

On Trial: A Critical Look at the Pfizer Phase 3 Covid Vaccine Study

James M. Eli on 2/4/2022

“I would rather have questions that can't be answered than answers that can't be questioned¹.”

How do you get more than a billion people to take an unapproved medical product²?

The first person in the world to receive an mRNA Covid vaccine outside a clinical trial was Margaret Keenan, a 90-year-old Englishwoman, on Dec. 8, 2020. Since then, 166 countries around the world have received 2.6 billion doses of the Pfizer-BioNTech vaccine. Pfizer and BioNTech have produced 3 billion doses in 2021 and they aim to produce 4 billion doses in 2022³.

On Jan 2, 2022, Israel's prime minister announced that the country would offer a fourth dose of the Pfizer Covid vaccine to healthcare workers and people older than 60 years⁴. A fourth dose was already approved for Israel's immunocompromised groups. Around two-thirds of Israelis have received two doses of the vaccine. 80% of the eligible population have received two doses

¹ Quote widely attributed to Richard P. Feynman, an American theoretical physicist, known for his work in quantum mechanics. However, there is no direct source for the quote.

² The Emergency Use Authorization authority allows the FDA via the Federal Food, Drug, and Cosmetic Act, when declared that an emergency use authorization is appropriate, to authorize *unapproved medical products or unapproved uses of approved medical products* to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

³ <https://www.pfizer.com/science/coronavirus/vaccine/working-to-reach-everyone-everywhere>

⁴ [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(22\)00010-8/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00010-8/fulltext)

plus a booster, including 90% of individuals over the age of 60. Israel began vaccinating 5 to 11-year-olds in November 2021. The efficiency of the early vaccination campaign, which had delivered two doses to over half of the population by April 2021, means that Israel is well-placed to observe the effectiveness of the Pfizer vaccine.

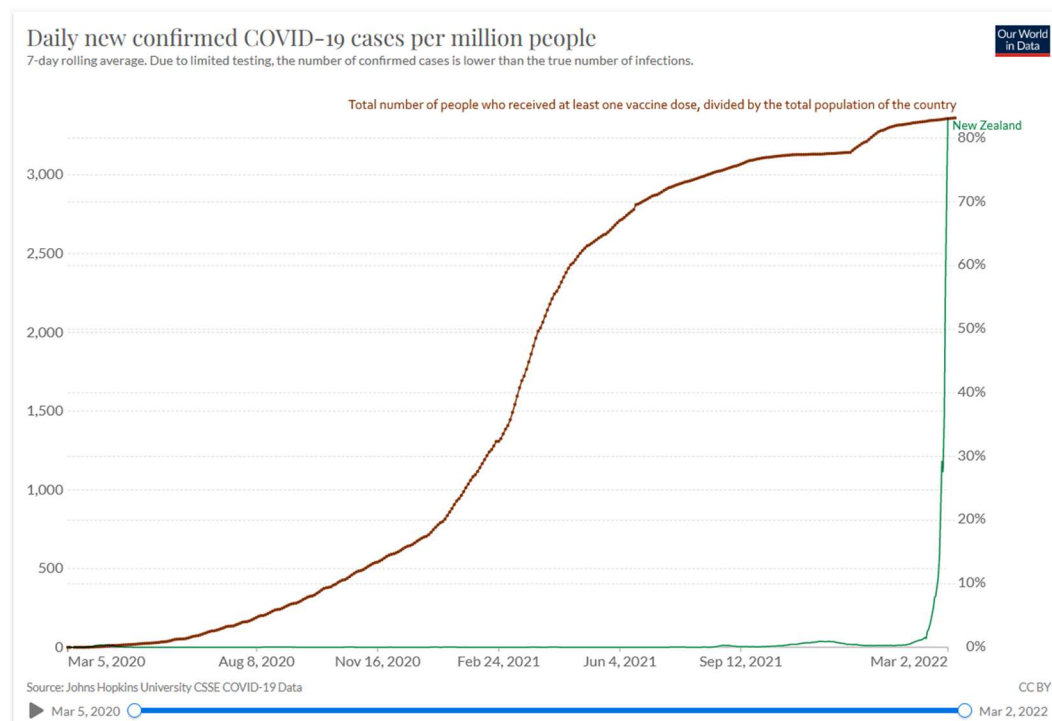
Israel has recently seen a surge in SARS-CoV-2 infections. Hospitalizations and deaths are also increasing.



Examine what is currently occurring in New Zealand just 44 weeks since it was claimed by both CNN and the New Zealand Minister of Health that they eliminated Covid. "That does give us confidence that we've achieved our goal of elimination, which never meant zero but it does mean we know where our cases are coming from."⁵ The country of New Zealand followed one

⁵ <https://edition.cnn.com/2020/04/28/asia/new-zealand-coronavirus-outbreak-elimination-intl-hnk/index.html>

of the toughest 'Zero Covid' strategies for the longest time and persisted with arguably the harshest measures worldwide attempting to prevent and rid the country of the disease. The New Zealand Ministry of Health claims 94% of the 12+ age group and 52% of the 5 to 11-year-old category are fully vaccinated with nearly 2.5 million booster shots administered (New Zealand's population is roughly 5 million)⁶. Yet, at this level of vaccination, new Covid infections are undeniably out-of-control in the country⁷.



What is going on?

