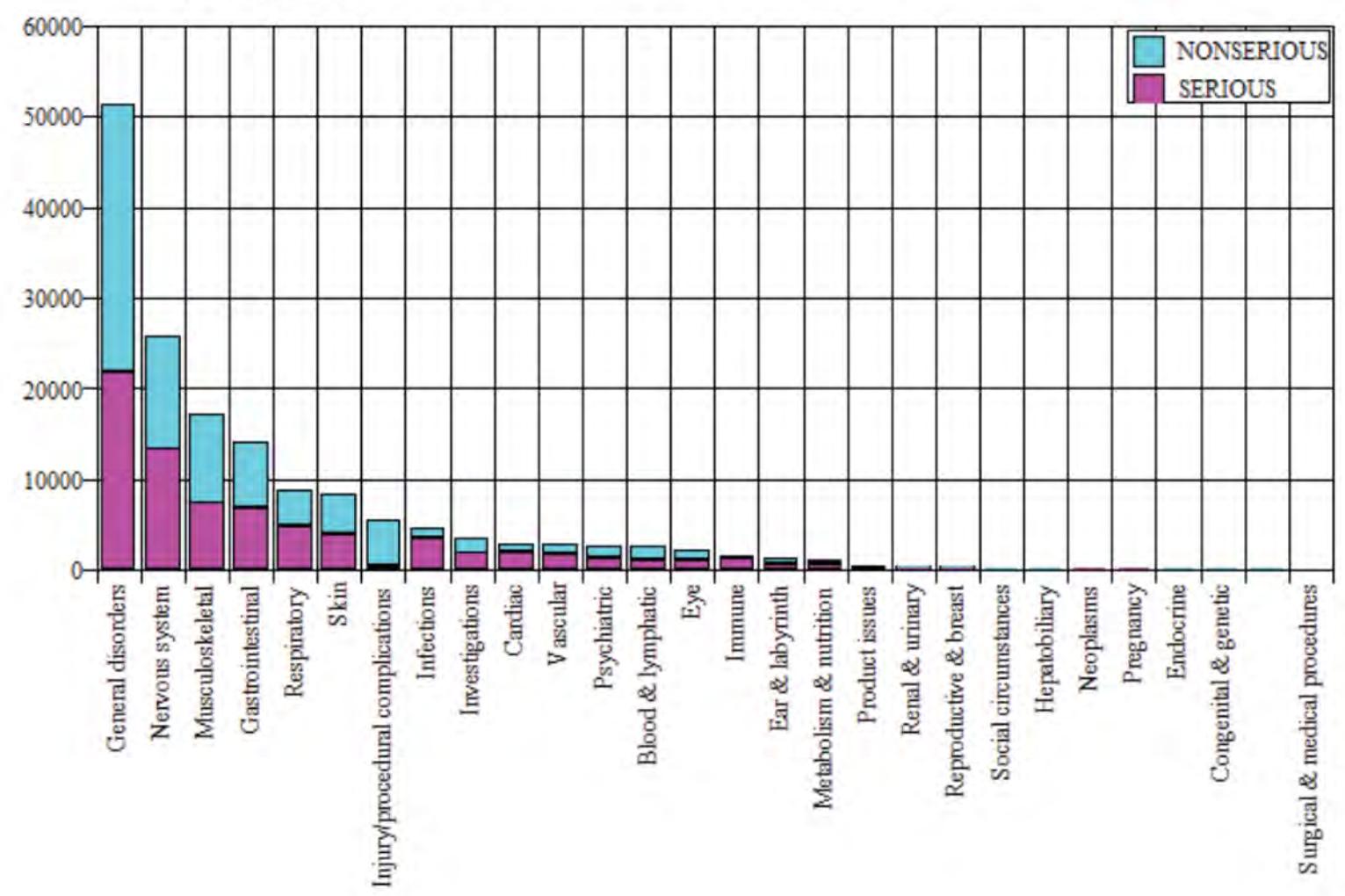
- On Nov 17, 2021, the FDA released the first batch of what will ultimately be **329,000 pages** they were ordered by a court to provide to satisfy a Freedom of Information request by a group called Public Health and Medical Professionals for Transparency who want access to the **data used by the FDA 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)	
	Female	Male
Gender:	29914	9182
No Data	2990	
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	175 ^a 4953 13886 7884 3098 5214 6876	175 ^a 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering Recovered with sequelae Not recovered at the time of report Fatal Unknown	19582 520 11361 1223 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 \$10.75 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.

REUTERS
World Business Markets Breakingviews Video More
HEALTHCARE & PHARMA DECEMBER 9, 2010 / 9:45 AM / UPDATED 8 YEARS AGO

US high court leaves intact \$142 million verdict against Pfizer

By Lawrence Hurley

WASHINGTON (Reuters) - The \$142 million jury verdict against drug Neurontin.