⁶ <https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data>

⁷ New Zealand is an interesting study from the vantage point of Covid vaccine safety since, unlike most all other countries, it had nearly no Covid while the vaccines were being rolled out. At the time of this writing, there have been 63 Covid deaths in New Zealand in the span of two years. With such high vaccination rates, the reason they just exceeded the highest worldwide per capita Covid infection rate demands investigation. One plausible suggestion is that there truly is a "negative vaccine efficacy."

People don't realize that these vaccines are vastly different from the many childhood vaccines we received early in life. According to the CDC, a vaccine is "a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease." Immunity, in turn, is defined as "Protection from an infectious disease," meaning that "If you are immune to a disease, you can be exposed to it without becoming infected." However, Pfizer doesn't claim this to be the case for its Covid "vaccine." In their clinical trials, Pfizer specifically did not test for immunity.

Unlike the vaccines of our youth, which use an antigen of the disease they're trying to prevent, the Covid injections contain synthetic RNA fragments encapsulated in a carrier compound. The sole purpose of the Pfizer vaccine is to lessen the clinical symptoms associated with the S-1 spike protein, not the actual virus. They're not imparting immunity or inhibiting the transmissibility of the disease. Stated otherwise, they don't keep you from getting sick with SARS-CoV-2. As such, these products do not meet the legal or medical definition of a vaccine, and as you can guess, there are concomitant immense legal ramifications for this deception⁸.

There are several factors associated with the Pfizer vaccine that lack precedent:

- The first-ever use of mRNA gene transfer technology against an infectious agent.
- The first-ever use of PEG in an injection.
- The first-ever coronavirus vaccine ever tested on humans (previous coronavirus vaccines all failed due to antibody-dependent enhancement, a condition in which the antibodies facilitate infection rather than defend against it).
- The first-ever use of genetically modified polynucleotides in the general population.

⁸ https://www.theepochtimes.com/covid-19-vaccines-a-case-of-false-advertising_4321714.html

The new technology behind the mRNA and DNA vaccine⁹ bring with them many potentially unknown consequences to health. Vaccines normally take ten to twelve years to develop, with only a 2% success rate, but these unprecedented vaccines were developed and brought to market in less than a year. As a consequence, we completely lack direct knowledge of any effects that the vaccines might have on our health over the long term.

Somewhat more worrisome is the possibility these vaccines may be a pathway to crippling disease¹⁰ sometime in the future. Unfortunately, we won't know whether the vaccines cause this increase, because of the lengthy time between vaccination and disease diagnosis. This would be a very convenient situation for the vaccine manufacturers, who stand to make huge profits off of our misfortunes — both from the sale of the vaccines themselves and from the large medical cost of treating all these debilitating diseases.

The vaccines were approved for emergency use based on minimal and as shown below, undoubtedly inadequate studies to evaluate their safety and effectiveness. We should all find it shocking that vaccine developers, government officials, media, and vaccine fanatics are recklessly pushing these vaccines on an unsuspecting population.

Are you ready for this?

⁹ <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC6631684/>

¹⁰ <https://www.ijvtp.com/index.php/IJVTPr/article/view/23>

One needs to look no further than the Pfizer reports^{11, 12, 13, 14} and the FDA's authorization documents^{15, 16} to make jaw-dropping discoveries about the Pfizer Covid vaccine. These primary documents are the source for everything noted herein. Currently, all of these documents are publicly available.

Recently the FDA removed the Summary Basis for Regulatory Action on the Moderna vaccine from their website¹⁷, so availability of these documents in the future is not guaranteed. Furthermore, many of the Pfizer and FDA vaccine documents have not been made public. The FDA argued against a FOIA request for the release of thousands of these associated documents¹⁸, even though the FDA is the public agency entrusted with confirming the vaccine's safety and approving its use. All this is especially dubious, given that the American public has paid for both the research and production of these vaccines and Congress has given Pfizer total immunity from liability¹⁹.

Assisting in the suppression of valuable information is the Centers for Disease Control and Prevention, commonly referred to as the CDC. The New York Times reported:

“Two full years into the pandemic, the agency leading the country's response to the public health emergency has published only a tiny fraction of the data it has collected, several people familiar with the data said. Much of the withheld

¹¹ <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>

¹² <https://www.nejm.org/doi/full/10.1056/NEJMoa2110345>

¹³ <https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>

¹⁴ <https://www.nejm.org/doi/full/10.1056/NEJMoa2110345>

¹⁵ <https://www.fda.gov/media/144245/download>

¹⁶ <https://www.fda.gov/media/144245/download>

¹⁷ https://www.theepochtimes.com/fda-document-on-moderna-vaccine-approval-removed-from-agencys-website_4254453.html

¹⁸ <https://phmpt.org/wp-content/uploads/2022/01/044-PL-PHPMTS-MOL-IN-OPPOSITION-TO-DEFENDANTS-MOTION-TO-MODIFY-THE-SCHEDULING-ORDER-OF-THE-COURT.pdf>

¹⁹ PREP Act immunity covers all liability except death or serious physical injury caused by misconduct greater than any form of recklessness or negligence, <https://crsreports.congress.gov/product/pdf/LSB/LSB10443>

information could help state and local health officials better target their efforts to bring the virus under control²⁰.”

The CDC claims one of the reasons for not releasing their data, “is fear that the information might be misinterpreted.” This is like banning evidence in a judicial trial because it could be used to convict and also to acquit.

Why doesn’t Pfizer, the FDA, and the CDC want this information made public?

The top executives at Pfizer and partner BioNTech have made billions of dollars since the beginning of the pandemic selling their vaccines. The Pfizer company forecasts \$54 billion in Covid-related sales for 2022.

Is it reasonable to ask the Pfizer executives to remain objective about what they sell with so much money at stake?

Pfizer didn’t become the third-largest pharmacological company in the world without employing every conceivable ploy and ruse in their drug trials to ensure approval by the FDA. And not every ploy and ruse has been legal too. In fact, Pfizer’s past is filled with fraudulent drug development. For example, in late 2009, Pfizer and a subsidiary agreed to pay \$2.3 billion, the largest health care fraud settlement in the history of the Department of Justice²¹, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. In 2008, experts who reviewed thousands of Pfizer documents in a lawsuit testified that Pfizer manipulated the publication of scientific studies to bolster the use of its epilepsy drug

²⁰ <https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html>

²¹ <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history>

Neurontin for other disorders while suppressing research that did not support those uses²². Also, Pfizer managers paid academics \$1,000 per paper, according to a document released in litigation²³. Most companies have sworn off the practice of writing "research" papers for doctors and then paying them to add their names as authors even when they had little involvement or the results were trivial.

Concerning the Pfizer Covid vaccine, the biggest problem is the inadequate evidence supporting that the benefits outweigh the risks. The question turns out to be far more complicated than simply determining if the vaccines reduce the number of Covid infections, serious infections, or even death. Moreover, the question is especially worrying for people under 50, who have a much lower risk of serious illness or death from Covid but often suffer severe short-term side effects after vaccination. Individuals over 75 are at a higher risk from Covid yet appear somewhat less likely to suffer severe side effects.

A fundamental yet essential step in the development of a vaccine is demonstrating that they help people make antibodies that attack the virus. Without a doubt, the Pfizer vaccine does help make protective antibodies. But we also know that older people generally make fewer antibodies than younger people²⁴. In their trial report, Pfizer didn't disclose anything specific about how older people responded to their vaccines.

Pfizer ultimately reported 170 Covid infections in their trial, beginning 7 days after the second shot. This is supposedly the timeframe when the vaccine becomes fully effective (more about this later). Eight of the infections occurred in vaccine recipients, while the other 162 occurred in those who received the placebo, out of more than 40,000 participants.

²² <https://www.nytimes.com/2008/10/08/health/research/08drug.html>

²³ <https://www.cbsnews.com/news/inside-pfizers-ghostwriting-shop-friendly-drug-studies-for-just-1000/>

²⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1315345/>

What most didn't notice was that the majority of these infections did not require hospitalization or intensive care. They were principally mild to moderate cases involving a positive Covid test in concert with symptoms such as a cough or low-grade fever. Serious illness from Covid in the trial was rare among both vaccine and placebo recipients. Of those who received the placebo, only nine became what Pfizer termed "severely" ill, compared to one vaccine recipient. No one died of Covid in the trial, and only 6 people died for a reason other than Covid (two people who received the vaccine, and 4 who received the placebo).

Given the trial size, does such a small difference provide compelling evidence that the vaccine saves lives?

Why did so few people die in the trial if Covid has killed more than 910,373²⁵ Americans (1 out of roughly every 600 people)? Was it because Pfizer tested their vaccines primarily on healthy people and those under 65?

According to the CDC, as of February 2, 2022, 53% of the total U.S. Covid deaths occurred in the 75-plus age group,²⁶ (3,680,069 total), while 74% of the deaths were in the 65-and-over age group²⁷.

²⁵ <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>, accessed 2/11/2022.

²⁶ Provisional COVID-19 Deaths by Sex and Age, Deaths involving coronavirus disease 2019 (COVID-19), pneumonia, and influenza reported to NCHS by sex, age group, and jurisdiction of occurrence. <https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-by-Sex-and-Age>

²⁷ <https://www.cdc.gov/nchs/covid19/mortality-overview.htm>

A review of recent data released by the U.K. government in response to a FOIA²⁸ request shows that the number of deaths during 2020 in England and Wales, where Covid was the sole cause of death, was 9,400. Of those, 7,851 (83%) were aged 65 and older. The median age of death was 81.5 years.

The demographics of the Pfizer study participants show that most (79%) were under the age of 65. Only 1,700 of them were over 75, and only half of those received the vaccine. This represents less than 2% of the study participants. Additionally, Pfizer enrolled only five people over 85. Furthermore, these older people were relatively healthy. In fact, “healthy participants²⁹” were specified by Pfizer as an eligibility criterion for the trial. Most lacked comorbidities like high blood pressure, diabetes, cardiovascular disease, dementia, etc. Yet, most people who died of Covid had multiple comorbidities³⁰.

Wishful thinking has it that, “those who conduct clinical trials ‘enrich’ study populations in a variety of ways in order to identify a population of patients in whom a drug effect, if present, is more likely to be demonstrable³¹.” Clinical trial enrichment strategies are a well-documented subject. But, “trials also sometimes actively recruit patients who are likely to respond well to treatment.³²”

Did Pfizer purposely not test the vaccine in the “right” people?