The jury had ruled in favor of a for the drug for "off-label" uses

In 2010, the jury in Massachusetts drug for off-label uses, Kaiser largest health maintenance org they paid for prescriptions relat treat.

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, \$26.64 million will go to a former company adviser who brought a lawsuit under a federal "whistleblower" law.

NOVEMBER 18 2021

42

The Guardian For 200 years

Pfizer pays out to Nigerian families of meningitis drug trial victims

Search International edition Search jobs Sign in

THE UNITED STATES DEPARTMENT OF JUSTICE

ABOUT OUR AGENCY TOPICS NEWS RESOURCES CAREERS

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

CTV NEWS

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

Published Tuesday, August 7, 2012 11:47AM EDT Last Updated Tuesday, August 7, 2012 2:52PM EDT

BBC NEWS

Pfizer fined record £84.2m for overcharging NHS

By Tom Espiner Business reporter, BBC News

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.

AboutLawsuits.com

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

NEWS MEDICAL LIFE SCIENCES

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.

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 that did not support those uses, according to experts who reviewed



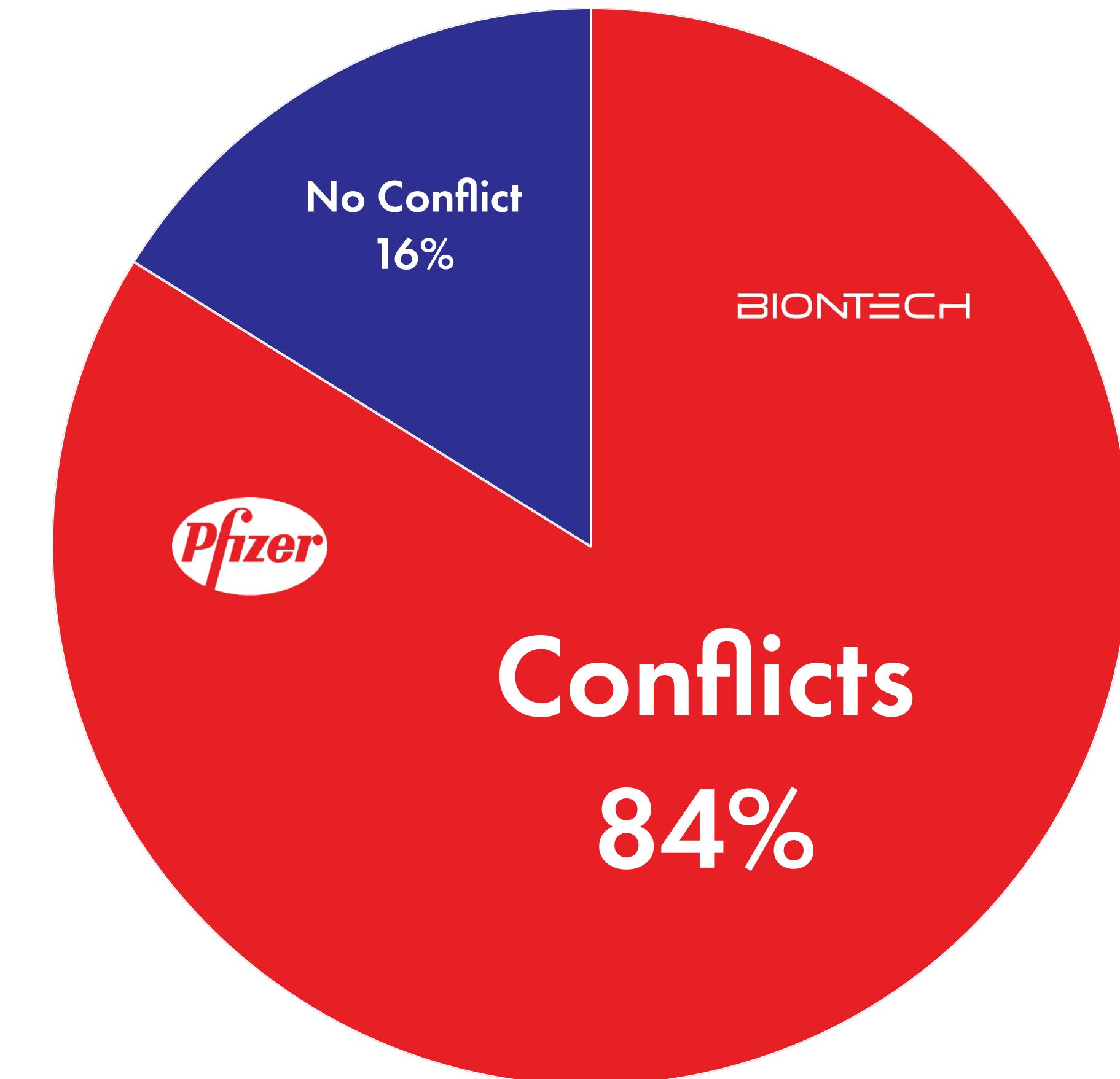
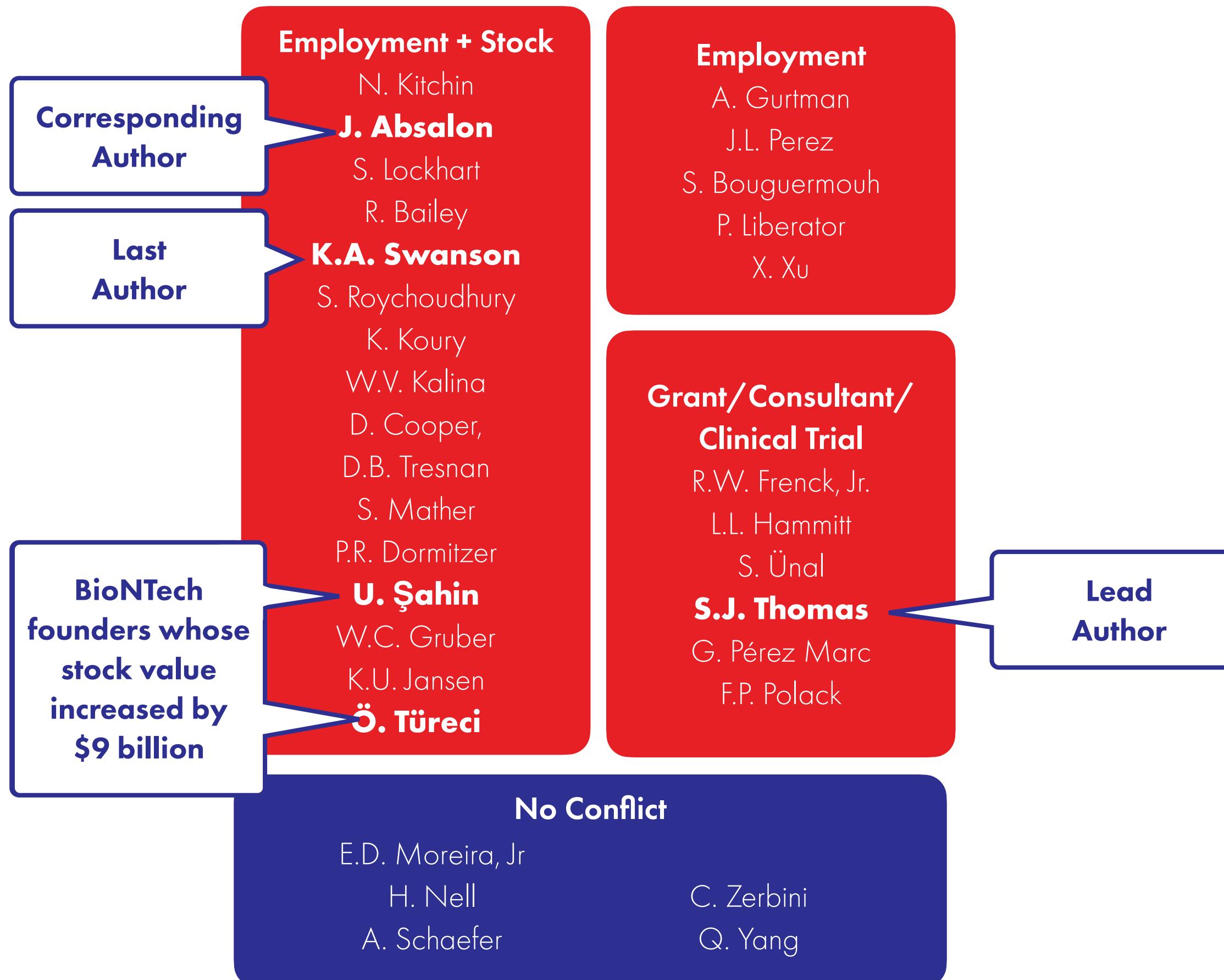
LINKS TO THE PUBLIC RECORD OF PFIZER'S CORPORATE CULTURE

- **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/2012-2012-152.htm>
- **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

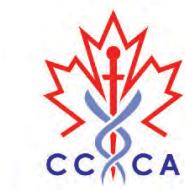
6 MONTH REPORT AUTHORS





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

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



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/vleg43-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/gLZZ5JmRIM4>



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