²⁸ The FOIA request to the ONS asked for all deaths in which Covid had been given as the sole cause on the death certificate, which is about a tenth of the generally stated toll, <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/preexistingconditionsofpeoplewhodiedduetocovid19englandandwales>

²⁹ https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf

³⁰ 94% of deaths mention more than one condition, https://www.cdc.gov/nchs/data/health_policy/covid19-comorbidity-expanded-12092020-508.pdf

³¹ <https://pubmed.ncbi.nlm.nih.gov/20944560/>

³² <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC1488890/>

Pfizer's original trial report was published in the New England Journal of Medicine on December 21, 2020, and showed 2 months-worth of safety and efficacy data. It was a randomized double-blind placebo-controlled trial, widely considered the "gold standard" of epidemiologic studies. It described starting with 43,548 people divided into 2 groups, a treatment (received inoculation) and a control group (received saline). The trial lasted for 2 months to see who developed Covid. Pfizer claimed that the inoculations were safe and showed 95% vaccine efficacy 7 days after the 2nd dose.

While the vaccine efficacy of 95% was being celebratorily hyped, nothing in the report indicated confirmed infections rates for the population where the study took place. Thus, it would be impossible to know actual infection rates in the total population. If there was very low exposure in the study group, efficiency could seem very high when in fact the results were not significant due to very low infection rates in the total population. Since the study was conducted during a period of lockdowns, limited interactions, and ongoing infection control measures, the actual infection rate for the entire population in which the study was conducted should have been tracked.

Why didn't Pfizer want to know?

As it is, the oft-quoted 95% vaccine efficacy is just another name for "relative risk reduction". Relative risk reduction sounds impressive because of the high number, which is why it is used in press releases widely disseminated to news agencies. But, if the relative risk reduction is presented alone, it introduces a reporting bias³³ and tells only half of the story.

33 Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials, *medicina*, 26 February 2021, Ronald B. Brown, <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7996517/>

The “absolute risk reduction” is more relevant to the person getting the vaccine because it is the difference between attack rates with and without a vaccine and considers the whole population. The absolute risk reduction tells us about the effectiveness of the vaccine related to an individual. The unpublished absolute risk reduction of the Pfizer vaccine was 0.84%³⁴.

The Pfizer data, absent absolute risk reduction, was reviewed and approved by the members of the FDA’s Vaccines and Related Biological Products Advisory Committee. Ironically, and revealing evidence of “regulatory capture³⁵”, the omission of absolute risk reduction contradicts the FDA guidelines for communicating evidence-based risks and benefits to the public. The FDA’s advice for information providers includes:

“Provide absolute risks, not just relative risks. Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an absolute risk format should be used³⁶.”

Would people have taken the vaccine knowing that it only reduced their chance of infection by less than 1%?

Pfizer documented 166 participants (80 in the treatment and 86 in the placebo arm) as “Lost to Follow Up,” with another 3,410 participants categorized as “suspected, but unconfirmed cases”

34 COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room, *The Lancet Microbe*, Volume 2, ISSUE 7, e279-e280, July 01, 2021, Piero Olliaro, Els Torreele, Michel Vaillant, [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00069-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext)

³⁵ <https://www.e-education.psu.edu/ebf483/node/683>

³⁶ Fischhoff, B.; Brewer, N.; Downs, J. *Communicating Risks and Benefits: An Evidence-Based User’s Guide*; Food and Drug Administration (FDA), US Department of Health and Human Services: Silver Spring, MA, USA, 2011.

(1,594 in the treatment and 1,816 in the placebo arm). Additionally, there were 311 cases excluded for protocol deviations in the treatment arm along with 60 placebo arm exclusions. Pfizer excluded, without documenting the justification, over 9% of the trial's participants.

Could exclusions of this magnitude call into question the validity of the trial?

The basis for the FDA's Emergency Use Authorization was the confirmed Covid cases of 8 versus 162. But when dealing with such a small number of cases, a minor change would cause a meaningful impact on the results.

Why were five times as many cases in the treatment arm excluded versus the control arm for protocol deviation? And what were the protocol deviations— did they die?

“Lost to follow up,” means they lost touch with those subjects and can't confirm whether they got sick or not. Considering that “people who drop out of trials are statistically much more likely to have done badly, and much more likely to have had side-effects. They will only make your drug look bad.”³⁷ “Suspected, but unconfirmed cases” means these people were symptomatic for Covid but were never tested. 3,410 unconfirmed cases of Covid in a Covid trial is like a cancer trial of 1,000 participants and excluding 90 of them with tumors that increased in size simply because you didn't measure the tumors.

The fact that the Lost to Follow Up and Suspected but Unconfirmed numbers are significantly higher than the trial endpoint numbers conceivably indicate “attrition bias³⁸,” but at least signifies that the data is suspect and untrustworthy. For example, a mere 4.5% of the lost

³⁷ Goldacre, Ben, Bad Science, Quacks, Hacks and Big Pharma Flacks, Faber and Faber, 2010

³⁸ <https://s4be.cochrane.org/blog/2017/02/13/attrition-bias-randomized-controlled-trials/>

participants alone, could have completely reversed the outcome of the trial. This is not normal scientific practice. The study should never have been accepted in this state.

Why didn't Pfizer investigate further?

Without a test, asymptomatic infection would be missed entirely. Pfizer noted this in the test limitations section stating, "These data do not address whether vaccination prevents asymptomatic infection." So, prevention or reduction of transmission of Covid was never studied in the trial and it was inappropriate to assign that capability to these inoculations. There was never any evidence at all that the vaccine reduced the spread of disease and transmission; it wasn't one of the study's endpoints. This begs the question, how can we even call these inoculations, "vaccines?" Because vaccine trial endpoints have to do with immunity and transmission reduction, neither of which was measured. It also makes the characterization that one takes these vaccines to protect others a complete falsehood.

Why didn't Pfizer want the vaccine's (in)ability to provide sterilizing immunity, a very fundamental aspect of a vaccine to be discovered?

The phase 3 portion of the study was designed to evaluate the safety and efficacy of the Pfizer vaccine for the prevention of Covid disease occurring *at least 7 days after the second dose of the vaccine*. Seven days after the second dose is supposedly when the vaccine provides an acceptable level of immunity to Covid. That is all well and good, except, what if something bad happens before day 7 post-dose 2? What then? One can't simply withdraw the vaccine from the body once the process started.

A perfect analogy of this illogical accounting would be to compare it to landing on the Normandy beachhead in WWII. Do we count among the D-Day injured or dead ONLY those that crossed the open beach and attained the relative safety of the rock cliffs? Are those injured or dead in the water and the beach attributed to something other than D-Day?

Once you start down the road of inoculation, every adverse reaction, disease, and infection counts, regardless of when it happens. Ignoring all consequences for an initial interlude of up to 7-days is like a childish schoolyard “timeout break” which completely violates the basic “intention-to-treat³⁹” principle. The period also allows entities like Pfizer, the FDA, and the CDC to perform statistical shenanigans by calling a pre-7-day-post-second/booster dose individual as “unvaccinated”.

But more importantly, bad things did happen in the trial during the ludicrous 7-day interlude:

“Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group⁴⁰.”

First, we must assume all of the 287 placebo positives are excluded from the trial results as the 409 vaccine recipients were. And second, the total cases should now be, 417 versus 449 and this would have drastically lowered the vaccine efficacy to near 52%, plainly meaning the trial failed. Hmm, maybe that’s the real reason for the 7-day exclusion period...

Would a vaccine efficacy of 52% have received a EUA?

³⁹ <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC3159210/>

⁴⁰ Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum, <https://www.fda.gov/media/144416/download>

Another concern that was almost completely overlooked, was the possibility of antibody dependent enhancement (ADE) which is a common occurrence in past attempts to create a coronavirus vaccine⁴¹. If you are not familiar with ADE, you should be. It is a very serious risk with a coronavirus vaccine (two reports about ADE are listed below⁴²). Pfizer reported only “nonclinical studies,” (what were they, performed in somebody’s garage?), and no numbers of test subjects among either mice or Rhesus monkeys were given. One, two, who knows? It’s also a very rare event for a trial in animals to make a faultless and direct transfer to humans.

Pfizer was “reassured” by their non-clinical studies of ADE, are you?

Lastly, the Pfizer study selected the wrong clinical endpoints. It should have focused on “all-cause mortality and illness.” The risk versus benefit of Covid vaccines is arguably most accurately measured by comparing the all-cause mortality rate of the vaccinated against unvaccinated since it not only avoids most confounders relating to case definition but also fulfills the WHO/CDC definition of “vaccine effectiveness” for mortality. Why is “all-cause mortality” the most appropriate measure for the overall risk-benefit analysis of Covid vaccines? Several reasons:

- Simply put, the count of all-cause deaths should be higher among the unvaccinated than the vaccinated (in all age groups), confirming that the benefits of vaccination outweigh the risks.
- Counting all-cause deaths completely bypasses the problem of defining what constitutes a ‘Covid case’ or a ‘Covid related death’ (definitions which can be easily manipulated to fit different narratives).
- It defines a person as ‘vaccinated’ if they have received at least one dose. Since we are not interested in whether a person becomes a ‘Covid case’, any other definition is

⁴¹ <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8438590/>

⁴² ADE reports: <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8438590/> and <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8512237/>

flawed as it will fail to acknowledge that adverse reactions (including death) from vaccines often occur shortly after vaccination.

- The fact that the CDC and other agencies now count a person as 'unvaccinated' if they die within 14 days of the second dose, or after just one dose, might make some sense if we are interested only in the vaccine's ability to stop infection. But in the context of death attribution, it makes no sense.

The fear with Covid was that it was going to either kill people or make them sick. So, any Covid 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 and death should be the clinical endpoints for the trial. And not just illness and death with Covid, but any illness and death, 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 the cancer; they were killing patients. This forced a change to the design of trials and a switch to "all-cause mortality" as the primary endpoint.

On July 28, Pfizer and its partner BioNTech posted a six-month data update from their original clinical trial. Pfizer claimed the vaccine's efficacy remained relatively strong, at 84% after six months. It also reported 15 of those who received the vaccine in the trial had died, compared to 14 of the people who received placebo. These were not just Covid deaths, and in fact, they were mostly not from Covid. Only three of the people in the trial died of Covid-related illnesses, two who received the vaccine, and one who received the placebo. The other deaths were from other illnesses and diseases, mostly cardiovascular.

Although the researchers released their update in July, the data was already more than four months old. They stopped collecting information about deaths on March 13, the “data cut-off.” Furthermore, Pfizer buried these details in an appendix to the report.

In their initial safety report to the FDA, which contained data through November 2020, the researchers said four placebo recipients and two vaccine recipients died, one after the first dose and one after the second. The July update reversed that trend. Between November 2020 and March 2021, 13 vaccine recipients died, compared to only 10 placebo subjects.

Further, nine vaccine recipients had died from cardiovascular events such as heart attacks or strokes, compared to six placebo recipients who died of those causes. The imbalance was small but notable, especially considering that regulators worldwide had found that Pfizer’s mRNA vaccine was linked to heart inflammation in young men. At best, these results suggest that the Pfizer vaccine did ultimately nothing to reduce overall deaths.

Then later, the FDA said more. On November 8, the agency released its “Summary Basis for Regulatory Action,⁴³” a 30-page note explaining why on August 23 it granted full approval to Pfizer’s vaccine, replacing its emergency authorization of December 2020.

In this report the FDA unexpectedly stated:

“From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY [vaccine] group and 17 in the placebo group⁴⁴.”

⁴³ <https://www.fda.gov/media/151733/download>

⁴⁴ <https://www.fda.gov/media/151733/download>

Pfizer said publicly in July it had found 15 deaths among vaccine recipients by mid-March. But it told the FDA there were 21 - at the same data cutoff date, March 13. 21 had died and not 15 as Pfizer had stated. The placebo numbers in the trial were also wrong. Pfizer had 17 deaths among placebo recipients, not 14. Nine extra deaths overall, six among vaccine recipients. The FDA did not report any additional details about the deaths.

How could Pfizer publicly misreport the number of deaths in one of the most important clinical trials in the history of medicine?

Pfizer began their phase 3 trial on July 27, 2020, as a blind study. On Dec 31, 2020, Pfizer released the 2-month data report and then unblinded the trial several months earlier than initially planned. This meant the participants from the placebo group were allowed to take the inoculation. By early 2021, the majority of them had crossed over to the inoculated group. Therefore, the study is no longer a randomized control trial, as the control group doesn't exist anymore.

Pfizer contended this was an ethical decision. At a Dec. 10 meeting of an advisory committee regarding the emergency use authorization of the Pfizer/BioNTech vaccine, the FDA discussed how the placebo crossover should be handled. At that session, Steven Goodman, associate dean of clinical and translational research at the Stanford University School of Medicine, argued that there was no ethical reason that volunteers in the placebo group deserved to receive

vaccines before the general public⁴⁵. Consent forms given to volunteers made no mention of when or if those who received a placebo would get the vaccine.

Pfizer set the future date of May 2, 2023, as the end of the phase 3 clinical trial. The long-term safety data that was supposed to be assessed at this point is no longer possible. Pfizer destroyed our best chance to compare the long-term health of a large number of vaccine recipients with a scientifically balanced group of people who had not received the drug. The July 28 report appeared to be the last clean safety data update we will ever have.

What vaccine safety information has Pfizer lost forever?

Pfizer took the results from their adult trial, which started July 27, 2020, and then added the results from the 12 to 15-year-olds' trial, even though the adolescent trial started four months later. Since it's well known that the efficacy of the inoculation 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 a combined result.

Doesn't that seem like outright fraud?

It is undeniable that the vaccines caused a wide array of adverse events, not all of them fully understood. While the side effects are somewhat abundant⁴⁶ they are mostly ignored. As of December 3, 2021, the U.S. Vaccine Adverse Event Reporting System (VAERS) has logged an

⁴⁵ <https://www.statnews.com/2021/01/01/pfizer-and-biontech-speed-up-timeline-for-offering-covid-19-to-placebo-volunteers/>

⁴⁶ <https://openvaers.com/>

astounding 927,738 Covid jab-related adverse events, including 19,886 deaths. VAERS can receive reports from vaccine manufacturers and other international sources, and if we exclude those, the death toll reported in U.S. territories exclusively stands at 9,136. Pfizer shots account for the vast majority of the VAERS deaths and hospitalizations. It's essential to note, VAERS is notoriously underreported, so the real-world impact of these shots is far greater than what those data suggest. While it's hard to assess the population-wide impact of the adverse effects, it is no longer reasonable to doubt that they're substantially more dangerous than ordinary vaccines. Rough calculations from the VAERS data suggest that they're at least several hundred times more dangerous than flu shots.

A recent paper published by the CDC in The Lancet shows just how substantial severe side effects became. Oddly, the legacy media immediately promoted the study as proof that the vaccines are safe and effective. Here is a typical headline, this one from USA Today, reference the study, "Huge study finds most COVID-19 vaccine side effects were mild for Pfizer-BioNTech and Moderna."⁴⁷

However, the Lancet paper documents the percent of severe adverse events (6.6%), compared to non-severe adverse events (92.1%). Death was a separate category determined to be around 1.3% of all adverse events. So, including the deaths, the severe event ratio of 7.9% of all reported adverse events should be understood as shockingly high. 12.6% of adverse events are severe as defined by the VAERS system. Quoting the study, "VAERS reports were classified as serious if any of the following outcomes were documented: inpatient hospitalisation, prolongation of hospitalisation, permanent disability, life-threatening illness, congenital anomaly or birth defect, or death."⁴⁸ One out of every eight reported adverse events were

⁴⁷ <https://www.usatoday.com/story/news/health/2022/03/07/covid-19-vaccine-mild-side-effects-moderna-pfizer/9376671002/>

⁴⁸ [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00054-8/fulltext#%20](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext#%20)

classified as serious, but somehow the USA Today headline concludes that the side effects are “mild.”

Did the mainstream media deliberately ignore the objectionable evidence about the vaccine?

As an example of the disregard of side effects, Pfizer reported four cases of Bell’s Palsy among the vaccinated but none among the control group. They stated that this was within the normal rates that would occur in the population and was therefore not statistically significant nor a concern.

This doesn’t seem to jive with the fact that Bell’s palsy only affects about 40,000 people in the U.S. each year. It can affect anyone of any gender and age, but its incidence seems to be highest in those in the 15 to 45-year-old age group⁴⁹. It is also believed by some that the Governor of California contracted Bell’s palsy after receiving a vaccine booster shot⁵⁰.

Since Bell’s Palsy is an infection-related neurological phenomenon, it seems it would have been prudent to expand the study to a larger group before continuing population-wide application. Only 40,000 participants are inadequate to pick up rare side effects. And two months is just not long enough to pick up longer-term adverse effects.

Pfizer acknowledged that the frequency and severity of adverse events increase as the age of the recipient decreases. “The frequency and severity of systemic AEs were higher in the younger than the older age groups. Within each age group, the frequency and severity of

⁴⁹ https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Bells-Palsy-Fact-Sheet#3050_4

⁵⁰ <https://stevekirsch.substack.com/p/gavin-newsom-is-out-of-sight-likely>

systemic Adverse Events (AEs) was higher after Dose 2 than Dose 1, except for vomiting and diarrhea, which was generally similar regardless of dose.⁵¹ So, let's briefly examine the Pfizer adolescent trial since Pfizer liked to mix results. The 12 to 15-year-old's trial was severely underpowered, with an inoculated group of 1,005 (0 tested positive for Covid), and a placebo group of 978 (18 tested positive for Covid). Such a small study will conceal many risks.

Was the small size selected on purpose?

Pfizer claimed the results were great, but keep in mind, there were no severe Covid cases in either the treatment or placebo groups, therefore any serious AE should be grounds for denial of authorization. And, since adolescents are at a statistically zero risk of death from Covid, and very low risk of severe illness, the inoculation is obviously of little benefit to them.

Yet the vaccination presents a very real risk of adverse events. But the adolescent Pfizer study wasn't designed to find these. A serious AE, including death, occurring at a rate of 1 in 800, might not even show up in a sample of 1,005 people. But in this case, it did. Among the 1,005 adolescents, there were several serious adverse events:

- 1 related life-threatening fever
- 1 related life-threatening anaphylaxis
- 1 related with "reasonable possibility" myopericarditis, hospitalized, with "limited activity" advised at 2 months
- 3 on SSRI medication for depression, each hospitalized with symptom "exacerbation"

⁵¹ <https://www.fda.gov/media/144416/download>

There was also an event in the open-label study of a life-threatening serious AE which hospitalized a 16-year-old with "depression" There is no indication the youngster was taking an SSRI or depressed before.

And, then there is Maddie de Garay.

Maddie de Garay is a 12-year-old trial participant who developed a serious reaction after her second dose and was hospitalized within 24 hours⁵². 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 a 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 a 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 date⁵³."

Did Pfizer Intentionally and consciously fail to report this as a serious adverse event?

⁵² <https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair>

⁵³ <https://www.fda.gov/media/148542/download>

Aside from the 7 youngsters exhibiting serious AEs mentioned above, lymphadenopathy, swollen lymph nodes, occurred at a statistically significantly higher rate in the treatment group (9 versus 2). Related events of lymphadenopathy as a consequence of treatment occurred in an additional 7 vaccine recipients (only 1 in the placebo group). The reactogenicity safety data is dramatic. Post dose 2, in the treatment group, 51% used antipyretic medication while only 9% used it in the placebo group.

Further, In the 5 to 11-year-old cohort in the table below, Pfizer used predictive modeling to acknowledge that their inoculations will cause myocarditis and optimistically claimed there will be zero deaths from myocarditis in any of their model scenarios.

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 90% vs. COVID-19 cases and 100% 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% that of Scenario 1.
Scenario 6: COVID-19 incidence as of September 11, 2021, VE 70% vs. COVID-19 cases and 80% vs. COVID-19 hospitalization, excess myocarditis cases 50% of Scenario 1.

Afterward, an Israeli study⁵⁴ observed that 30 days after the second vaccine dose a rate ratio of 1 in 6637 in male recipients between the ages of 16 and 19 years. Furthermore, a huge British study⁵⁵ released in late December 2021, showed that the risk of myocarditis almost doubled after the first Pfizer shot in men under 40. It then doubled again after the second and doubled again after the third shot. That's almost eight times the baseline risk.

The Mayo Clinic said, "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 attack⁵⁶." Likewise, a study published in the Journal of Cardiovascular Magnetic Resonance claims, "the mortality rate is up to 20% at 6.5 years⁵⁷."

Is Pfizer overlooking the seriousness of myocarditis?

Oddly, the CDC Director claimed none of these complications even exist. On Dec. 10, 2021, she told ABC News that the CDC had seen no adverse events among vaccine recipients, and denied seeing any cases of myocarditis among vaccinated kids between 5 and 11⁵⁸. On that same day, data released by her agency showed the CDC was aware of at least eight cases of myocarditis⁵⁹ within that age group, making her statement demonstrably false.

Throughout, the mantra has always been to follow the "science," as if scientists were imbued with a magical ability to discern and pronounce absolute truth. When vaccine effectiveness quickly started to wane, the trope was surpassed by claims that the variants were causing the

⁵⁴ <https://www.nejm.org/doi/full/10.1056/NEJMoa2109730>

⁵⁵ <https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf>

⁵⁶ <https://test.kcms.mayoclinic.org/diseases-conditions/myocarditis/symptoms-causes/syc-20352539?p=1>

⁵⁷ <https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7>

⁵⁸ <https://abcnews.go.com/Health/cdc-director-rochelle-walensky-concerns-myocarditis-million-children/story?id=81659883>

⁵⁹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/05-COVID-Su-508.pdf>

science to change. While it's acknowledged that science is rarely settled before more-recent discoveries alter previous ones, the vaccines from the start were inaccurately promoted as sterilizing, capable of preventing infection, serious illness, and death. Misrepresentations were made not because the science was necessarily wrong, but rather the science was misinterpreted. Science is a process, not an institution, and it's ultimately a process we derive conclusions from, not an absolute truth. However, it became clear early during vaccine deployment, that questioning the science to strengthen the truth would be summarily subjugated for political purposes. Throughout the pandemic, the CDC and other health agencies have promoted inconsistent policies and recommendations. Many Americans who voiced concerns about these shifting policies have been subjected to ridicule, vilification, and censorship from the press. Rather than provide the public with complete access to relevant data to justify its Covid policies, the Biden Administration favors censorship over transparency.

In an interview on March 3, 2022, at the Washington University in St. Louis, Dr. Walensky, the CDC director admitted her ignorance of the science, "I can tell you where I was when the CNN feed came that it was 95% effective, the vaccine. So many of us wanted to be hopeful, so many of us wanted to say, okay, this is our ticket out, right, now we're done. So, I think we had perhaps too little caution and too much optimism for some good things that came our way."⁶⁰ Most recently, she started pushing for more vaccine doses in 12 to 15-year-olds, against the advice of the FDA advisory committee and WHO guidance. When it comes to vaccination, the CDC has a single policy, all Americans should get three doses, regardless of age or medical conditions. This is not science as such, but science as political propaganda. If that sounds like an exaggeration, consider the CDC's near-total dismissal of natural immunity. Many other countries consider recovery from prior infection as a vaccination equivalent or better. All this, while keeping key Covid data cloistered and hidden from the public⁶¹. It is left to the reader to draw the line between hiding critical data and supplying fraudulent data.

⁶⁰ Video recording of the interview located at: <https://infectiousdiseases.wustl.edu/dr-rochelle-walensky-cdc-director-2022-gerald-medoff-visiting-professor/>

⁶¹ <https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html>

Exactly who is anti-science?

In October 2021, Pfizer announced the results from their Phase 3 randomized, controlled trial evaluating the efficacy and safety of a booster dose. Pfizer claimed the trial showed vaccine efficacy of 95.6% for a boosted individual⁶². Pfizer has chosen not to release the trial report, and the CDC has only published selective crumbs, overwhelmingly in support of boosters. However, a curious aspect emerges when the public results of Pfizer's booster trial are related to their earlier initial trial. Most notably, the incidence rate of symptomatic Covid among the vaccinated people with no booster in the second trial is more than 40% higher than the rate among the unvaccinated in the early trial⁶³. Either Pfizer's numbers aren't adding up, or something is seriously wrong with their vaccine.

Or is it both?

But, just don't take my word for it.

"Drugs are tested by the people who manufacture them, in poorly designed trials, on hopelessly small numbers of weird, unrepresentative patients, and analysed using techniques which are flawed by design, in such a way that they exaggerate the benefits of treatments. Unsurprisingly, these trials tend to produce results that favour the manufacturer. When trials throw up results that companies don't like, they are perfectly entitled to hide them from doctors and

⁶² <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing>

⁶³ <https://www.bmj.com/content/375/bmj.n2814/rr-0>

patients, so we only ever see a distorted picture of any drug's true effects. Regulators see most of the trial data, but only from early on in a drug's life, and even then they don't give this data to doctors or patients, or even to other parts of government. This distorted evidence is then communicated and applied in a distorted fashion.... And finally, academic papers, which everyone thinks of as objective, are often covertly planned and written by people who work directly for the companies, without disclosure. Sometimes whole academic journals are even owned outright by one drug company. Aside from all this, for several of the most important and enduring problems in medicine, we have no idea what the best treatment is, because it's not in anyone's financial interest to conduct any trials at all.⁶⁴

As the US approaches the 1 million-mark in deaths, it is clear that the response to the pandemic has been tragically flawed. Public health officials have sown fear and earned distrust. From near the beginning of the pandemic, we were told that the only way out was via vaccination. Vaccines were rapidly developed and their emergency use was quickly adopted worldwide. They were pushed via vaccine drives and clinics, and before long boosters became part of the scenario. Then came the mandates, even for people who had acquired natural immunity, followed by vaccination of children. Meanwhile, the silencing of any negative information about vaccines, including vaccine safety, continued.

All along it has been all about vaccines, and less about the disease. However, it should be clear that vaccines are not the goal—they are merely the means to help humanity overcome the pandemic. The means should never become the goal.

⁶⁴ This quote is from the introduction to Ben Goldacre's book, written pre-pandemic in 2012. Ben is a self-described "doctor, researcher, author, Bad Science person," who is very outspoken in his support of the covid vaccines. Goldacre, Ben, *Bad Pharma-How Drug Companies Mislead Doctors and Harm Patients*, Faber and Faber, 2012, pg. x.

So, how do you get more than a billion people to take an unapproved medical product? You employ the same method Hitler and the Nazis did in the Holocaust to systematically kill more than 6 million European Jews and 5 million non-Jews before and during World War II⁶⁵. By hiding the truth from them⁶⁶.

⁶⁵ Andrews, Andy, How Do You Kill 11-Million People? Why the Truth Matters More Than You Think, Thomas Nelson, 2012.

⁶⁶ “For more than a year, the Centers for Disease Control and Prevention has collected data on hospitalizations for Covid-19 in the United States and broken it down by age, race and vaccination status. But it has not made most of the information public.”, <https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html>